Safety is the Top Priority

The United States has one of the safest drug distribution systems in the world¹, yet its drug supply is at risk of illegal activities that could seriously impact public health and safety, ranging from theft and diversion of legitimate drugs to counterfeiting.

Theft and diversion of pharmaceuticals present significant risks to the public because quality cannot be verified for products that leave—and are later reintroduced to—the legitimate supply chain. Counterfeit drugs may contain inactive ingredients, or they may contain harmful ingredients or dosages. The pharmaceutical industry and government regulators are working to increase safety and visibility in the supply chain to prevent theft and diversion, and counterfeiting:

• **Drug Supply Chain Security Act (DSCSA)** outlines critical steps to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed within the United States.

• **U.S. Food and Drug Administration (FDA)** is working to establish standards for the interoperable exchange of product tracing information in the pharmaceutical supply chain pursuant to the DSCSA.

• **Manufacturers** are interested in gaining better visibility into the movement of products to improve production planning.

• **Wholesalers and distributors** are looking for automation in the supply chain to improve fulfillment and tracking.

• **Pharmacies and healthcare providers** need access to lot and expiration information to improve inventory management, recall management, and patient safety.
Why GS1 Standards?

Track-and-trace requires a certain level of interoperability among systems used by supply chain participants. With GS1 Standards, supply chain participants can achieve interoperability.

The GS1 System is an integrated suite of global standards for identifying, capturing, and sharing supply chain information. By implementing GS1 Standards as a foundational component of their business processes, organizations that participate in the pharmaceutical supply chain can leverage the power of information to strengthen supply chain integrity, increase efficiencies, and reduce costs.

Increase Security, Visibility, and Control—It’s the Law!

The DSCSA law can be viewed as a three-phase implementation over 10 years. These measures significantly impact the pharmaceutical supply chain. GS1 Standards are integral to U.S. pharmaceutical industry efforts to prepare for and implement DSCSA requirements in each phase:

- **Starting in 2015**, Phase 1 of the DSCSA requires that supply chain participants share chain-of-ownership data by exchanging lot-level Transaction Information, Transaction History, and Transaction Statement at each sale/transfer of ownership.

- **Starting in 2017**, Phase 2 of the DSCSA 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.

- **Starting in 2023**, Phase 3 of the 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).

Get Ready for Serialization and Track-and-Trace

Trading partners across the supply chain, including manufacturers, wholesalers, retail pharmacies, and hospitals, are participating in readiness activities, including those sponsored by GS1 Healthcare US®, to prepare for DSCSA requirements. Activities include:

- Using the Global Trade Item Number® (GTIN®) to identify products, and implementing methods to manage serial numbers across production lines and contract manufacturers.

- Developing the best ways to authenticate serial numbers and DSCSA information.

- Establishing cross-functional internal and partner teams to address serialization and DSCSA data exchange needs and capabilities. Members include those from supply chain and logistics, packaging, IT, regulatory, marketing, brand protection, and finance, among others.

- Evaluating and implementing barcode grading/quality, track-and-trace architecture, inference strategy, implementation support, and pilot preparedness programs.
Identify, Capture, and Share Critical Data

Implementing GS1 Standards helps organizations identify, capture, and share important supply chain information that moves from the point of manufacture to the pharmacy.

**Identify**

These are the numbers behind the barcodes. Used in both the physical and digital worlds, GS1 Identification Numbers uniquely identify products, logistics units, locations, assets, documents, shipments, consignments, and service relationships in the supply chain—from manufacturer to dispensers. GS1 identifiers used to support the pharmaceutical supply chain and DSCSA include:

- **Global Trade Item Number (GTIN)**, which uniquely identifies trade items and can be combined with extended data such as serial numbers, lot numbers, and expiration dates.
- **Serial Shipping Container Code (SSCC)**, which uniquely identifies logistics units such as mixed cases and pallets.
- **Global Location Number (GLN)**, which uniquely identifies locations and business entities.

**Capture**

GS1 data carriers are capable of capturing varying amounts of data to accommodate different business needs, including DSCSA lot number, serial number, and expiration date. Data carriers include **Linear** and **2D DataMatrix** barcodes, and **EPC-enabled Radio Frequency Identification (RFID)**. Many manufacturers are using the **GS1 DataMatrix** at the “each” level and a combination of GS1-128 barcodes and some RFID at the case and pallet levels.

**Share**

GS1 Standards promote interoperability and support data exchange between trading partners, including DSCSA requirements. These data standards enable electronic information and commerce to flow through the supply chain, and include:

- **Global Data Synchronization Network™ (GDSN™)**—a synchronized master data source that ensures the continual real-time exchange of consistent, accurate product information among supply chain partners.
- **Electronic Product Code Information Services (EPCIS)**—a standard for sharing event data between trading partners. The FDA DSCSA guidance selected EPCIS as one of only two electronic means for exchanging DSCSA data.

GS1 Healthcare US facilitates industry forums, educational symposia, case study development, and publication of implementation guidelines and best practices to help industry prepare for DSCSA requirements. Some of the key resources, available at [www.gs1us.org/dscsa](http://www.gs1us.org/dscsa), include:

- **Applying GS1 Standards to U.S. Pharmaceutical Supply Chain Business Processes for the Drug Supply Chain Security Act and Traceability** (Implementation Guideline)
- **2015 Readiness Pilot Report: Lessons Learned About Serialization Using GS1 Standards—Pharmaceutical Manufacturer**
• The Practice of Inference in the U.S. Pharmaceutical Supply Chain (white paper about inference, a mechanism that enables healthcare trading partners to leverage best practices to meet challenges associated with receiving and shipping of serialized items)

• Global Traceability Standard for Healthcare (GTSH) (describes the traceability process and defines minimum capabilities and the corresponding GS1 Standards to be used in combination with information management tools)

• Healthcare Provider and Supplier GLN, GTIN, and GDSN Tool Kits

GS1 US® also offers tools and training to ensure optimal performance and quality of its data carriers, including:

• Calibrated Conformance Standard Test Cards (CCSTC). A primary reference standard that contains barcode symbols of exact dimensional and reflectance values; used to determine if your barcode verifier is accurate and operating within published tolerances.

• AIDC Certification. Certification training in implementation and application of the GS1 General Specifications and GS1 barcode standards.

Get Involved in GS1 Healthcare US

GS1 Healthcare US works with members of the U.S. pharmaceutical industry to help prepare companies for DSCSA lot-level management, DSCSA 2017 serialization requirements, and DSCSA 2023 item-level traceability requirements using GS1 Standards. Join open industry calls on topics related to DSCSA. They take place regularly and exist to share candid insights and perspectives or to ask questions. Contact gs1healthcareus@gs1us.org for next call date.

GS1 Healthcare US brings together members from all segments of the healthcare industry to address supply chain issues that most impact healthcare in the United States. Find out more about the GS1 Healthcare US workgroups and how you can get involved.

For more information:
Visit: www.gs1us.org/dscsa