



The Global Language of Business

GS1 US Advisory Services Solutions for the Healthcare Industry



Build your successful FDA Unique Device Identification (UDI) strategy on a foundation of GS1 Standards, supported by industry expertise

The U.S. Food and Drug Administration's (FDA) rule requiring manufacturers to label their products with unique device identifiers can help the FDA find problems with medical devices much earlier, track recalls more efficiently, and improve patient safety. GS1, a leading global standards organization, is an FDA-Accredited Issuing Agency for unique device identifiers. Global GS1 Standards, administered in the United States by GS1 US, are authorized for use by manufacturers to address the requirements of the new FDA UDI regulation.

As implementation deadlines approach, industry partners are challenged to:

- Understand the UDI regulation and what role GS1 Standards play in helping to prepare for compliance
- Implement the multiple components necessary to meet requirements
- Apply industry best practices to the tactical implementation to meet future deadlines

The GS1 US Advisory Services Program for Healthcare offers a combination of technical and business expertise to address specific challenges your organization may face in integrating the GS1 System of Standards into your operations.

GS1 US Advisory Services

Offer a full introduction to UDI regulation and associated GS1 Standards

Deliver a precise mix of technical and business expertise to help you meet regulatory requirements

Help your business with the tactical execution of UDI implementation for your company

Customized Education and Implementation Support

GS1 US can create an implementation program consistent with your company's initiative and specific to your organization's deployment plan. With a special mix of industry, technology, and standards expertise, we can provide the exact services you need. Services include, but are not limited to, the examples described in each section below.

GS1 US One-Day On-Site Custom Workshop: GTIN/FDA UDI & GDSN/FDA GUDID Implementation

Customizable for medical device manufacturers (GS1 Company Prefix holders and those new to GS1 Standards) or UDI "receiver companies" (e.g., healthcare providers)

This one-day workshop is designed to bring a cross-functional team together from your organization to address your company's unique implementation challenges. It can be conducted on site at your location for professionals in the field of regulatory compliance, data management, EDI, marketing, operations, supply chain management, production, or manufacturing with front-line responsibility for UDI implementation.

Value to Your Organization:

To gain a full introduction to UDI requirements and the associated GS1 Standards and to understand the best practices from which an implementation plan can be developed specifically for your organization. Attendees will leave the workshop with:

- An understanding of your company's "readiness" for UDI implementation
- A framework for developing an implementation plan
- A general understanding of UDI best practices for implementation staff
- An understanding of how to tactically execute UDI implementation for your products, business, or hospital utilizing GS1 Standards

GS1 US Two-Day On-Site Custom Workshop: GTIN/FDA UDI & GDSN/FDA GUDID Implementation

with Executive Overview, Customer Readiness Assessment, and Detailed Implementation Plan

Customizable for medical device manufacturers (GS1 Company Prefix holders and those new to GS1 Standards) or UDI "receiver companies" (e.g., healthcare providers)

This two-day workshop, conducted on site at your location, is designed for healthcare provider or medical device manufacturer company executives with a focus on developing an actionable implementation plan for your regulatory, compliance, data management, EDI, marketing, operations, supply chain, production, and manufacturing professionals with front-line responsibility for UDI implementation.

Value to Your Organization:

To gain an executive-level overview of the implications of UDI requirements and the associated GS1 Standards and to understand the best practices from which an implementation plan can be developed. Attendees will leave the workshop with:

DAY 1:

- An executive-level understanding of UDI compliance, implementation needs, and ROI opportunities
- An understanding of your company's "readiness" for UDI implementation
- Company-specific guidance for developing an implementation plan

DAY 2:

- A general understanding of UDI best practices for front-line implementation staff
- An understanding of how to tactically execute UDI implementation for your products or business utilizing GS1 Standards

GS1 US Data Quality Solutions

To support industry implementation of the GS1 US National Data Quality Program, we offer a variety of solutions to help you meet your specific data quality challenges

Education & Training

Gain foundational education, overview of data quality

Data quality workshops and on-site customized education and/or training

GS1 Standards Assessment

Improve adherence to GS1 Standards

Focus on GS1 Standards assessment and implementation status/benchmark

Data Governance Assessment

Improve data governance process

Focus on data governance assessment and procedures development

Implementation Support

Integrate data quality into your operations

Customized implementation guidance for any or all three components of the GS1 US National Data Quality Program leveraging results of GS1 Standards and data governance assessments

Attribute Audit

Verify product data accuracy

Physical audit of products compared to the most recent information shared about those products

Certification

Demonstrate proficiency and excellence in data quality

Verification of proficiency in all three components of the GS1 US National Data Quality Program

For more information and resources available to implement an effective data quality program, visit www.gs1us.org/data-quality

GS1 Standards Solutions

Supports implementation of GS1 Standards to suit your organization's deployment plan

Education & Training

- GS1 Standards Fundamentals
- Global Trade Item Number® (GTIN®) Allocation Rules
- Package Measurement Rules
- Electronic Data Interchange (EDI) Implementation Best Practices

Implementation & Planning Support

- Merger and Acquisition Support
 - GS1 US Prefix consolidation
 - Global Location Number (GLN) cleansing
 - Focus towards product data management
- Global Data Synchronization Network™ (GDSN®) Implementation Support

Assessment

- Benchmark report (including gap analysis and opportunities for improvement)
- Implementation recommendations for product and location identification and strategy, package measurement, and new item setup
- Detailed next-step guidance for industry best practices





Customized Education and Implementation Support

GS1 US Advisory Services has a suite of programs to help industry members, from manufacturers to providers, meet the requirements and timelines of the UDI rule. With the use of GS1 Standards, healthcare organizations are able to uniquely identify and locate medical devices through every step of the product lifecycle, improving supply chain visibility and patient safety.

Industry Momentum

Utilizing GS1 Standards, healthcare organizations around the world are able to uniquely identify and locate medical devices through the supply chain and at every step of the product's lifecycle, improving supply chain visibility and patient safety.

Get Started

To learn more about how GS1 US Advisory Services can help you strengthen your business relationships, collaborate with supply chain partners more efficiently, and improve patient safety, contact us at:

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