The Global Language of Business

Healthcare

Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability

Implementation Guideline

Release 1.3, December 21, 2022

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Document Summary

Document Item	Current Value
Document Title	Implementation Guideline: Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability
Date Last Modified	December 2022
Document Description	This implementation guideline was developed to provide direction for the communication of chain of custody events between supply chain partners using EPCIS.

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Part I: Foundational Concepts

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1 Preface

1.1 Introduction

The U.S. Food and Drug Administration (U.S. FDA) Drug Supply Chain Security Act (DSCSA) traceability requirements became mandatory for the pharmaceutical industry in 2015, marking the beginning of the journey to lot-level management, product serialization, and finally item-level traceability in the healthcare supply chain. In response, members of the United States pharmaceutical industry have been preparing their systems and business processes to meet those requirements. During this journey, the pharmaceutical industry has rallied around the use of Electronic Product Code Information Services (EPCIS) for item-level serialized traceability. EPCIS is a GS1 Standard that enables supply chain partners to capture event information about supply chain events (e.g., commissioned, packed, shipped, and received; etc.), and to share that information with their trading partners securely and in near real-time.

EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. There are numerous options for how the standard can be implemented in order to accommodate different applications and environments. Nonetheless, there still needs to be a certain level of consistency in terms of how the standards are implemented by individual trading partners in order to support collaborative supply chain solutions such as interoperable serialized item-level traceability. Therefore, members of the U.S. pharmaceutical industry have joined forces to determine how the standards can best be applied to support these applications. Over forty-five organizations from across the U.S. pharmaceutical supply chain have participated in this on-going effort. Leading manufacturers, wholesalers, retail pharmacies, healthcare providers, government agencies, solution providers and industry associations have all been working together to analyze business processes and business requirements, consider the various options, and decide how the standards could best be applied. This guideline records the decisions points from that effort, defining each event and data element needed to support serialization, pedigree and track and trace, and showing industry members how to apply the standards to their own business processes.

The previous Release 1.2 of this guideline was updated to align with the updated GS1 EPCIS standard (Version 1.2) and the updated GS1 Core Business Vocabulary (CBV) standard (Version 1.2). In addition, it provides additional choreographies for item-level serialization and updates the lot-level management events to align with Version 1.2 of EPCIS and CBV.

With this latest Release 1.3, the focus is on item-level serialized traceability required for 2023 interoperability across the US pharmaceutical industry. A few chapters are newly introduced in this version of the guideline covering the importance of EPCIS Conformance testing and highlighting the role of GS1 lightweight Message Standard for DSCSA Verification of Returned Product Identifiers.

In April 2021, GS1 US Healthcare published the R1.1 Implementation Guideline: Applying GS1 System of Standards to Pharmaceutical Chain of Custody, for business processes for unregulated transactions between manufacturing/wholesaler trading partners. This guideline is designed for Contact Manufacturers (CMOs), Contract Packagers (CPOs), Third Party Logistics Providers (3PL), and Reverse Logistics Providers (RLP) who manage serialized Chain of Custody business transactions, on behalf of manufacturers, wholesale distributors, and dispensers, for prescription drugs governed by DSCSA. You may download the Guideline from the GS1 US website at the following link: *https://www.gs1us.org/industries-and-insights/by-industry/healthcare/standards-in-use/pharmaceutical/chain-of-custody*

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1.2 Document Information

This implementation guideline was prepared by GS1 US® and the Rx Secure Supply Chain Workgroup to assist the U.S. pharmaceutical industry in implementing GS1 System of Standards to support traceability. It is based on the *GS1 General Specifications* Release 21.0.1, Ratified, Jan 2021, the *EPC Tag Data Standard* (Version 1.13), the *EPCIS Standard* (Version 1.2), and the *Core Business Vocabulary Standard* (Version 1.2). It was developed using information obtained from a wide variety of members of the U.S. pharmaceutical supply chain from manufacturers to providers.

Important: As with all GS1 Standards and solutions, this guideline is voluntary, not mandatory. It should be noted that use of the words "must" and "require" throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation.

1.3 Participants

This updated and enhanced R1.3 guideline was developed through the commitment and dedication of the Rx Secure Supply Chain Workgroup, as the industry continues to implement GS1 System of Standards to Identify, Capture, and Share unique serialized identification in support of the requirements of DSCSA.

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1.4 Purpose

This document identifies the GS1 Standards used and provides details about how they can be applied to support item-level traceability. It includes the EPCIS *Business Step* and *Disposition* combinations to express each supply chain event. By so doing, this document serves as a voluntary implementation guideline that provides guidance to industry members about how to apply the GS1 System of Standards to their own business processes to support item-level traceability.

1.5 Future Releases

This guideline presents the current wisdom in industry for how GS1 system of Standards can be applied to U.S. pharmaceutical supply chain business processes to support serialized item-level traceability. It may be updated to reflect feedback from industry pilots, architecture work being conducted by GS1® and GS1 US, and potential future releases of EPCIS, as well as other industry efforts which advance the level of thought. The reader should be aware that changes may be made and should not expect any particular section of content to remain unchanged.

1.6 Scope

This guideline defines the EPCIS events (XML data format) to support DSCSA requirements for serialized item-level information. **It does not provide any guidance or advice regarding regulatory compliance.** Federal requirements for traceability in the pharmaceutical supply chain are specified in the DSCSA and subsequent FDA Guidance(s).

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This guideline reflects current industry understanding of the DSCSA traceability requirements. Those requirements, and the statutes and regulations affecting them, are subject to change and may evolve in a manner this guideline cannot anticipate.

This guideline does not address other considerations or factors, apart from DSCSA compliance, that might impact or inform the adoption of optimal traceability processes or procedures for any particular company or product.

Important: Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and their products. Consult with your company's legal counsel or compliance team (regulatory or quality) for more specific information about current statutory and regulatory requirements applicable to your company and products.

1.7 Normative References

This implementation guideline is based on the *GS1 General Specifications*, the *EPC Tag Data Standard*, the *EPCIS Standard*, and the *Core Business Vocabulary Standard*. The specific standards referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- *GS1 General Specifications*
- *EPC Tag Data Standard (TDS) 2.0*
- *EPCIS 1.2 Standard*
- *Core Business Vocabulary (CBV) 1.2 Standard*
- *GTIN Management Standard* (formerly known as the GTIN Allocation Rules)
- *Healthcare GTIN Allocation Rules*

1.8 Non-Normative References

Material in this implementation guideline is based on a number of non-normative guidelines and references available from GS1 and GS1 US. The specific guidelines and documents referenced in this guideline are listed below.

- *GS1 RFID Bar Code Interoperability Guideline*

1.9 Additional Considerations & Resources

- GS1 DataMatrix requires camera-based scanners. Traditional laser barcode scanners cannot read the GS1 DataMatrix. As a result, it is important for supply chain partners to communicate prior to implementing GS1 DataMatrix to ensure that the appropriate scanners are in place.
- There are many reasons why a barcode may not scan. Many times, it is not the barcode, but the scanner itself. For example, the lens could be dirty, or the batteries discharged. GS1 US prepared another document entitled *Procedure for Responding to Troublesome Barcodes* to help resolve barcode scanning issues. This document offers a simplified process to rectify barcode scanning issues based on the experiences of healthcare users. It is recommended that you download this document as a reference to help you respond if a barcode does not scan.

1.10 The GS1 US DSCSA Implementation Suite

To promote ease of use, the content for applying GS1 system of Standards to DSCSA and traceability has been split into four documents. All of these documents are available in the GS1 US DSCSA Implementation Suite. The three documents in that suite are:

- *Implementation Guideline: Applying GS1 Standards for DSCSA and Interoperable Traceability*

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- *Addendum: Guidance and XML Examples for Supply Chain Choreographies in Serial-Level Management*
- *Addendum: Diagrams and XML Examples for Serialized Exceptions Processing*

1.11 Summary of Changes from Release 1.2

The following changes have been made in this Release 1.3 of the guideline as compared to Release 1.2:

- Content has been focused on serialized item traceability
  - Removed content related to lot level traceability
  - Refined the required, optional and conditional usage requirements of event fields
  - Replaced the additional trade item identification value associated with GTIN with FDA NDC instead of CMS NDC
  - Revised construct for identifying direct and indirect serialized item purchases
  - Enabled quick identification of drop shipments
  - Applied collective industry corrections and enhancements from evolved learnings
- Streamlined and corrected values in EPCIS Header attributes (such as setting Authority to GS1 instead of sGLN)
- Added Implementation Guideline Version, `guidelineVersion`, attribute in the EPCIS Header to specify the version of implementation guideline distinctly from the EPCIS standard version
- Promoted defining new GLNs not GLN extensions for internal physical locations for trading partner event exchanges
- Include guidance on reflecting individual licensed GLNs in EPCIS party and location fields
- Guidance has been added to help mitigate large files by including best practices on grouping commissioning events
- Enhanced rules for populating event fields
- Enhanced identification of required business transaction documents
- Illustrated with data flow diagrams and XML examples the serialized exchange for 22 Serialized Supply Chain Choreographies
- Included references to complementary standards and guidelines for product identifier verification and EPCIS Conformance testing

1.12 Changes to EPCIS Event Specifications for Serialized Item Traceability

The following summarizes the changes to EPCIS event specifications for serialized item traceability:

- Changes affecting all events:
  - Addition of the Guideline Version in EPCIS Header
- Changes to the *Commissioning* event:
  - Change of the value for the additionalTradeItemIdentificationTypeCode to be US_FDA_NDC and the additionalTradeItemIdentification to the value of the 3-segment NDC number, including dashes.
  - For readPoint and bizLocation, allow the GLN (SGLN) values to be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.
  - Updated XML example

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- Added business rule for grouping together commissioning object events to optimize size of EPCIS document which capture high volume throughput of commissioned serialized products

- Changes to the *Packing* event:
  - Updated XML example
- Changes to the *Shipping* event:
  - Provide additional guidance for *sourceList* and *destinationList* to include one source/destination of type *urn:epcglobal:cbv:sdt:owning_party* and another source/destination of type *urn:epcglobal:cbv:sdt:location*.
  - Provided more streamlined identification of direct and indirect purchased serialized items
  - Added *dropShipment* indicator flag
  - Updated XML example
- Changes to the *Transformation* event:
  - Added to provide guidance for populating transformation event for repackaging
  - Included XML example
- Changes to the *Receiving* event:
  - Provide additional guidance for sourceList and destinationList to include one source/destination of Updated to provide guidance for how to best capture received serialized products that are physically scanned.
  - Included guidance for how an Aggregation Event can be used in addition to Object Event when items inside are inferred to be received in a container which is not scanned and unpacked
  - Updated XML examples showing receipt variations of multi-level containers
- Changes to the *Unpacking* event:
  - Updated XML example
- Changes to the *Dispensing* event:
  - Provided guidance for populating *disposition* and *bizLocation* elements for full dispensing versus partial dispensing
  - Updated XML example
- Changes to the *Inspecting* event:
  - Newly added to provide guidance for capturing the physical activity of inspecting a product to assess its disposition
  - Updated XML example
- Changes to the *Destroying* event:
  - Updated XML example
- Changes to the *Decommissioning* event:
  - Updated XML example
- Changes to *Void Shipping* event:
  - Corrected population rule for *eventTime* to reflect the event time when the datetime the shipment was voided.
  - Added language to increase awareness on the importance of trading partner engaging in communication with their downstream trading partners due to the complexity and variety of business use cases involving resolution of cancellation or voiding.

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- Updated XML example

- Changes to *Error Declaration* event:
  - Added language to increase awareness on the importance of trading partner engaging in communication with their downstream trading partners due to the complexity and variety of business use cases involving resolution of previously transmitted erroneous event information.
  - Updated XML example

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2 Application to the Drug Supply Chain Security Act (DSCSA)

For the purposes of this guideline, the DSCSA can be viewed as a three-phase implementation over ten years.

- The first phase, started on January 1, 2015 and ending November 2023, requires that supply chain participants share chain-of-ownership data.
- The second phase of DSCSA, started November 2018, requires that pharmaceutical products be marked with a National Drug Code (NDC), Serial Number, Lot Number, and Expiration Date in both machine-readable and human-readable format. The use of GS1 identification keys, Application Identifiers, and Data Carriers (barcodes, RFID tags) are covered in Part I *Chapter 5* and *Chapter 6* of this guideline. In the GS1 System, the GS1 Global Trade Item Number® (GTIN®) currently embeds the 10-digit NDC and is currently used to represent the NDC.
- The third phase of DSCSA requires that trading partners share chain-of-ownership data in a manner that allows for serialized item traceability back to the product origin (usually the manufacturer). The expanded use of EPCIS events for serialized item traceability are covered in *Part II* of this document.

Although the DSCSA specifies 2023 as the year when serialized item traceability is required, many trading partners have already made significant investments in serializing product lines and implementing serialized item traceability systems. This current release of the guideline (Release 1.3) provides the details on how to identify and mark products, as well as how to share change-of-ownership information with EPCIS at the serialized item-level.

2.1 GS1 Standards for DSCSA Phase 2: Item-Level Identification & Marking

Phase 2 of the DSCSA involved item-level identification and marking. Supply chain participants identify pharmaceutical products with an NDC (GTIN in GS1 Standards), Serial Number, Lot Number, and Expiration Date, and marking product identifiers on products in both machine-readable (e.g., barcode) and human-readable format.

Part I *Chapter 5* and *Chapter 6* of this guideline present the application of GS1 Standards for item-level identification for Phase 2 of the DSCSA.

2.2 EPCIS Approach to DSCSA Phase 3: Item-Level Traceability

Phase 3 of the DSCSA establishes package level requirements for the interoperable, electronic tracing of products. This will involve sharing chain-of-ownership data in a manner that allows for serialized item traceability back to the product origin (usually the manufacturer), including the electronic exchange of transaction information for each sale of certain prescription drugs and verification of product identifiers at the package level.

Using EPCIS, *Commissioning* events declare that specified serial numbers have been introduced into the supply chain, *Packing* events convey the hierarchical relationships (e.g., item-to-case, case-to-pallet) between objects as they exist at the point of shipping, and *Shipping* events indicate that objects have been shipped to a downstream trading partner and provide serialized item-level traceability information governing the shipment. The *Shipping* events only reference the outermost (i.e., top-level) products in the packaging hierarchy. For any given transaction, a collection of *Shipping* events, *Packing* events (if applicable), and *Commissioning* events (if applicable), together with master data and Transaction Statement data, comprise the DSCSA Transaction Information and Transaction Statement.

Part III of this guideline presents the application of EPCIS for item-level traceability for Phase 3 of the DSCSA.

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2.3 Industry Transitions to DSCSA

DSCSA specifies 2023 as the year when serialized item traceability is required. Many trading partners have already made significant investments in serializing product lines and implementing serialized item traceability systems. As more and more trading partners start to transition from lot-level management to serialized item traceability, it is reasonable to expect that the U.S. pharmaceutical industry will experience a mixed environment of lot-based and serialized item-based product marking and information sharing throughout the 2015 – 2023 timeframe.

- **Product Marking Transition:** Phase 1 of the DSCSA did not require lot information to be marked on products in machine-readable form. Phase 2 of the DSCSA required pharmaceutical products to be marked with a product identifier (GTIN/NDC), Serial Number, Lot Number, and Expiration Date starting in 2017. For the purposes of DSCSA, pharmaceutical products will migrate from being marked with only a product identifier (GTIN/NDC) to being marked with a product identifier (GTIN/NDC), Serial Number, Lot Number, and Expiration Date. Therefore, as industry implemented Phase 2 item-level marking requirements, the supply chain experienced a mixed environment in which products were marked with product identifier (GTIN/NDC) only and/or marked with a product identifier (GTIN/NDC), Serial Number, Lot Number, and Expiration Date.
- **Information Sharing Transition:** Phase 1 of the DSCSA called for trading partners to share change of ownership information at the lot-level. Starting in 2023, Phase 3 of the DSCSA requires trading partners to share change of ownership information at the item-level. Therefore, as industry implemented Phase 1 lot-level sharing in 2015 and works to implement Phase 3 item-level sharing by 2023, the supply chain will likely experience a mixed environment in which change of ownership data will be shared at the lot-level and/or the item level.

Serialized product identification does provide for item-level traceability. Item-level information conveys the product identifier and serial number. The combination of Product ID and Serial Number produces a unique identifier for each and every instance of a product. This enables each individual product to be identified both physically (through a barcode or RFID tag) and within company systems. As a result, it is possible to determine the exact path through the supply chain that any serialized item traveled, and to trace each item back to its source. Using a serialized item-level information sharing system in the example above, the different Product ID + Serial Number on each product would allow us to distinguish one bottle from the other and identify their separate paths through the supply chain. This is referred to as “serialized item-level traceability.”

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3 Overview of the GS1 System of Standards Used

This Section provides a brief definition of each GS1 Standard used in this guideline. (Refer to the *Appendices* of this document for more information about GS1 Standards that support serialized item-level traceability.)

3.1 Global Location Number (GLN)

The Global Location Number (GLN) is the globally unique GS1 identification key for parties and locations. The GLN can be used to identify a *function* (like a hospital pharmacy department or accounting department), a *physical location* (like a warehouse or hospital wing or even a nursing station), a *legal entity* (like a health system corporation), or a *digital location* (like an EDI gateway). The attributes defined for each GLN (e.g., name, address, location type) help users to ensure that each GLN is specific to one unique party or location throughout the world.

3.2 Global Trade Item Number (GTIN)

The Global Trade Item Number (GTIN) is the globally unique GS1 identification key used to identify "trade items" (i.e., products and services that may be priced, ordered, or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The GTIN is used to uniquely identify a product at each packaging level (e.g., a bottle of 100 aspirin tablets: a case of 200 bottles of aspirin tablets, etc.).

3.3 Serial Shipping Container Code (SSCC)

The Serial Shipping Container Code (SSCC) is the globally unique GS1 identification key used to identify individual logistic units (i.e., an item of any composition established for transport and/or storage which needs to be tracked individually and managed through the supply chain). The SSCC is assigned for the lifetime of the transport item and is a mandatory element on the GS1 Logistic Label. SSCCs serve as "license plates" from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

3.4 GS1 Data Carriers

GS1 Data Carriers provide *machine-readable representations* of GS1 identification keys that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports multiple data carriers, barcode symbologies (i.e., GS1 barcodes) and RFID tags [i.e., GS1 Electronic Product Code (EPC®)-enabled radio frequency identification tags (EPC/RFID Tags)].

3.5 GS1 Application Identifiers

GS1 Application Identifiers (AIs) are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two-, three-, or four-digit numeric code. (When rendered in human-readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode's encoded data.) Each data element in a barcode is preceded by its AI. For example, the AI for GTIN is 01. Thus, when "01" appears in the encoded content of a barcode, it means the next 14 digits comprise a GTIN. There are approximately 100 AIs. There is an AI for each GS1 identification key. In addition, there are AIs for various types of secondary information to enable supply chain partners to communicate item-specific information wherever the barcode is scanned (e.g., expiration date; lot number; batch number). GS1 AI's commonly used in healthcare include AI (10) for Lot/Batch Number, AI (17) for Expiration Date, and AI (21) for Serial Number.

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3.6 Electronic Product Code Information Services (EPCIS)

The Electronic Product Code Information Services (EPCIS) standard defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain. The EPCIS specification provides technical standards, as well as a standardized set of service operations and associated data elements. In addition, the EPCIS standard also incorporates data standards for how to populate EPCIS data elements. (See Core Business Vocabulary below.)

3.7 Core Business Vocabulary (CBV)

The Core Business Vocabulary (CBV) provides data standards for populating EPCIS data elements. The CBV provides lists of acceptable values for how to express what business process was operating on an object and the status of the object upon exiting the process. It includes syntaxes, vocabularies, and element values (with definitions).

3.8 GS1 US Data Hub | Company

GS1 US Data Hub® | Company allows you to validate the relationship between products and companies by providing verified company information for over 5 million GS1 Company Prefix and identifier licensees.

3.9 GS1 US Data Hub | Product

GS1 US Data Hub® | Product provides access to an ever-expanding, GS1 US-validated GS1 Company Prefix database driving reliable product identification and barcodes to grow your business. Use it to search, view, and verify manufacturer and brand owner data, match company data from your list of Global Trade Item Numbers (GTINs) or Global Location Numbers (GLNs) with List Match, export the full list of GS1 US-validated GS1 Company Prefix data, and improve the quality of the data in your business applications.

3.10 GS1 US Data Hub | Location

GS1 US Data Hub® | Location provides trading partners with a single source of information for locations and how they are related. You may identify locations like companies and warehouses, or locations within locations, like shipping or receiving departments, improve the speed and accuracy of your supply chain activities, and ensure the right item is shipped to the right place in the supply chain at the right time. The GLN is the globally recognized identification key used in the GS1 System to uniquely identify parties (legal entities and functions) and locations (physical and digital) in electronic commerce transactions. Data Hub | Location enables subscribers to view, create, manage, and share up-to-date, reliable location information, validated by the U.S. Postal Service, for manufacturers, wholesale distributors, hospitals, dispensers, as well as retail and mail-order pharmacies in order to improve the accuracy of their supply chain activities.

Important: It is recommended that trading partners to share their GLNs within the GS1 US Data Hub | Location to all subscribers to help enable visibility and searchability in support of trading partners within their supply chain.

3.11 GS1 US Data Hub | Location - Create/Manage

GS1 US Data Hub® | Location—Create/Manage enables traceability and efficiency by providing a single source of accurate information on locations and how they're related.

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Important: It is recommended that trading partners share their GLNs within the GS1 US Data Hub │ Location to all subscribers to enable visibility and searchability in support of trading partners within their supply chain.

3.12 GS1 US Data Hub │ Location - View/Use

GS1 US Data Hub® | Location—View/Use provides validated location information from over 730,000 GLNs (Global Location Numbers).

3.13 Global Data Synchronization Network (GDSN)

The Global Data Synchronization Network™ (GDSN®) provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly formatted, and (3) sharing that information with supply chain partners. The GDSN is a network of interoperable data pools connected by the GS1 Global Registry®. The GDSN-certified Data Pools store and manage supply chain information for their users, and the GS1 Global Registry connects those data pools together. The GDSN offers a continuous, automated approach to data management that promotes alignment of supply chain information among trading partners, increasing data accuracy, and driving costs out of the supply chain.

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4 Background Concepts

4.1 Relationship between NDC – GTIN – SGTIN

The FDA National Drug Code (NDC) is a U.S. regulatory identifier used to identify pharmaceutical products for regulatory purposes. The GTIN is a supply chain identifier used to identify *products* for supply chain purposes. The SGTIN is a supply chain identifier used to identify *individual instances of a product* for supply chain purposes. There is a cohesive, hierarchical relationship between these identifiers. As illustrated in the figure below, NDCs can be embedded into GTINs so that identification of pharmaceutical products for supply chain purposes is consistent with identification of pharmaceutical products for regulatory purposes. GTINs can then be supplemented with serial numbers to identify individual instances of the pharmaceutical product.

Figure 4-1 Relationship of the NDC, GTIN and SGTIN

4.2 US FDA NDC Labeler Code & GS1 Company Prefix

The US FDA NDC is an identifier comprising two segments: a *Labeler Code* assigned by the FDA and a *Product/Package Code* assigned by the manufacturer. The *Labeler Code* is a variable length identifier assigned by the FDA (and encoded into NDCs) to identify a company that manufactures a drug or distributes a drug under its own name (including repackagers or relabelers).

GS1 US has reserved a placeholder in the GS1 Company Prefix numbering system that enables the NDC *Labeler Code* to be integrated into the GS1 Company Prefix for pharmaceutical companies. The placeholder (named the "GS1 Prefix") is **03**, and the GS1 Company Prefix for a pharmaceutical company is simply its *Labeler Code* with "03" appended in front. For example:

GS1 Prefix	**03**
FDA-assigned *Labeler Code*	**61414**
GS1 Company Prefix	**0361414**

Important: In order to use a Labeler Code as a concatenated GS1 Company Prefix, manufacturers should first contact GS1 US to obtain a license to a GS1 Company Prefix that embeds their Labeler Code assigned to the company.

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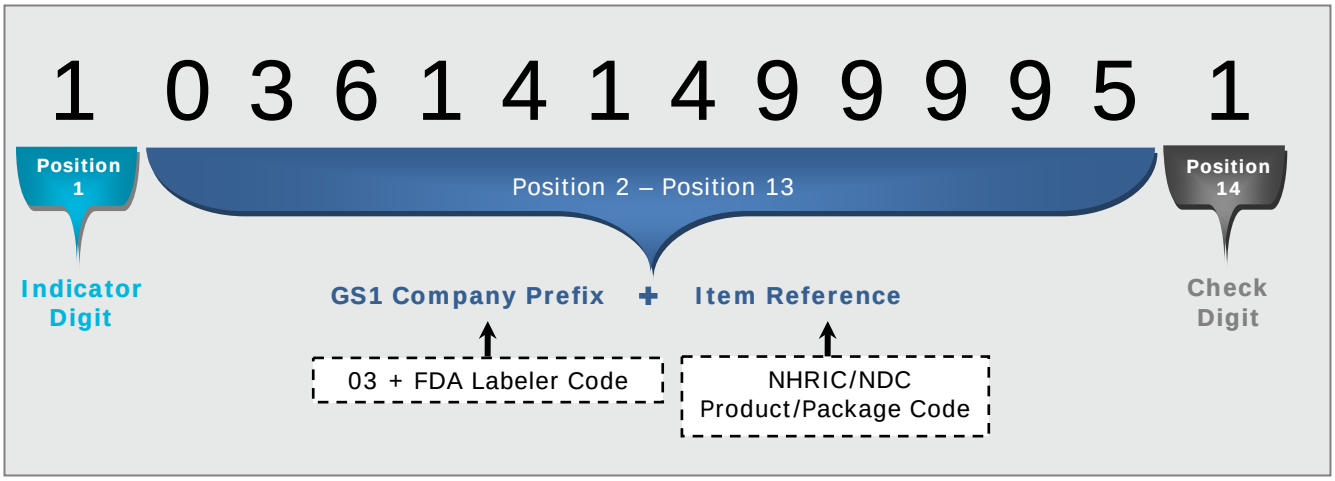
Pharmaceutical companies may have more than one GS1 Company Prefix (e.g., one GS1 Company Prefix that integrates their NDC *Labeler Code*, and other GS1 Company Prefixes that do not). Those companies will need to use the GS1 Company Prefix that integrates their *Labeler Code* when assigning GTINs that embed NDCs (discussed below). However, they may use whichever GS1 Company Prefix they prefer to generate SSCCs and GLNs.

4.3 Integrating NDCs into GTINs

As noted above, NDCs can be integrated into GTINs. The figure below illustrates how the two NDC segments (i.e., *Labeler Code* and *Product/Package Code*) are integrated into the segments of a GTIN-14. The NDC *Labeler Code* is integrated into a GS1 Company Prefix (as described above). The NDC *Product/Package Code* is used to populate the Item Reference segment of the GTIN.

Figure 4-2 Segments of a GTIN-14 that embeds an NDC (based on the hypothetical GTIN "10361419999951")



4.4 "GTIN-12" vs. "GTIN-14" vs. "GTIN-12 in 14-digit format"

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length. Within the U.S. pharmaceutical supply chain, the 12-digit GTIN (known as the "GTIN-12") and the 14-digit GTIN (known as the "GTIN-14") are predominantly used. Nonetheless, most barcodes require GTINs to be encoded in a 14-digit format. To accommodate that requirement, GTINs of less than 14-digits can be padded with leading zeros for encoding. For example, to encode a GTIN-12 in a barcode that requires GTINs in 14-digit format (e.g., GS1 DataMatrix), two leading zeros are added to the GTIN-12 as shown below:

GTIN-12	**316141499995**
GTIN-12 in 14-digit format	**00316141499995**

Note that a GTIN-12 remains a GTIN-12 whether it is in its original 12-digit format or represented in a 14-digit format using leading zeros. Technically speaking, the padded GTIN-12 is called a "GTIN-12 in 14-digit format."

Important: PER THE GS1 GENERAL SPECIFICATIONS, THIS MUST NOT BE DONE IN THE OPPOSITE DIRECTION (i.e., assign a GTIN-14 and remove the first two digits in an attempt to create a GTIN-14 in a 12-digit format). A true GTIN-14 (one with digits other than "00" in the 1st and 2nd positions) cannot be converted to a 12-digit format because, among other reasons, removing these non-zero digits creates an entirely different GTIN.

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4.5 Assigning vs. Storing vs. Encoding GTINs

As discussed above, GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length. Regardless of how they are assigned, it is important to understand that GTINs are always stored in databases and encoded in barcodes* in 14-digit format. The only exceptions are U.P.C. and EAN-13 barcodes, which are the only GS1 barcodes in which GTINs are encoded as 12 or 13 digits.

Table 4-1 Key to Assigning, Storing and Encoding GTINs

Assigning GTINs	Storing GTINs	Encoding GTINs
GTIN-12 or GTIN-14	**14-digit format** (i.e., GTIN-14 or GTIN-12 in 14-digit format using leading zeros)	**14-digit format *** (i.e., GTIN-14 or GTIN-12 in 14-digit format using leading zeros)

4.6 Marking Products with Both UPC-A and GS1 DataMatrix

As of this writing, FDA regulations require pharmaceutical products to be marked with a linear barcode that carries their NDC. However, DSCSA requires pharmaceutical products to be marked with a barcode that carries their NDC, serial number, lot number, and expiration date. To satisfy these requirements, many pharmaceutical manufacturers are marking products that move through a Point of Sale (POS) with both a UPC-A *(to satisfy the FDA linear barcode requirement)* and a GS1 DataMatrix *(to satisfy DSCSA serialization/traceability requirements)*. (See the section entitled *Marking Products with Both UPC-A and GS1 DataMatrix* for more information.)

The UPC-A holds a maximum of 12 digits, but the GS1 DataMatrix requires the GTIN to be in a format that is 14 digits long. In order to assure that the GTIN encoded in both barcodes is the same, manufacturers should follow the recommendations below for all products that will be marked with both a UPC-A and a GS1 DataMatrix:

- assign a GTIN-12 to identify the product at the lowest saleable level (i.e., the bottle or pack)
- create the UPC-A linear barcode using the GTIN-12
- pad the GTIN-12 with two leading zeros to create a "GTIN-12 in 14-digit format"

GTIN-12	**31414 199999 5**
GTIN-12 in 14-digit format	**00 31414 199999 5**

- when storing GTIN-12s in databases, store them in the 14-digit format
- use the "GTIN-12 in 14-digit format" when encoding the GS1 DataMatrix (along with expiration date, lot number and serial number for DSCSA purposes)

Important: **PER THE GS1 GENERAL SPECIFICATIONS, THIS MUST NOT BE DONE IN THE OPPOSITE DIRECTION** (i.e., assign a GTIN-14 and remove the first two digits in an attempt to create a GTIN-14 in a 12-digit format). A true GTIN-14 (one with digits other than "00" in the 1st and 2nd positions) cannot be converted to a 12-digit format because, among other reasons, removing these non-zero digits creates an entirely different GTIN.

Important: A GTIN-12 remains a GTIN-12 whether it is in its original 12-digit format or represented in a 14-digit format using leading zeros. Technically speaking, the padded GTIN-12 is called a "GTIN-12 in a 14-digit format." It is not a GTIN-14. Therefore, when a product needs to be marked with a UPC-A, it should be assigned a GTIN-12 (not a GTIN-14) in order to preserve

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the manufacturer's ability to represent the GTIN in a 12-digit U.P.C. as well as any barcode that requires a 14-digit format.

4.7 Case Identification

Cases can be identified using GTIN + serial number or using SSCC, depending on how the case is being used:

- **Use GTIN + serial number** if the case is orderable and if your customer is expecting to identify the contents from the case barcode or EPC/RFID tag
- **Use SSCC** if the case is to be treated as a logistics unit

4.8 Location Identification: Data Capture vs. Data Reporting

The guideline includes a table that provides a reference between a business location (i.e., a building with an address) and internal locations (e.g., loading dock; doorway; etc.). The model captures EPCIS events at the internal location level and produces EPCIS events for trading partners at the business location level. For example, a manufacturer may capture the location of a palletizer as cases are aggregated or packed onto a pallet. The EPCIS event that is generated for trading partners will include the location of the manufacturing site, not the palletizer itself. The manufacturer may decide to store the lower-level location (palletizer) for their own purposes and report a higher-level location (the production plant) for the purposes of external track and trace.

4.9 EPCIS & the URI

EPCIS stores identifiers (e.g., GTIN + serial number; SSCC; GLN; etc.) in URI format. "URI" stands for Uniform Resource Identifier, which is used in many Internet-based software systems to refer to any resource on the network. There are two types of URIs: Uniform Resource Names (URNs) and Uniform Resource Locator (URLs). The EPCIS data format standard is a URN which takes the following form:

`urn:epc:id:`*`scheme`*`:`*`component1`*`.`*`component2`*`....`

Scheme names an EPC scheme, and the content and format of the remainder of the URI string (i.e., *component1*, *component2*, etc.) depends on which EPC scheme is being used. Each EPC scheme provides a namespace of identifiers that can be used to identify physical objects of a particular type. There are seven EPC schemes that correspond to GS1 identifiers. For example, the EPC scheme for SGTIN is provided below:

SGTIN:	

General syntax: urn:epc:id:sgtin:*CompanyPrefix*.*ItemRefAndIndicator*.*SerialNumber*

Example: urn:epc:id:sgtin:0614141.112345.400806

The URI scheme to be used for GTIN + serial number, GTIN + lot number, SSCC and GLN are provided in the relevant sections of this guideline.

4.10 Determining the Length of GS1 Company Prefixes for URIs

When translating data from URI formats, it is necessary to indicate the length of the GS1 Company Prefix (i.e., how many digits within the GS1 identification key belong to the GS1 Company Prefix). Because GS1 Company Prefixes are issued in varying lengths, you will need to obtain the length of each GS1 Company Prefix you expect to encounter in your EPCIS events. Optimally, the GS1 Company Prefix(es) and pertinent identification keys (e.g., GTINs, GLNs) of trading partners will be exchanged prior to the start of exchanging EPCIS events. The on boarding process for trading partners is a good moment for this to occur. In some situations, EPCIS event data may be received without previously

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exchanging GS1 Company Prefixes. To aid software in those situations, GS1 has published the GS1 Company Prefix (GCP) Length Table (https://www.gs1.org/standards/bc-epc-interop) which is comprised of a list starting digits of GCPs and the length of GCPs associated with each set of starting digits. This table is updated regularly with data from many GS1 Member Organizations.

4.11 Inference

Inference is the process a supply chain partner uses to ensure there is enough evidence to infer the serialized number without physically reading ALL serialized numbers. Inference applies in instances where a collection is moved through the supply chain in an outer container (e.g., pallets; cases; totes; etc.), and less than 100% of data carriers in that collection are read by recipients. In such circumstances, inference enables the recipient of the collection to leave the outer container intact (un-opened) so as not to undermine tamper-evident security features. To gain a more complete understanding of what is contained in the entire collection, the recipient reads the serialized identifiers for the visible items, cross-checks them with the shipping documents for the collection and outer container bundle and verifies the integrity of the outer container bundle and its security features. If all three conditions are confirmed, the rest of the items in the collection can be inferred to be present.

Inference is a mechanism that enables supply chain partners to leverage strong supply chain practices to meet the potential challenges associated with the receiving/shipping of serialized items.

Use of Inference in examples:

For internal levels of packaging where either barcode is used or EPC/RFID devices are unreadable, the trading partner in possession of the object is said to have inferred the existence of internal layers of packaging that cannot be read at the time of the event and may exercise an inference SOP for that purpose.

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5 Identify

GS1 identification keys globally and uniquely identify supply chain objects (e.g., products, assets, logistic units, etc.), as well as parties (legal entities and functions) and locations (physical and digital). The table below lists the GS1 identification standards used in this guideline to support serialized item-level traceability.

Table 5-1 GS1 Identifiers[1]

Supply Chain Object, Party, or Location	Serialized Item-Level
Physical location	GLN
Specific physical locations within physical locations (if shared with trading partners)	GLN
Parties (Legal entities, functions)	GLN
Item	GTIN + serial number
Kit	GTIN + serial number
Homogeneous Case	GTIN + serial number, or SSCC
Mixed / Partial Case	SSCC
Pallet	SSCC
Tote	SSCC

5.1 Identifying Trade Units (Products, Cases & Kits): GTIN

In the GS1 System, products, cases, and kits[2] are identified with the GTIN. A GTIN is a globally unique, standards-based, identification key for trade items. When a manufacturer assigns ("allocates") a GTIN, they define a prescribed set of data about the product to which that GTIN relates. These *product description attributes* define master data that is consistent across all instances of the product (e.g., size; color; brand information; etc.). GS1 Standards specify the list of attributes to be defined for each GTIN, as well as the permissible values. Once the GTIN is allocated and the attributes are defined, the GTIN and its associated attributes are then saved in a database (like a GDSN-certified Data Pool) and shared among supply chain partners. (The *Master Data* section of this guideline explains how this information can be combined with EPCIS event information to obtain efficient supply chain visibility.)

Note: GS1 US provides an online tool, known as GS1 US Data Hub®, to support users in allocating GTINs and defining the associated attributes. Visit https://www.gs1us.org/tools/gs1-us-data-hub for more information.

5.2 Assigning GTINs from a GS1 Company Prefix

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14, respectively). However, within the U.S. pharmaceutical supply chain, the GTIN-12 and the GTIN-14 are predominantly used. The choice of format is related to point of sale:

- **Assign a GTIN-12** to pharmaceuticals products that will be scanned at point of sale (See *Marking Products with Both UPC-A and GS1 DataMatrix* for more information)
- **Assign a GTIN-14** to pharmaceuticals that will not be scanned at point of sale

[1] There may be other layers of packaging that are not specified here.
[2] Consult the FDA UDI (Unique Device Identification) Rule for Kits that include a medical device.

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5.2.1 Creating a GTIN-12

Each GTIN-12 is a numerical string comprising three distinct segments. The 3 segments within a GTIN-12 are:

- **U.P.C. Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTIN). The U.P.C. Company Prefix is a specific representation of a GS1 Company Prefix that serves as the foundation for generating GTIN-12 identifiers. U.P.C. Company Prefixes vary in length depending on the company/organization's needs. (In a GTIN-12 that embeds an NDC, the U.P.C. Company Prefix segment is populated with the NDC Labeler Code with a "3" appended in front.)
- **Item Reference:** A number assigned by the holder of the U.P.C. Company Prefix to uniquely identify a trade item. The *Item Reference* varies in length as a function of the U.P.C. Company Prefix length. (Refer to the *GS1 General Specifications* and the *GTIN Allocation Rules for the Healthcare Sector* for additional information.) In a GTIN-12 that embeds an NDC, the *Item Reference* segment is populated with the NDC Product/Package Code.
- **Check Digit:** A one-digit number calculated from the first 11 digits of the GTIN-12 used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you.

Although the length of the U.P.C. Company Prefix and the length of the *Item Reference* vary, they will always be a combined total of 11 digits in a GTIN-12. The addition of the *Check Digit* completes the 12 digits of the GTIN-12. The figure below provides a color-coded example of a hypothetical GTIN-12 that embeds an NDC, and a key explaining how each digit is populated.

Figure 5-1 Populating the 12 digits of a GTIN-12 with an US NDC embedded

Example of a GTIN-12 with an NDC embedded

GTIN-12	3	1	2	3	4	5	6	7	8	9	0	6
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12

How to Populate Each Digit ***(color-coded to coordinate with the GTIN-12 shown above)***

Position 1	GS1 Prefix "3"
Position 2 through 11	NDC *Labeler Code* as assigned by FDA plus NDC *Product/Package Code* created by the manufacturer (Although the length of the *Labeler Code* and the *Product/Package Code* vary, they will always be a combined total of 10 digits.)
Position 12	Check Digit

5.2.2 Creating a GTIN-14

Each GTIN-14 is a numerical string comprising four distinct segments. The four segments in a GTIN-14 are:

- **GS1 Indicator Digit:** The indicator digit identifies packaging level. The field consists of a numeric value from 1 to 9.

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Note: Packaging specialists should review the Indicators used on all other packaging levels prior to incorporating a new packaging level for a product to assure that there is a unique GTIN on every packaging level. This is imperative to preserve the uniqueness of each GTIN.

- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs. In a GTIN-14 that embeds an NDC, the GS1 Company Prefix segment is populated with the NDC Labeler Code with a "03" appended in front.
- **Item Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a trade item. The *Item Reference* varies in length as a function of the GS1 Company Prefix length. (Refer to the *GS1 General Specifications* and the *GTIN Allocation Rules for the Healthcare Sector* for additional information.) In a GTIN-14 that embeds an NDC, the *Item Reference* segment is populated with the NDC Product/Package Code.
- **Check Digit:** A one-digit number calculated from the first 13 digits of the GTIN used to assure data integrity. GS1 US provides a *check digit calculator* to automatically calculate check digits for you.

Although the length of the GS1 Company Prefix and the length of the Item Reference vary, they will always be a combined total of 12 digits in a GTIN-14. The *Indicator Digit* and the *Check Digit* comprise the remaining 2 digits of the GTIN-14. The figure below provides a color-coded example of a hypothetical GTIN-14 that embeds an NDC, and a key explaining how each digit is populated.

Figure 5-2 Populating the 14 digits of a GTIN-14 with an FDA NDC embedded

Example of a GTIN-14 with an NDC embedded

GTIN	2	0	3	6	1	4	1	4	5	6	7	8	9	8
Digit / Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14

How to Populate Each Digit ***(color-coded to coordinate with the GTIN-14 shown above)***

Position 1*	Indicator Digit (numeric value from 1 to 9)
Position 2 and 3	GS1 Prefix "03"
Positions 4 through 13	NDC *Labeler Code* as assigned by FDA plus NDC *Product/Package Code* created by the manufacturer (Although the length of the *Labeler Code* and the *Product/Package Code* vary, they will always be a combined total of 10 digits.)
Position 14	Check Digit

* This indicator digit position could be populated with a numeric value of 1 to 8 for fixed measure trade items, and 9 for variable measure items.

5.2.3 Data Format for Databases & Applications

Although the U.S. pharmaceutical supply chain uses both GTIN-14 and GTIN-12, EPCIS requires GTINs to be in a 14-digit format. Therefore, a GTIN should always be represented in software applications as 14 digits by adding leading zeros as necessary to make 14 digits. In order to preserve any leading

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zeros that may be present, the GTIN field should be represented in a database as a text field (not numeric). **This is especially important for manufacturers who currently have many GTIN-12s in their systems due to the Barcode Rule.**

5.2.4 Data Format for EPCIS

Within the EPCIS, GTIN is stored with a serial number in EPC URI format.

- The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (*SGTIN EPC*).

This is discussed in detailed in the *serial number section* below.

5.3 Batch / Lot Numbers

5.3.1 Assigning Batch/Lot Numbers

The *GS1 General Specifications* define a batch/lot number as an alphanumeric string whose length is variable between one and 20 characters *(the specific characters allowed are defined in the GS1 General Specifications)*. In GS1 Barcodes, batch/lot numbers are represented using AI (10). Any batch/lot number consisting of 1-20 alphanumeric characters may be used in a GS1 Barcode per the standard. Although barcodes can accommodate any 1-20 character batch/lot number, the size of the barcode may vary depending on how many characters are used. Many production systems prefer a consistent barcode size in order to conform to package artwork constraints and to simplify the quality assurance process. For this reason, manufacturers often adopt a consistent batch/lot number length rather than allow their batch/lot numbers to vary between 1 and 20 characters.

5.3.2 Data Formats for Databases & Applications

Databases, applications, and messages that need to contain a batch/lot number should be designed to accommodate any batch/lot number consisting of 1-20 alphanumeric characters. "Zero" characters in batch/lot numbers are treated as any other alphanumeric character such that batch/lot numbers 7, 07, and 007 are all *different* batch/lot numbers according to the standard. Databases and applications should treat the batch/lot number as a text field so that leading zeros are not inadvertently stripped off.

Example – Converting a GTIN-12 + batch/lot into EPC URI Format:

To find the EPC URI corresponding to the combination of a GTIN-12 and a batch/lot number, first convert the GTIN-12 to a 14-digit number by adding two leading zero characters. The first leading zero will serve as the Indicator Digit, and the second leading zero will serve as the first place of the U.P.C. Company Prefix as shown below:

GTIN-12	**31234** 567890 **6**
GTIN-12 in 14-digit format	**00 31234** 567890 **6**
Batch/Lot Number	**D4E5F6**
Corresponding Barcode Human Readable Interpretation (HRI) Text	**(01) 00 31234** 567890 **6 (10) D4E5F6**

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5.4 Serial Numbers

5.4.1 Assigning Serial Numbers

The combination of a GTIN plus a unique serial number is used to identify a specific instance of a trade item. For example, if hypothetical GTIN 00361414567894 is assigned to identify a 100-count bottle of XYZ tablets, then the combination of GTIN 00361414567894 plus a serial number would identify a *specific* 100-count bottle of XYZ tablets. All bottles of XYZ tablets would have the same GTIN, but each bottle would be assigned a unique serial number.

The *GS1 General Specifications* define a serial number for use with a GTIN as an alphanumeric string whose length is variable between one and 20 characters *(the specific characters allowed are defined in the GS1 General Specifications)*. In GS1 Barcodes, serial numbers are represented using AI **(**21**)**. Any serial number consisting of 1-20 characters may be used in a GS1 Barcode per the standard. Although barcodes can accommodate any 1-20 character serial number, the size of the barcode may vary depending on how many characters are used. However, many production systems prefer a consistent barcode size in order to conform to package artwork constraints and to simplify the quality assurance process. For this reason, manufacturers often adopt a consistent serial number length rather than allow their serial numbers to vary between 1 and 20 characters.

When using EPC/RFID tags, however, certain limitations apply. As with barcodes, EPC/RFID tags having at least 198 bits of EPC memory capacity can accommodate any 1-20 character serial number. However, EPC/RFID tags having 96–197 bits of EPC memory capacity use a 96-bit encoding format (called SGTIN-96) that places limitations on the serial numbers that can be encoded. When using the SGTIN-96 encoding, the serial number must be numeric only (that is, the only characters permitted are the digits '0' through '9'), must not have any leading zeros, and must have a numeric value that is less than or equal to 274877906943.

The following Best Practices have been defined to accommodate the considerations described above:

- Business applications, messages, and databases should be designed to accept data from any data carrier. Specifically, this means that applications and databases should be designed to accept the full range of data values defined by GS1 Standards, including a full 14-digit GTIN and a serial number between one and 20 alphanumeric characters. The restrictions on data values that certain data carriers impose (e.g., 96-bit EPC/RFID tags) should not be carried through to this level.
- Applications should not add or remove leading zeros to serial numbers.
- While the standards support serial numbers beginning with "0", applications that assign serial numbers for use with GTIN should avoid serial numbers that begin with a "0" character in order to avoid errors associated with incorrect implementations.
- If 96-bit EPC/RFID tags are to be used, serial numbers must fit within the encoding constraints of the 96-bit SGTIN format as defined by the GS1 EPC Tag Data standard (described above).
- In order to support both barcodes and 96-bit EPC/RFID tags, and to achieve a consistent barcode size, a good policy would be to assign either 11-digit numeric serial numbers within the range 10000000000 – 99999999999, or 12-digit numeric serial numbers within the range 100000000000 – 274877906943.
- The GTIN and serial number identifies a unique instance of a product. Therefore, reuse of serial numbers for a given GTIN is not permitted under the standards.

5.4.2 Data Format for Databases & Applications

As described above, the industry best practice is for manufacturers to assign all numeric serial numbers of only 11-12 digits in length in order to ensure compatibility of serial numbers across barcodes and 96-bit EPC/RFID tags. Nonetheless, databases and messages that need to contain a serial number should be designed to accept the full range of data values defined by GS1 Standards. Therefore, serial

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numbers should always be stored in a text field (not numeric) that is capable of handling between one and 20 alphanumeric characters.

Important: "Zero" characters in serial numbers are treated as any other alphanumeric character such that serial numbers 7, 07, and 007 are all different serial numbers according to the standard. Leading zeros should never be added or removed from serial numbers.

5.4.3 Data Format for EPCIS: SGTIN URI

Within the EPCIS, GTIN + serial number are stored in EPC URI format. The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (SGTIN EPC).

Important: The SGTIN EPC is based on a 14-digit GTIN. Therefore, GTIN-12s will first need to be converted to a 14-digit number by adding two leading zeros. (An example of the conversion is provided below.)

General syntax:

`urn:epc:id:sgtin:`*`CompanyPrefix.ItemRefAndIndicator.SerialNumber`*

Example:

`urn:epc:id:sgtin:0614141.112345.400806`

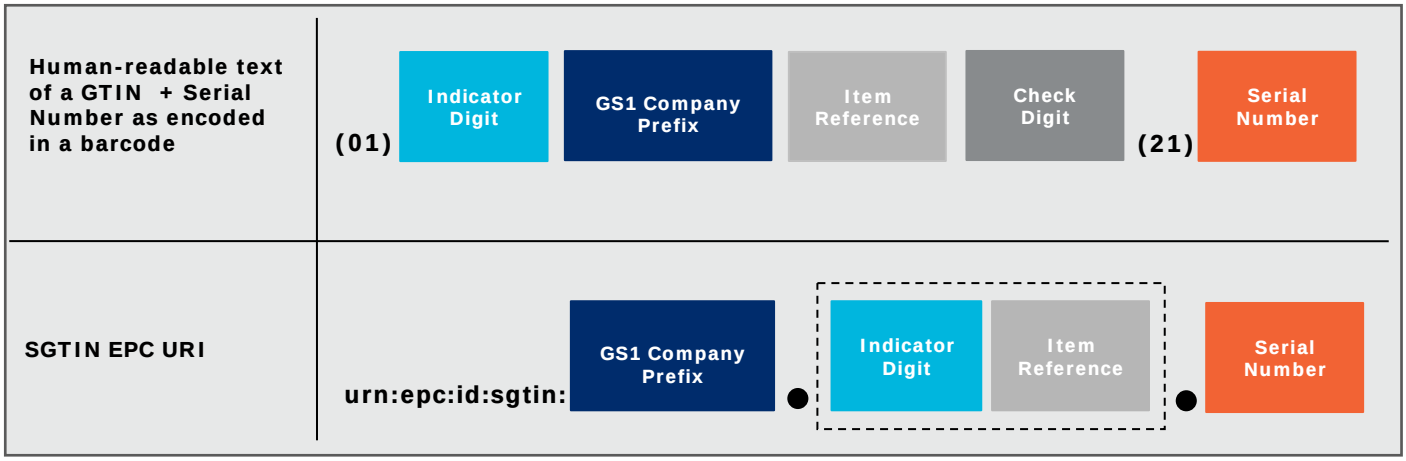
Grammar:

SGTIN-URI ::= "urn:epc:id:sgtin:" SGTINURIBody

SGTINURIBody ::= 2*(PaddedNumericComponent ".") GS3A3Component

The number of characters in the two PaddedNumericComponent fields should total 13 (not including any of the dot characters). The Serial Number field of the SGTIN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the (AI) 21 Serial Number according to the GS1 General Specifications. The figure below depicts how the element string of a GTIN + serial number corresponds to the element string of a SGTIN EPC URI:

Figure 5-3 How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format



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- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GTIN key.
- The *Item Reference* as it appears in the SGTIN EPC URI is derived from the GTIN key by concatenating the Indicator Digit of the GTIN and the Item Reference digits and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.
- The *Serial Number* is the equivalent of AI (21).

Example – Converting a GTIN-14 + serial number into EPC URI Format:

GTIN-14	**2 030001 123498 7**
Serial Number	**123456789012**
Corresponding Barcode Human Readable Interpretation (HRI) Text	**(01) 2 030001 123498 7 (21)123456789012**
Corresponding SGTIN-EPC URI	**urn:epc:id:sgtin: 030001 . 2 123498 . 123456789012**

Note: The spaces in the example above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.

Example – Converting a GTIN-12 + serial number into EPC URI Format:

To find the EPC URI corresponding to the combination of a GTIN-12 and a serial number, first convert the GTIN-12 to a 14-digit number by adding two leading zero characters. The first leading zero will serve as the Indicator Digit, and the second leading zero will serve as the first place of the U.P.C. Company Prefix as shown below:

GTIN-12	**31234 567890 6**
GTIN-12 in 14-digit format	**00 31234 567890 6**
Serial Number	**123456789012**
Corresponding Barcode Human Readable Interpretation (HRI) Text	**(01) 00 31234 567890 6 (21)123456789012**
Corresponding SGTIN-EPC URI	**urn:epc:id:sgtin: 031234 . 0 567890 . 123456789012**

Note: The spaces in the example above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.

5.4.4 Data Storage Options for GTIN + Serial Number

GTIN and serial number are assigned as separate data elements but are saved together as an SGTIN in EPCIS. Users have several options for how to store GTIN + serial number in databases and applications: (1) GTINs and serial numbers can be saved in their own fields; (2) saved together in the SGTIN EPC URI format (to be parsed by backend systems as needed), or (3) saved as both.

Thus, there are three options for storing GTINs and serial numbers in databases:

2 fields =	GTIN field and Serial Number field
1 field =	One field containing serialized GTIN in EPC URI format
3 fields =	GTIN field, Serial Number field, and field containing serialized GTIN in EPC URI format

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Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in the table below.

Table 5-2 Data Formats for GTIN + Serial Number Fields

Field	Data Format
GTIN	▪ 14 digits ▪ text field (not numeric)
Serial Number	▪ 1-20 characters ▪ text field (not numeric)

Serialized GTIN EPC URI	▪ 33-52 characters:
	  ▪ 17 characters for "urn:epc:id:sgtin:"
	  ▪ 13 characters for the GTIN (without the Check Digit)
	  ▪ 1-20 characters for the serial number
	  ▪ 2 periods (".")
	▪ text field (not numeric)

5.5 Identifying Logistics Units (Cases, Pallets & Totes): SSCC

In the GS1 System, logistics units such as cases, pallets, and totes are identified with the Serial Shipping Container Code (SSCC). The SSCC is an 18-digit, globally unique, standards-based, identification key for logistics units. SSCCs serve as "license plates" from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

5.6 Assigning SSCCs from a GS1 Company Prefix

Suppliers are responsible for assigning (*allocating*) SSCCs to their logistics units. Each SSCC is a numerical string comprising four distinct segments. The four segments within an SSCC are:

- **Extension Digit:** The Extension Digit has no defined logic. It is available to the company to increase the capacity of the *Serial Reference*. The field consists of a numeric value from 0 to 9.
- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs; SSCCs; etc.). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs.
- **Serial Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a logistic unit. This segment is the "serial" part of the number assigned one-by-one by the company to create a globally unique SSCC. The *Serial Reference* varies in length as a function of the GS1 Company Prefix length.
- **Check Digit:** A one-digit number calculated from the first 17 digits of the SSCC used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you.

Although the length of the GS1 Company Prefix and the length of the Serial Reference vary, they will always be a combined total of 18 digits in an SSCC. The figure below provides a color-coded example of a hypothetical SSCC, and a key explaining how each digit is populated.

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Figure 5-4 Populating the 18 digits of an SSCC

Example of an SSCC

SSCC	0	0	3	3	4	5	6	7	8	9	1	2	3	4	5	6	0	4
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18

How to Populate Each Digit ***(color-coded to coordinate with the SSCC shown above)***

Position 1	Extension Digit (numeric value from 0 to 9)
Positions 2 through 17	GS1 Company Prefix as assigned by GS1 US plus Serial Reference number as assigned by the owner of the logistics unit
Position 18	Check Digit

5.7 Data Format for Databases

In databases, SSCC fields should be 18 characters in length. The SSCC should be represented in a database as a text field (not numeric), so that leading zeros are not inadvertently dropped.

5.8 Data Format for EPCIS: SSCC URI Format

Within the EPCIS, SSCCs are stored in EPC URI format. The EPC URI format for an SSCC is the SSCC EPC.

General syntax:

`urn:epc:id:sscc:CompanyPrefix.SerialReference`

Example:

`urn:epc:id:sscc:0614141.1234567890`

Grammar:

SSCC-URI ::= “urn:epc:id:sscc:” SSCCURIBody

SSCCURIBody ::= PaddedNumericComponent “.” PaddedNumericComponent

The number of characters in the two PaddedNumericComponent fields should total 17 (not including any of the dot characters). The figure below depicts how the element string of an SSCC corresponds to the element string of a SSCC EPC URI.

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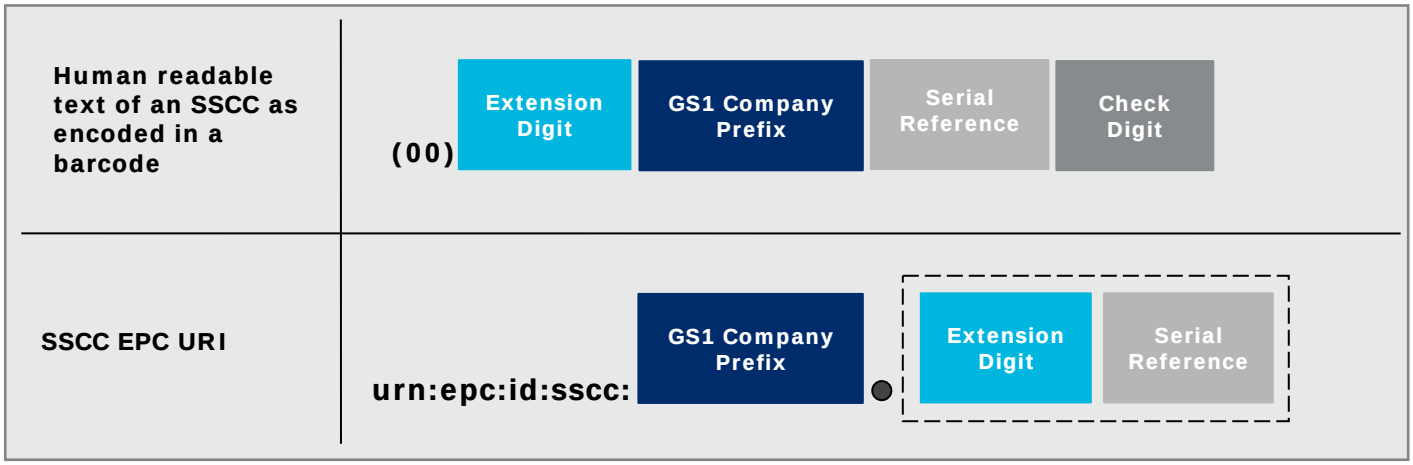
Figure 5-5 How the segments of an SSCC are represented in the SSCC EPC URI format



- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 SSCC key.
- The *Serial Reference* as it appears in the SSCC EPC URI is derived from the SSCC key by concatenating the Extension Digit of the SSCC and the Serial Reference digits and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.

5.9 Data Storage Options

When storing SSCCs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing SSCC in databases:

1 field =	SSCC
1 field =	SSCC in EPC URI format
2 fields =	SSCC field and a field containing SSCC in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in the table below.

Table 5-3 Data Formats for SSCC Fields

Field	Data Format
SSCC	▪ 18 digits ▪ text field (not numeric, to avoid dropping leading zeros)

SSCC URI	▪ 34 characters:
	  ▪ 16 characters for "urn:epc:id:sscc:"
	  ▪ 17 characters for the SSCC (without the Check Digit)
	  ▪ 1 period (".")
	▪ text field (not numeric)

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5.10 Identifying Parties & Locations: GLN

In the GS1 System, parties and locations are identified with the Global Location Number (GLN). The GLN is a 13-digit, globally unique, standards-based, identification key for legal entities, functions, physical locations, and digital locations. Each company is responsible for assigning (*allocating*) GLNs to its own parties and locations. When a user assigns a GLN, they define a prescribed set of data about the party/location to which that GLN relates (e.g., street address, floor, etc.). These GLN attributes define master data about the party/location (e.g., name, address, class of trade, etc.), which help to ensure that each GLN is specific to one, very precise location within the world. The GLN and its associated attributes are then saved in a database (like GS1 US Data Hub │ Location) and shared among supply chain partners.

5.11 Assigning GLNs from a GS1 Company Prefix

Each GLN is a numerical string comprising three distinct segments. The three segments in a GLN are:

- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs; SSCCs; etc.). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs.
- **Location Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a location within the company. The length of the *Location Reference* varies as a function of the GS1 Company Prefix length.
- **Check Digit:** A one-digit number calculated from the first 12 digits of the GLN used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you.

Although the length of the GS1 Company Prefix and the length of the Location Reference vary, they will always be a combined total of 12 digits in a GLN. The addition of the *Check Digit* completes the 13 digits of the GLN. The figure below provides a color-coded example of a hypothetical GLN, and a key explaining how each digit is populated.

Figure 5-6 Populating the 13 digits of a GLN

Example of a GLN

GLN	0	3	2	1	0	1	2	3	4	5	6	7	6
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13

How to Populate Each Digit ***(color-coded to coordinate with the GLN shown above)***

Positions 1 through 12	GS1 Company Prefix as assigned by GS1 US plus Location Reference number as assigned by the owner of the GS1 Company Prefix
Position 13	Check Digit

5.12 Individual Licensed GLNs

Some organizations only need to identify their company or a few locations and nothing else. For those who do not need to create other GS1 Identification Keys, like GTINs or SSCCs, they have the option to license individual GLNs that are not part of a GS1 Company Prefix. This option works well for those with limited identification needs to get started identifying their parties and locations. These individually licensed GLNs, also known as individually assigned GLNs in the EPC Tag Data Standard, are issued as full, thirteen-digit numbers and are to be used in their entity. As defined in Similar content as in EPC

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Tag Data Standard R1.3, an individually licensed GLN is encoded in EPC format by specifying the entire individually assigned GLN stripped of its check digit into the *CompanyPrefix* component of the EPC as shown in the syntax below.

General syntax:

`urn:epc:id:sgln:CompanyPrefix..Extension`

Example:

Given an example of individually assigned GLN value of 1234567890128, the corresponding EPC URN without GLN extension is as follows:

`urn:epc:id:sgln:123456789012..0`

Individual Licensed GLN's structure is also used for GLN managed programs.

- Two existing examples of these managed programs are:
  - The Group Purchasing Organization (GPO) managed program for Healthcare Providers
  - The Wholesale Distributor managed program for independent Dispensers and their sub-group of Practitioners acting as dispensers
- With both programs, the GLN is issued a thirteen-digit number and is to be used in its entirety. The GLN is not derived from a GCP. For systems requiring a GCP structure, use the first 12-digits as the GCP.
- Therefore, the GS1 US Data Hub® | Location is used to facilitate correct location identification. GEPIR is not an applicable tool for managed GLN programs as the GLN will not be tied to the legal entity of the location's organization.
- These programs and individual licensed GLNs are for parties that only need to receive.
- For the Wholesale Distributor managed program, one GLN is assigned per entity as the ship to and sold to are the same and not differentiated.

Note: For the Wholesale Distributor managed program:

- Expanding beyond one GLN per entity will be the responsibility of the party, not the program.
- Please reference the *GS1 US Pharmaceutical Supplier GLN Quick Start Guide* and *GS1 US Pharmaceutical Dispenser/Healthcare Provider GLN Quick Start Guide f*or additional GLN requirements beyond the minimum supported by the Wholesale Distributor managed program

Illustrative Example of GLNs without an extension component

- Given an example of a GLN assigned from a GS1 Company Prefix without extension component, the corresponding EPC URN without GLN extension is as follows:

  urn:epc:id:sgln:**0614141**.**12345**.**0**

  No GLN extension component present; value = 0
- For GLNs that are not assigned from a GS1 Company Prefix, but rather an individually licensed GLN, the only thing that changes when creating an SGLN is where the dot goes

  urn:epc:id:sgln:**123456789012**..**0**

  No GLN extension component present; value = 0

Note: The difference between the two options below in yellow.

urn:epc:id:sgln: **0614141.12345.0**

urn:epc:id:sgln: **123456789012..0**

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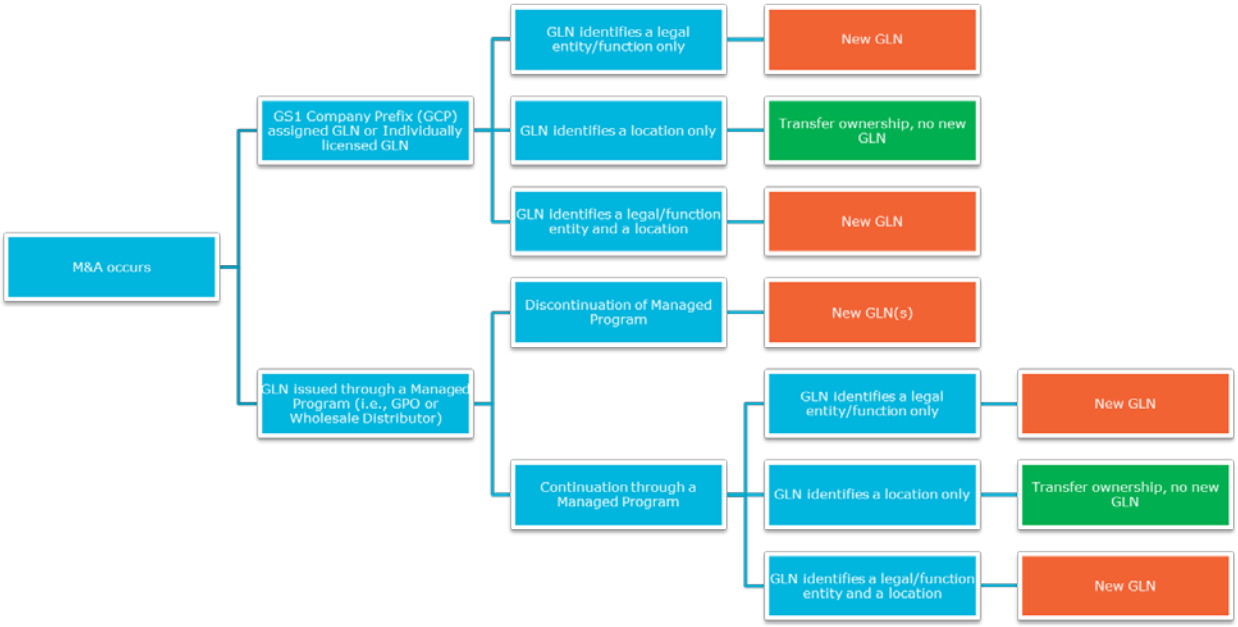
5.13 Mergers and Acquisitions (M&A) Impact on GLNs

Global Location Numbers serve a critical role in the identification of legal entities, functions, and physical locations. As each merger and acquisition (M&A) is unique and different, the impact on GLN(s) needs to be evaluated based on the end state of the M&A, who is the definitive owner of the GLN. In M&A situations, GLNs should be treated as regulatory information as they are the identifiers of the seller and buyer in transactions governed by DSCSA.

Below illustrates potential impacts on GLNs when an M&A occurs



Note: For the transfer of ownership options, these would be dependent on the GS1 Company Prefix (GCP) or Individually licensed GLN officially moving to the organization.

For additional clarity please reference the *GS1 GLN Management* Rules specifically regarding:

- *Guiding principles*
- *Party/location split*
- *Merger*

How to notify GS1 US of a change in your company's ownership due to a merger, acquisition, or divestiture, please refer to *https://www.gs1us.org/who-we-are/membership/mergers-acquisitions*.

Follow these steps to submit your Prefix Transfer Request:

- **Step 1:** Complete the *Company Prefix Transfer Request Form*.
- **Step 2:** Download and have a duly authorized officer of the selling company complete and sign the *Prefix Release Letter*.
- **Step 3:** Submit your completed Company Prefix Transfer Request Form and Company Prefix Release Letter via email to *dmaintenance@gs1us.org*. Alternatively, if you are an existing GS1 US customer, you may submit a request online via the *myGS1 US Customer Support Portal*

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5.14 Data Format for Databases

In databases, GLN fields should be 13 digits in length. The GLN should be represented in a database as a text field (not numeric). The GLN extension should be represented in a database as a text field capable of handling from one to 20 characters.

5.15 Data Format for EPCIS: SGLN URI Format

Within EPCIS, GLNs are stored in EPC URI format. The EPC URI format for a GLN (with or without Extension) is the SGLN EPC.

The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS. The SGLN syntax is capable of representing a plain GLN (without extension) or a GLN plus extension. Therefore, the same SGLN syntax can be used for any location identifier based on the GLN.

Unlike in the acronym SGTIN, the "S" in "SGLN" does *not* stand for "serialized," as the GLN all by itself refers to a specific location and so in that sense is already serialized. The "S" does not stand for anything.[3]

General syntax:

`urn:epc:id:sgln:`*`CompanyPrefix.LocationReference.Extension`*

Example:

`urn:epc:id:sgln:0614141.12345.0`

Grammar:

SGLN-URI ::= "urn:epc:id:sgln:" SGLNURIBody

SGLNURIBody ::= PaddedNumericComponent "."

PaddedNumericComponentOrEmpty "." GS3A3Component

The number of characters in the two PaddedNumericComponent fields should total 12 (not including any of the dot characters). The Extension field of the SGLN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the GS1 Application Identifier (254) GLN extension component according to the GS1 General Specifications. A SGLN EPC appearing within EPCIS events supporting DSCSA requirements shall have a single digit zero ("0") in the GLN Extension portion of the URI syntax.

The figure below depicts how the element string of a GLN corresponds to the element string of an SGLN EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GLN.
- The *Location Reference* is the same as it appears in the GLN.
- The *Check Digit* is not used in the EPC URI format.
- The *Extension* is the same as the *GLN extension component* assigned by the managing entity to an individual unique location. If there is no GLN extension component for this location, enter a single zero digit to indicate that the SGLN stands for a GLN without an extension.

[3] Frequently Asked Questions (FAQs) by the Pharmaceutical Industry in Preparing for the U.S. DSCSA R1.0.1 September 22, 2022

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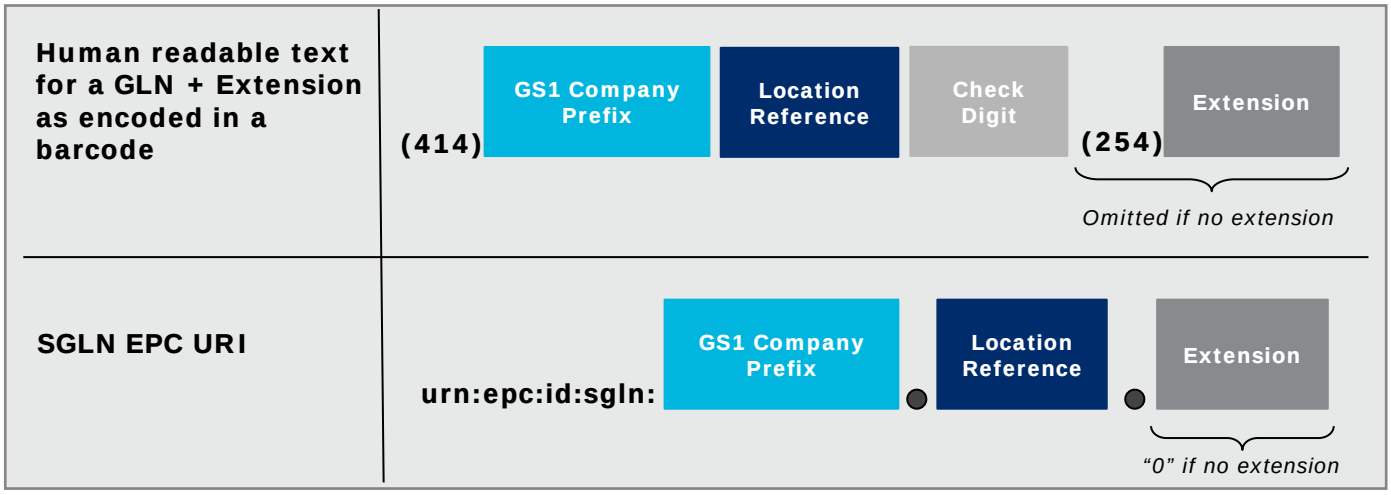
Figure 5-7 How the segments of a GLN (with or without extension) are represented in the SGLN EPC URI format



5.16 Caution on Assignment of GLN extension component

The Rx Secure Supply Chain Workgroup does not view the GLN extension component as suitable for EPCIS events to support DSCSA requirements for serialized item-level information. The U.S. pharmaceutical industry is an open value network comprised of a continually shifting landscape of trading partners. The GLN extension component is an optional means of identifying internal physical locations which reside within another physical location. This internal identification can be exchanged with trading partners by mutual agreement but is not suitable for open value networks. Consequently, an SGLN EPC appearing within EPCIS events supporting DSCSA requirements shall have a single digit zero ("0") in the GLN Extension portion of the URI syntax. For more information on the format of the SGLN EPC, consult section 5.15 of this guideline. Further, U.S. pharmaceutical industry companies wishing to identify internal physical locations that will be shared with trading partners within EPCIS events shall assign new GLNs not GLN extensions to those internal physical locations.

5.17 Data Storage Options

When storing SGLNs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing a GLN with extension in databases:

2 fields = GLN field and GLN Extension field

1 field = One field containing GLN + extension in EPC URI format

3 fields = GLN field, GLN Extension field, and field containing GLN + extension in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in the table below.

Table 5-4 Data Formats for GLN Fields

Field	Data Format
GLN	▪ 13 digits ▪ text field (not numeric)
GLN extension component	▪ 1-20 characters ▪ text field (not numeric)

SGLN EPC URI	▪ 31-50 characters:
	  ▪ 16 characters for "urn:epc:id:sgln:"
	  ▪ 12 characters for the GLN (no Check Digit)

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	▪ 1-20 characters for the GLN extension ▪ 2 periods ('.') ▪ text field (not numeric)

5.18 Additional Party Identifier: DEA Number

A **DEA number** (DEA Registration Number) is an identifier assigned to a health care provider (such as a physician, physician assistant, nurse practitioner, optometrist, dentist, or veterinarian) by the United States Drug Enforcement Administration allowing them to write prescriptions for controlled substances.

The DEA Number may be used in addition to the GLN but does not replace the GLN. In those cases, the following URI form may be used.

DEA Number in URI Form:

```
http://epcis.gs1us.org/hc/dea/loc/DEANumber
```

Example:

```
http://epcis.gs1us.org/hc/dea/loc/12345678
```

Examples of DEA used in various EPCIS event attributes:

```
<readPoint>http://epcis.gs1us.org/hc/dea/loc/12345678</readPoint>

<bizLocation>http://epcis.gs1us.org/hc/dea/loc/12345678</bizLocation>

<sourceList>

    <source
type="urn:epcglobal:cbv:sdt:location">http://epcis.gs1us.org/hc/dea/loc/12345678</source>

</sourceList>

<destinationList>

   <destination
type="urn:epcglobal:cbv:sdt:location">http://epcis.gs1us.org/hc/dea/loc/12345678</destination>

</destinationList>
```


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6 Capture

GS1 Data Carriers provide *machine-readable representations* of GS1 identification keys that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports multiple data carriers, barcode symbologies (i.e., GS1 barcodes) and RFID tags [i.e., GS1 Electronic Product Code (EPC®)-enabled radio frequency identification tags (EPC/RFID Tags)].

The table below lists the GS1 data carriers used in this guideline to support serial-level management and item-level traceability. Because this guideline documents a specific application of the standards to support serialized item-level traceability, only data carriers that can carry serial numbers are shown.

Table 6-1 GS1 Data Carriers Used in this Guideline

Supply Chain Object	GS1 Data Carrier Options
TRADE ITEMS: Products, Cases & Kits	GS1 DataMatrix
	GS1-128
	EPC/RFID Tag *(serialized trade items only)*
LOGISTICS UNITS: Cases, Pallets & Totes	GS1-128
	GS1 DataMatrix
	EPC/RFID Tag

6.1 Encoding GS1 Data Carriers

Examples in this guideline use four GS1 Data Carriers: three GS1 barcodes and one EPC/RFID tag. Guidance for encoding those data carriers is provided in this section.

6.2 Barcodes

The data elements within a barcode are demarcated through the use of GS1 Application Identifiers (AIs). GS1 AIs are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two, three, or four digit numeric code. (When rendered in human readable interpretation (HRI) text, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode's encoded data.) Each data element in a barcode is preceded by its AI. There are more than 180 AIs, including one AI for each GS1 identifier (e.g., GTIN, GLN, SSCC, etc.) as well as numerous AIs for secondary information. The AI's that are relevant to this guideline are:

- **AI (01)** GTIN
- **AI (00)** SSCC
- **AI (414)** GLN (physical location)
- **AI (715)** NDC National Drug Code
- **AI (21)** Serial Number
- **AI (10)** Batch/Lot Number
- **AI (17)** Expiration Date

More than one AI can be carried in one barcode. The table below presents some high-level concepts and principles that should be followed when encoding barcodes.

Table 6-2 Encoding Principles

Principle	Example / Illustration	
Each barcode data element has a two- to four-digit AI that defines data type and field size.	GTIN	**AI (01)**
	Serial Number	**AI (21)**
	Batch/Lot Number	**AI (10)**
	Expiration Date	**AI (17)**
	SSCC	**AI (00)**

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When encoding, each data element is preceded by its corresponding AI.	GTIN	**01**00361414123410
	Serial Number	**21**BLC0485
	Batch/Lot Number	**10**0192837
	Expiration Date	**17**241120
	SSCC	**00**003345678912345604

Note: Do not expect Application Identifiers (AIs) to be encoded in a defined order or sequence.

Human Readable Interpretation (HRI) is the printed representation of the data encoded in a barcode (e.g., GS1 DataMatrix or GS1-128 barcode). HRI text always appears immediately adjacent to the barcode (typically underneath linear barcodes and to the side of GS1 DataMatrix barcodes) and is subject to formatting rules specified in the GS1 General Specifications.

(01)00361414123410
(17)241120
(10)0192837
(21)BLC0485

Due to regulatory requirements, as in the example of the U.S. FDA's requirements for the NDC and expiration date in human readable form, the data content between the HRI and human readable form is equivalent in meaning but can be represented differently. As an example, in the human readable form, the NDC is listed as itself in a 3-segment hyphenated format per the U.S. FDA while in the human readable interpretation would show the NDC embedded in the GTIN with no hyphens.

Examples of the difference between the two:

	Human Readable Interpretation (HRI)	U.S. FDA Human Readable Form
National Drug Code (NDC)	(01) 003**61414123410** *NDC is embedded in the GTIN	NDC 61414-1234-1
Expiration Date	(17) 241120	EXP 20 Nov 2024

GTIN (01) 00361414123410
NDC (715) 61414 1234 1
EXP (17) NOV 20 2024
Lot (10) 0192837
SN (21) BLC0485

Recommendation: Owner of the product should ensure the quality of the barcode.

6.2.1 Trade Items: Products, Cases & Kits

As a way of gaining uniformity throughout the supply chain, this guideline includes two best practice barcode options for items, cases, and kits: GS1 DataMatrix and GS1-128. DSCSA requirements, which commenced in 2017 include the marking of pharmaceutical products with a product identifier, serial number, batch/lot number, and expiration date.

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Table 6-3 Barcodes for Items, Cases & Kits

Barcodes for Items, Cases & Kits		
Required Identification Information	GTIN	AI (01)
	Serial Number	AI (21)
	Batch/Lot Number	AI (10)
	Expiration Date	AI (17)
GS1 Barcode Options	GS1 DataMatrix (on Rx Packages – e.g., Lowest Saleable Unit or homogeneous case) GS1-128	

6.2.2 Encoding Principles

GTIN

- Begin with the two-digit AI "**01**" to indicate GTIN.
- A fixed-length field comprising the 14 numeric characters of a GTIN data follows the AI.
- *For GTIN-12: encode in 14-digit format using two leading zeros*
- The data syntax for the GTIN component is n2 + n14 (where n2 is the AI and a14 is the GTIN).
- EXAMPLE: **01 00312345678906**

Serial Number

- Begin with two-digit AI "**21**" to indicate the *Serial Number*.
- A variable-length field of up to 20 alphanumeric characters of *Serial Number* data follows the AI.
- *If using a barcode with a 96-bit EPC/RFID tag: be sure to note the associated* limitations on serial number
- The data syntax for the *Serial Number* component is n2 + a1..20 (where n2 is the AI and a1..20 is the *Serial Number*).
- EXAMPLE: **21 ABCDEFG123456789**

Batch/Lot Number

- Begin with the two-digit AI "**10**" to indicate *Batch/Lot Number*.
- A variable-length field of up to 20 alphanumeric characters representing the *Batch/Lot Number* follows the AI.
- The data syntax for the *Batch/Lot Number* component is n2 + a1..20 (where n2 is the AI and a1..20 is the *Batch/Lot Number*).
- EXAMPLE: **10 987654321gfedcba**

Expiration Date

- The two-digit AI "**17**" is used to indicate *Expiration Date*.
- A fixed-length field of six numeric characters representing the *Expiration Date* as **YYMMDD** follows the AI.
- YY = the tens and units of the year (e.g., 2023 = 23).
- MM = the number of the month (e.g., March = 03).
- DD = the number of the day of the relevant month (e.g., second day = 02).
- The data syntax for *Expiration Date* is n2 + n6 (where n2 is the AI and n6 is the *Expiration Date*).
- EXAMPLE: **17 230331**
- *See Rules for Expressing Expiration Date for more information*

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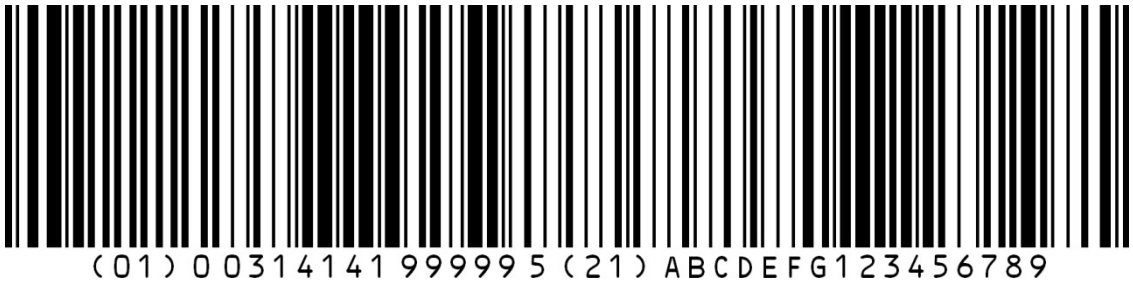
6.2.2.1 Examples

Figure 6-1 GTIN with Serial Number Encoded in a GS1 DataMatrix

Figure 6-2 GTIN with Serial Number Encoded in a GS1-128



6.2.3 Marking Products with Both UPC-A and GS1 DataMatrix

The FDA 2004 Pharmaceutical Barcode Rule (updated in 2006) requires prescription drug products to carry the NDC in one of two standard linear barcode formats. However, starting in 2017, the DSCSA required items to be marked with a 2D data matrix barcode. The industry and GS1 have asked the FDA whether the requirement to use linear barcodes will be sunset in light of the DSCSA in order to reduce duplicate data, free label space, and lessen ambiguity for clinicians determining which barcode to read. Until there is guidance from the FDA, manufacturers and repackagers will need to encode both linear and 2D DataMatrix barcodes on products that are serialized. Many pharmaceutical manufacturers are marking products that move through a Point of Sale with both a UPC-A and a GS1 DataMatrix:

- Any item that passes through a POS is typically marked with a UPC-A. The UPC-A is a linear barcode that holds a maximum of 12 digits, which promotes readability by traditional POS systems. The UPC-A can be used to satisfy the FDA's linear barcode requirement. However, because it is limited to 12 digits, the UPC-A cannot carry the information needed to satisfy serial-level management or serialized item-level traceability requirements.
- The GS1 DataMatrix is a 2D barcode that can carry more data (e.g., GTIN, serial number, expiration date, etc.) in a smaller space. Most manufacturers are choosing to use the GS1 DataMatrix to satisfy serialization and/or traceability requirements. However, as a 2D barcode, the GS1 DataMatrix does not satisfy the FDA's linear barcode requirement.

Marking pharmaceutical products that cross POS with both barcodes satisfies both types of requirements (i.e., the UPC-A for the FDA linear barcode requirement, and the GS1 DataMatrix for serialization/traceability requirements). To ensure that the GTIN encoded in both barcodes is the same, manufacturers should follow the *recommendations* outlined for all products that will be marked with both a UPC-A and a GS1 DataMatrix.

Figure 6-3 GTIN-12 in a UPC-A and GS1 DataMatrix

GTIN-12 encoded in a UPC-A

GTIN-12 encoded in a GS1 DataMatrix

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6.2.4 Rules for Expressing Expiration Date

The following rules specify how the expiration date is expressed in a barcode, in human readable form, and in EPCIS events pursuant to the standards.

1. EPCIS data SHALL contain an expiration date that includes a year, month, and non-zero day, in YYYY-MM-DD format as required by XML standards.
2. It is STRONGLY RECOMMENDED that the barcode contain an expiration date that includes a year, month, and non-zero day, in YYMMDD format according to the *GS1 General Specifications*. While the *GS1 General Specifications* permit a day of 00, it is NOT RECOMMENDED that this be used.
3. The human readable form on the package SHOULD include an expiration date that includes a year, month, and non-zero day, but the human readable form MAY, if necessary, only include a year and month.
4. The expiration dates as expressed in EPCIS, all barcodes, and human readable form, SHALL be consistent with each other. "Consistent" means that all three have an identical year, month, and non-zero day; or if one or more forms do not specify a day of the month (omitted from human readable form and/or 00 in the bar code) that the remaining forms, specify the last day of the month. This is in keeping with United States Pharmacopeia (USP) guidance which specifies that an expiration date on a label lacking a day, should be understood to refer to the last day of the month.

Important: How the day of the month is expressed for regulated healthcare products will change starting 1 January 2025. As of that date the day of the month SHALL NOT be expressed as two zeros. A valid day of the month (e.g., last day of July = 31) SHALL be included.

The following examples illustrate the application of these standards rules.

Example 1: **CONFORMING** -- all three specify an identical year, month, and non-zero day

EPCIS: `<cbvmda:itemExpirationDate>2023-12-31</cbvmda:itemExpirationDate>`
Barcode: (17)231231
HR: 2023-12-31

Example 2: CONFORMING (though not preferred) -- all three specify an identical year and month, HR omits the day, and the others have end of month

EPCIS: `<cbvmda:itemExpirationDate>2023-12-31</cbvmda:itemExpirationDate>`
Barcode: (17)231231
HR: 2023-12

Example 3: CONFORMING (though NOT RECOMMENDED) -- all three specify an identical year and month, HR and barcode omits the day, and EPCIS has end of month

EPCIS: `<cbvmda:itemExpirationDate>2023-12-31</cbvmda:itemExpirationDate>`
Barcode: (17)231200
HR: 2023-12

Example 4: NOT CONFORMING -- they do not match

EPCIS: `<cbvmda:itemExpirationDate>2023-12-15</cbvmda:itemExpirationDate>`
Barcode: (17)231231
HR: 2023-02

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Example 5: NOT CONFORMING -- omitted day in HR does not match EPCIS/barcode which specify something other than end of month. Under USP guidance, the HR would be understood to mean 2023-12-31 which is different than what EPCIS and barcode say

EPCIS: <cbvmda:itemExpirationDate>2023-12-15</cbvmda:itemExpirationDate>
Barcode: (17)231215
HR: 2023-12

Example 6: NOT CONFORMING -- omitted day in HR and barcode does not match EPCIS which specifies something other than end of month. Under USP guidance, the HR or barcode would be understood to mean 2023-12-31 which is different than what EPCIS says.

EPCIS: <cbvmda:itemExpirationDate>2023-12-15</cbvmda:itemExpirationDate>
Barcode: (17)231200
HR: 2023-12

Example 7: NOT CONFORMING -- omitted day in HR does not match EPCIS and barcode which specify something other than end of month. Under USP guidance, the HR would be understood to mean 2023-02-28 which is different than what EPCIS and the barcode say.

EPCIS: <cbvmda:itemExpirationDate>2023-02-15</cbvmda:itemExpirationDate>
Barcode: (17)230215
HR: 2023-02

Example 8: NOT CONFORMING – because of leap years. It would be conforming if EPCIS and barcode had Feb 29, instead of 28.

EPCIS: <cbvmda:itemExpirationDate>2024-02-28</cbvmda:itemExpirationDate>
Barcode: (17)240228
HR: 2024-02

6.2.5 Logistics Units: Pallets, Cases & Totes

This guideline includes two barcode options for pallets, cases, and totes: GS1-128 and GS1 DataMatrix. There is one required data element to be encoded: SSCC.

Table 6-4 Barcodes for Pallets, Cases & Totes

Barcodes for Cases Pallets & Totes		
Required Identification Information	SSCC	AI (00)
GS1 Barcode Options	GS1-128 GS1 DataMatrix	

Encoding Principles:

SSCC

- The two-digit AI (00) is used to indicate SSCC.
- A fixed-length field comprising the 18 numeric characters of SSCC data follows the AI.
- The data syntax for the SSCC component is n2 + n18.
- **EXAMPLE: 00003345678912345604**

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Examples:

Figure 6-4 SSCC Encoded in a GS1-128

Figure 6-5 SSCC Encoded in a GS1 DataMatrix

6.3 EPC/RFID Tags

EPC/RFID tags use a specialized binary encoding to hold data equivalent to barcode data. Software that reads and writes EPC/RFID tags translates between this binary encoded form and the barcode form (and/or the EPC URI form). See the *EPC Tag Data Standard* for details about how the translations are performed.

6.4 Translating Captured Data

EPCIS stores identifiers (e.g., GTIN + serial number; SSCC; GLN; etc.) in EPC URI format, which differs from both the AI-based format used in GS1 barcodes and the binary encoding used in EPC/RFID tags. Therefore, identification information read from either barcodes or EPC/RFID tags need to first be translated into EPC URI format in order to be stored in EPCIS.

Most commercial RFID and/or EPCIS products already have the translation technology integrated into their software so that data read from either barcodes or EPC/RFID tags is automatically translated into EPC URI format when an EPCIS event is created. However, if a company is implementing their own software, they can either write their own translation module or license one of the commercially available software libraries on the market.

In order to translate barcode data into EPC URI format, it is necessary to know the length of the GS1 Company Prefix (i.e., what is the length of the GS1 Company Prefix in this barcoded GTIN?). Optimally, the GS1 Company Prefix(es) and pertinent identification keys (e.g., GTINs, GLNs) of trading partners will be exchanged prior to the start of exchanging EPCIS events. The on boarding process for trading partners is a good moment for this to occur. In some situations, EPCIS event data may be received without previously exchanging GS1 Company Prefixes. To aid software in those situations, GS1 has published the GS1 Company Prefix (GCP) Length Table (https://www.gs1.org/standards/bc-epc-interop) which is comprised of a list starting digits of GCPs and the length of GCPs associated with each set of starting digits. This table is updated periodically with data from many GS1 Member Organizations.

(NOTE: EPC/RFID tags already include the length of the GS1 Company Prefix in the encoded binary form. Therefore, no additional lookup is needed to translate binary data from EPC/RFID tags into EPC URI format.)

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6.5 GTIN + Serial Number

6.5.1 EPC URI Format

The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (SGTIN EPC).

General syntax:

`urn:epc:id:sgtin:`*`CompanyPrefix.ItemRefAndIndicator.SerialNumber`*

Example:

`urn:epc:id:sgtin:0614141.112345.400806`

Grammar:

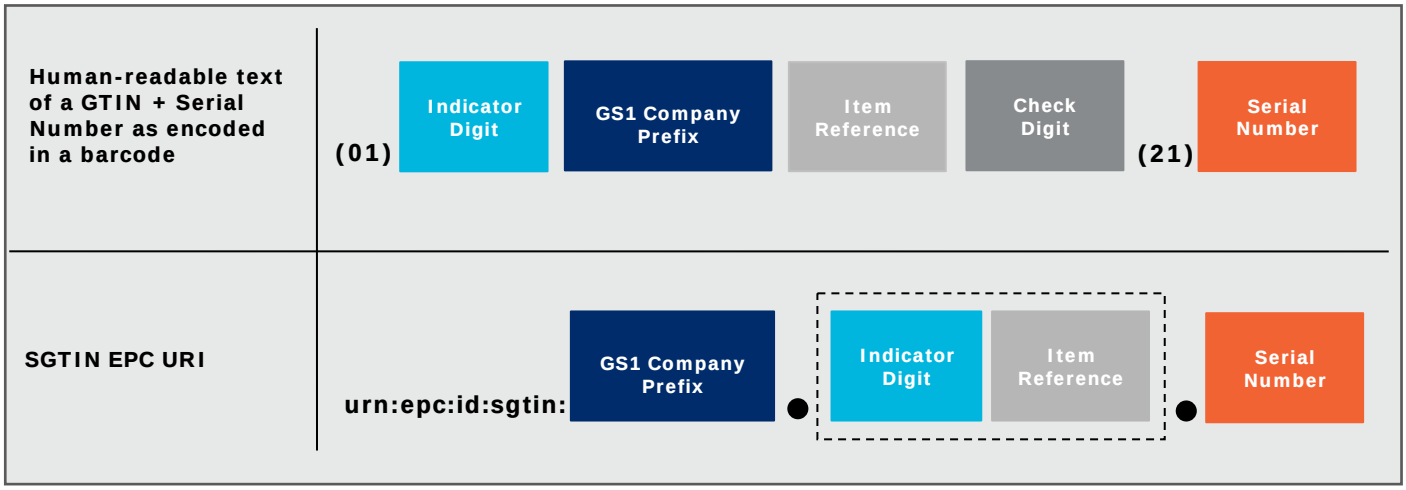
SGTIN-URI ::= “urn:epc:id:sgtin:” SGTINURIBody

SGTINURIBody ::= 2*(PaddedNumericComponent “.”) GS3A3Component

The number of characters in the two PaddedNumericComponent fields should total 13 (not including any of the dot characters). The Serial Number field of the SGTIN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the (AI) 21 Serial Number according to the GS1 General Specifications. The figure below depicts how the element string of a GTIN + serial number corresponds to the element string of a SGTIN EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GTIN key.
- The *Item Reference* as it appears in the SGTIN EPC URI is derived from the GTIN key by concatenating the Indicator Digit of the GTIN and the Item Reference digits and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.
- The *Serial Number* is the equivalent of AI (21).

Figure 6-6 How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format



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Example – Converting a GTIN-14 + serial number into EPC URI Format:

GTIN-14	**2 030001 123498 7**
Serial Number	**123456789012**
Corresponding Barcode Human Readable Interpretation (HRI) Text	**(01) 2 030001 123498 7 (21)123456789012**
Corresponding SGTIN-EPC URI	**urn:epc:id:sgtin: 030001 . 2 123498 . 123456789012**

Note: The spaces in the example above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.

6.5.2 Data Storage Options for GTIN + Serial Number

When storing GTIN + serial number in databases, GTINs and serial numbers can be saved in their own fields, saved together in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing GTINs and serial numbers in databases:

2 fields =	GTIN field and Serial Number field
1 field =	One field containing serialized GTIN in EPC URI format
3 fields =	GTIN field, Serial Number field, and field containing serialized GTIN in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in the table below.

Table 6-5 Data Formats for GTIN + Serial Number Fields

Field	Data Format
GTIN	▪ 14 digits ▪ text field (not numeric)
Serial Number	▪ 1-20 characters ▪ text field (not numeric)

Serialized GTIN EPC URI	▪ 33-52 characters:
	  ▪ 17 characters for “urn:epc:id:sgtin:”
	  ▪ 13 characters for the GTIN (without the Check Digit)
	  ▪ 1-20 characters for the serial number
	  ▪ 2 periods (“.”)
	▪ text field (not numeric)

6.6 Serialized Shipping Container Code - SSCC

6.6.1 EPC URI Format

Within EPCIS, SSCCs are stored in EPC URI format. The EPC URI format for an SSCC is the SSCC EPC.

General syntax:

```
urn:epc:id:sscc:CompanyPrefix.SerialReference
```


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Example:

urn:epc:id:sscc:0614141.1234567890

Grammar:

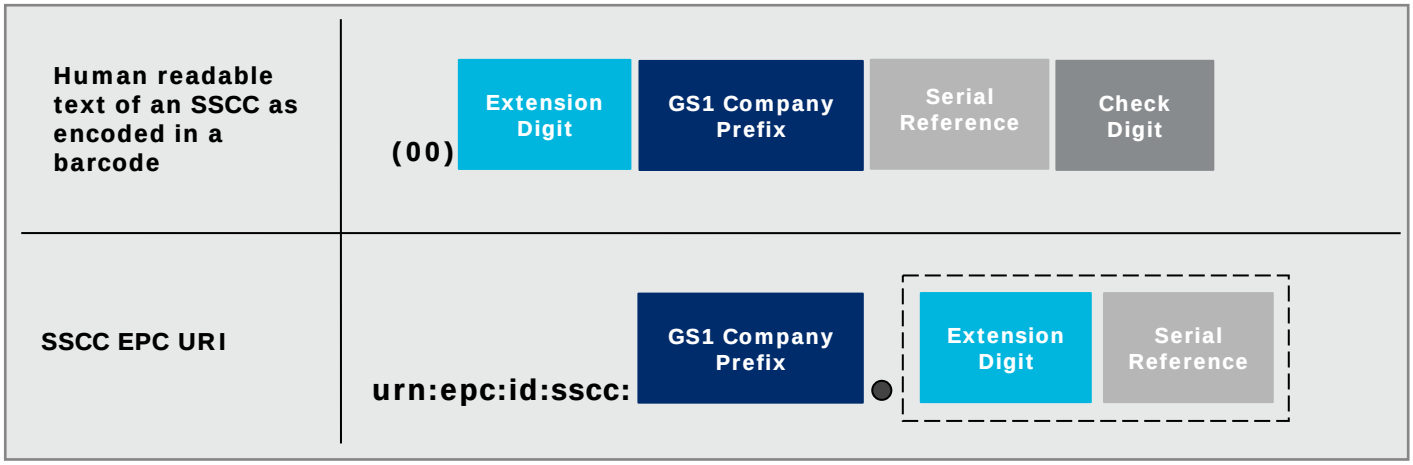
SSCC-URI ::= “urn:epc:id:sscc:” SSCCURIBody

SSCCURIBody ::= PaddedNumericComponent “.” PaddedNumericComponent

The number of characters in the two PaddedNumericComponent fields should total 17 (not including any of the dot characters). The figure below depicts how the element string of an SSCC corresponds to the element string of a SSCC EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 SSCC key.
- The *Serial Reference* as it appears in the SSCC EPC URI is derived from the SSCC key by concatenating the Extension Digit of the SSCC and the Serial Reference digits and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.

Figure 6-7 How the segments of an SSCC are represented in the SSCC EPC URI format



6.6.2 Data Storage Options

When storing SSCCs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing SSCC in databases:

1 field =	SSCC
1 field =	SSCC in EPC URI format
2 fields =	SSCC field and a field containing SSCC in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in the table below.

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Table 6-6 Data Formats for SSCC Fields

Field	Data Format
SSCC	▪ 18 digits ▪ text field (not numeric, to avoid dropping leading zeros)
SSCC URI	▪ 34 characters: ▪ 16 characters for “urn:epc:id:sscc:” ▪ 17 characters for the SSCC (without the Check Digit) ▪ 1 period (“.”) ▪ text field (not numeric)

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7 Share Concepts

7.1 Master Data

When users assign a GS1 identification key, they define a set of standardized information (known as *attributes*) about the object to which that identifier relates. The GS1 System specifies the list of attributes to be defined for each GS1 Identifier and provides a precise definition as well as acceptable values and data formats for each attribute. This set of attributes constitutes the "master data" about the object. For example:

- The GTIN is the globally unique GS1 identification key used to identify products. Standardized GTIN attributes about products include selling unit, item dimensions, and product classification. Once defined by the user, those attributes are then stored in a GDSN-certified Data Pool and shared with supply chain partners using the Global Data Synchronization Network (GDSN).
- The GLN is the globally unique GS1 identification key for parties and locations. When a user assigns a GLN, they define a prescribed set of data about the party/location to which that GLN relates (e.g., street address, floor, etc.). These GLN attributes define master data about the party/location (e.g., name, address, class of trade, etc.), which help to ensure that each GLN is specific to one, very precise location within the world. The GLN and its associated attributes are then saved in a database (like GS1 US DataHub | Location) and shared among supply chain partners.

From there, GS1 identification keys can be encoded into GS1 Data Carriers for identification and automatic data capture and used in supply chain transactions. Because of this, master data, transaction data, and event data related to supply chain objects are all connected by their GS1 identification key.

GS1 identification keys provide a link to information, and GS1 Standards for data sharing enable supply chain partners to share data and link it up in their systems to avoid re-entering it for every application that needs the data:

Sharing Master Data	Products = GDSN, RxNorm, Prime Vendor Database, EPCIS Locations = GS1 US Data Hub | Location, EPCIS
Sharing Event & Disposition	EPCIS
Item Event Locator	Discovery Services or Checking Service (future)

This is especially important for EPCIS applications like traceability where trading partners capture and share information about numerous supply chain events for each product. Use of GS1 Identifiers minimizes the data collected for each event and maximizes the data that can be linked to the event. This enables trading partners to avoid massive duplication of data in their systems by managing master data separately from traceability data. For example, a distributor records a traceability Event. The *Object ID* (i.e., GTIN) provides the link to finding master data about the product:

Name: Product X, 50 Tabs

The *BizLocation* (i.e., GLN) provides the link to master data about the location using GS1 US Data Hub | Location:

LocationName: Smithfield Distribution Center
Address: 123 Main Street
City: Lawrenceville
State: NJ
Zip Code: 08648

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Best Practices:

- Because master data is managed separately from event/traceability data, it is essential to archive the original/previous version of master data whenever master data about products or locations is updated or changed. This will ensure that the historic master data is still available if ever needed after the update.
- Need to validate and establish the source and governance of your master data.

7.2 Event Data

Electronic Product Code Information Services (EPCIS) is a GS1 Standard for capturing and communicating data about the movement and status of objects in the supply chain (e.g., products, logistics units, returnable assets, etc.). It enables supply chain partners to capture event information about objects as they move through the supply chain (e.g., shipped, received, etc.), and to share that information with their trading partners securely and in near real-time. EPCIS defines technical standards for a data-sharing interface between applications that capture EPC-related data and those that need access to it. EPCIS also provides data standards for how to express what business process was operating on the object and the status of the object upon exiting the process. For the data standards, EPCIS makes use of a second standard named the Core Business Vocabulary (CBV), which offers a pre-defined vocabulary for a large set of business events and scenarios.

The data elements captured and recorded for each EPCIS event are grouped into four dimensions: *what*, *when*, *where*, and *why*. The *GS1 General Specifications* and the GS1 EPC Tag Data Standard define identifiers for physical objects used in the "*what"* dimension, and identifiers for locations used in the "*where"* dimension. The GS1 EPC Core Business Vocabulary provides lists of acceptable values for *Business Step, Disposition*, and *Business Transaction Type* used in the *why* dimension, as well as the format for the business transaction identifiers used in the *why* dimension. Beyond the four dimensions of *what*, *where*, *when*, and *why* defined in the EPCIS standard, this guideline defines extension fields used to provide additional business data for serial-level management and serialized item-level traceability in certain EPCIS events. The data elements captured and recorded for each EPCIS are presented in the table below.

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Table 7-1 EPCIS Data Elements

Dimension	Data	Definition	Examples
	Event Type Action	the event type and the action together define the type of EPCIS event, e.g., object creation, object observation, aggregation, disaggregation, etc.	Object Event with Action = ADD Aggregation Event with Action = DELETE etc.
What	EPC List	the item's unique identifier, expressed as an EPC Pure Identity URI. Depending on the event type, this will either be a list of EPCs, or the combination of a Parent ID and a list of child EPCs	GTIN + Serial number formatted as the SGTIN EPC URI syntax (See 5.4.3), SSCC formatted as the SSCC EPC URI syntax (See 5.8), etc.
	Parent ID		
	Child EPCs		
When	Event Time	the moment in time at which the event occurred	March 15, 2023 at 10:07am UTC
	Event Timezone Offset	indicates the local time zone in effect at the place where the event occurred. This is not needed to interpret Event Time (which carries its own time zone indicator) but instead helps software to display data to users in local time	UTC -05:00
Where	Read Point	the location at which the event took place expressed as an EPC Pure Identity URI	GLN formatted as the SGLN EPC URI syntax with "0" in the extension portion (See 5.14)
	Business Location	the location at which the objects are presumed to be following the event until a subsequent event says otherwise, expressed as an EPC Pure Identity URI	GLN formatted as the SGLN EPC URI syntax with "0" in the extension portion (See 5.14)
Why	Business Step	the business process taking place at the time of this event	*Shipping*, *Receiving*, *Picking*, etc.
	Disposition	business condition of the objects named in the *what* dimension that is presumed to hold until a subsequent event occurs	Saleable, Recalled, etc.
	Business Transaction	one or more references to associated business transactions, each comprised of a business transaction type (e.g., purchase order, invoice, etc.) and a globally unique reference to a specific transaction of that type	Acme Corp Purchase Order #1234
	Source	transferring entity expressed as an EPC Pure Identity URI	GLN formatted as the SGLN EPC URI syntax with "0" in the extension portion (See 5.14)
	Destination	transferred-to entity expressed as an EPC Pure Identity URI	GLN formatted as the SGLN EPC URI syntax with "0" in the extension portion (See 5.14)

EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. To serve the needs of a particular business application, supply chain partners must come to an agreement with regard to the EPCIS events and data that will be shared. Therefore, members of the U.S. pharmaceutical industry joined forces to determine how EPCIS can best be applied to support serialized item-level traceability.

The remainder of this document specifies how the EPCIS standard is applied to support serialized item-level traceability for the US pharmaceutical industry.

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8 EPCIS Principles for this Guideline

EPCIS events consist of data captured by each party in the supply chain as they handle a product in the course of the product's lifecycle. As such, EPCIS events provide visibility of handling operations for either internal business applications (i.e., if the EPCIS events are consumed internally), or across the supply chain (i.e., if the events are shared with trading partners). Visibility data in the form of EPCIS events may be used to automate a variety of business processes, including, serialized item-level traceability, recall, etc. This section presents information and concepts related to the application of EPCIS for DSCSA requirements within this guideline.

8.1 Master Data in EPCIS Events for DSCSA

Initial stages of the DSCSA consider product and location data to be part of the serial-level management data set. Companies that have implemented the best practice of a Master Data Management architecture may wish to obtain and manage product and location master data separate from the EPCIS events themselves. For example, the DSCSA serial-level management data set includes both the unique identifier for a pharmaceutical product (i.e., the GTIN), as well as its dose and strength information. When using EPCIS events to assemble DSCSA content, companies that use master data management strategies will obtain the GTIN from the EPCIS event data itself and obtain the dose and strength information from the master data associated with that GTIN to assemble the full DSCSA data set. In contrast, other trading partners who are unable to, or have yet to, adopt a master data management strategy may require the product and location master data be provided in the EPCIS Header that accompanies the EPCIS events. To support both scenarios, product and location master data attributes are shown as "optional" in the EPCIS Header.

8.2 Data Rules for this Guideline

8.2.1 EPCIS Event Time

The *Event Time* data element in an EPCIS event is defined as the moment in time when the event occurred. When sharing EPCIS events with trading partners for serialized item traceability purposes, it is permissible for the *Event Time* to be different from the actual moment in time when the event occurred, provided that the rules in this section are followed. These rules are designed to give freedom to supply chain parties to capture the *Event Time* in a manner that is not overly burdensome and to hide certain internal business details from trading partners (e.g., the lag in time between packing a shipment and dispatching the shipment through the door), while at the same time ensuring that applications receiving EPCIS events will see a "reasonable" sequence of *Event Times*. When a party shares EPCIS events with a trading partner, the *Event Time* in those events should conform to the following rules.

Note: The *Event Time* shared with trading partners may differ from the *Event Time* captured internally, so long as the rules are followed; that is, a party may keep a more detailed *Event Time* for internal use but modify the *Event Time* to obscure certain details not appropriate to share with trading partners.

Rules for this Guideline:

- The *Event Time* shared with trading partners may differ from the *Event Time* captured internally. However, for any given event, the *Event Time* shared with trading partners should be the same across all trading partners.
- EPCIS provides for millisecond precision in the *Event Time*. The *Event Time* shared with trading partners may be expressed with less precision, provided that the reported *Event Time* is within one minute of the actual *Event Time* (except for event times that are artificially advanced, as specified below).

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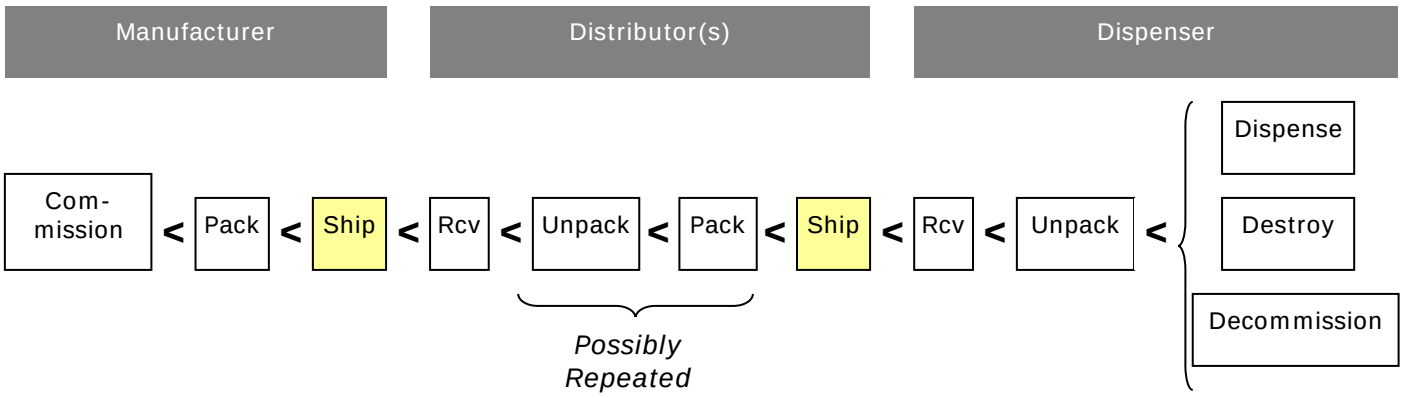
- Business processes such as packing, and shipping may take place over a span of time rather than a moment in time. Normally, the *Event Time* shared with trading partners should correspond to the time of completion of the process. However, any time within the span may be used as long as the other rules are adhered to.
- The diagram below shows the chronological sequence of *Event Times* that should hold between events that refer to the same object identifier:
  - The *Event Time* reported for *Shipping*, *Receiving*, and end-of-life events should reflect the true time of those events (subject to the rules above).
  - The *Event Time* for other events (e.g., *Commissioning*, *Packing*, *Unpacking*) as shared with trading partners may be advanced in time up to (but not equal to) the time of the subsequent *Shipping* or end-of-life as long as the relationships in the diagram continue to hold between events that pertain to the same physical objects.
  - The order in which EPCIS events are listed in an EPCIS document has no significance. Applications that receive EPCIS events use *Event Time* or other data within the events to understand the sequence in which they occurred.
  - The event time relationships for pairs of events pertaining to the same physical objects shown in Figure 8-1 below SHALL BE strictly less than the preceding event time and have non-identical times.
  - Event times of adjacent events of the same type SHALL have non-identical event times and SHALL appear in a logical chronological sequence. Adjacent events of the same type refer to an EPC ID undergoing successive events with the same bizStep (e.g., packing of item 123 into case 481, followed by packing of case 481 onto pallet 789 cannot share the same Event Time.)

The figure below shows the relationships of Event Times. The " < " symbol indicates that the first Event Time must be strictly less than the second Event Time. ***These relationships only apply to pairs of events that pertain to the same physical objects*** (e.g., a given *Commissioning* event needs to have an earlier event time than a given *Packing* event if one or more of the objects in that *Commissioning* event is part of that *Packing* event. The *Commissioning* event does not need to have an earlier event time if none of the objects are part of the *Packing* event).

Figure 8-1 Event Time Relationships for Event Management Purposes



The "<" symbol shows the relationships of Event Times for any single EPC. The "<" indicates that the first Event Time must be strictly less than the second Event Time.

It is permissible for the Event Time to be different from the actual moment in time provided that the rules in section 8.1 of the Implementation Guideline R1.3 are followed. The event time relationships for

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pairs of events pertaining to the same physical objects, as diagramed in Figure 8-1, **SHALL** be strictly less than the preceding event time and **SHALL have non-identical** Event Times. Adjacent process steps (including but not limited to Commissioning, Packing and Shipping) **SHALL have non-identical** Event Times and **SHALL appear** in a chronological sequence. The Event Time of a given process step, pertaining to one uniquely serialized object, **SHALL be later** than the Event Time of the preceding adjacent step for that same uniquely serialized object This also applies to The Event Times of adjacent events of the same type, pertaining to different objects (e.g., packing of item 123 into case 481, followed by packing of case 481 onto pallet 789), **SHALL be** the real time when the event was created and recorded.

Best Practice:

For change of ownership situations where the process does not provide a natural change in time difference between shipping and receiving (consignment inventory), Receiving times should be created with a time greater than the related *Shipping* events (when used). When creating events to share with a trading partner, the timing of events should reflect the sequence of events that naturally would occur.

8.2.2 EPCIS Read Points and Business Locations

The EPCIS standard defines two data elements that provide the *where* dimension for an EPCIS event: *Read Point* and *Business Location*. The *Read Point* is an EPC URI that identifies the location where the event took place. The *Business Location* is an EPC URI that identifies the location where the object named in the event is presumed to be until a subsequent event says otherwise. The *Business Location* is useful for answering questions about where objects are right now (or at any prior moment between events).

Supply chain parties may capture *Read Points* and *Business Locations* at a coarse level (e.g., identifying a site or campus) or at a granular level (e.g., identifying a specific area or door within a building). A supply chain party may also choose to share location information with trading partners at a coarser level of granularity than it captures for internal purposes. For example, a supply chain party may capture the specific loading dock door where a *Shipping* event took place for internal purposes. However, when sharing data with a trading partner, that party may choose to only share the site without providing information about which dock door was used.

Rules for this Guideline:

EPCIS events for serialized item traceability purposes should conform to the following rules for *Business Locations* and *Read Points*:

- The *Business Location* for an event should be a site-level GLN (without extension) expressed as an EPC URI. Such a URI begins with `urn:epc:id:sgln:` and ends with `.0`. (Note that *Business Location* is omitted from a *Shipping* event. See section 4.8.)
- The *Read Point* for an event should be a site-level GLN (without extension) expressed as an EPC URI. Such a URI begins with `urn:epc:id:sgln:` and ends with `.0`.

8.2.3 EPCIS Business Transactions

The *Business Transaction* list in EPCIS events is used for purchase order and invoice information to be included in *Shipping* and *Receiving* events. The EPCIS standard specifies that *Business Transactions* be globally unique identifiers expressed in URI syntax.

Rules for this Guideline:

Business Transactions in EPCIS events should conform to the following rules:

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- The *Business Transaction* type should be one of the URIs defined in Section 7.3 of the GS1 EPC Core Business Vocabulary. Typically, this is either `urn:epcglobal:cbv:btt:po` denoting a purchase order, `urn:epcglobal:cbv:btt:desadv` denoting despatch advice of delivery, or `urn:epcglobal:cbv:btt:inv` denoting an invoice.
- The *Business Transaction* identifier should conform to the syntax defined in Section 8.4.2 of the GS1 EPC Core Business Vocabulary. This syntax constructs a globally unique identifier in URI syntax by combining the transaction identifier (e.g., purchase order number) with a GLN that identifies the party that issued the transaction identifier. This combined identifier is globally unique and leaves no ambiguity about the system from which a transaction identifier comes. For example, urn:epcglobal:cbv:bt:0614141123452:A123 identifies a transaction whose native identifier (e.g., purchase order number) is A123 and which comes from a party identified by GLN 0614141123452.
- The GLN used in a *Business Transaction* identifier as specified above should match the GLN provided in the *Source* or *Destination* attributes in a *Shipping* event. For example, in normal forward logistics, the GLN in the *Business Transaction* identifier for an invoice would match the *Source*, and the GLN in the *Destination* for a purchase order would match the *Destination*. (See *Table 7-1 EPCIS Data Elements* for the definition of *Source* and *Destination*.)

8.2.4 The Standard Business Document Header

To support message routing and processing, the EPCIS standard leverages the Standard Business Document Header (SBDH) as an optional component for EPCIS data exchanges. The SBDH contains fields identifying the sender and receiver as well as declarations about the nature of the data contained in the message. It was originally developed for transactional data such as EDI interchanges or GS1 XML.

This guidance directs implementers to use the EPCIS Header for conveying necessary Master Data for traceability in support of DSCSA. When the EPCIS Header is utilized, the SBDH shall appear with the following elements and corresponding values:

Element	Value
HeaderVersion	1.0
Sender / Identifier (with Authority = GS1)	[SGLN EPC URI, with zero (“0”) in the extension portion, of the logical party who created the EPCIS event data]
Receiver / Identifier (with Authority = GS1)	[SGLN EPC URI, with zero (“0”) in the extension portion, of the logical party who is receiving the EPCIS event data]
DocumentIdentification / Standard	EPCglobal
DocumentIdentification / TypeVersion	1.0
DocumentIdentification / InstanceIdentifier	[A String containing an identifier distinctly identifying this instance of the document exchanged between sender and receiver]
DocumentIdentification / Type	Events
DocumentIdentification / CreationDateAndTime	[Date and Time when the document was created in xs:dateTime format]

The following XML snippet is an example of a conforming SBDH appearing within the EPCIS data for traceability in support of DSCSA:

```
…
<EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
                  <sbdh:Sender>
```

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```
                <sbdh:Identifier
                Authority="GS1">urn:epc:id:sgln:0353579.00001.0</sbdh:Identifi
                er>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
                Authority="GS1">urn:epc:id:sgln:5012345.00000.0</sbdh:Identifi
                er>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1234567890</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2023-06-02T15:14:27.574-
                04:00</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
    </sbdh:StandardBusinessDocumentHeader>
```

…

8.2.5 EPCIS Expiration Date

See *Rules for Expressing Expiration Date* regarding the synchronization of the expiration date as represented in EPCIS with the expiration date as marked on the package.

8.2.6 Checking EPCIS Event Contents

The following are recommended approaches for verifying matching *Receiving* events and *Shipping* events.

- Pay attention to the dates. Dates should match your business expectations. Your systems should alert you to events outside of your normal business practice.
- The GTIN in the barcode should match the GTIN in the *Shipping* or its related Aggregation event.
- The GTIN in the *Receiving* or its related Aggregation event should match the *Shipping* event GTIN.
- All events should conform to the attributes / extensions that are outlined in this guideline.
- Mandatory attributes should exist.
- Location identifier should belong to the expected party.

8.3 EPCIS Extension Elements

The EPCIS standard provides for data elements not specified in the standard to be included in EPCIS events as extensions. This is done by including additional XML elements just before the closing tag for an event, where those XML elements are in an XML namespace other than the EPCIS namespace.

All extension elements defined in this guideline are defined in the following XML namespace:

`http://epcis.gs1us.org/hc/ns`

All XML illustrations in this guideline use the prefix “gs1ushc” to denote this XML namespace. This means that an extension would look like this:

```
<epcis:EPCISDocument xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" ...>
  <EPCISBody>
     <EventList>
        <ObjectEvent>
           <eventTime>...</eventTime>
```


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```
            ...
            <bizTransactionList>
               ...
            </bizTransactionList>
            <gs1ushc:directPurchase value="true" />
         </ObjectEvent>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

Note: The EPCIS standard XML schema defines an element <extension>. This is reserved for use by future versions of the EPCIS standard to introduce new standard data elements in a forward compatible way and may not be used to define extensions outside of the EPCIS standard. Extensions outside the standard are defined as illustrated above (i.e., in a different XML namespace and not enclosed in the <extension> element).

Specific extensions can be used amongst trading partners determined by their business needs even if not aiding a technical or regulatory requirement.

Note: Inclusion of additional values is technically allowed. Caution though that with greater customization, the ability to be interoperable can be at risk and therefore additional extensions could be counterproductive.

Recommendation: Work with trading partners as to what the business needs are for extensions and evaluate the impact on the data exchange throughout the supply chain as part of the discovery process in establishing a partner agreement. The recommended path to implementing a new extension beyond what has been defined in this guideline is as follows:

- Propose the extension to the GS1 Healthcare US Rx Secure Supply Chain workgroup to be evaluated
- If agreed upon then it will be added to the following XML namespace: http://epcis.gs1us.org/hc/ns
  - Present GS1 US extension as a candidate for global standard integration by determining if the extension has benefits to other geography or sector.

Here are some examples of extended vocabulary for bizStep, disposition, and business transaction type:

- These are business vocabulary extensions with business requirements emerging and can later be candidates for inclusion in global standard vocabulary extensions.
- Because GS1 US extensions are documented in GS1 US implementation guidelines, the industry expectations on their meaning and uses are known and set.
- Extensions created by businesses for internal tracking and processing will need to be documented and communicated with their trading partners to ensure expectations are set, rendering the scope of these extensions to be limited and therefore not mandated for sector or industry.
- Here are some examples of extended vocabulary for bizStep, disposition, and business transaction type:
  - *http://epcis.example.com/bizstep/sampling*
    - The example bizStep represents an extension that was promoted to core business vocabulary in CBV 2.0
  - *http://epcis.example.com/disp/newdisposition*
  - *http://epcis.example.com/btt/importpermit*
  - *http://epcis.example.com/btt/notafiscal*

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- Listed below are examples of how an extension would be expressed:
  - <bizStep>*http://epcis.example.com/bizstep/sampling*</bizStep>
  - <disposition>*http://epcis.example.com/disp/newdisposition*</disposition>
  - <bizTransaction type="*http://epcis.example.com/btt/importpermit*">urn:epcglobal:cbv:bt:0300011111116:A123</bizTransaction>

8.4 Core Business Vocabulary (CBV) Extensions

The EPCIS standard specifies that the *Business Step*, *Disposition*, and *Business Transaction Type* fields of EPCIS events should be populated with URI strings (each denoting a specific business step, disposition, or business transaction type, respectively). The GS1 EPC Core Business Vocabulary (CBV) standard provides standardized URI strings for a variety of commonly occurring *Business Steps*, *Dispositions*, and *Business Transaction Types*.

In this version of the guideline, only CBV standard *Business Step*, *Disposition*, and *Business Transaction Type* values are used, so no CBV extensions are defined.

8.5 EPCIS Event Fields

The EPCIS standard defines many fields of EPCIS events to be optional. In the context of a specific event defined in this guideline, a field that is optional in the EPCIS standard may be required to be present (or required to be omitted) for serialized item traceability purposes. For clarity, the EPCIS event details tables throughout this section include “Usage” with the following notations to indicate what is required for serialized item traceability purposes:

Required	The field is required in the context of this specific event. (This is always the case if the field is specified as required in the EPCIS standard.)
Optional	The field may or may not be included in the context of this specific event.
Conditional	In the context of this specific event, the field may be required, optional, or omitted depending on circumstances. The circumstances are specified in the description.
Omitted	The field is always omitted in the context of this specific event.

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Part II: Application of EPCIS for Serialized Item-Level Traceability

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9 Overview of Serialized Item-Level Traceability Concepts

Phase 3 of the DSCSA establishes package level requirements for the interoperable, electronic tracing of products. This will involve sharing chain-of-ownership data in a manner that allows for serialized item traceability back to the product origin (usually the manufacturer), including the electronic exchange of transaction information for each sale of certain prescription drugs and verification of product identifiers at the package level.

A set of EPCIS events pertaining to a specific instance or instances of a product, inclusive of all events from the point of origin (i.e., commissioning) to the present provides the data needed to support serialized item-level traceability. In this part, we specify the minimum set of EPCIS events to support serialized item-level traceability pursuant to Phase 3 of the DSCSA. Key points:

- Events will be captured at the instance-level, where an instance is identified by a GTIN+serial (item or homogeneous case) or SSCC (mixed tote, heterogeneous case, or pallet).
- DSCSA change-of-ownership transaction information is integrated into the EPCIS *Shipping* event. Each trading partner records and exchanges this *Shipping* event for each sale/transfer of ownership.
- EPCIS *Packing* and *Unpacking* events record the packaging hierarchy of item to case, to pallet. To the extent that *Shipping* events reference only outer-level identifiers, accompanying *Packing* and *Unpacking* events provide the details of what is inside the outer containers.
- EPCIS *Commissioning* events provide a means for the manufacturer to affirm the validity of serial numbers (and for any party to affirm the validity of an SSCC), as well as to provide associated product master data.
- EPCIS *Transformation* events provide a means for the re-packager to record the relationship between the original product and the repackaged product.
- EPCIS *Receiving*, *Void Shipping*, *Dispensing*, *Decommissioning*, and *Destroying* events, as well as EPCIS error declarations, are specified to provide a standardized way to record the complete lifecycle of products for business purposes beyond DSCSA compliance.
- A suitable collection of the above events comprises the Transaction Information, and Transaction History **(DSCSA sunsets the TH requirement as November 27, 2023)** for purposes of DSCSA. Those events may be collected into a single EPCIS Document, with a **Transaction Statement** included in the EPCIS Document header, in order to create a single XML document containing all DSCSA-required information (Transaction Information, Transaction History **(TH sunset as of November 2023)**, and **Transaction Statement**) for a transaction. To avoid repetition of product master data (e.g., drug name, dosage form, etc.) and party/location master data (e.g., postal address), such attributes are also carried in the header of the EPCIS document rather than repeated within each EPCIS event.
- The specification of EPCIS events and master data in this guideline is also intended to support a possible future state where event and master data are shared on-demand through EPCIS queries rather than through point-to-point delivery of EPCIS documents.
- Supply chain parties may collect additional EPCIS events not required for item-level traceability. These events are used for other business applications.

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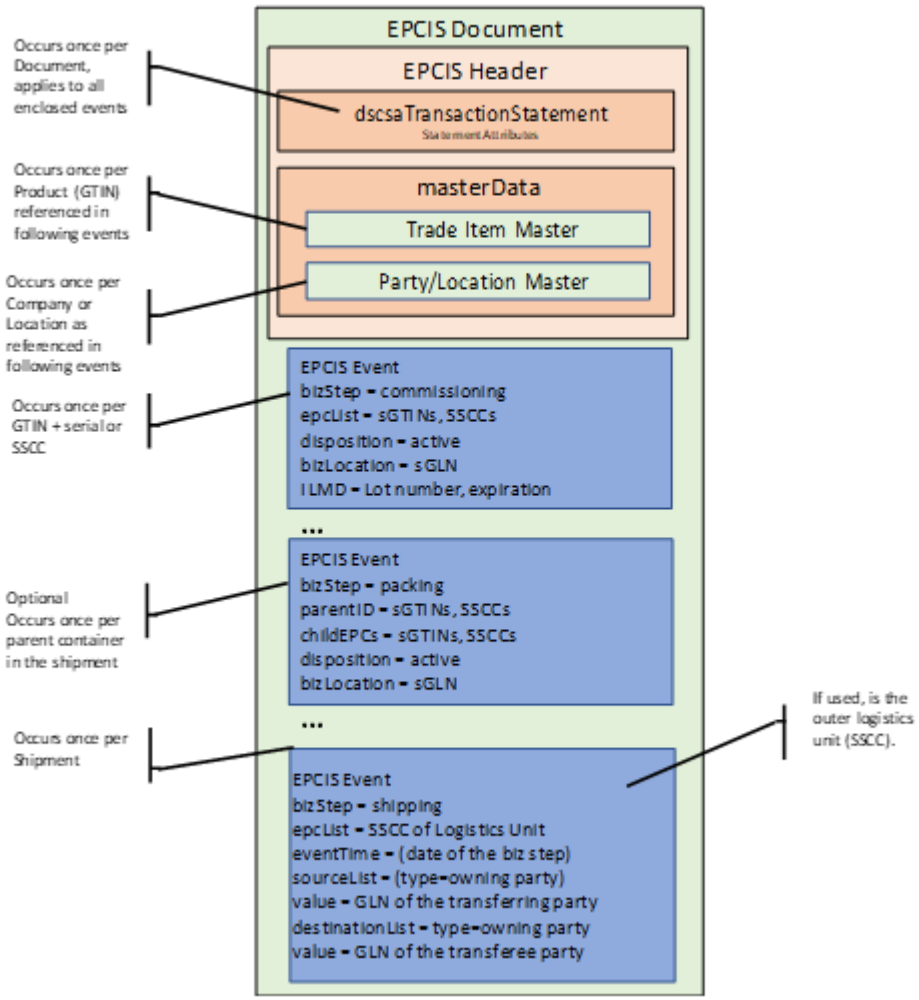
All events covered by the same Transaction Statement are bundled together into one EPCIS Document

Figure 9-1 EPCIS Document Structure



For purposes of serialized item traceability, each party in the supply chain captures and shares a certain set of EPCIS events. The EPCIS events that need to be captured and shared by each party depend on that party's position in the supply chain. An overview of EPCIS events to be captured by each party for serialized item traceability is provided below. Detailed definitions of each EPCIS event are specified in subsequent subsections in this section.

9.1 Events Captured and Shared by the Party at the Beginning of the Supply Chain (e.g., manufacturer)

- **Commissioning Events (Section *10.2*)** declaring that specified serial numbers have been introduced into the supply chain and providing information about the corresponding products.
- **Packing Events (Section *10.3*)** providing the hierarchical relationships (e.g., item-to-case, case-to-pallet) between objects as they exist at the point of shipping. The beginning-of-supply-chain party does not need to reflect any internal unpacking and packing activity that may have taken place, as long as the events that are shared fully account for the hierarchy as shipped.

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- Specific to location in commissioning (serialization) and packing (aggregation) events, readPoint and bizLocation are not required for compliance to DSCSA but may be provided.

It is further acknowledged that these values may be required between some parties, as the current systems are operational, and may have requirements where the values are needed. The details and precision that is necessary between some parties such as a CMO, and a Marketing Authorization Holder* (MAH) are deemed, in general, not to be a required to be shared with downstream partners such as wholesalers or dispensers.

To minimize the maintenance burden of maintaining 3rd party agent GLN master data and protecting stakeholder privacy, it is acknowledged that for DSCSA, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.

Please note: that this practice would not be extended to shipping events within DSCSA EPCIS transactions.

- **Shipping Events (Section *10.4*)** indicating that objects have been shipped to a downstream trading partner and providing serialized item-level traceability information governing the shipment. The *Shipping* events only reference the outermost (i.e., top-level) products in the packaging hierarchy. The full hierarchy is specified by inference from the prior *Packing* events.

9.2 Events Captured by Re-Packagers

- **Commissioning Events (Section *10.2*)** declaring that specified serial numbers have been introduced into the supply chain and providing information about the corresponding products.
- **Packing Events (Section *10.3*)** providing the hierarchical relationships (e.g., item-to-case, case-to-pallet) between objects as they exist at the point of shipping. The beginning-of-supply-chain party does not need to reflect any internal unpacking and packing activity that may have taken place, as long as the events that are shared fully account for the hierarchy as shipped
- Specific to location in commissioning (serialization) and packing (aggregation) events, readPoint and bizLocation are not required for compliance to DSCSA but may be optionally provided.

It is further acknowledged that these values may be required between some parties, as the current systems are operational, and may have requirements where the values are needed. The details and precision that is necessary between some parties such as a CMO and a Marketing Authorization Holder (MAH) are deemed, in general, not to be a required to be shared with downstream partners such as wholesalers or dispensers.

To minimize the maintenance burden of maintaining 3rd party agent GLN master data and protecting stakeholder privacy, it is acknowledged that for DSCSA, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.

Please note: that this practice would not be extended to Shipment events within DSCSA EPCIS transactions.

- **Shipping Events (Section *10.4*)** indicating that objects have been shipped to a downstream trading partner and providing serialized item-level traceability information governing the shipment. The *Shipping* events only reference the outermost (i.e., top-level) products in the packaging hierarchy. The full hierarchy is specified by inference from the prior *Packing* events.

9.3 Events Captured and Shared by Intermediate Parties (e.g., distributor)

- **Receiving Events (Section *10.6*)** indicating that objects have been received from an upstream trading partner and providing traceability information governing the receipt. The receiving party may only verify the identifiers of the outermost (i.e., top-level) products in the packaging hierarchy, in which case the full hierarchy inferred from prior Packing events is inferred to have been received. Alternatively, the receiving party may verify one or more inner levels of hierarchy (in which case the

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verified levels are declared explicitly in the Receiving event, and inference is only used for inner levels not declared explicitly or not at all if all levels are declared explicitly).

- **Unpacking Events (Section 10.7), Commissioning Events (Section 10.2), and Packing Events (Section 10.3)** as needed to reflect changes in the packaging hierarchy that have occurred prior to shipment. *Commissioning* events in this instance are only used to introduce new identifiers for logistic units (e.g., new SSCCs for pallets packed to order), not to introduce new products. The intermediate party does not need to reflect all internal unpacking, commissioning, and packing activity that may have taken place, as long as the events that are shared fully account for all changes in hierarchy between receiving and shipping.
- **Shipping Events (Section 10.4)** indicating that objects have been shipped to a downstream trading partner and providing serialized item-level traceability information governing the shipment. The *Shipping* events only reference the outermost (i.e., top-level) products in the packaging hierarchy. The full hierarchy is specified by inference from the prior *Unpacking* and *Packing* events (possibly including *Unpacking* and *Packing* events from prior supply chain parties).

9.4 Events Captured and Shared by the Party at the End of the Supply Chain (e.g., Hospital, Pharmacy, etc.)

- **Receiving Events (Section 10.6)** indicating that objects have been received from an upstream trading partner and providing serialized item-level traceability information governing the receipt. The receiving party may only verify the identifiers of the outermost (i.e., top-level) products in the packaging hierarchy, in which case the full hierarchy inferred from prior *Packing* events is inferred to have been received. Alternatively, the receiving party may verify one or more inner levels of hierarchy (in which case the verified levels are declared explicitly in the Receiving event, and inference is only used for inner levels not declared explicitly or not at all if all levels are declared explicitly).
- **Unpacking Events (Section 10.7) and Packing Events (Section 10.3)** as needed to reflect changes in the packaging hierarchy that have occurred prior to end-of-life events. The final party does not need to reflect all internal unpacking and packing activity that may have taken place, as long as the *Unpacking* and *Packing* events that are shared fully account for all changes in hierarchy between *Receiving* and end-of-life events.
- **End-of-life Events including Dispensing (Section 10.8), Destroying (Section 10.10), and Decommissioning (Section 10.11)** represent business processes that occur at the end of the supply chain (typically at a hospital or pharmacy) indicating that specific products have been removed from the supply chain. (NOTE: Periodically, end-of-life events could occur with earlier trading partners in the supply chain.)

9.5 Events Captured and Shared by a Party for Exception Processing

- The Applying GS1 Standards for DSCSA and Traceability Addendum: Diagrams and XML Examples for Serialized Exceptions Processing R1.3 is being further defined and enhanced. It will replace the previous version.
  - This will outline acceptable scenario-based corrections on specific applications of EPCIS/CBV constructs that will be sent by the seller and received and processed by the buyer.
- Potential exception management processes included in this implementation guideline show technically how they could be used are the following:
  - **Void Shipping Events (Section 10.12)** indicating that objects previously indicated as having been shipped by their appearance in one or more prior *Shipping* events were, in fact, not shipped. This event is created by a shipper upon discovery that the prior *Shipping* event is in error.
  - **Error Declaration Events (Section 10.13)** used to indicate that a prior EPCIS event is in error and should be disregarded in its entirety.

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Note: These are not widely adopted practices and are not currently a part of the interoperable system to meet DSCSA requirements.

The remainder of Part II defines individual EPCIS events for different steps in the pharmaceutical supply chain process for serialized item traceability purposes. Some of these events are required for DSCSA compliance as well as for other traceability applications; others are defined for the benefit of traceability applications but are not required for DSCSA compliance.

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10 DSCSA Item-Level Data Elements

DSCSA data elements are derived from both the data in the EPCIS events themselves, as well as certain product and location master data that is referenced by product and location identifiers found in the EPCIS event. For example, traceability information includes both the unique identifier for a pharmaceutical product (i.e., the GTIN), as well as its dose and strength information. When using EPCIS events to provide DSCSA content, the GTIN is present in the EPCIS event data itself, while the dose and strength information is obtained from the master data associated with the GTIN.

A list of the DSCSA data elements (from the DSCSA law) is provided in the table below.

Table 10-1 DSCSA Item-Level Data Elements

Type of Information	DSCSA Data Attribute	EPCIS Segment
Transaction Statement	affirmTransactionStatement	dscsaTransactionStatement extension
	directPurchaseStatement	*Shipping* event Extension
	receivedDirectPurchaseFromPrevWhlsDistStatement	*Shipping* event Extension
Transaction Information	the proprietary or established name or names of the product	GTIN-level product master data accompanying an EPCIS *Commissioning* Event
	the strength and dosage form of the product	GTIN-level product master data accompanying an EPCIS *Commissioning* Event
	Product Identifiers: ▪ the NDC number of the product	GTIN-level product master data accompanying an EPCIS *Commissioning* Event
	▪ the lot number of the product	Instance-level product master data in the Instance/Lot Master Data (ILMD) section of an EPCIS Commissioning Event
	▪ the expiration date of the product	Instance-level product master data in the Instance/Lot Master Data (ILMD) section of an EPCIS *Commissioning* Event
	▪ the serial number of the product (SGTIN)	EPC event list within EPCIS *Commissioning* Event
	the container size	GTIN-level product master data accompanying an EPCIS *Commissioning* Event
	the number of containers	Events declaring the serialized product identifier which represents an instance of one
	the date of the transaction	If the date of the shipment is less than 24 hours after the date of the transaction, then use EPCIS *Shipping* Event (eventTime). If the date of the shipment is more than 24 hours after the date of the transaction, then use *Shipping* Event Extension (transactionDate)
	the date of the shipment, if more than 24 hours after the date of the transaction	EPCIS *Shipping* Event (eventTime)
	the business name and address of the person from whom ownership is being transferred	Party master data accompanying an EPCIS *Shipping* Event
	the business name and address of the person to whom ownership is being transferred	Party master data accompanying an EPCIS *Shipping* Event

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10.1 EPCIS Header Extensions for Shipping Events for Serial-Level Management

In addition to the EPCIS standard fields listed above, the following data are also included in the EPCIS Header associated with a group of *Shipping* events for serial-level management.

Element	Usage	Type	Value
affirmTransactionStatement	Required	Boolean	True / False ***See Note below***
legalNotice	Optional	String	Any additional text the shipper wishes to provide to affirm the transaction statement.

Note: By indicating "True" to the "affirmTransactionStatement" attribute, the transfering company affirms all applicable statements included in DSCSA Sec. 581. (27), which reads:

''(27) TRANSACTION STATEMENT. — The 'transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction —

''(A) is authorized as required under the Drug Supply Chain Security Act;

''(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

''(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

''(D) did not knowingly ship a suspect or illegitimate product;

''(E) had systems and processes in place to comply with verification requirements under section 582;

''(F) did not knowingly provide false transaction information; and

''(G) did not knowingly alter the transaction history."[4]

Here is an example showing the suggested legalNotice value string to be included in the EPCIS header extension.

```
        </EPCISMasterData>
    </extension>
    <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
    <gs1ushc:dscsaTransactionStatement>
        <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
        <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
        Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
    </gs1ushc:dscsaTransactionStatement>
</EPCISHeader>
```

DSCSA lot level traceability runs until November 27, 2023. Starting November 27, 2023, item level traceability begins. While the inclusion of transaction history in item level traceability exchanges sunsets at the start of item level traceability, the specific use "applicable subsection" qualifier in the legalNotice statement above allows the same legalNotice string value to be used for the period prior to November 27, 2023 and beginning November 27, 2023.

[4] Since transactional history sunsets beginning November 27, 2023, DSCSA Sec. 581. (27) (G) will no longer apply.

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10.1.1 Guideline Version in EPCIS Header

The previous release of this guideline addressed changes to EPCIS data resulting from a new version of the core EPCIS standard. This release of the guideline specifies changes to EPCIS data without migrating to a new version of the Standard.

The schema version in the root of the EPCIS file indicates which version of the EPCIS core standard is followed in the file. EPCIS files following this release (R1.3) of the guideline, will need to add a new element to the EPCIS Header of the file to reflect that fact.

What follows is an example of the new element and where it should be placed within EPCIS data:

```
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>
            <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
            Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
</EPCISHeader>
```

10.2 Commissioning

Commissioning is the process of associating an object (e.g., bottle, case, tote, pallet, etc.) with an EPC (i.e., an identifier representing a GTIN / Serial Number, SSCC, etc.). The EPC may be encoded in a data carrier (i.e., a barcode or EPC/ RFID tag) and applied to the object during this step, or the data carrier may have been previously encoded.

10.2.1 Populating a Commissioning Event

A *Commissioning* event should be an EPCIS Object Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the commissioned item in EPC Pure Identity URI format. ▪ If more than one EPC is included, they should all have the same value for ILMD attributes defined below or should all require these attributes to be omitted. ▪ EPCs having different values for these attributes should be shared in different *Commissioning* events.	Because the ILMD attributes below are at the *event-level*, they should be the same for all EPCs in the event.
action	Required	String	ADD	EPCIS standard definition

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Element	Usage	Type	Value	Reason
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:commissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:active	CBV standard definition: the disposition value "active" is always used with the bizStep "commissioning."
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	To minimize the maintenance burden of maintaining 3rd party agent GLN master data and protecting stakeholder privacy , it is acknowledged that for DSCSA, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	To minimize the maintenance burden of maintaining 3rd party agent GLN master data and protecting stakeholder privacy , it is acknowledged that for DSCSA, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.
bizTransactionList	Omitted	List of biz transactions	Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	Omitted in *Commissioning* events as there are no relevant business transactions to share.

10.2.2 Commissioning Event Instance/Lot Master Data (ILMD) Attributes

In addition to the EPCIS standard fields shown above, the following Instance/Lot Master Data (ILMD) attributes are also included in a *Commissioning* event. All of these ILMD attributes are defined in the EPCIS Core Business Vocabulary (CBV) and are in namespace `urn:epcglobal:cbv:mda`.

Element	Usage	Type	Value
lotNumber	Conditional *(See rules in the next sections)*	String	The lot or batch number for all of the EPCs in the epcList of the ObjectEvent.
itemExpirationDate	Conditional *(See note below)*	Date	The expiration date for all of the EPCs in the epcList of the ObjectEvent, formatted as an xsd:date. (See 6.2.4.)

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10.2.3 Commissioning Event Master Data

When an EPCIS document includes one or more *Commissioning* events, the EPCIS header should contain master data including the following attributes for each distinct GTIN referenced in any *Commissioning* event. Since the master data attribute values are associated with the National Drug Code (NDC), GTINs for the lowest sellable unit and higher levels of packaging for the same NDC will therefore have the same master data attribute values defined. Additionally, note that if several *Commissioning* events in the same EPCIS document reference the same GTIN, the master data attributes for that GTIN need only be included *once* in the header.

All of the following master data attributes are defined in the EPCIS Core Business Vocabulary (CBV) and are in namespace `urn:epcglobal:cbv:mda`.

Element	Transaction Information (TI)[5]	Usage	Type	Value
additionalTradeItemIdentification	National Drug Code (NDC)	Conditional *	String	The additional trade item identification associated with this GTIN. * For DSCSA the US_FDA_NDC is a unique 3-segment number, including dashes.
additionalTradeItemIdentificationTypeCode	National Drug Code (NDC)	Conditional *	String	The additional trade item identification type. *For DSCSA, this is always the value US_FDA_NDC.
regulatedProductName	Proprietary or established name of the product	Required	String	The prescribed, regulated, or generic product name or denomination that describes the true nature of the product and is sufficiently precise to distinguish it from other products according to country specific regulation. For DSCSA, this should exactly match the regulatory filing for the product.
manufacturerOfTradeItemPartyName		Required	String	Party name information for the manufacturer of the trade item. For DSCSA, refer to the definition of a manufacturer as defined in section 581(10) of the FD&C Act (*Appendix D: Glossary*)
dosageFormType	Dosage of the product	Required	String	Standard forms of drugs (AEROSOL, CAPSULE, GEL, PILL, TABLET) as defined by the FDA. The FDA currently defines 143 dosage forms.
strengthDescription	Strength of the product	Required	String	Free text describing the strength or potency of the product, including the unit of measure (for example, 60 mg, 25 ml). This should match the regulatory filing for the product.
netContentDescription	Container size	Required	String	Free text describing the number of units contained in a package of the product (for example, 60 Tablets, 100 ounces). This is also known as pack size. This should match the regulatory filing for the product.

[5] *Enhanced Drug Distribution Security in 2023 Under the Drug Supply Chain Security Act (DSCSA), FDA Public meeting presentation, November 16, 2021, slide 26*

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10.2.4 Commissioning Object Event Rules

- ObjectEvents for commissioning item serial numbers SHALL include the ILMD elements to define the lot number and expiration date, and the containing EPCIS Document SHALL include the GTIN-level product master data.
- ObjectEvents for commissioning homogeneous containers (e.g., cases and pallets of the same object) MAY include the ILMD elements to define the lot number and expiration date, and the containing EPCIS Document MAY include the GTIN-level product master data.
- ObjectEvents for commissioning non-homogeneous containers (e.g., cases and pallets of different items, lots, etc.) SHOULD NOT include the ILMD elements to define the lot number and expiration date, and the containing EPCIS Document SHOULD NOT include GTIN-level product master data (except to the extent that the same document contains other *Commissioning* events that do indicate the inclusion of product master data for the same GTINs).
- All of the EPCs within a single *Commissioning* event SHALL either be item serial numbers and/or homogeneous containers having the same lot number and expiration date or be non-homogeneous containers. Multiple *Commissioning* events SHALL be used for EPCs that differ in lot number or expiration date, or for non-homogeneous containers vs. items and homogeneous containers. (This is because the lot number and expiration date given in a single *Commissioning* event applies to *all* of the EPCs in that event.)

10.2.5 XML Example of a Commissioning Event

This example shows *Commissioning* events for lowest saleable units, cases and pallets including the ILMD section that provides instance-level master data, as well as an EPCIS Header that includes GTIN-level product master data for lowest saleable unit and homogeneous case, party master data. This example also illustrates the population of Standard Business Document Header (SBDH) attributes and shows how to populate the EPCIS Header with the GS1 US HC extensions, guidelineVersion and dscsaTransactionStatement..

```
<?xml version="1.0" encoding="UTF-8"?>
<!—Commissioning Event Example →
<!—Manufacturer commissions 2 pallets, each with 2 cases of GTIN A ->4 cases
      each case has 4 LSUs -> 4 LSUs x 4 cases = 16 LSUs
→
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-01T08:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-12-01T08:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
```


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```
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!—master data for lowest saleable unit →
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                            <!—master data for case →
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!—Manufacturer →
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!—Wholesaler →
```


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```
                        <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                    </VocabularyElementList>
                </Vocabulary>
            </VocabularyList>
        </EPCISMasterData>
    </extension>
    <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
    <gs1ushc:dscsaTransactionStatement>
        <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
        <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
    </gs1ushc:dscsaTransactionStatement>
</EPCISHeader>
<EPCISBody>
    <EventList>
        <!—E1: Commissioning events (16 LSUs: 4 LSUs per case = 4x4 cases) →
        <ObjectEvent>
            <eventTime>2022-12-01T07:04:16Z</eventTime>
            <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
            <epcList>
                <epc>urn:epc:id:sgtin:030001.0012345.11</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.12</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.13</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.14</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.15</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.16</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.17</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.18</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.19</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.20</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.21</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.22</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.23</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.24</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.25</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.26</epc>
            </epcList>
            <action>ADD</action>
            <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
            <disposition>urn:epcglobal:cbv:disp:active</disposition>
            <readPoint>
                <id>urn:epc:id:sgln:030001.111111.0</id>
            </readPoint>
            <bizLocation>
                <id>urn:epc:id:sgln:030001.111111.0</id>
            </bizLocation>
            <extension>
                <ilmd>
```

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```
                    <cbvmda:lotNumber>A123</cbvmda:lotNumber>
                    <cbvmda:itemExpirationDate>2025-01-31</cbvmda:itemExpirationDate>
                </ilmd>
            </extension>
        </ObjectEvent>
        <!—E2: Commissioning events (4 case SNs 110, 111, 121, 131) →
        <ObjectEvent>
            <eventTime>2022-12-01T07:10:16Z</eventTime>
            <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
            <epcList>
                <epc>urn:epc:id:sgtin:030001.1012345.110</epc>
                <epc>urn:epc:id:sgtin:030001.1012345.111</epc>
                <epc>urn:epc:id:sgtin:030001.1012345.121</epc>
                <epc>urn:epc:id:sgtin:030001.1012345.131</epc>
            </epcList>
            <action>ADD</action>
            <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
            <disposition>urn:epcglobal:cbv:disp:active</disposition>
            <readPoint>
                <id>urn:epc:id:sgln:030001.111111.0</id>
            </readPoint>
            <bizLocation>
                <id>urn:epc:id:sgln:030001.111111.0</id>
            </bizLocation>
            <extension>
                <ilmd>
                    <cbvmda:lotNumber>A123</cbvmda:lotNumber>
                    <cbvmda:itemExpirationDate>2025-01-31</cbvmda:itemExpirationDate>
                </ilmd>
            </extension>
        </ObjectEvent>
        <!—E3: Commissioning events (2 pallets of GTIN A) →
        <ObjectEvent>
            <eventTime>2022-12-01T07:15:16Z</eventTime>
            <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
            <epcList>
                <epc>urn:epc:id:sscc:030001.41234567890</epc>
                <epc>urn:epc:id:sscc:030001.41234567895</epc>
            </epcList>
            <action>ADD</action>
            <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
            <disposition>urn:epcglobal:cbv:disp:active</disposition>
            <readPoint>
                <id>urn:epc:id:sgln:030001.111111.0</id>
            </readPoint>
            <bizLocation>
                <id>urn:epc:id:sgln:030001.111111.0</id>
            </bizLocation>
        </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

10.2.6 Grouping Together Commissioning Object Events

- High volume throughput of commissioning serialized products can result in hundreds of thousands of commissioned item serial numbers that can potentially generate extra-large EPCIS document file size. Capturing one event per commissioned EPC should be avoided to prevent the operational issues of processing massive EPCIS document files. Instead of capturing the commissioning event for each commissioned EPC as single events, the commissioning events for the same GTIN and batch SHOULD BE judiciously grouped together in a single commissioning event. The list of EPCs of

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the same packaging level (i.e., each, case, pallet) will be combined together in a single commissioning event. Given the example of a production batch for a specific GTIN yielding commissioned objects representing eaches, cases and pallets, there would be 3 commissioning events for the same GTIN and batch: a commissioning event grouping eaches, a second commissioning event grouping cases, and a commissioning event grouping pallets.

- When combining the commissioning of EPCs for the same GTIN, batch and packaging level into a single EPCIS commissioning object event, a single eventTime SHOULD BE defined to represent the commissioning event of these judiciously grouped EPCs.

10.3 Packing

Packing denotes a specific activity within a business process that includes putting an object (e.g., individuals, inners, cases, pallets, etc.) into a larger container (e.g., cases, totes, pallets, etc.) usually for the purposes of storing or shipping. Aggregation of one unit to another occurs at this point.

10.3.1 Populating a Packing Event

A *Packing* event should be an EPCIS Aggregation Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition
eventTime ZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
parentID	Required	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition
childEPCs	Required	List of URI	EPC(s) of the item(s) being packed into the parent presented in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:packing	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	To minimize the maintenance burden of maintaining 3rd party agent GLN master data and protecting stakeholder privacy , it is acknowledged that for DSCSA, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	To minimize the maintenance burden of maintaining 3rd party agent GLN master data and protecting stakeholder privacy, it is acknowledged that for DSCSA, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.

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Element	Usage	Type	Value	Reason
bizTransactionList	Omitted	List of biz transactions	Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	Omitted in the *Packing* event as there are no relevant business transactions to share.

10.3.2 XML Example of a Packing Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!—Packing Event Example →
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-11-26T17:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-11-26T17:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!—master data for lowest saleable unit →
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                            <!—master data for case →
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
```


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```
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!—Manufacturer →
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!—Wholesaler →
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>
            <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
```

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```
        <EventList>
            <AggregationEvent>
                <eventTime>2022-11-26T17:10:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <parentID>urn:epc:id:sgtin:030001.1012345.22222223333</parentID>
                <childEPCs>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000001003</epc>
                </childEPCs>
                <action>ADD</action>
                <bizStep>urn:epcglobal:cbv:bizstep:packing</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </bizLocation>
            </AggregationEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.4 Shipping

Shipping is the process of initiating the transfer an object from one trading partner to another. A data carrier (i.e., a linear or 2-dimensional barcode) may have been read during this process. Only the outermost containers in the packaging hierarchy are included.

10.4.1 Populating a Shipping Event

A *Shipping* event should be an EPCIS Object Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1).	EPCIS standard definition. For purposes of DSCSA, this is considered the shipping date (when bizStep = shipping).
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	The EPC(s) of the outermost containers in the packaging hierarchy. Most likely, SSCCs of Cases or Pallets.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. **disposition** value “in_transit” is always paired with **bizStep** “shipping” for forward logistics
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition

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Element	Usage	Type	Value	Reason
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section *8.2.2*)	For a *Shipping* event, this is unknown until a *Receiving* event occurs. Thus, bizLocation is always omitted in *Shipping* events. (Note: **source** and **destination** elements in this event provide "Ship from/to" and "Transfer from/to" information.)
bizTransactionList	Optional	List of biz transactions	Business transactions governing this *Shipping* event, which may include a purchase order, delivery number or an invoice. (See Section *8.2.3* for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. If more than one business transaction of the same type is included, then this event does not specify which objects in the epcList are associated with which business transaction. Optionally, the shipper may include one or more *Shipping Transaction Detail* events (Section 10.4.5) to associate specific objects with each business transaction.	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for PO, Delivery Number, Invoice or other ID's.
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party and another source of type urn:epcglobal:cbv:sdt:location. • The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transferring party. • The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list.	Optional in the EPCIS standard but required in this guideline to provide party information for DSCSA.
destinationList	Required	List of destinations	Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type urn:epcglobal:cbv:sdt:owning_party and another destination of type urn:epcglobal:cbv:sdt:location.	Optional in the EPCIS standard but required in this guideline to provide party information for DSCSA.

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Element	Usage	Type	Value	Reason
			• The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transfer-to party. • The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-to GLN. Each GLN URI must match one of the companies in the company master data list.	

10.4.2 Shipping Event Extension

In addition to the EPCIS standard fields listed above, the following extension fields may also be included in the EPCIS *Shipping* event. (See Section 8.2.5 for general notes about extensions)

Element	Usage	Type	Value
transactionDate	Conditional *	Timestamp	The date in which the transfer of ownership occurred. Due to operational differences, it is possible for the shipping date (event time) to be different than the transaction date. * NOTE: DSCSA requires Transaction Date for *certain* shipments. Consult with your regulatory advisor to determine what is required for your products/shipments.
directPurchase	Conditional *Not applicable for certain trading partners (e.g., Manufacturers, Repackagers)	Complex Type *(See elements at bottom of this table)*	Used to indicate if products were purchased directly from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that purchased directly from the manufacturer. ▪ If the products in the shipment were purchased entirely direct from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that purchased directly from the manufacturer, then the **directPurchase** qualifier will be set to "ENTIRELY_DIRECT" and *indirectPurchaseEPCs* will be omitted. ▪ If the products in the shipment were purchased entirely indirect from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that purchased directly from the manufacturer, then the **directPurchase** qualifier will be set to "ENTIRELY_INDIRECT" and *indirectPurchaseEPCs* will be omitted. ▪ If the products in the shipment were purchased partially indirect from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that purchased directly from the manufacturer, then the **directPurchase** qualifier will be set to "PARTIALLY_DIRECT" and *indirectPurchaseEPCs* will be specified.

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Element	Usage	Type	Value
receivedDirectPurchaseFromPrevWhlsDist	Optional *Only applicable for certain trading partners (e.g., Wholesalers distributors that purchased from a previous wholesale distributor)	Complex Type *(See elements at bottom of this table)*	Used to indicate if product(s) shipped in this event was received directly from a wholesaler who provided a direct purchase statement in its transaction information. ▪ If the products in the shipment were purchased entirely direct by the previous wholesaler from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that purchased directly from the manufacturer, then the **receivedDirectPurchaseFromPrevWhlsDist** qualifier will be set to "ENTIRELY_DIRECT" and *prevReceivedinDirectPurchaseEPCs* will be omitted. ▪ If the products in the shipment were purchased by the previous wholesaler entirely indirect from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that purchased directly from the manufacturer, then the **receivedDirectPurchaseFromPrevWhlsDist** qualifier will be set to "ENTIRELY_INDIRECT" and *prevReceivedinDirectPurchaseEPCs* will be omitted. ▪ If the products in the shipment were purchased partially indirect by the previous wholesaler from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that purchased directly from the manufacturer, then the **receivedDirectPurchaseFromPrevWhlsDist** qualifier will be set to "PARTIALLY_DIRECT" and *prevReceivedinDirectPurchaseEPCs* will be specified.
dropShipment	Conditional	Boolean	Flag indicating that the products are being shipped directly by the seller to the buyer's customer while the transfer of ownership transaction is between the seller and the buyer. For example, a manufacturer sells the product to the wholesaler and the manufacturer is drop shipping the product to the dispenser who is the wholesaler's customer. ▪ Default value is false ▪ It is recommended to capture and send EPCIS events related to drop shipments in a separate EPCIS document. An example of this is when the seller ships the product directly to the buyer's customer [shipped from Manufacturer to Dispenser but sold to Wholesaler]. Therefore, serialized products that are not drop shipped will be captured in a separate EPCIS document than serialized products that are drop shipped.
directPurchase elements *Not applicable for certain trading partners (e.g., Manufacturers, Repackagers)			
@qualifier			Characterizes the content of the shipment to be one of the following: ▪ ENTIRELY_DIRECT ▪ ENTIRELY_INDIRECT ▪ PARTIALLY DIRECT

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indirectPurchaseEPCs	Conditional	List of EPCs	When the shipment partially includes serialized products not purchased directly from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that was purchased directly from the manufacturer, then it is required to enumerate *indirectPurchaseEPCS* with the list of indirectly purchased products or packages in the shipment, including products contained inside any specified package. Each EPC shall either be: ▪ an EPC listed in the main epcList of this *Shipping* event, **or** ▪ an EPC that is aggregated to one of the EPCs listed in the main epcList of this Shipping event. Populate only when the **directPurchase** @qualifier is "PARTIALLY_DIRECT". When the **directPurchase** @qualifier is "ENTIRELY_INDIRECT", *indirectPurchaseEPCs* should be omitted since the EPCs of indirectly purchased products can be derived from the EPC listed in the main epcList of this *Shipping* event. When the **directPurchase** @qualifier is "ENTIRELY_DIRECT", *indirectPurchaseEPCs* SHALL be omitted since there are no applicable indirectly purchased EPCs.
directPurchaseStatement	Conditional	String	Any additional text the shipper wishes to provide to affirm the direct purchase statement. The default **directPurchaseStatement** is set to "Seller affirms that indicated product(s) were purchased directly from the manufacturer, exclusive distributor of the manufacturer, or a repackager who purchased directly unless noted as being indirectly sourced."
receivedDirectPurchaseFromPrevWhIsDist elements *Only applicable for certain trading partners (e.g., Wholesalers distributors that purchased from a previous wholesale distributor)			
@qualifier			Characterizes the content of the shipment to be one of the following: ▪ ENTIRELY_DIRECT ▪ ENTIRELY_INDIRECT ▪ PARTIALLY_DIRECT

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prevReceivedinDirectPurchaseEPCs	Optional	List of URI	When the shipment partially includes serialized products not purchased directly by the selling wholesaler from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that was purchased directly from the manufacturer, then it is required to enumerate *prevReceivedinDirectPurchaseEPCs* with the list of indirectly purchased products or packages in the shipment, including products contained inside any specified package. Each EPC shall either be: ▪ an EPC listed in the main epcList of this *Shipping* event, **or** ▪ an EPC that is aggregated to one of the EPCs listed in the main epcList of this Shipping event. Populate only when the **receivedDirectPurchaseFromPrevWhlsDist** @qualifier is "PARTIALLY_DIRECT". When the **receivedDirectPurchaseFromPrevWhlsDist** @qualifier is "ENTIRELY_INDIRECT", *prevReceivedinDirectPurchaseEPCs* should be omitted since the EPCs of indirectly purchased products can be derived from the EPC listed in the main epcList of this *Shipping* event. When the **receivedDirectPurchaseFromPrevWhlsDist** @qualifier is "ENTIRELY_DIRECT", *prevReceivedinDirectPurchaseEPCs* SHALL be omitted since there are no applicable indirectly purchased EPCs.
receivedDirectPurchaseFromPrevWhlsDistStatement	Optional	String	Any additional text the shipper wishes to provide to affirm the direct purchase statement received from the previous wholesaler. The default **receivedDirectPurchaseFromPrevWhlsDistStatement** is set to "Seller affirms receipt of directly purchased statement from previous wholesaler distributor for the indicated product(s)."

10.4.2.1 Since the shipping content can be a mixture of direct and indirect purchases, three variations for the direct purchase extension to *Shipping* event are supported by the *directPurchase* data construct. The following examples illustrate the three variations for the direct purchase extension to the *Shipping* event:

Variation 1: All products on the pallets named in this shipping event are direct purchased products.

```
<gs1ushc:directPurchase qualifier="ENTIRELY_DIRECT"/>
```

Variation 2: A subset of the products contained in the *Shipping* event are directly purchased.

Below is an example of a shipping event scenario containing three pallets, wherein pallet #1 is directly purchased, two out of the four cases inside pallet #2 are directly purchased, and pallet #3 is indirectly purchased. In this example shipment scenario, 2 cases from pallet #2 and pallet#3 shall be listed indirectEPCs.

```
<gs1ushc:directPurchase qualifier="PARTIALLY_DIRECT">
```


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```
  <indirectPurchaseEPCs>
    <!-- Pallet#3 and all of its contents are indirectly purchased. The
EPC below is the SSCC of Pallet #3 -->
    <epc>urn:epc:id:sscc:030001.02468024680</epc>
    <!-- Pallet#2 contains 4 homogeneous cases but only case1 and case2
are indirectly purchased. The two EPCs below are the SGTINs of those two
cases. -->
    <epc>urn:epc:id:sgtin:030001.1123456.400</epc>
    <epc>urn:epc:id:sgtin:030001.1123456.401</epc>
  </indirectPurchaseEPCs >
  <directPurchaseStatement> Seller affirms that indicated product(s) were
purchased directly from the manufacturer, from the manufacturer's
exclusive distributor of the manufacturer, or from a repackager who
purchased directly from the manufacturer unless noted as being indirectly
sourced.</directPurchaseStatement>
</gs1ushc:directPurchase>
```

Variation 3: All products on the pallets named in this shipping event are indirectly purchased products.

```
<gs1ushc: directPurchase@qualifier="ENTIRELY_INDIRECT"/>
```

10.4.2.2 The following example illustrates a shipment of products purchased by the indirect wholesaler from the primary wholesaler and how to efficiently identify the products in the shipment that were purchased directly by the primary wholesaler and the indirect wholesaler received direct purchase information from the direct wholesaler.

The example content is a mixture of direct and indirect purchases, three variations for the receivedDirectPurchaseFromPrevWhlsDist extension to Shipping event. The following examples illustrate the three variations for the receivedDirectPurchaseFromPrevWhlsDist extension to the Shipping event:

Variation 1: All products on the pallets named in this shipping event are direct purchased products by previous wholesaler.

```
<gs1ushc:receivedDirectPurchaseFromPrevWhlsDist qualifier="ENTIRELY_DIRECT"/>
```

Variation 2: A subset of the products contained in the *Shipping* event are directly purchased by previous wholesaler.

Below is an example of a shipping event scenario containing three pallets, wherein pallet #1 is directly purchased, two out of the four cases inside pallet #2 are directly purchased, and pallet #3 is indirectly purchased. In this example shipment scenario, 2 cases from pallet #2 and pallet#3 shall be listed indirectEPCs.

```
<gs1ushc:receivedDirectPurchaseFromPrevWhlsDist
qualifier="PARTIALLY_DIRECT">
  <prevReceivedinDirectPurchaseEPCs>
    <!-- Pallet#3 and all of its contents are indirectly purchased. The
EPC below is the SSCC of Pallet #3 -->
    <epc>urn:epc:id:sscc:030001.02468024680</epc>
```

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```
    <!-- Pallet#2 contains 4 homogeneous cases but only case1 and case2
are indirectly purchased. The two EPCs below are the SGTINs of those two
cases. -->
    <epc>urn:epc:id:sgtin:030001.1123456.400</epc>
    <epc>urn:epc:id:sgtin:030001.1123456.401</epc>
  </prevReceivedinDirectPurchaseEPCs>
  <receivedDirectPurchaseFromPrevWhlsDistStatement>Seller affirms receipt
of directly purchased statement from previous wholesaler distributor for
the indicated
product(s).</receivedDirectPurchaseFromPrevWhlsDistStatement>
</gs1ushc:receivedDirectPurchaseFromPrevWhlsDist>
```

Variation 3: All products on the pallets named in this shipping event are indirectly purchased products by the previous wholesaler.

```
<gs1ushc:receivedDirectPurchaseFromPrevWhlsDist qualifier="ENTIRELY_INDIRECT"/>
```

10.4.3 Shipping Event Master Data

When an EPCIS document includes one or more *Shipping* events, the EPCIS header should contain master data including the following attributes for each distinct party or location referenced in the source list or destination list of any *Shipping* event. Note that if several *Shipping* events in the same EPCIS document reference the same party or location, the master data attributes for that party or location need only be included *once* in the header.

Party or location master data elements
(Include one set of attributes for each trading partner found in any Shipping event within scope of the header. This group of attributes may be available via an EPCIS query in future versions of this guideline.)

name	Required	String	The name of the location or party expressed in text
streetAddressOne	Required	String	The first line of the street address.
streetAddressTwo	Optional	String	The second line of the street address.
streetAddressThree	Optional	String	The third line of the street address.
city	Required	String	The city.
state	Conditional	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Conditional	String	The ZIP or other postal code.
countryCode	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

10.4.4 XML Example of a Shipping Event

This example shows both a single *Shipping* event, as well as an EPCIS Header that includes party master data for the source and destination. This example also illustrates the population of Standard Business Document Header (SBDH) attributes and shows how to populate the EPCIS Header with the GS1 US HC extensions, guidelineVersion and dscsaTransactionStatement.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Shipping Event Example -->
<!-- Manufacturer ships a pallet to the Wholesaler
```


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```
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-01T08:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-12-01T08:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Manufacturer -->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Manufacturer owned DC-->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111121.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">7244 S
Century Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
101</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40041</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
```


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```
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler's DC-->
                            <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>
            <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <ObjectEvent>
                <eventTime>2022-12-01T07:45:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sscc:030001.01234567890</epc>
                </epcList>
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111121.0</id>
                </readPoint>
                <!-- 2 business documents: PO from buying wholesaler, Delivery Document created
by Manufacturer -->
                <bizTransactionList>
```

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```
                    <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:XYZPO567</bizTransaction>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0300011111116:ABCDEL234</bizTransactio
n>
                </bizTransactionList>
                <extension>
                    <!-- Source Owning Party is Manufacturer, Source Location is Manufacturer
owned DC -->
                    <sourceList>
                        <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
                        <source
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:030001.111121.0</source>
                    </sourceList>
                    <!-- Destination Owning Party is Wholesaler Corp Office, Destination
Location is Wholesaler Distribution Center -->
                    <destinationList>
                        <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
                        <destination
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:039999.345678.0</destination>
                    </destinationList>
                </extension>
                <gs1ushc:dropShipment>false</gs1ushc:dropShipment>
            </ObjectEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.4.5 Shipping Business Transaction Detail Event

As specified in Section 10.4.5, a *Shipping* event may optionally contain references to business transactions such as purchase orders or invoices. In some cases, a shipment may contain objects that belong to two or more business transactions of the same type (two or more purchase orders, two or more invoices, etc.). Separate *Shipping* events may be used so that each *Shipping* event only refers to a single business transaction of each type.

Sometimes, however, a single object listed in the `epcList` of a *Shipping* event contains objects belonging to two or more business transactions; for example, a single pallet (identified by SSCC) that contains several cartons belonging to one purchase order and several more cartons belonging to a different purchase order. In this situation, the *Shipping* event will list the pallet identifier in the `epcList`, and list both purchase orders in the `bizTransactionList`. The *Shipping* event itself, therefore, does not indicate which cartons belong to which purchase order.

In such situations, the shipper may optionally include one or more *Shipping Business Transaction Detail* events as specified in this section. Each *Shipping Business Transaction Detail* indicates a single business transaction of a given type, and in its `epcList` indicates just those objects that are associated with that business transaction. These may be objects that are contained within the objects listed in the corresponding *Shipping* event. In the example above, each *Shipping Business Transaction Detail* event would list the identifiers of the cartons (SSCCs or SGTINs) that belong to a given purchase order.

A *Shipping Business Transaction Detail* event shall be an EPCIS Transaction Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1) This should precede the date and time of the corresponding *Shipping* event.	EPCIS standard definition For purposes of DSCSA, the shipping

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Element	Usage	Type	Value	Reason
				business transaction detail event time precedes the shipping date (when bizStep = shipping).
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	▪ EPC Pure Identity URI for each object associated with the business transactions listed in this event. ▪ If the EPC of a container is indicated, all of its contents are associated with the business transaction.	EPCIS standard definition
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The **disposition** value "in_transit" is always paired with the **bizStep** "shipping" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2) This should match the readPoint of the corresponding *Shipping* event.	EPCIS standard definition
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	For a *Shipping* event, this is unknown until a *Receiving* event occurs. Thus, bizLocation is always omitted in *Shipping* events.
bizTransaction List	Required	List of biz transactions	Business transactions governing this *Shipping Business Transaction Detail* event, which may include a purchase order, delivery number or an invoice (See Section 8.2.3 for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. In a *Shipping Business Transaction Detail* event, only one business transaction of a given type shall be included.	EPCIS standard definition

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10.4.6 XML Example of a Shipping Business Transaction Detail Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Shipping Business Transaction Event Detail Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-11-27T17:30:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-11-27T17:30:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Manufacturer -->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
```


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```
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>
            <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <TransactionEvent>
                <eventTime>2022-11-27T17:10:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <bizTransactionList>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991: XYZPO567</bizTransaction>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0300011111116:
ABCDEL234</bizTransaction>
                </bizTransactionList>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.1012345.22222223333</epc>
                    <epc>urn:epc:id:sgtin:030001.1012345.22222224444</epc>
                </epcList>
                <action>ADD</action>
                <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111121.0</id>
                </readPoint>
            </TransactionEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.4.7 XML Example of a Shipment Covered by Multiple Purchase Orders

This example shows how to capture a shipment containing 3 pallets with SSCCs and illustrates how to associate 2 Purchase Orders (POs) to the specific shipment content.

- SSCC 003000100000001012 is the first pallet with all of its contents covered by PO# 1234.
- SSCC 003000100000001029 is the second pallet with all of its contents covered by PO# 4567.
- SSCC 003000100000001036 is the third pallet which contains 5 cases of which:
  - 2 cases (SGTINs with serials 401, 402) belong to PO# 1234 and
  - 3 cases (SGTINs with serials 501, 502, 503) belong to PO#4567.

This XML example shows one *Shipping* event and two additional *Shipping Business Transaction Detail* events to map the specific content to individual POs.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Example Shipment with Multiple POs illustrating how to capture with Object and Transaction
```

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```
Events -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-01T10:13:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-12-01T10:13:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Manufacturer -->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Manufacturer owned DC-->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111121.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">7244 S
Century Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
101</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40041</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
```


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```
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler's DC-->
                            <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>
            <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <!-- Using a Transaction Event, record the shipping contents specifically
associated with PO# 1234 -->
            <TransactionEvent>
                <!-- The transaction event’s eventTime should precede the date and time of the
corresponding Shipping event.  -->
                <eventTime>2022-12-01T10:08:12Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <bizTransactionList>
                    <!-- Associate PO# 1234 to the EPCs in the business transaction -->
                    <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:1234</bizTransaction>
                </bizTransactionList>
                <epcList>
                    <epc>urn:epc:id:sscc:030001.00000000101</epc>
                    <epc>urn:epc:id:sgtin:030001.1123456.401</epc>
```

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```
                    <epc>urn:epc:id:sgtin:030001.1123456.402</epc>
                </epcList>
                <action>ADD</action>
                <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </readPoint>
            </TransactionEvent>
            <!-- The transaction event's eventTime should precede the date and time of the
corresponding Shipping event. -->
            <TransactionEvent>
                <eventTime>2022-12-01T10:09:12Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <bizTransactionList>
                    <!-- Associate PO# 4567 to the EPCs in the business transaction -->
                    <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:4567</bizTransaction>
                </bizTransactionList>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.1123456.501</epc>
                    <epc>urn:epc:id:sgtin:030001.1123456.502</epc>
                    <epc>urn:epc:id:sgtin:030001.1123456.503</epc>
                    <epc>urn:epc:id:sscc:030001.00000000102</epc>
                </epcList>
                <action>ADD</action>
                <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </readPoint>
            </TransactionEvent>
            <!-- Shipping event for 3 SSCCs 101, 102, and 103.
                  Shipment is covered by 2 Purchase Orders (POs) #1234 and #4567. -->
            <ObjectEvent>
                <eventTime>2022-12-01T10:11:12Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sscc:030001.00000000101</epc>
                    <epc>urn:epc:id:sscc:030001.00000000102</epc>
                    <epc>urn:epc:id:sscc:030001.00000000103</epc>
                </epcList>
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </readPoint>
                <bizTransactionList>
                    <!-- Both PO# 1234 and PO#4567 are associated with this shipment -->
                    <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:1234</bizTransaction>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:4567</bizTransaction>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0300011111116:DEL123
                    </bizTransaction>
                </bizTransactionList>
                <extension>
                    <sourceList>
                        <source
```

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```
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
                        <source
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:030001.111121.0</source>
                    </sourceList>
                    <destinationList>
                        <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
                        <destination
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:039999.345678.0</destination>
                    </destinationList>
                </extension>
                <gs1ushc:dropShipment>false</gs1ushc:dropShipment>
            </ObjectEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.5 Transformation Event for Repackaging

The EPCIS *Transformation* event is used in repackaging scenarios to record the relationship between the original product and the repackaged product. A *Transformation* event for serial-level management should be an EPCIS *Transformation* Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
inputEPCList	Required	List of URI	List of repackaging input EPC(s) in EPC Pure Identity URI format	List of *input EPC*s to the repackaging process; the products that are consumed to create the repackaged product
outputEPCList	Required	List of URI	List of repackaging output EPC(s) in EPC Pure Identity URI format	List of SGTINs that are the *outputs* of the repackaging process; the repackaged products that are produced.
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:commissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:active	CBV standard definition. The **disposition** value “active” is always paired with the **bizStep** “commissioning” for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Required	URI	The location where the objects are presumed to be following the event.	EPCIS standard definition

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Element	Usage	Type	Value	Reason
bizTransactionList	Optional	List of biz transactions	Business transactions governing this *Transformation* event, which may include a purchase order or an invoice (See Section 8.2.3 for details) (Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.)	Optional
Instance level master data (ilmd) elements				
lotNumber	Required	String	The lot or batch number for all of the EPCs in the outputEPCList of the repackaged product.	
itemExpirationDate	Required	Date	The expiration date for all of the EPCs in the outputEPCList of the of the repackaged product, formatted as an xsd:date. (See Section 6.2.4.)	

10.5.1 Transformation Event Example XML

This example shows a transformation event from a repackager who purchased product the manufacturer. The following XML example illustrates how to capture the commissioning of repackaged serialized products.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Transformation Event Example -->
<!-- Repackager transforms serialized GTIN A products to serialized GTIN B -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-
1_2.xsd" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-
02T09:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:0374132.45902.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100340005</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-12-
02T09:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!-- master data for lowest saleable unit GTIN A -->
                            <VocabularyElement
id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
```


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```
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribu
te>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#netContentDescription">250 pills</attribute>
                            </VocabularyElement>
                            <!-- master data for repackaged lowest saleable unit GTIN B
-->
                            <VocabularyElement
id="urn:epc:idpat:sgtin:0374132.057913.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">74132-579-13</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribu
te>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Celentia</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Repackager</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Repackager -->
                            <VocabularyElement id="urn:epc:id:sgln:0374132.45902.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1
Repackager</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">114 Delta Street</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite 1000</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Austin</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#state">TX</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">78653</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug
Distro LLC</attribute>
                                <attribute
```

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```
id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
                                    <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
                                    <attribute id="urn:epcglobal:cbv:mda#city">New
York</attribute>
                                    <attribute
id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                    <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                    <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                </VocabularyElement>
                            </VocabularyElementList>
                        </Vocabulary>
                    </VocabularyList>
                </EPCISMasterData>
            </extension>
            <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
            <gs1ushc:dscsaTransactionStatement>

<gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
                <gs1ushc:legalNotice>Seller has complied with each applicable subsection of
FDCA Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
            </gs1ushc:dscsaTransactionStatement>
        </EPCISHeader>
        <EPCISBody>
            <EventList>
                <!-- E1: Transformation Event from GTIN A to GTIN B -->
                <extension>
                    <TransformationEvent>
                        <eventTime>2022-12-02T07:04:16Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <inputEPCList>
                            <epc>urn:epc:id:sgtin:030001.0012345.11</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.12</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.13</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.14</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.15</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.16</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.17</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.18</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.19</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.20</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.21</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.22</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.23</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.24</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.25</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.26</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.27</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.28</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.29</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.30</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.31</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.32</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.33</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.34</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.35</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.36</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.37</epc>
                            <epc>urn:epc:id:sgtin:030001.0012345.38</epc>
```


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```
                        <epc>urn:epc:id:sgtin:030001.0012345.39</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.40</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.41</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.42</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.43</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.44</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.45</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.46</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.47</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.48</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.49</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.50</epc>
                    </inputEPCList>
                    <outputEPCList>
                        <epc>urn:epc:id:sgtin:0374132.057913.1001</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1002</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1003</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1004</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1005</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1006</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1007</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1008</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1009</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1010</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1011</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1012</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1013</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1014</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1015</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1016</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1017</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1018</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1019</epc>
                        <epc>urn:epc:id:sgtin:0374132.057913.1020</epc>
                    </outputEPCList>
                    <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
                    <disposition>urn:epcglobal:cbv:disp:active</disposition>
                    <readPoint>
                        <id>urn:epc:id:sgln:0374132.45902.0</id>
                    </readPoint>
                    <bizLocation>
                        <id>urn:epc:id:sgln:0374132.45902.0</id>
                    </bizLocation>
                    <ilmd>
                        <cbvmda:lotNumber>R123</cbvmda:lotNumber>
                        <cbvmda:itemExpirationDate>2025-12-
31</cbvmda:itemExpirationDate>
                    </ilmd>
                </TransformationEvent>
            </extension>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.6 Receiving

Receiving is the process of completing the transfer of an object from one trading partner to another.

Receiving is primarily recorded in the following way:

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- Only the outermost containers in the packaging hierarchy are included in the *Receiving* event, in which case the full hierarchy inferred from prior Packing events are inferred to have been received.
  - The *Receiving* event should be an EPCIS Object Event populated as specified below.

10.6.1 Populating a *Receiving* Event with an Object Event

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date & time of event. (See Section 8.2.1)	EPCIS standard definition
eventTime ZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date & time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the received item(s) in EPC Pure Identity URI format. An Object Event is used when the EPC is physically scanned. ▪ Could be only the outermost container ▪ Could be all or some contents of the innermost containers with unpacking	*See the discussion above regarding receiving options.*
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:receiving	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	EPCIS standard definition
bizTransactionList	Optional	List of biz transactions	Business transactions governing this *Receiving* event, which may include a purchase order, delivery number, or an invoice. (See Section 8.2.3 for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	Optional from an EPCIS standard perspective, but certain regulations & business agreements may require for PO, Delivery Number, Invoice or other ID's.
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party and another source of type urn:epcglobal:cbv:sdt:location. • The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transferring party.	EPCIS standard definition

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Element	Usage	Type	Value	Reason
			• The source value with source type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-from GLN. • Each GLN URI must match one of the companies in the company master data list.	
destination List	Required	List of destinations	Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type urn:epcglobal:cbv:sdt:owning_party and another destination of type urn:epcglobal:cbv:sdt:location. • The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transfer-to party. • The destination value with destination type of urn:epcglobal:cbv:sdt:location is the EPC Pure Identity URI of the ship-to GLN. Each GLN URI must match one of the companies in the company master data list.	EPCIS standard definition

Best Practice:

To help in later matching *Shipping* and *Receiving* events, if possible, use the same values found in your trading partner's *Shipping* event for sourceList and destinationList in your *Receiving* event.

10.6.2 Receiving Event Master Data

When an EPCIS document includes one or more *Receiving* events, the EPCIS header should contain master data including the following attributes for each distinct party or location referenced in the source list or destination list of any *Receiving* event. Note that if several *Receiving* events in the same EPCIS document reference the same party or location, the master data attributes for that party or location need only be included *once* in the header.

or location master data elements *(Include one set of attributes for each trading partner found in any Receiving event within the scope of the header. This group of attributes may be available via an EPCIS query in future versions of this guideline.)*			
name	Required	String	The name of the location or party expressed in text
streetAddressOne	Required	String	The first line of the street address.
streetAddressTwo	Optional	String	The second line of the street address.
streetAddressThree	Optional	String	The third line of the street address.
city	Required	String	The city.

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state	Conditional	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Conditional	String	The ZIP or other postal code.
countryCode	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

10.6.3 Capturing Receiving of Objects Scanned and XML Example

Example Business Scenario: A pallet containing 2 homogeneous cases of 4 bundles of inner packs containing 5 saleable eaches arrive at the wholesaler warehouse. At the receiving dock, the wholesaler scans pallet barcode and infers receipt of the contents. They capture the physical scanning of the pallet at the receiving dock using an Object Event.

```
<?xml version="1.0" encoding="UTF-8"?>
    <!-- Receiving Event Example -->
    <!-- Example use case: A pallet containing 10 homogeneous cases of 4 bundles of inner
    packs containing 5 saleable eaches arrive at the wholesaler warehouse.  At the
    receiving dock, the Wholesaler scans the pallet barcode and infers receipt of the
    contents. They capture the physical scanning of the pallet at the receiving dock
    using an Object Event.
    -->
    <epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
    xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
    xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
    schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-
    1_2.xsd" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-
    01T08:45:16Z">
        <EPCISHeader>
            <sbdh:StandardBusinessDocumentHeader>
                <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
                <sbdh:Sender>
                    <sbdh:Identifier
    Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
                </sbdh:Sender>
                <sbdh:Receiver>
                    <sbdh:Identifier
    Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
                </sbdh:Receiver>
                <sbdh:DocumentIdentification>
                    <sbdh:Standard>EPCglobal</sbdh:Standard>
                    <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                    <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
                    <sbdh:Type>Events</sbdh:Type>
                    <sbdh:CreationDateAndTime>2022-12-
    01T08:45:16Z</sbdh:CreationDateAndTime>
                </sbdh:DocumentIdentification>
            </sbdh:StandardBusinessDocumentHeader>
            <extension>
                <EPCISMasterData>
                    <VocabularyList>
                        <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                            <VocabularyElementList>
                                <!-- Manufacturer -->
                                <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                    <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
    LLC</attribute>
                                    <attribute
    id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George Ave</attribute>
```

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```
                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">12345-6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Manufacturer owned DC-->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111121.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
DC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">7244 S Century Ave</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite 101</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40041</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug
Distro LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New
York</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">10003-1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler's DC-->
                            <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug
Distro Warehouse</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main St</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite 100</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
```


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```
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>

<gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection
of FDCA Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <ObjectEvent>
                <eventTime>2022-12-01T07:45:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sscc:030001.01234567890</epc>
                </epcList>
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:039999.999999.0</id>
                </readPoint>
                <bizLocation>
                    <id> urn:epc:id:sgln:039999.999999.0</id>
                </bizLocation>
                <!-- 2 business documents: PO from buying wholesaler, Delivery
Document created by Manufacturer -->
                <bizTransactionList>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:XYZPO567</bizTrans
action>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0300011111116:ABCDEL234</biz
Transaction>
                </bizTransactionList>
                <extension>
                    <!-- Source Owning Party is Manufacturer, Source Location is
Manufacturer owned DC -->
                    <sourceList>
                        <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
                        <source
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:030001.111121.0</source>
                    </sourceList>
                    <!-- Destination Owning Party is Wholesaler Corp Office,
Destination Location is Wholesaler Distribution Center -->
                    <destinationList>
                        <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destinatio
n>
                        <destination
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:039999.345678.0</destination>
                    </destinationList>
                </extension>
            </ObjectEvent>
```

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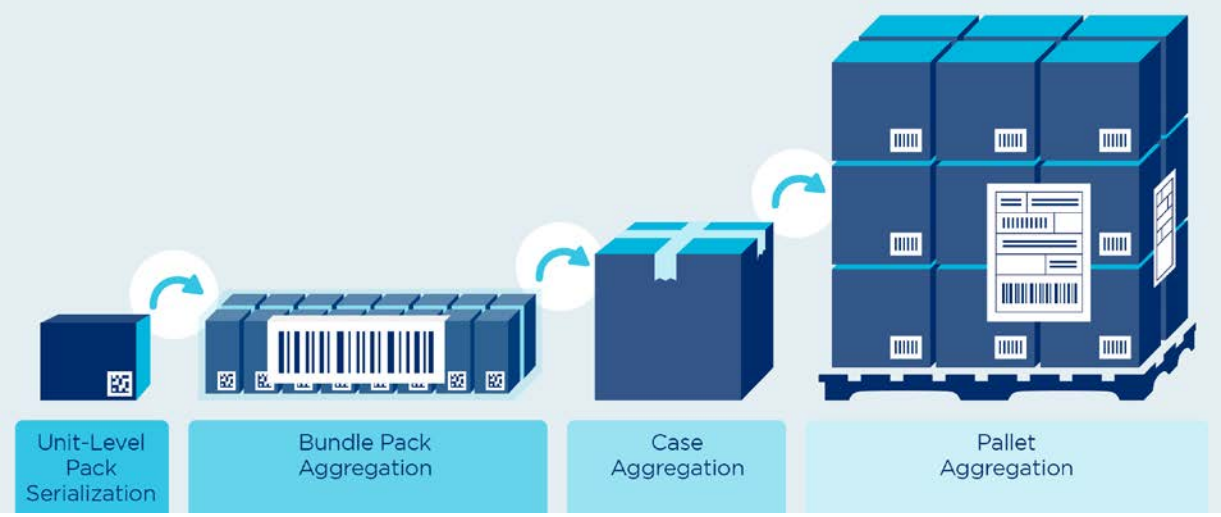
```
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

In the scenario, the packaging levels are:

- Parent = the pallet
- Child of Pallet = 2 homogeneous cases
- Child of Cases = 4 bundles of inner packs
- Child of Inner Packs = 5 eaches in each inner pack

Note: Aggregation is used in this example business scenario to associate a collection of trade items to a higher packaging level. It creates the parent-child relationship by associating the aggregated unit, which is the parent, with its innermost contents, the children.



10.6.4 Capturing Receiving under Inference

Without unpacking, companies may choose to capture the items inferred as part of the Receiving process. This can be accomplished by adding an *Aggregation* Event to the Receiving process for each inferred item to be recorded. While the Object Receiving event acknowledges which outermost containers were scanned. this Aggregation Receiving event is similar to the Object *Receiving* Event shown above with a few modifications.

10.6.4.1 Populating an Aggregation Event in Support of Receiving under Inference

An EPCIS Aggregation Event is populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
parentID	Required	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition

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Element	Usage	Type	Value	Reason
childEPCs	Required	List of URI	EPC(s) of the item(s) being packed into the parent presented in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:receiving	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	EPCIS standard definition

10.6.4.2 Aggregation Event Extension

In addition to the EPCIS standard fields listed above, the following extension field should also be included in the EPCIS *Aggregation* event. (See Section 8.2.5 for general notes about extensions)

Element	Usage	Type	Value
completeness_inferred	Required	Boolean	True if inference is being made at receiving, contents of the outermost container are not being scanned. False, if inference is not being made at receiving.

10.6.4.3 XML Examples of Business Scenarios for Receiving Under Inference

Example Business Scenario 1: Without unpacking, record **inferred** receiving into inventory of 2 homogeneous cases contained in a pallet that was physically scanned at the wholesaler warehouse's receiving dock. Capture receipt of 2 homogeneous cases **inferred** to be contained in the pallet using an **Aggregation Event**.

Note: The Aggregation Event used in capturing the inferred receipt of products that have not been unpacked utilizes *action=OBSERVE*, *bizStep=Receiving* and includes new GS1US Extension element of *completeness_inferred=true*.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Aggregation Event Example for receiving inferred contents of pallet using only EPCIS and
CBV 1.2 constructs and use of GS1 US extension element, completeness_inferred, to indicate the
inferred integrity of that aggregation (without unpacking the aggregated children from the
parent) on the basis of aggregation information
                    (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
-->
<!-- Example use case: A pallet containing 2 homogeneous cases of 4 bundles of inner packs
containing 5 saleable eaches arrive at the wholesaler warehouse.  At the receiving dock, the
Wholesaler scans the pallet barcode and infers receipt of the contents.
Without unpacking, record inferred receiving into inventory of 2 homogeneous cases contained in
a pallet that was physically scanned at the wholesaler warehouse's receiving dock. Capture
receipt of 2 homogeneous cases inferred to be contained in the pallet using an Aggregation
Event.
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
```


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```
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-01T08:46:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>11002200010</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-12-01T08:46:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!-- master data for lowest saleable unit -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                            <!-- master data for case -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
```

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```
                        </VocabularyElement>
                    </VocabularyElementList>
                </Vocabulary>
                <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                    <VocabularyElementList>
                        <!-- Manufacturer -->
                        <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                        <!-- Manufacturer owned DC-->
                        <VocabularyElement id="urn:epc:id:sgln:030001.111121.0">
                            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
DC</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">7244 S
Century Ave</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
101</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#postalCode">40041</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                        <!-- Wholesaler -->
                        <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                        <!-- Wholesaler's DC-->
                        <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                            <attribute
```

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```
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>
            <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <!--  Without unpacking, record inferred receiving into inventory of 2 homogeneous
cases contained in a pallet that was physically scanned
                  at the wholesaler warehouse’s receiving dock. Capture receipt of
2homogeneous cases inferred to be contained in the pallet using an Aggregation Event. -->
            <AggregationEvent>
                <eventTime>2022-12-01T07:46:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <parentID>urn:epc:id:sscc:030001.01234567890</parentID>
                <childEPCs>
                    <epc>urn:epc:id:sgtin:030001.1012345.110</epc>
                    <epc>urn:epc:id:sgtin:030001.1012345.111</epc>
                </childEPCs>
                <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:039999.999999.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:039999.999999.0</id>
                </bizLocation>
                <!-- Note the use of GS1 US extension element, completeness_inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the basis
of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
-->
                <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
            </AggregationEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

Example Business Scenario 2: Without unpacking, record **inferred** receiving into inventory the 8 bundles of inner packs containing 5 saleable units contained in each homogeneous case that has been inferred to be contained in the pallet that was physically scanned at the wholesaler warehouse’s receiving

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dock. For each homogeneous case, capture receipt of 4 bundles **inferred** to be contained in the homogeneous case using an **Aggregation Event**.

Note: The Aggregation Event used in capturing the inferred receipt of products that have not been unpacked utilizes *action=OBSERVE*, *bizStep=Receiving* and includes new GS1US Extension element of *completeness_inferred=true*.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Aggregation Event Example for receiving inferred contents of homogenous cases using only
EPCIS and CBV 1.2 constructs and use of GS1 US extension element, completeness_inferred, to
indicate the inferred integrity of that aggregation (without unpacking the aggregated children
from the parent) on the basis of aggregation information
                    (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
-->
<!-- Example use case: A pallet containing 2 homogeneous cases of 4 bundles of inner packs
containing 5 saleable eaches arrive at the wholesaler warehouse.  At the receiving dock, the
Wholesaler scans the pallet barcode and infers receipt of the contents.
Without unpacking, record inferred receiving into inventory of 4 bundles contained in each of
the 2 homogeneous cases in a pallet that was physically scanned at the wholesaler warehouse's
receiving dock. Capture receipt of 8 bundles inferred to be contained in the 2 homogeneous
cases using an Aggregation Event.
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-01T08:49:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>11002200010</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-12-01T08:49:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!-- master data for lowest saleable unit -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
```

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```
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                            <!-- master data for case -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                            <!-- master data for bundle -->
                            <VocabularyElement id="urn:epc:id:sgtin:030001.3012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Manufacturer -->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
```


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```
                            <!-- Manufacturer owned DC-->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111121.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">7244 S
Century Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
101</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40041</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler's DC-->
                            <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>
            <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
```

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```
            <!--  Without unpacking, record inferred receiving into inventory of 8 bundles
contained in 2 homogeneous cases. -->
            <!-- E1: Capture receipt 4 bundles inferred to be contained in first homogeneous
case using an Aggregation Event. -->
            <AggregationEvent>
                <eventTime>2022-12-01T07:47:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <parentID>urn:epc:id:sgtin:030001.1012345.110</parentID>
                <childEPCs>
                    <epc>urn:epc:id:sgtin:030001.3012345.300</epc>
                    <epc>urn:epc:id:sgtin:030001.3012345.301</epc>
                    <epc>urn:epc:id:sgtin:030001.3012345.302</epc>
                    <epc>urn:epc:id:sgtin:030001.3012345.303</epc>
                </childEPCs>
                <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:039999.999999.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:039999.999999.0</id>
                </bizLocation>
                <!-- Note the use of GS1 US extension element, completeness_inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the basis
of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
-->
                <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
            </AggregationEvent>
            <!-- E2: Capture receipt 4 bundles inferred to be contained in second homogeneous
case using an Aggregation Event. -->
            <AggregationEvent>
                <eventTime>2022-12-01T07:48:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <parentID>urn:epc:id:sgtin:030001.1012345.111</parentID>
                <childEPCs>
                    <epc>urn:epc:id:sgtin:030001.3012345.304</epc>
                    <epc>urn:epc:id:sgtin:030001.3012345.305</epc>
                    <epc>urn:epc:id:sgtin:030001.3012345.306</epc>
                    <epc>urn:epc:id:sgtin:030001.3012345.307</epc>
                </childEPCs>
                <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:039999.999999.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:039999.999999.0</id>
                </bizLocation>
                <!-- Note the use of GS1 US extension element, completeness_inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the basis
of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
```

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```
-->
                <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
            </AggregationEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

Example Business Scenario 3: Without unpacking, record **inferred** receiving into inventory the 40 saleable units contained in each inner pack bundle that has been inferred to be contained in the homogeneous case of the pallet that was physically scanned at the wholesaler warehouse's receiving dock. Capture receipt of 40 saleable units **inferred** to be contained in the 8 inner pack bundles (each containing 5 saleable units) using an **Aggregation Event**.

Note: The Aggregation Event used in capturing the inferred receipt of products that have not been unpacked utilizes *action=OBSERVE*, *bizStep=Receiving* and includes new GS1US Extension element of *completeness_inferred=true*.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Aggregation Event Example for receiving inferred contents of bundles using only
EPCIS and CBV 1.2 constructs and use of GS1 US extension element, completeness_inferred,
to indicate the inferred integrity of that aggregation (without unpacking the aggregated
children from the parent) on the basis of aggregation information
 (e.g., earlier EPCIS packing event data) provided by an upstream supplier. -->
<!-- A pallet containing 2 homogeneous cases of 4 bundles of inner packs containing 5
saleable eaches arrive at the wholesaler warehouse.  At the receiving dock, the
Wholesaler scans the pallet barcode and infers receipt of the contents.
Without unpacking, record inferred receiving into inventory of 4 bundles contained in
each of the 2 homogeneous cases in a pallet that was physically scanned at the wholesaler
warehouse's receiving dock. Capture receipt of 40 eaches inferred to be contained in the
8 homogeneous cases using an Aggregation Event.
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-
1_2.xsd" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-
01T08:58:16Z">
      <EPCISHeader>
            <sbdh:StandardBusinessDocumentHeader>
                  <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
                  <sbdh:Sender>
                        <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
                  </sbdh:Sender>
                  <sbdh:Receiver>
                        <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
                  </sbdh:Receiver>
                  <sbdh:DocumentIdentification>
                        <sbdh:Standard>EPCglobal</sbdh:Standard>
                        <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                        <sbdh:InstanceIdentifier>11002200010</sbdh:InstanceIdentifier>
                        <sbdh:Type>Events</sbdh:Type>
                        <sbdh:CreationDateAndTime>2022-12-
01T08:58:16Z</sbdh:CreationDateAndTime>
                  </sbdh:DocumentIdentification>
            </sbdh:StandardBusinessDocumentHeader>
            <extension>
                  <EPCISMasterData>
```

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```
                        <VocabularyList>
                              <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                                    <VocabularyElementList>
                                          <!-- master data for lowest saleable unit
-->
                                          <VocabularyElement
id="urn:epc:idpat:sgtin:030001.0012345.*">
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribut
e>
                                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
                                          </VocabularyElement>
                                          <!-- master data for case -->
                                          <VocabularyElement
id="urn:epc:idpat:sgtin:030001.1012345.*">
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribut
e>
                                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
                                          </VocabularyElement>
                                          <!-- master data for bundle -->
                                          <VocabularyElement
id="urn:epc:id:sgtin:030001.3012345.*">
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribut
e>
                                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
                                          </VocabularyElement>
```

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```
                                    </VocabularyElementList>
                              </Vocabulary>
                              <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                                    <VocabularyElementList>
                                          <!-- Manufacturer -->
                                          <VocabularyElement
id="urn:epc:id:sgln:030001.111111.0">
                                                <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George Ave</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">12345-6789</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                          </VocabularyElement>
                                          <!-- Manufacturer owned DC-->
                                          <VocabularyElement
id="urn:epc:id:sgln:030001.111121.0">
                                                <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Pharma DC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">7244 S Century Ave</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite 101</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40041</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                          </VocabularyElement>
                                          <!-- Wholesaler -->
                                          <VocabularyElement
id="urn:epc:id:sgln:039999.999999.0">
                                                <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro LLC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">10003-1502</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                          </VocabularyElement>
                                          <!-- Wholesaler's DC-->
                                          <VocabularyElement
id="urn:epc:id:sgln:039999.345678.0">
```


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```
                                                <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro Warehouse</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main St</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite 100</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                          </VocabularyElement>
                                    </VocabularyElementList>
                              </Vocabulary>
                        </VocabularyList>
                  </EPCISMasterData>
            </extension>
            <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
            <gs1ushc:dscsaTransactionStatement>

      <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
                  <gs1ushc:legalNotice>Seller has complied with each applicable
subsection of FDCA Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
            </gs1ushc:dscsaTransactionStatement>
      </EPCISHeader>
      <EPCISBody>
            <EventList>
                  <!--  Without unpacking, record inferred receiving into inventory of
40 Lowest Saleable Unit (LSUs) contained in 8 bundles. -->
                  <!-- E1: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be
contained in first bundle using an Aggregation Event. -->
                  <AggregationEvent>
                        <eventTime>2022-12-01T07:47:16Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <parentID>urn:epc:id:sgtin:030001.3012345.300</parentID>
                        <childEPCs>
                              <epc>urn:epc:id:sgtin:030001.0012345.11</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.12</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.13</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.14</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.15</epc>
                        </childEPCs>
                        <!-- Populate with action=OBSERVE since the Aggregation Event
is used to reflect the children being received without unpacking the contents-->
                        <action>OBSERVE</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </readPoint>
                        <bizLocation>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </bizLocation>
                        <!-- Note the use of GS1 US extension element,
completeness_inferred, to indicate the inferred integrity of that aggregation
                        (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                        (e.g., earlier EPCIS packing event data) provided by an upstream
```

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supplier. -->

      <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
                  </AggregationEvent>
                  <!-- E2: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be
contained in 2nd bundle using an Aggregation Event. -->
                  <AggregationEvent>
                        <eventTime>2022-12-01T07:48:16Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <parentID>urn:epc:id:sgtin:030001.3012345.301</parentID>
                        <childEPCs>
                              <epc>urn:epc:id:sgtin:030001.0012345.16</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.17</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.18</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.19</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.20</epc>
                        </childEPCs>
                        <!-- Populate with action=OBSERVE since the Aggregation Event
is used to reflect the children being received without unpacking the contents -->
                        <action>OBSERVE</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </readPoint>
                        <bizLocation>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </bizLocation>
                        <!-- Note the use of GS1 US extension element,
completeness_inferred, to indicate the inferred integrity of that aggregation
                         (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                         (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->

      <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
                  </AggregationEvent>
                  <!-- E3: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be
contained in 3rd bundle using an Aggregation Event. -->
                  <AggregationEvent>
                        <eventTime>2022-12-01T07:49:16Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <parentID>urn:epc:id:sgtin:030001.3012345.302</parentID>
                        <childEPCs>
                              <epc>urn:epc:id:sgtin:030001.0012345.21</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.22</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.23</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.24</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.25</epc>
                        </childEPCs>
                        <!-- Populate with action=OBSERVE since the Aggregation Event
is used to reflect the children being received without unpacking the contents -->
                        <action>OBSERVE</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </readPoint>
                        <bizLocation>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </bizLocation>
```


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```
                        <!-- Note the use of GS1 US extension element,
completeness_inferred, to indicate the inferred integrity of that aggregation
                        (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                        (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->

      <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
                  </AggregationEvent>
                  <!-- E4: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be
contained in 4th bundle using an Aggregation Event. -->
                  <AggregationEvent>
                        <eventTime>2022-12-01T07:50:16Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <parentID>urn:epc:id:sgtin:030001.3012345.303</parentID>
                        <childEPCs>
                              <epc>urn:epc:id:sgtin:030001.0012345.26</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.27</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.28</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.29</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.30</epc>
                        </childEPCs>
                        <!-- Populate with action=OBSERVE since the Aggregation Event
is used to reflect the children being received without unpacking the contents -->
                        <action>OBSERVE</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </readPoint>
                        <bizLocation>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </bizLocation>
                        <!-- Note the use of GS1 US extension element,
completeness_inferred, to indicate the inferred integrity of that aggregation
                        (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                        (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->

      <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
                  </AggregationEvent>
                  <!-- E5: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be
contained in 5th bundle using an Aggregation Event. -->
                  <AggregationEvent>
                        <eventTime>2022-12-01T07:51:16Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <parentID>urn:epc:id:sgtin:030001.3012345.304</parentID>
                        <childEPCs>
                              <epc>urn:epc:id:sgtin:030001.0012345.31</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.32</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.33</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.34</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.35</epc>
                        </childEPCs>
                        <!-- Populate with action=OBSERVE since the Aggregation Event
is used to reflect the children being received without unpacking the contents -->
                        <action>OBSERVE</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                        <readPoint>
```

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```
                        <id>urn:epc:id:sgln:039999.999999.0</id>
                    </readPoint>
                    <bizLocation>
                        <id>urn:epc:id:sgln:039999.999999.0</id>
                    </bizLocation>
                    <!-- Note the use of GS1 US extension element,
completeness_inferred, to indicate the inferred integrity of that aggregation
                    (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                    (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->

        <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
                </AggregationEvent>
                <!-- E6: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be
contained in 6th bundle using an Aggregation Event. -->
                <AggregationEvent>
                    <eventTime>2022-12-01T07:52:16Z</eventTime>
                    <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                    <parentID>urn:epc:id:sgtin:030001.3012345.305</parentID>
                    <childEPCs>
                        <epc>urn:epc:id:sgtin:030001.0012345.36</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.37</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.38</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.39</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.40</epc>
                    </childEPCs>
                    <!-- Populate with action=OBSERVE since the Aggregation Event
is used to reflect the children being received without unpacking the contents -->
                    <action>OBSERVE</action>
                    <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                    <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                    <readPoint>
                        <id>urn:epc:id:sgln:039999.999999.0</id>
                    </readPoint>
                    <bizLocation>
                        <id>urn:epc:id:sgln:039999.999999.0</id>
                    </bizLocation>
                    <!-- Note the use of GS1 US extension element,
completeness_inferred, to indicate the inferred integrity of that aggregation
                    (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                    (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->

        <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
                </AggregationEvent>
                <!-- E7: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be
contained in 7th bundle using an Aggregation Event. -->
                <AggregationEvent>
                    <eventTime>2022-12-01T07:53:16Z</eventTime>
                    <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                    <parentID>urn:epc:id:sgtin:030001.3012345.306</parentID>
                    <childEPCs>
                        <epc>urn:epc:id:sgtin:030001.0012345.41</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.42</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.43</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.44</epc>
                        <epc>urn:epc:id:sgtin:030001.0012345.45</epc>
                    </childEPCs>
                    <!-- Populate with action=OBSERVE since the Aggregation Event
```

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```
is used to reflect the children being received without unpacking the contents -->
                        <action>OBSERVE</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </readPoint>
                        <bizLocation>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </bizLocation>
                        <!-- Note the use of GS1 US extension element,
completeness_inferred, to indicate the inferred integrity of that aggregation
                  (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                  (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->

      <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
                  </AggregationEvent>
                  <!-- E8: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be
contained in 8th bundle using an Aggregation Event. -->
                  <AggregationEvent>
                        <eventTime>2022-12-01T07:54:16Z</eventTime>
                        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                        <parentID>urn:epc:id:sgtin:030001.3012345.307</parentID>
                        <childEPCs>
                              <epc>urn:epc:id:sgtin:030001.0012345.46</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.47</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.48</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.49</epc>
                              <epc>urn:epc:id:sgtin:030001.0012345.50</epc>
                        </childEPCs>
                        <!-- Populate with action=OBSERVE since the Aggregation Event
is used to reflect the children being received without unpacking the contents -->
                        <action>OBSERVE</action>
                        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
                        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                        <readPoint>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </readPoint>
                        <bizLocation>
                              <id>urn:epc:id:sgln:039999.999999.0</id>
                        </bizLocation>
                        <!-- Note the use of GS1 US extension element,
completeness_inferred, to indicate the inferred integrity of that aggregation
                  (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                  (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->

      <gs1ushc:completeness_inferred>true</gs1ushc:completeness_inferred>
                  </AggregationEvent>
            </EventList>
      </EPCISBody>
</epcis:EPCISDocument>
```

Note: If the pallet as used in the example above is unpacked and therefore all contents are scanned, then only an Object Event would be used to receive in EPCIS to represent what was done physically.

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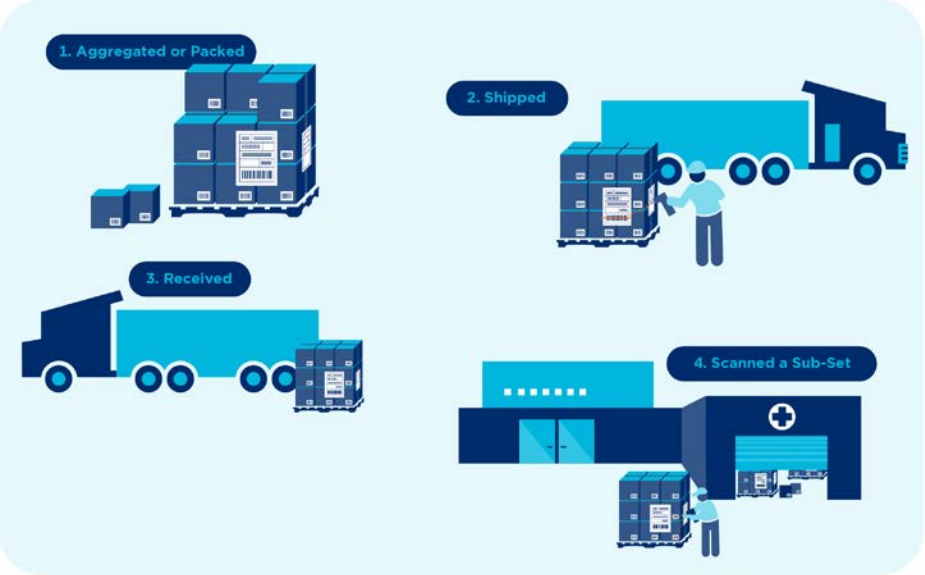
10.6.5 Confirming Packaging Hierarchy during Receiving

During receiving, companies may choose to scan a sub-set of contained inner items, in addition to the outermost containers, in order to confirm the aggregation. If no unpacking occurs and the scanned inner items are placed back as before to the outer parent item, this will not require an event as the original receiving event would still represent these items.

Caution: If you break a sealed homogeneous case to scan a sub-set, you, therefore, unpack the case and are no longer able to transact the case sGTIN.



10.7 Unpacking

Unpacking denotes a specific activity within a business process that includes removing an object (e.g., individuals, inners, cases, pallets, etc.) from a larger container (e.g., cases, totes, pallets, etc.) – usually for the purposes of storing or shipping. Unpacking is the reverse of packing, and the *Unpacking* EPCIS event disaggregates specific aggregation relationships created by *Packing* events.

10.7.1 Populating an Unpacking Event

An *Unpacking* event should be an EPCIS Aggregation Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
parentID	Required	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition
childEPCs	Required	List of URI	EPC(s) of the item(s) unpacked from the parent in EPC Pure Identity URI format.*	EPCIS standard definition. * Although the EPCIS standard permits childEPCs to be omitted to indicate that all children are disaggregated from the parent, this usage is not permitted for this guideline.)

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Element	Usage	Type	Value	Reason
action	Required	String	DELETE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:unpacking	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions	Business transactions governing this event.	Omitted in the *Unpacking* event as there are no relevant business transactions to share

10.7.2 XML Example of an Unpacking Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Unpacking Event Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-11-29T17:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-11-29T17:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!-- master data for lowest saleable unit -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
```


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```
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                            <!-- master data for case -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Manufacturer -->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
```


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```
                    </VocabularyElementList>
                </Vocabulary>
            </VocabularyList>
        </EPCISMasterData>
    </extension>
    <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
    <gs1ushc:dscsaTransactionStatement>
        <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
        <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
    </gs1ushc:dscsaTransactionStatement>
</EPCISHeader>
<EPCISBody>
    <EventList>
        <AggregationEvent>
            <eventTime>2022-11-29T17:10:16Z</eventTime>
            <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
            <parentID>urn:epc:id:sgtin:030001.1012345.22222223333</parentID>
            <childEPCs>
                <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
            </childEPCs>
            <action>DELETE</action>
            <bizStep>urn:epcglobal:cbv:bizstep:unpacking</bizStep>
            <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
            <readPoint>
                <id>urn:epc:id:sgln:039999.999999.0</id>
            </readPoint>
            <bizLocation>
                <id>urn:epc:id:sgln:039999.999999.0</id>
            </bizLocation>
        </AggregationEvent>
    </EventList>
</EPCISBody>
</epcis:EPCISDocument>
```

10.8 Dispensing

Dispensing is the process of removing a portion of a product for use while retaining the remainder for subsequent dispensing, such as when individual tablets are removed from a bottle to fill a prescription. The EPCIS event indicates the item from which the portion was dispensed. Unlike *Destroying* or *Decommissioning* events, the item continues to exist after *Dispensing*, but a special disposition value is used to indicate that the item is no longer in its original state. After all portions have been dispensed from an item, it is subsequently destroyed. Although not required by DSCSA, this event can aid in recall notification.

10.8.1 Populating a Dispensing Event

The dispensing event is populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition
eventTime ZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition

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Element	Usage	Type	Value	Reason
epcList	Required	List of URI	EPC of the dispensed item in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:dispensing	CBV standard definition
disposition	Required	URI	For full dispensing, use urn:epcglobal:cbv:disp:dispensed. For partial dispensing, use urn:epcglobal:cbv:disp:partially_dispensed.	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Conditional	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	EPCIS standard definition For full dispensing, this is unknown and therefore omitted. For partial dispensing, the object is presumed to remain at the same place where the event took place until all portions have been dispensed.
bizTransactionList	Optional	List of biz transactions	Business transactions governing this *Dispensing* event. Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	The pharmacy **could** choose to insert the prescription ID if they wanted to extend traceability to the patient. (There may already be this type of function in the pharmacy system).

10.8.2 XML Example of a Full Dispensing Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Dispensing Event: Full Dispensing Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-11-30T17:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:084436921.568.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:084436921.567.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-11-30T17:45:16Z</sbdh:CreationDateAndTime>
```


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```
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!-- master data for lowest saleable unit -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Pharmacy Corporate -->
                            <VocabularyElement id="urn:epc:id:sgln:084436921.567.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 DISP
PHRM</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">671
Grand Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
201</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">Memphis</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">TN</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">38103</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Pharmacy Store -->
                            <VocabularyElement id="urn:epc:id:sgln:084436921.568.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 DISP PHRM
STORE</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">142 Hill
St</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">Memphis</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">TN</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">38108</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
```


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```
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <ObjectEvent>
                <eventTime>2022-11-30T17:10:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
                </epcList>
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:dispensing</bizStep>
                <disposition>urn:epcglobal:cbv:disp:dispensed</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:084436921.568.0</id>
                </readPoint>
            </ObjectEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.8.3 XML Example of a Partial Dispensing Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Dispensing Event: Partial Dispensing Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-11-30T17:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:084436921.568.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:084436921.567.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-11-30T17:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!-- master data for lowest saleable unit -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
```

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```
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Pharmacy Corporate -->
                            <VocabularyElement id="urn:epc:id:sgln:084436921.567.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 DISP
PHRM</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">671
Grand Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
201</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">Memphis</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">TN</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">38103</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Pharmacy Store -->
                            <VocabularyElement id="urn:epc:id:sgln:084436921.568.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 DISP PHRM
STORE</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">142 Hill
St</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">Memphis</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">TN</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">38108</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <ObjectEvent>
                <eventTime>2022-11-30T17:10:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
                </epcList>
```

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```
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:dispensing</bizStep>
                <disposition>urn:epcglobal:cbv:disp:partially_dispensed</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:084436921.568.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:084436921.568.0</id>
                </bizLocation>
            </ObjectEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.9 Inspecting

An *Inspecting* event should be an EPCIS Object Event to capture the physical activity of inspecting a product to assess its disposition. For example, an Inspecting event is captured when damaged product is discovered by a supply chain partner.

10.9.1 Populating an Inspecting Event

The inspecting event is populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition
eventTime ZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC of the inspected item in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:inspecting	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:inspected	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	EPCIS standard definition
bizTransactionList	Optional	List of biz transactions	Business transactions governing this *Inspecting* event. Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	Optional from an EPCIS standard perspective. May specify quality certificate or test result document.

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10.9.2 XML Example of an Inspecting Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Inspecting Event Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-11-30T17:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-11-30T17:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!-- master data for lowest saleable unit -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Manufacturer -->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
```

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```
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler's DC-->
                            <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <ObjectEvent>
                <eventTime>2022-11-30T17:10:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
                </epcList>
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:inspecting</bizStep>
                <disposition>urn:epcglobal:cbv:disp:damaged</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:039999.345678.0</id>
                </readPoint>
```

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```
            <bizLocation>
                <id>urn:epc:id:sgln:039999.345678.0</id>
            </bizLocation>
        </ObjectEvent>
    </EventList>
</EPCISBody>
</epcis:EPCISDocument>
```

10.10 Destroying

Destroying is the process of destroying a product so that it no longer exists, as opposed to decommissioning which implies that the item may still exist even though it no longer carries serialized identification. Destroying occurs when a party at the end of the supply chain physically destroys a product.

10.10.1 Populating a Destroying Event

A *Destroying* event should be an EPCIS Object Event populated as follows:

Element	Type	Usage	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition
eventTime ZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the destroyed item(s) in EPC Pure Identity URI format	EPCIS standard definition
action	Required	String	DELETE	EPCIS standard definition. (Action DELETE in an Object Event indicates that the EPCs no longer exist.)
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:destroying	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:destroyed	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Omitted	URI		The bizLocation is the location where the object is presumed to be following the event. For a *Destroying* event, the object no longer exists following the event. Therefore, bizLocation is always omitted for a *Destroying* event.
bizTransactionList	Omitted	List of biz transactions	Business transactions governing this event.	Omitted in the *Destroying* event as there are no relevant business transactions to share.

10.10.2 XML Example of a Destroying Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Destroying Event Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
```


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```
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-11-30T17:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-11-30T17:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Manufacturer -->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
```


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```
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <ObjectEvent>
                <eventTime>2022-11-30T17:10:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
                </epcList>
                <action>DELETE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:destroying</bizStep>
                <disposition>urn:epcglobal:cbv:disp:destroyed</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </readPoint>
            </ObjectEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.11 Decommissioning

Decommissioning is the end-of-life event for the EPC identifier. Unlike the destroying business process, the item may still physically exist after decommissioning even though it no longer carries serialized identification. Decommissioning occurs when a party at the end of the supply chain removes the serialized identification (i.e., at point of sale).

10.11.1 Populating a Decommissioning Event

A *Decommissioning* event should be an EPCIS Object Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. See Section 8.2.1)	EPCIS standard definition
eventTime ZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the decommissioned item(s) (in EPC Pure Identity URI format)	EPCIS standard definition
action	Required	String	DELETE	EPCIS standard definition. Action DELETE in an Object Event indicates that the EPCs no longer exist
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:decommissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:inactive	CBV standard definition

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Element	Usage	Type	Value	Reason
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Omitted	URI		The bizLocation is the location where the objects are presumed to be following the event. For a *Decommissioning* event, the location of objects can no longer be tracked following the event and so bizLocation is always omitted for a *Decommissioning* event.
bizTransactionList	Omitted	List of biz transactions	Business transactions governing this event	Omitted in the *Decommissioning* event as there are no relevant business transactions to share

10.11.2 XML Example of a Decommissioning Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Decommissioning Event Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-11-30T17:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-11-30T17:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Manufacturer -->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
```

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```
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <ObjectEvent>
                <eventTime>2022-11-30T17:10:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
                </epcList>
                <action>DELETE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:decommissioning</bizStep>
                <disposition>urn:epcglobal:cbv:disp:inactive</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </readPoint>
            </ObjectEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.12 Void Shipping

Void Shipping is the standard EPCIS mechanism for indicating that objects previously recorded in one or more prior *Shipping* events were, in fact, not shipped. Potential business situations wherein a *Void Shipping* event should be considered include:

- Shipment Cancellation after a prior *Shipping* event has been recorded and sent to a trading partner
- Late discovery that a shipment believed to have occurred did not actually occur
- Late discovery that some of the lowest saleable units intended to be in the shipment were not included

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Void Shipping is one of many mechanisms within EPCIS to manage issues in previously recorded events. *Void Shipping* is not a widely adopted practice and is not a part of the interoperable system to meet DSCSA requirements.

This section shows technically how a *Void Shipping* event can be captured to foundationally enable companies to internally capture such *Void Shipping* scenarios as part of their serialized exception management. In anticipation of exceptions stemming from serialized EPCIS trading partner exchanges, industry stakeholders will be developing technical approaches to solving data misalignment exceptions in an upcoming updated Applying GS1 Standards for DSCSA and Traceability Addendum: Diagrams and XML Examples for Serialized Exceptions Processing, R1.3. This will outline acceptable scenario-based corrections on specific applications of EPCIS/CBV constructs that will be sent by the seller and received and processed by the buyer. The adoption of this function may increase at some future point as serialized exception resolution process matures.
Due to the complexity and variety of business use cases involving cancellation or voiding, it is required for trading partners to engage in communication to identify, investigate and resolve issues. Therefore, at this time, exception communication and resolution processes are not fully automated.

Note: Data already sent to a downstream trading partner must require additional business processes and communication between trading partners to determine the best resolution.

10.12.1 Populating a Void Shipping Event

Upon the discovery that the prior *Shipping* event is in error, the shipper creates a *Void Shipping* event. A *Void Shipping* event should be an EPCIS Object Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition For purposes of DSCSA, this is considered the event time when the datetime the shipment was voided.
eventTime ZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	If voiding the entire shipment, the epcList is identical to the epcList of the original *Shipping* event. If partially voiding a shipment (i.e., selected content that was discovered to not have been shipped), the epcList enumerates the EPCs of the objects that were erroneously included in the original *Shipping* event.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:void_shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition. The **disposition** value "in_progress" is always paired with the **bizStep** "void_shipping".
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition

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Element	Usage	Type	Value	Reason
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2)	EPCIS standard definition
bizTransactionList	Optional	List of biz transactions	Business transactions governing this Void Shipping event, which may include a purchase order or an invoice. (See Section 8.5 for details) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. Should match the bizTransactionList of the prior *Shipping* event, so that the *Void Shipping* event will be included if events are queried by business transaction.	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for PO, Invoice, Delivery Number, or other ID's.
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party whose value is the EPC Pure Identity URI for the GLN of the transferring party. If the ship-from GLN is different from the transferring party's GLN, sourceList shall also include a second source of type urn:epcglobal:cbv:sdt:location whose value is the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list. Should match the sourceList of the prior *Shipping* event, so that the *Void Shipping* event will be included if events are queried by source.	EPCIS standard definition
destination List	Required	List of destinations	Each destination in the desintationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include 1 destination of type urn:epcglobal:cbv:sdt:owning_party whose value is the EPC Pure Identity URI for the GLN of transfer-to party. If ship-to GLN is different from the transfer-to party's GLN, destinationList shall also include a 2nd destination of type urn:epcglobal:cbv:sdt:location whose value is EPC Pure Identity URI of ship-to GLN. Each GLN URI must match one of the companies in the company master data list. Should match the destinationList of the prior *Shipping* event, so that the *Void Shipping* event will be included if events are queried by destination.	EPCIS standard definitions

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10.12.2 Void Shipping Event Master Data

When an EPCIS document includes one or more *Void Shipping* events, the EPCIS header should contain master data including the following attributes for each distinct party or location referenced in the source list or destination list of any *Void Shipping* event. Note that if several *Void Shipping* events in the same EPCIS document reference the same party or location, the master data attributes for that party or location need only be included *once* in the header.

Party or location master data elements *(Include one set of attributes for each trading partner found in any Void Shipping event within scope of the header. This group of attributes may be available via an EPCIS query in future versions of this guideline.)*			
name	Required	String	The name of the location or party expressed in text.
streetAddressOne	Required	String	The first line of the street address.
streetAddressTwo	Optional	String	The second line of the street address.
streetAddressThree	Optional	String	The third line of the street address.
city	Required	String	The city.
state	Conditional	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Conditional	String	The ZIP or other postal code.
countryCode	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

10.12.3 XML Example of a Void Shipping Event (entire shipment cancellation)

This example illustrates how to declare a shipment cancellation using a *Void Shipping* event. This shows both a single *Void Shipping* event, as well as an EPCIS Header that includes party master data for the source and destination.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Void Shipping Event - Example of Full Shipment Cancellation -->
<!-- Manufacturer cancels entire shipment to the Wholesaler
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-07T08:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
```


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```
            <sbdh:CreationDateAndTime>2022-12-07T08:45:16Z</sbdh:CreationDateAndTime>
        </sbdh:DocumentIdentification>
    </sbdh:StandardBusinessDocumentHeader>
    <extension>
        <EPCISMasterData>
            <VocabularyList>
                <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                    <VocabularyElementList>
                        <!-- Manufacturer -->
                        <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                        <!-- Manufacturer owned DC-->
                        <VocabularyElement id="urn:epc:id:sgln:030001.111121.0">
                            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
DC</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">7244 S
Century Ave</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
101</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#postalCode">40041</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                        <!-- Wholesaler -->
                        <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                            <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                        <!-- Wholesaler's DC-->
                        <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
                            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
```

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```
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>
            <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <ObjectEvent>
                <eventTime>2022-12-07T07:45:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sscc:030001.01234567890</epc>
                </epcList>
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:void_shipping</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111121.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:030001.111121.0</id>
                </bizLocation>
                <!-- 2 business documents: PO from buying wholesaler, Delivery Document created
by Manufacturer -->
                <bizTransactionList>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:XYZPO567</bizTransaction>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0300011111116:ABCDEL234</bizTransactio
n>
                </bizTransactionList>
                <extension>
                    <!-- Source Owning Party is Manufacturer, Source Location is Manufacturer
owned DC -->
                    <sourceList>
                        <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
                        <source
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:030001.111121.0</source>
                    </sourceList>
                    <!-- Destination Owning Party is Wholesaler Corp Office, Destination
Location is Wholesaler Distribution Center -->
                    <destinationList>
                        <destination
```

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```
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
                        <destination
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:039999.345678.0</destination>
                    </destinationList>
                </extension>
            </ObjectEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

10.12.4 XML Example of a Void Shipping Event (partial shipment cancellation)

This example illustrates how to declare that one of the lowest saleable unit (LSU) was erroneously not included in the prior physical shipment. This shows both a single *Void Shipping* event, as well as an EPCIS Header that includes product and party master data for the source and destination.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Void Shipping Event - Example of Partial Shipment Cancellation -->
<!-- Manufacturer partially cancels shipment to the Wholesaler
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-12-07T08:45:16Z">
      <EPCISHeader>
            <sbdh:StandardBusinessDocumentHeader>
                  <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
                  <sbdh:Sender>
                        <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
                  </sbdh:Sender>
                  <sbdh:Receiver>
                        <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
                  </sbdh:Receiver>
                  <sbdh:DocumentIdentification>
                        <sbdh:Standard>EPCglobal</sbdh:Standard>
                        <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                        <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
                        <sbdh:Type>Events</sbdh:Type>
                        <sbdh:CreationDateAndTime>2022-12-
07T08:45:16Z</sbdh:CreationDateAndTime>
                  </sbdh:DocumentIdentification>
            </sbdh:StandardBusinessDocumentHeader>
            <extension>
                  <EPCISMasterData>
                        <VocabularyList>
                              <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                                    <VocabularyElementList>
                                          <!-- Manufacturer -->
                                          <VocabularyElement
id="urn:epc:id:sgln:030001.111111.0">
                                                <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George Ave</attribute>
                                                <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
```

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```
                                                    <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#postalCode">12345-6789</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                                </VocabularyElement>
                                                <!-- Manufacturer owned DC-->
                                                <VocabularyElement
id="urn:epc:id:sgln:030001.111121.0">
                                                    <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Pharma DC</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">7244 S Century Ave</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite 101</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#postalCode">40041</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                                </VocabularyElement>
                                                <!-- Wholesaler -->
                                                <VocabularyElement
id="urn:epc:id:sgln:039999.999999.0">
                                                    <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro LLC</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#postalCode">10003-1502</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                                </VocabularyElement>
                                                <!-- Wholesaler's DC-->
                                                <VocabularyElement
id="urn:epc:id:sgln:039999.345678.0">
                                                    <attribute
id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro Warehouse</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main St</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite 100</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#state">KY</attribute>
                                                    <attribute
id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
```


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```
                                                        <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                                                </VocabularyElement>
                                        </VocabularyElementList>
                                </Vocabulary>
                        </VocabularyList>
                </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>

    <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
                <gs1ushc:legalNotice>Seller has complied with each applicable subsection of
FDCA Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <ObjectEvent>
                <eventTime>2022-12-07T07:45:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000003</epc>
                </epcList>
                <action>OBSERVE</action>
                <bizStep>urn:epcglobal:cbv:bizstep:void_shipping</bizStep>
                <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111121.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:030001.111121.0</id>
                </bizLocation>
                <!-- 2 business documents: PO from buying wholesaler, Delivery
Document created by Manufacturer -->
                <bizTransactionList>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:XYZPO567</bizTransaction>
                    <bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0300011111116:ABCDEL234</bizTransactio
n>
                </bizTransactionList>
                <extension>
                    <!-- Source Owning Party is Manufacturer, Source Location is
Manufacturer owned DC -->
                    <sourceList>
                        <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
                        <source
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:030001.111121.0</source>
                    </sourceList>
                    <!-- Destination Owning Party is Wholesaler Corp Office,
Destination Location is Wholesaler Distribution Center -->
                    <destinationList>
                        <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
                        <destination
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:039999.345678.0</destination>
                    </destinationList>
                </extension>
            </ObjectEvent>
```

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```
            </EventList>
        </EPCISBody>
</epcis:EPCISDocument>
```

10.13 EPCIS Error Declaration Mechanism

Error Declaration is not a widely adopted practice and is not currently a part of the interoperable system to meet DSCSA requirements.

This section shows technically how an Error Declaration can be used and potential situations for its use. In anticipation of exceptions stemming from serialized EPCIS trading partner exchanges, industry stakeholders will be developing technical approaches to solving data misalignment exceptions in an upcoming updated Applying GS1 Standards for DSCSA and Traceability Addendum: Diagrams and XML Examples for Serialized Exceptions Processing, R1.3. This will outline acceptable scenario-based corrections on specific applications of EPCIS/CBV constructs that will be sent by the seller and received and processed by the buyer. The adoption of this function may increase at some future point as serialized exception resolution process matures.

Due to the complexity and variety of business use cases involving serialized exception management, it is required for trading partners to engage in communication to identify, investigate and resolve issues. Therefore, at this time, exception communication and resolution processes are not fully automated.

Note: Data already sent to a downstream trading partner must require additional business processes and communication between trading partners to determine the best resolution.

The Error Declaration mechanism allows a new event to be created whose effect is to indicate that a prior event was in error and should be disregarded completely; such an event is referred to here as an Error Declaration event. The Error Declaration event may also include a reference to one or more new events whose intent is to provide corrected information; however, this may be omitted if the corrective events have not yet been generated or if the correct outcome is to have no event at all (i.e., the prior event did not simply have incorrect data – it should not have been created in the first place).

An Error Declaration event is not a new business step or event type. Rather, it is an exact copy of the erroneous event, with an added section that marks it as an error declaration. This is so that any query that matches the erroneous event will also match the corresponding error declaration, so that the querying party will know the original event should be disregarded.

Note: See Section 7.4.1.2 of the EPCIS 1.2 standard for details about the *Error Declaration* mechanism.

The following example shows an EPCIS document containing (1) an *Error Declaration* for a *Commissioning* event, and (2) a corrected *Commissioning* event that has an updated lot number and expiration date.

10.13.1 XML Example of EPCIS Declaration Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Error Declaration Event Example -->
<!-- This example first shows an Error Declaration event for a Commissioning event which
references a corrective event..
      The Error Declaration event is followed by an example of the corrected  Commissioning
event capturing the updated lot number and expiration date.
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
```

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```
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2022-11-30T18:45:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2022-11-30T18:45:16Z</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <!-- master data for lowest saleable unit -->
                            <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <!-- Manufacturer -->
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S
George Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
```

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```
                            </VocabularyElement>
                            <!-- Wholesaler -->
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park
Ave S</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                        </VocabularyElementList>
                    </Vocabulary>
                </VocabularyList>
            </EPCISMasterData>
        </extension>
        <gs1ushc:guidelineVersion>GS1 US DSCSA R1.3</gs1ushc:guidelineVersion>
        <gs1ushc:dscsaTransactionStatement>
            <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
            <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA
Sec. 581(27)(A)-(G).</gs1ushc:legalNotice>
        </gs1ushc:dscsaTransactionStatement>
    </EPCISHeader>
    <EPCISBody>
        <EventList>
            <!--  Error Declaration event for an invalid Commissioning event.
               This also shows the error declaration event referencing a corrective event -->
            <ObjectEvent>
                <eventTime>2022-11-25T17:10:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <baseExtension>
                    <errorDeclaration>
                        <declarationTime>2022-11-30T10:12:13Z</declarationTime>
                        <reason>urn:epcglobal:cbv:er:incorrect_data</reason>
                        <correctiveEventIDs>
                            <correctiveEventID>urn:uuid:f81d4fae-7dec-11d0-a765-
00a0c91e6bf6</correctiveEventID>
                        </correctiveEventIDs>
                    </errorDeclaration>
                </baseExtension>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000002</epc>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000003</epc>
                    <epc>urn:epc:id:sgtin:030001.1012345.22222222222</epc>
                </epcList>
                <action>ADD</action>
                <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
                <disposition>urn:epcglobal:cbv:disp:active</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </bizLocation>
                <extension>
```

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```
                    <ilmd>
                        <cbvmda:lotNumber>A123</cbvmda:lotNumber>
                        <cbvmda:itemExpirationDate>2025-11-15</cbvmda:itemExpirationDate>
                    </ilmd>
                </extension>
            </ObjectEvent>
            <!-- Corrective Commissioning event updating the lot number and expiration date -->
            <ObjectEvent>
                <eventTime>2022-11-29T17:10:16Z</eventTime>
                <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <baseExtension>
                    <eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</eventID>
                </baseExtension>
                <epcList>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000002</epc>
                    <epc>urn:epc:id:sgtin:030001.0012345.10000000003</epc>
                    <epc>urn:epc:id:sgtin:030001.1012345.22222222222</epc>
                </epcList>
                <action>ADD</action>
                <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
                <disposition>urn:epcglobal:cbv:disp:active</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:030001.111111.0</id>
                </bizLocation>
                <extension>
                    <ilmd>
                        <cbvmda:lotNumber>B456</cbvmda:lotNumber>
                        <cbvmda:itemExpirationDate>2026-11-15</cbvmda:itemExpirationDate>
                    </ilmd>
                </extension>
            </ObjectEvent>
        </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```


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Part III: Application of the Message Standard for Product Verification

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11 Application of the Message Standard for Product Verification

11.1 Introduction

The Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to achieve an interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. As part of those requirements, product verification is required by law in certain circumstances. The law is being enacted in a stepwise fashion with requirements increasing as milestones are met. The stepwise process will reach its final phase on November 27, 2023, ten years after enactment.

Commencing November 27, 2019, the DSCSA required parties engaged in wholesale distribution to verify the product identifier of returned products before these products can be placed into inventory for resale.[6] The DSCSA defines verification as the process of "*determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the product identifier assigned to the product by the manufacturer or the repackager*."[7] A manufacturer who receives a verification request from a repackager, wholesale distributor, or dispenser must respond to that request within 24 hours.[8] In preparation, pharmaceutical supply chain stakeholders collaborated with GS1® and GS1 US® to develop a verification messaging standard to enable system interoperability and prevent the proliferation of multiple messaging formats. In addition, the GS1 Messaging Standard Workgroup collaborated with the Healthcare Distribution Alliance (HDA) Verification Routing Services (VRS) Taskforce. These efforts produced the *GS1 Lightweight Messaging Standard for Verification of Product Identifiers*.

The *GS1 Lightweight Messaging Standard* was designed to support Requests and Responses for verification of product identifiers for serialized pharmaceutical products. It is intended to provide a simple, standardized lightweight messaging framework for asking verification questions and receiving actionable information. Designed to support Verification Routing Services (VRS) systems for DSCSA verification, the messaging standard defines a verification Request message and a corresponding Output Response message.

As November 27, 2023 approaches, the increased use and experience of the Verification Routing Service (VRS) utilizing the Lightweight Verification Messaging Standard (LVMS) to operate has identified additional needs beyond saleable returns. The pharmaceutical industry has expanded the use of verification to include suspect or illegitimate product investigations, exception processing and status check.

This Guideline offers an approach to implement that messaging standard for DSCSA verification of product identifiers.

Important: As with all GS1 Standards and solutions, this guideline is voluntary, not mandatory. It should be noted that use of the words "must" and "require" throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation.

11.1.1 Document Purpose

The purpose of this document is to assist the U.S. pharmaceutical industry in implementing the *GS1 Lightweight Messaging Standard* to support DSCSA product identifier verification. It provides technical information including localization query parameters and settings, the OpenAPI schema, configuration

[6] Drug Supply Chain Security Act, Section 582(c)(4)(D). Pub. Law No. 113-54, 127 Stat 587, 613 (2013). Retrieved November 3, 2018 from: https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/html/PLAW-113publ54.htm
[7] Drug Supply Chain Security Act, Section 581(28). Pub. Law No. 113-54, 127 Stat 587, 605 (2013).
[8] Drug Supply Chain Security Act, Section 582(b)(4)(C). Pub. Law No. 113-54, 127 Stat 587, 610 (2013).

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and set-up, verification requests, and verification responses. **It does not provide any guidance or advice regarding compliance with applicable law, nor providing any guarantee or warranty with respect to same.**

Important: Each company is individually responsible for complying with applicable law. Consult with your company's legal counsel or compliance team (regulatory or quality) for more specific information about current statutory and regulatory requirements applicable to your company and products.

11.1.2 Scope

Under DSCSA, parties engaged in the commercial pharmaceutical supply chain distribution should verify the product identifier of suspect product investigations, illegitimate product investigations, and returned products before these products can be placed into inventory for resale[9], further distribution or dispensing. The response message and this guideline is intended to respond to that need.

DSCSA defines verify as "*determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the product identifier assigned to the product by the manufacturer or the repackager.*"[10] Following that definition, the "verified" field in the response message is used to indicate whether a product identifier submitted in the request message matches a product identifier affixed or imprinted by the manufacturer or the repackager (i.e., true) or not (i.e., false).

Important: The "verified" field in the response message does not and should not be interpreted as indicating whether a returned product can or should be placed into inventory for resale, further distribution, or dispensing.

The ultimate decision as to whether a returned product can be placed back in inventory for resale may be subject to and/or dependent on additional regulatory/statutory requirements and/or business considerations. These requirements and considerations are beyond the scope of the response message and this guideline.

Although the response message includes fields for "Reason for Failure" and "Additional Info" to enable manufacturers or repackagers to communicate more information in the message than just whether the product identifier matches if they so desire, it is assumed trading partners will continue to use whatever communication approaches they deem appropriate for those other regulatory, statutory, or business needs.

11.2 GS1 Standards for DSCSA Product Identifier Data Elements

DSCSA defines the term "product identifier" as, "a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier (SNI), lot number, and expiration date of the product."[11] Accordingly, a DSCSA product identifier comprises the following four data elements:

- National Drug Code (NDC)
- Serial Number
- Batch or Lot Number
- Expiration Date

[9] Drug Supply Chain Security Act, Section 582(c)(4)(D). Pub. Law No. 113-54, 127 Stat 587, 613 (2013). Retrieved November 3, 2018 from: https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/html/PLAW-113publ54.htm

[10] Drug Supply Chain Security Act, Section 581(28). Pub. Law No. 113-54, 127 Stat 587, 605 (2013).

[11] Drug Supply Chain Security Act. Pub. Law No. 113-54, 127 Stat 587 (2013). Accessed November 1, 2018 from: https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/html/PLAW-113publ54.htm

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(When using GS1 Standards for DSCSA implementation, the NDC is represented by a Global Trade Item Number (GTIN)).

These data elements can be encoded in a GS1 barcode using the following GS1 Application Identifiers (AIs):

DSCSA Product Identifier Data Element	GS1 Application Identifier (AI)
GTIN	AI (01)
Serial Number	AI (21)
Batch or Lot Number	AI (10)
Expiration Date	AI (17)

The concatenated AI element string for encoding those four data elements appears as follows:

(01){gtin}(17){exp}(10){lot}(21){ser}

where {gtin}, {exp}, {lot} and {ser} are placeholders for the actual values.

These data elements can also be expressed within a single Web URI using the GS1 Digital Link syntax. The GS1 Digital Link structure (or URI template) for expressing the four data elements in the DSCSA product identifier appears as follows:

https://other.example.com/gtin/{gtin}/lot/{lot}/ser/{ser}?exp={exp}

where {gtin}, {exp}, {lot} and {ser} are placeholders for the actual values

EXAMPLE Consider a product instance with the following information:

DSCSA Product Identifier Data Element	Sample Value	ENCODED AS IN BARCODE
GTIN	00361414567894	AI (01) 00361414567894
Serial Number	400806	AI (21) 400806
Batch or Lot Number	1908642E	AI (10) 1908642E
Expiration Date	July 28, 2023	AI (17) 230728

Those four data elements would be encoded in a barcode using the following concatenated AI element string:

(01)00361414567894(17)230728(10)1908642E(21)400806

And they can be expressed in a Web URI format using the following GS1 Digital Link syntax:

`https://other.example.com/gtin/00361414567894/lot/1908642E/ser/400806?exp=230728`

Important: This example illustrates how expiration date is *encoded in GS1 barcodes* and *represented in the GS1 Digital Link* syntax using YYMMDD per GS1 Standards. It is not illustrating how to express expiration date in human-readable presentations on drug packages and/or within systems, which often use YYYYMMDD.

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Together, these standardized formats enable users to encode the four DSCSA data elements in a GS1 barcode, express them in a single Web URI, and translate between the two. As such, they provide the foundation for automating the verification of product identifiers using barcoded data and the GS1 Lightweight Messaging Standard, as described throughout the remainder of this document.

Note about "00" in the day portion of expiration date

- It is **STRONGLY RECOMMENDED** that the barcode contains an expiration date that includes a year, month, and non-zero day, encoded in YYMMDD format according to the *GS1 General Specifications*.
- With respect to verification of saleable returns, the data encoded from returned serialized products may be scanned with "00" day in the day portion of expiration date. In keeping with United States Pharmacopeia (USP) guidance, which specifies that an expiration date on a label lacking a day should be understood to refer to the last day of the month, verification services and Responders are expected to appropriately handle this scenario as outlined in Section *6.2.4*.

Important: How the day of the month is expressed for regulated healthcare products will change starting 1 January 2025. As of that date, the day of the month SHALL NOT be expressed as two zeros. A specific day of the month (e.g., last day of July = 31) SHALL be included.

11.3 GS1 Lightweight Messaging Standard for Verification of Product Identifiers

The *GS1 Lightweight Messaging Standard for Verification of Product Identifiers* is designed to support requests and responses for verification of product identifiers for serialized pharmaceutical products. This standard has been developed and designed to support VRS systems for U.S. DSCSA verification of product identifiers. The standard defines a verification Request message and a corresponding Output Response message. It is intended to provide a simple, standardized lightweight messaging framework for asking verification questions and receiving information based on a check of the DSCSA Product Identifier and associated data.

This standard is the first GS1 technical standard to make use of the new GS1 Digital Link syntax. It enables a basic automated check of a serialized product identifier and the associated expiration date and batch number via a lightweight web-based Request/Response message pair, initiated by a simple HTTP/HTTPS GET Request and returning a lightweight machine-readable Response message formatted in JavaScript Object Notation (JSON).

Note: Additional information about the GS1 Lightweight Messaging Standard may be accessed through the following link: *https://www.gs1.org/verification-messaging*

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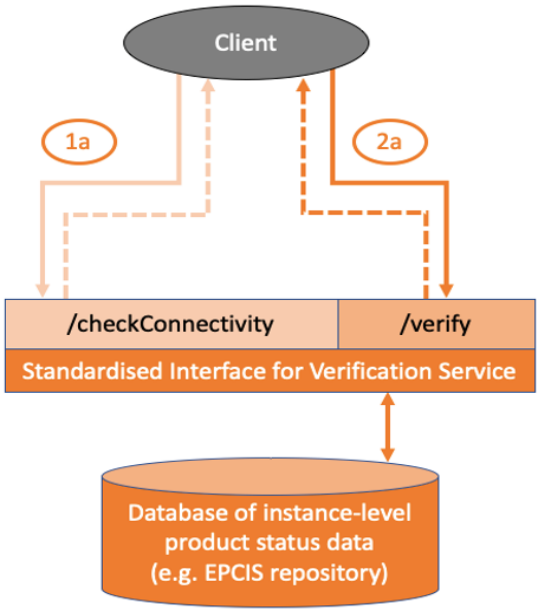
Figure 11-1 Methods by which a client may interact directly with a known VRS system, using either the checkConnectivity method (1a) or the verify method (2a)



In situations where the Requestor does not know in advance which VRS to use for a specific GTIN, they may make use of the resolver or look-up directory infrastructure as shown in **Figure 3-2**. A look-up directory has its own internal database of redirection, which it uses to match against the GTIN within the GS1 Digital Link Web URI, to provide a redirection pointer to the appropriate verification service, depending on information configured by the respective brand owner of that GTIN.

To indicate that the client wants to interact with a verification service, the client specifies within the URI query string a `linkType` value equal to **`'verificationService'`**.

A look-up directory will redirect the Request to the appropriate verification service for that GTIN, and the server for the Responder will respond.

The role of the Lookup Directory (LD) is to provide redirection so that instead of the client maintaining its own lookup table mapping every GTIN to a specific URL of a verification service, a resolver or LD provides up-to-date redirection information.

To distinguish between the two methods (`checkConnectivity` and `verify`) defined for the standardized interface, the client either appends '`&checkConnectivity=true`' to the GS1 Digital Link URI or does not.

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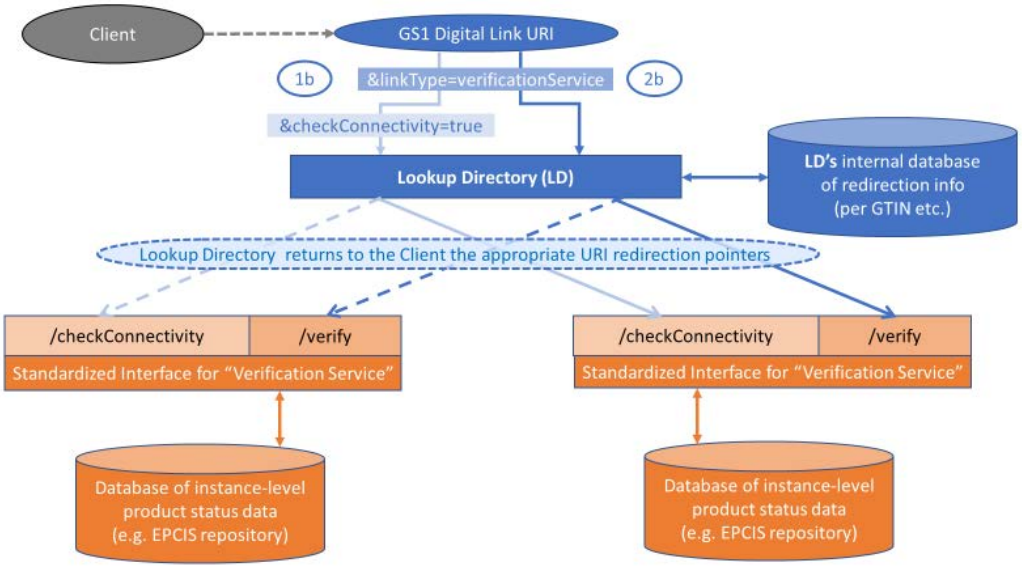
Figure 11-2 A client may use a Lookup Directory infrastructure for GS1 Digital Links to be redirected to the appropriate verification service for a specific GTIN, as specified by the respective brand owner



11.3.1 Relationship to GS1 Digital Link

This standard is the first GS1 technical standard to make use of the new GS1 Digital Link syntax. A GS1 Digital Link resolver is already operational at `id.gs1.org` and can be configured with several typed redirection links by each licensee of a GS1 identification key. One of these typed links can point to the relevant service for verification of product identifiers, as nominated by the respective brand owner.

The team developing the GS1 Digital Link resolver prototype at `id.gs1.org` are carefully examining HDA requirements and draft specifications for Lookup Directories to assure that equivalent functional capabilities can be supported by the GS1 Digital Link resolver at `id.gs1.org`, including the ability to handle redirection to multiple verification services for the same GTIN concurrently to deal with specific merger and acquisition issues (i.e., when mergers and acquisitions of companies and brands require concurrent operations over a period of time during the changeover period while products with the same GTIN from the previous brand owner and new brand owner coexist within the supply chain).

11.3.2 Relationship to EPCIS

This standard is independent of GS1 Electronic Product Code Information Services (EPCIS) and does not require the use of EPCIS, although users are encouraged to implement EPCIS to capture their supply chain events and to leverage the EPCIS query interface to retrieve data to support their response to a Request for product verification. Although EPCIS event data can record the commissioning or decommissioning of products, as well as current disposition (such as 'recalled') and instance/lot master data (such as 'expiration date'), it does not provide a sufficiently convenient interface to perform a simple verification check of product identifiers at batch or serial level.

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11.4 Configuration and Set-up for a DSCSA Verification Request

11.4.1 Making a DSCSA Verification Request

Using the GS1 Lightweight Messaging Standard, an HTTPS GET request can be made to request verification of a DSCSA product identifier on a given product by specifying `linkType=verificationService` and by specifying the verification `context=dscsaSaleableReturn or dscsaSuspectIllegitimate or dscsaExceptionVerification or dscsaStatusCheck` , as well as the following details of the request supplied via the URI query string:

- Requestor GLN (to uniquely identify the Requestor).
- Correlation UUID (universally unique identifier, uniquely generated by the Requestor).
- Control or Possession Attestation (a boolean indicating the requestor's attestation that they have possession or control of the product).
- Email or Telephone (of the contact point responsible for verification request).

Although a Web request typically returns a synchronous response, both the request and corresponding response may also be archived for audit purposes. It is for this reason that both share the same Correlation UUID, in order that each request may be matched with the corresponding response even when archived.

The Requestor GLN may be used by a verification service as an input to an access control decision, where access may only be granted to recognized values of Requestor GLN, and requests with unrecognized values of Requestor GLN may be redirected to a registration page (via an `HTTP 403 'Forbidden' response`) through which the Requestor can register for access by providing appropriate credentials and justification.

When ATP verifiable credential is utilized to prove authorized trading partner status, the ATP Credential in JWT format provided in the ATP-Authorization header field of the verification request message will serve as input to the access control decision logic performed by the verification service to grant access only to valid ATP Credential holders and reject access to requestors with ATP credential that is expired, revoked, or contains an invalid signature.

The full GS1 Digital Link Web URI template for a verification request for a DSCSA product identifier on a product is therefore generated by adding the following additional query parameters to the URI query string:

```
&linkType=verificationService
&context=dscsaSaleableReturn
&reqGLN={RequestorGLN}
&corrUUID={CorrelationUUID}
&ctrlPossessAtt={true or false}
&email={email}
&telephone={telephone}
```

This results in the following URI template:

`https://other.example.com/gtin/{gtin}/lot/{lot}/ser/{ser}?exp={exp}&linkType=verificationService&context=dscsaSaleableReturn&reqGLN={Requestor GLN}&corrUUID={CorrelationUUID}&ctrlPossessAtt={true or false}&email{email}&telephone{telephone}`

A resolver for GS1 Digital Link URI could be configured to redirect a GS1 Digital Link URI with these additional parameters in the query string (and the absence of the `checkConnectivity=true`

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parameter) to the verify method/operation of the appropriate verification service specified by the respective brand owner and licensee of that GTIN.

Note: Some of these parameters (e.g., Requestor GLN, Correlation UUID, Control or Possession Attestation, and email or telephone) are explicitly required by the context associated with DSCSA but may not be relevant to other uses of the GS1 Lightweight Messaging Standard in other sectors or regulatory jurisdictions.

Note: Additional query parameters in the verification requests beyond the query parameters defined in this implementation guideline are permissible but should be ignored since they are not part of the interoperable exchange. Please be sure to consult the specific GS1US-Version attribute in the header of the verification request and response message for the industry expected request and response message structure.

11.4.2 Example of a JSON verification request

The examples below use the following values for GTIN, Batch or Lot Number, Serial Number and Expiration Date, Requestor GLN, Correlation UUID and context:

- **GTIN:** 00361414567894
- **Batch or Lot Number:** 1908642E
- **Serial Number:** 400806
- **Expiration Date:** 230728
- **linkType:** verificationService
- **context:** dscsaSaleableReturn
- **Requestor GLN:** 0321012345676
- **Correlation UUID:** 21EC2020-3AEA-4069-A2DD-08002B30309D
- **Attestation of Control/Possession:** true
- **Email:** anyone@anynet.com
- **Telephone:** 011234567890

Inputting these values into the full GS1 Digital Link Web URI template shown above produces the following URI:

`https://other.example.com/gtin/00361414567894/lot/1908642E/ser/400806?exp=230728&linkType=verificationService&context=dscsaSaleableReturn&reqGLN=032101234567&corrUUID=21EC2020-3AEA-4069-A2DD-08002B30309D&ctrlpossessAtt=true&email=anyone@anynet.com&telephone=011234567890`

By making a simple HTTPS GET request for such Web URIs, the Requestor would be redirected to the respective brand owner's verification service (provided this is known to a resolver for GS1 Digital Link Web URIs), which could then use the translation functions to extract the data, convert it to a searchable format, and then process the verification request by searching their systems and issuing an appropriate response.

The example below illustrates a sample JSON verification request with the `context` of `dscsaSaleableReturn` when communicating with a known verification service. The HTTP header `Accept:` with value `application/json` is used to indicate to the verification service that the client would like to receive a response to the verification request in JavaScript Object Notation (JSON) format.

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The optional HTTP header `ATP-Authorization:` with the ATP Requestor credential in JWT format can be provided to enable ATP Requestor verifiable credential checks.

```
GET
https://verificationService.example.com/verify/gtin/01234567890128/lot/1908642E/ser/400806?exp=230728&linkType=verificationService&context=dscsaSaleableReturn&reqGLN=0321012345678&corrUUID=21EC2020-3AEA-4069-A2DD-08002B30309D&ctrlpossessAtt=true&email=anyone@anynet.com&telephone=011234567890
Accept: application/json
GS1US-Version: 1.3.0
ATP-Authorization: eyJraWQiOiIwOXdoVHNEM1JR…
```


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Part IV: GS1 US Rx EPCIS Conformance Testing Program

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12 Rx EPCIS Conformance Testing Program Overview

The *GS1 US Rx EPCIS Conformance Testing Program* ("the Program") is a voluntary but recommended program offered to support pharmaceutical industry members implementing EPCIS for DSCSA and traceability pursuant to the GS1 US Rx Guideline (Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability Implementation Guideline). The Program is designed to remove ambiguity from the challenges of DSCSA EPCIS standards conformance and enable independent, objective, and certified testing services to manufacturers, wholesalers, and solution providers on behalf of their customers. To assure consistency in conformance testing, each GS1 Certified Conformance Testing Service must demonstrate the ability of their solutions to meet the GS1 US Rx Guideline technical requirements and successfully evaluate representative DSCSA test use-cases.

Conformance testing facilitates the sharing of serialized transactions among trading partners by evaluating submitted EPCIS event files against the format and structure defined in the GS1 US Rx Guideline. Fully conforming DSCSA EPCIS event files are known to be exchanged and consumed without issue, greatly reducing the time and expense of establishing interoperability among pharmaceutical trading partners.

A test service is used to gain an in-depth assessment of adherence to GS1 Standards and the GS1 US Rx Guideline (including schema files) as well as completeness of necessary data. GS1 US Rx EPCIS Trustmarks are issued for EPCIS event files which fully conform to all requirements and adhere to one of 16 pharmaceutical traceability scenarios.

Getting tested early accelerates the onboarding of EPCIS and enables an understanding and visibility of gaps and shortcomings that can be addressed prior to the start of the onboarding process.

Benefits:

- Offers a level of assurance about technical conformance and readiness to exchange serialized information with trading partners pursuant to the GS1 US Rx Guideline
- Enables readiness to exchange serialized information with trading partners pursuant to the GS1 US Rx Guideline
- Offers a testing platform with diagnostic information and guidance to help support a trading partner's implementation process

Note: Additional information about the GS1 US Rx EPCIS Conformance Testing Program may be accessed through the following link: *https://www.gs1us.org/industries-and-insights/by-industry/healthcare/standards-in-use/pharmaceutical/epcis-conformance-testing*

Note: The GS1 US Rx EPCIS Conformance Testing Program is NOT the same as GS1 EPCIS certification program and is NOT a substitute for software validation testing. The GS1 US Rx EPCIS Conformance Testing Program DOES NOT:

- test for DSCSA compliance
- test the accuracy of the data
- address EPCIS transport mechanism
- replace trading partner pilots

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Appendix A: Converting a U.S. FDA NDC to an 11-digit derivative U.S. Centers for Medicare and Medicaid Services (CMS) NDC format

This section is provided for the benefit of billing system suppliers and users. FDA National Drug Codes (NDCs) are displayed on drug packaging in a 10-digit format. Many billing systems require the US CMS NDC number in an 11-digit derivative 5-4-2 format. The following table shows FDA NDC formats indicated on packaging and the appropriate conversion to an 11-digit US CMS numeric derivative format for billing systems.

In the table below:

- The additional "0" in the 11-digit US CMS numeric derivative converted example is shown in **bold** and underlined.
- Hyphens have been inserted for visual clarity to illustrate the various formatting examples of NDCs. Do not use hyphens when entering the NDC in your claim.

Table A-1 Converting an U.S. FDA NDC to an 11-digit U.S. CMS NDC derivative format

U.S. FDA NDC on Package	U.S. FDA NDC Example	NDC in an 11-Digit derivative U.S. CMS Format	Example of NDC in a U.S. CMS 11-Digit Converted Format
4 - 4 - 2	0002-7597-01 Zyprexa 10mg vial	5 - 4 - 2	**0**0002-7597-01
5 - 3 - 2	50242-040-62 Xolair 150mg vial	5 - 4 - 2	50242-**0**040-62
5 - 4 - 1	60575-4112-1 Synagis 50mg vial	5 - 4 - 2	60575-4112-**0**1

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Appendix B: GS1 Standards

From an information management point of view, supply chain applications like serial-level management and item-level traceability require all parties to systematically associate the physical flow of products with the flow of information about them. This is best attained by deploying a common business language within the framework of a comprehensive standards system. The GS1 System is such a system, providing a comprehensive platform for companies to identify products and other business entities, capture supply chain data, and share data with trading partners.

The GS1 System encompasses identification standards, data standards, automatic identification data capture (AIDC) standards, and data communication standards. The table below summarizes some of the GS1 Standards that support item-level traceability.

Table B-1 Overview of GS1 System of Standards to Support Traceability

GS1 Standards Supporting Serial-Level Management & Item-Level Traceability			
Identification Standards	**Trade Items**	Global Trade Item Number (GTIN)	
	Locations & Trading Partners	Global Location Number (GLN)	
	Logistics Units	Serial Shipping Container Code (SSCC)	
AIDC Standards	**GS1 Barcodes**	GS1-128 GS1 DataMatrix RSS EAN/UPC ITF-14 Composite Component	
	GS1 EPC/RFID		
Data Standards	**Master Data:** Global Data Dictionary Item Business Messaging Standard Party Business Messaging Standard	**Transactional Data:** eCom/EDI	**Event Data:** EPCIS Schema EPCIS Core Business Vocabulary
Sharing & Communication Standards	**Master Data:** GDSN Data Hub | Location EPCIS Master Data	**Transactional Data:** AS2	**Event Data:** EPCIS Capture EPCIS Query Discovery Services

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Appendix C: Acronyms

AI	Application Identifier
CBV	Core Business Vocabulary
CMS	Centers for Medicare and Medicaid Services
EPC/RIFD	Electronic Product Code / Radio Frequency Identification
EPCIS	Electronic Product Code Information Services
XML	eXtensible Markup Language
GDSN	Global Data Synchronization Network
GLN	Global Location Number
GTIN	Global Trade Item Number
NDC	National Drug Code
RFID	Radio Frequency Identification
SSCC	Serial Shipping Container Code
SGLN	EPC for Global Location Number (GLN)
SGTIN	Serialized Global Trade Item Number (GTIN)
U.P.C.	Universal Product Code (U.P.C.)
URI	Uniform Resource Identifier
URN	Uniform Resource Name

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Appendix D: Glossary

Term	Acronym	Definition
Government Definitions:		
Drug Supply Chain Security Act	DSCSA	The Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. [Source: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa]
National Drug Code	NDC	The National Drug Code is a 10-digit identification number established by the U.S. Food and Drug Administration (U.S. FDA) to identify drugs in accordance with Section 510 of the Federal Food, Drug and Cosmetic Act (Act), 21 U.S.C. §360.
Standardized Numerical Identification	SNI	SNI is the U.S. FDA's term for the unique identification mandated by the DSCSA.
Drug Enforcement Administration	DEA	The DEA was established in 1973 as the federal organization in charge of enforcing the controlled substances laws of the United States. [Source: https://www.dea.gov/who-we-are]
Trading Partner Definitions:		
Manufacturer		A manufacturer is defined in section 581(10) of the FD&C Act to mean: [W]ith respect to a product -- (A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).
Repackager		DSCSA defines repackager in section 581(16) of the FD&C Act as "a person who owns or operates an establishment that repacks and relabels a product or package for – (A) further sale; or (B) distribution without a further transaction."
Wholesaler		DSCSA defines wholesale distributor in section 581(29) of the FD&C Act to mean "a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the FD&C Act, as amended by [DSCSA])."
Primary Wholesale Distributor		Wholesale distributor that purchased product directly from the manufacturer.
Contract Manufacturing Organization	CMO	For the purposes of the DSCSA, a CMO is an entity that performs manufacturing operations for the NDA/ANDA/BLA holder or a co-licensed partner of the NDA/ANDA/BLA holder, to fulfill a contractual obligation with such manufacturer, but is not responsible for the introduction of the product into interstate commerce. [Source: http://pdsaonline.org/wp-content/uploads/2015/06/PDSA-Letter_DSCSA-QA_May-2014.pdf]

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Third Party Logistics	3PL	DSCSA defines a 3PL in section 581(22) of the FD&C Act to mean: [A]n entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product.
Dispenser		The term dispenser, as defined in section 581(3) of the FD&C Act: (A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).
GS1 Standards:		
GS1 Company Prefix	GCP	A GS1 Company Prefix is a unique string of 6–11 digits issued to your company by your local GS1 Member Organization.
Global Trade Item Number®	GTIN®	The Global Trade Item Number (GTIN) is the globally unique GS1 identification number used to identify "trade items" (i.e., products and services that may be priced, ordered, or invoiced at any point in the supply chain).
Serialized GTIN	SGTIN	An SGTIN is the combination of a GTIN and a unique serial number of up to 20 alphanumeric characters.
Global Location Number	GLN	The Global Location Number (GLN) is the globally unique GS1 Identification Number used to identify parties and locations.
S Global Location Number	SGLN	The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS. The SGLN syntax is capable of representing a plain GLN (without extension) or a GLN plus extension.
Serial Shipping Container Code	SSCC	The Serial Shipping Container Code (SSCC) is the globally unique GS1 identification number used to identify individual logistic units. A "logistic unit" is defined as an item of any composition established for transport and/or storage which needs to be tracked individually and managed through the supply chain.
Electronic Product Code	EPC®	The Electronic Product Code™ (EPC) is syntax for unique identifiers assigned to physical objects, unit loads, locations, or other identifiable entity playing a role in business operations.
Electronic Product Code Information Services	EPCIS	The EPC Information Services (EPCIS) standard defines a data model and a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain.
Data Carriers and Barcode Related:		
GS1 DataMatrix		GS1 DataMatrix is a two-dimensional (2D) barcode which may be printed as a square or rectangular symbol made up of individual squares.
Radio-Frequency Identification	RAIN RFID	The RAIN RFID alliance is a global alliance promoting the universal adoption of passive UHF RFID (called RAIN RFID). GS1 refers to "RAIN RFID" tags in this document whenever making reference to passive UHF RFID tags.

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		NOTE: Within the UHF RFID technology space, GS1 only endorses RAIN RFID implementations that are encoded per GS1's EPC standards(which are a subset of all RAIN RFID implementations).
Universal Product Code	U.P.C.	A U.P.C. is a type of barcode. Specifically, a UPC-A is a barcode that can hold a GTIN-12, and12 and is familiar from its use on consumer products in North America.
Human Readable Interpretation	HRI	Human Readable Interpretation (HRI) is the printed representation of the data encoded in a barcode (e.g., GS1 DataMatrix or GS1-128 barcode).
Human Readable Form		Human-readable refers to product identifiers on their packaging that can be read absent of requiring a machine.

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IAPMO

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*If applicable

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