GS1 US

The Global Language of Business

GS1 Standards for U.S. FDA UDI Online Certificate Course

Avoid common mistakes and receive guidance on how to use GS1 Standards for the U.S. FDA UDI Rule

This certificate training is designed for medical device labelers (e.g., manufacturers, repackagers, reprocessors, etc.) or any person involved in implementing U.S. FDA Unique Device Identification (UDI) using GS1 Standards.

The U.S. FDA UDI Rule establishes a unique device identification system for medical devices. Under the rule, medical devices will be marked with a Unique Device Identifier (UDI) that will appear on the label and package of a device. UDIs will be presented on device labels in both a human-readable format and a machine-readable format (e.g., a barcode). Reusable devices that need to be "reprocessed" before reuse will also be directly marked with a UDI. In addition, device labelers will submit device information to a U.S. FDA database called the Global Unique Device Identification Database (GUDID).*

This course is designed to help you gain a foundational understanding of specific GS1 Standards that can be used to address certain aspects of the requirements for product identification, product labeling, and submission of information to the GUDID.

Attend to Learn

- The GS1 Standards that can be used to implement U.S. FDA UDI requirements
- How to use GS1 Application Identifiers (AIs) for your Production Identifiers (PIs)
- How to create properly formatted GS1 Global Trade Item Numbers (GTINs) for use as Device Identifiers (DIs)
- Options for submitting data to the U.S. FDA GUDID

Take this certificate course to gain valuable knowledge about how to use GS1 Standards for U.S. FDA UDI requirements that you can bring back to your company and enhance your own professional development.

GS1 Standards for U.S. FDA UDI Certificate

Earn a Badge

Did you know when you successfully complete a GS1 US® certificate course, you can earn an important credential in the use of GS1 Standards? And you can add this new skill to your online profile with a GS1 US Badge and share it via social media.

GS1 is a U.S. FDA-accredited Issuing Agency for UDI, and GS1 Standards can be used to implement the U.S. FDA UDI Rule. Whether you are continuing your Class III or Class II implementation or preparing for Class I, the GS1 Standards for U.S. FDA UDI Certificate Course provides the most comprehensive training we offer to help you with using GS1 Standards for your UDI implementation, for all classes of medical devices.

*For information about the rule, see the U.S. FDA Unique Device Identification System

Course Modules

Modules 1 through 5 are also included in the GS1 Foundations for Healthcare Certificate Course.

Module 1: Overview of GS1 Standards

Module 2: How to Use Your GS1 Company Prefix (EAN/UPC)

Module 3: How to Create and Manage Your Global Trade Item Numbers (GTINs)

Module 4: GTIN Management Standard

Module 5: How to Barcode Your Products

Module 6: GS1 Standards for U.S. FDA UDI

- **Lesson 1:** U.S. FDA UDI Rule Overview and Definitions
- **Lesson 2-4:** GS1 Identify, Capture, and Share Standards for the U.S. FDA UDI Rule
- **Lesson 5:** Review of Exceptions, New U.S. FDA UDI Guidance, and FAQs
- **Lesson 6:** Implementation Readiness and the "Project vs. Program" Approach
- Module 6 also provides a Resource Library at the end, which includes links to key tools and implementation support resources.

Assessment

An assessment will be administered throughout this course to gauge your understanding of the material. There is no additional charge for the assessment, which is for review purposes only. Those who attend and complete the course will receive a Certificate of Completion and GS1 US Badge (note: badge is issued within three weeks of course completion).

Online Course

By taking the online certificate course, you will have the opportunity to:

- Learn at your own pace and access course content anytime, anywhere you have an internet connection.
- Gain unlimited access to course content for one year. Play, replay, and fast-forward to specific content as many times as you need.
- Complete knowledge checks designed to help you practice and learn the course material and to confirm knowledge transfer.

On-Site Training Requests

Interested in customized or on-site training for your staff? Contact us at **AdvisoryServices@gs1us.org**

Disclaimer: GS1 US is the local GS1 Member Organization that supports implementation of the GS1 System of Standards in the United States. GS1 US employees are not representatives or agents of the U.S. FDA, and the content herein has not been reviewed, approved, or authorized by the U.S. FDA.

GS1 is a U.S. FDA-accredited Issuing Agency for UDI, and GS1 Standards are authorized for use in implementing the requirements of the U.S. FDA UDI Rule.

Want to learn more?

For more information on this course, visit **www.gs1us.org/UDI_course** or contact us at **training@gs1us.org**.

About GS1 US

GS1 US®, a member of GS1® global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth, while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). For more information, visit www.gs1us.org.

GS1 US Corporate Headquarters
Princeton South Corporate Center, 300 Charles Ewing Boulevard
Ewing, NJ 08628 USA
T +1 937.435.3870 | **E** info@gs1us.org
www.gs1us.org

Connect With Us

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