

TLC & TLC Source for FSMA Rule 204

The traceability lot code (TLC) is an integral component of the FSMA Rule 204 requirements, linking to other required Key Data Elements (KDEs), including the **traceability lot code source**. Visit the U.S. Food and Drug Administration (U.S. FDA) traceability lot code webpage for additional details.

What Is the TLC?

The U.S. FDA defines the TLC as "a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source (defined below). This is similar to what industry currently refers to as a 'lot' or 'lot code."

Note: The Global Trade Item Number* (GTIN*) + batch/lot can be used as best practice to determine the TLC required by FSMA Rule 204.

What Is the TLC Source?

The TLC source is the **physical location** where the TLC is assigned. The TLC source location description includes the KDEs that describe that location (e.g., business name, address, contact, etc.).

What Is the TLC Source Reference?

The TLC source reference is an alternative method for giving the U.S. FDA access to the TLC source location description information. U.S. FDA examples include: U.S. FDA Facility Registration Number, **Global Location Number** (GLN), web address in a QR Code, GS1 Digital Link.

Note: A GLN can be used to identify the TLC source reference. The location description attributes can be stored and shared in a master data system such as GS1 US Data Hub | Location.

Who Assigns the TLC?

View supply chain examples from the U.S. FDA by visiting: https://www.fda.gov/media/169511/download?attachment

Supply Chain Examples

