



The Global Language of Business

Introduction to GS1 Standards for the Healthcare Supply Chain

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About GS1

GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

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 (EPC®)-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers, and distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US® in the United States.

About GS1 Healthcare US

GS1 Healthcare US® is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to help improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

Executive Summary

Quality healthcare depends upon a complex industry infrastructure, including a global supply chain that provides medical devices, pharmaceuticals and other products needed for patient care. Fast, efficient movement of those products is essential, and healthcare providers need reliable information about their availability and status at all times.

The healthcare industry has been slowly working to implement tech-enabled upgrades that will enable much better tracking of healthcare products in the future. Improved visibility will create day-to-day improvements in overall business operations, help to minimize disruptions during a crisis and support patient care and safety.

GS1 US works with healthcare industry stakeholders to help facilitate supply-chain solutions that advance this common cause. There is widespread agreement that the use of GS1 Standards is essential to enable different organizations to trade information with one another in real time, in interoperable formats to facilitate better supply-chain performance.

This document provides guidance to healthcare industry stakeholders about the use of GS1 Standards to achieve these ends. The GS1 Global Trade Item Number® (GTIN®) and the Global Location Number (GLN) are foundational to standards in healthcare, and their use is discussed within this document from the perspectives of both suppliers and healthcare providers. We will explain how using the GS1 System of standards can help:

- deliver quality care while lowering costs
- increase efficiencies, and
- adapt to new legislation, reform, and regulations.

1 Introduction

Digital technology provides infinite potential for gathering, sharing and exchanging all kinds of information between diverse groups and organizations, facilitating productive collaboration and business opportunities across a fully connected marketplace. The healthcare industry is rapidly discovering ways to harness the power of digital information to improve efficiency, cost savings, and most importantly, patient care. The supply chain is a case in point.

Healthcare providers need accurate, up-to-the-minute supply-chain information about the products they use at the point of care (e.g., Where are they now? If not in inventory, when will they arrive?). Massive amounts of data must be shared between suppliers, wholesalers and distributors, healthcare providers, and pharmacies. To be useful, that data must be standardized so that all trading partners can access, understand and maintain it.

Retail and other industries have already fully adopted GS1 Standards and demonstrated tangible benefits. After decades of relying on proprietary systems for identifying and managing product data, the healthcare industry is now beginning to fully recognize how standards can also support improvement in becoming efficient, effective stewards of patient safety.

Federal regulations, both in the United States and abroad, are also driving accelerated adoption of GS1 Standards in healthcare. Specifically, two U.S. Food and Drug Administration (FDA) regulations require suppliers to mark products with barcodes containing unique identifiers (e.g., GTINs), using standardized formats so that these products can be tracked and traced throughout their lifecycle, and even included in patient health records. The two applicable regulations are:

- U.S. FDA Unique Device Identification Rule (“UDI Rule”) – GS1 is an FDA-issuing agency for UDI, enabling medical device suppliers to use GTINs to meet UDI product identification requirements.
- U.S. FDA Drug Supply Chain Security Act (DSCSA) – As part of DSCSA requirements, pharmaceutical products must be marked with a National Drug Code (NDC), serial number, lot number, and expiration date. (When using GS1 Standards, the NDC is represented by a GTIN.)

GS1 Standards include product identification systems that meet the requirements of both regulations.

2 Why Standards are Needed in Healthcare

The use of data standards is not entirely new in healthcare, but full adoption across the industry is needed to produce transformative improvements. And although momentum is beginning to build, progress to date has been slow.

Without standards, companies are left to develop their own product identifiers and data formats, resulting in numerous proprietary systems for healthcare suppliers and providers to manage, which is cumbersome and expensive. The result is an error-prone, inefficient approach to product identification that undermines supply-chain management and efficiency, adding high unnecessary costs and risks.

Only by using globally recognized interoperable data standards can healthcare organizations effectively communicate with one another to promote patient safety, improve analytics and efficacy reporting, and reinforce a more efficient supply chain with improved visibility, traceability and sustainability. Using standards to deliver accurate product and location information is essential to support efficient orders, invoices, deliveries and more.

Accordingly, a growing number of hospitals, healthcare suppliers and healthcare-related organizations have chosen the GS1 System of Standards to help them optimize operations and provide the best possible quality of care.

2.1 Growing Challenges in a Dynamic Environment

Properly and proactively applied, data standards can help minimize or eliminate many issues related to regional or global supply-chain stresses such as those encountered during the COVID-19 pandemic.

Product visibility and traceability are key. A lack of visibility into products deployed in the supply chain or products on hand within healthcare facilities and networks proved to be a significant blind spot early in the pandemic, preventing products from being positioned when and where they were most needed.

Likewise, the lack of visibility into a product's country or point of origin made it difficult to foresee potential product delays due to manufacturing shutdowns in certain geographic areas. It also increased the risk of counterfeit product introduction into the supply channel -- especially when regulations were loosened to make personal protective equipment (PPE) available faster and alleviate shortages.

These system-wide supply chain issues can only be solved with a unified approach. An interoperable, standards-based system is needed to integrate all stakeholders' information needs so they can, together, improve operations and ultimately provide better patient care.

Global standards are so important because they facilitate simplicity, consistency and accuracy in supply-chain communications.

How Standards Can Support Healthcare

Global standards enable and support healthcare business processes and lead to:

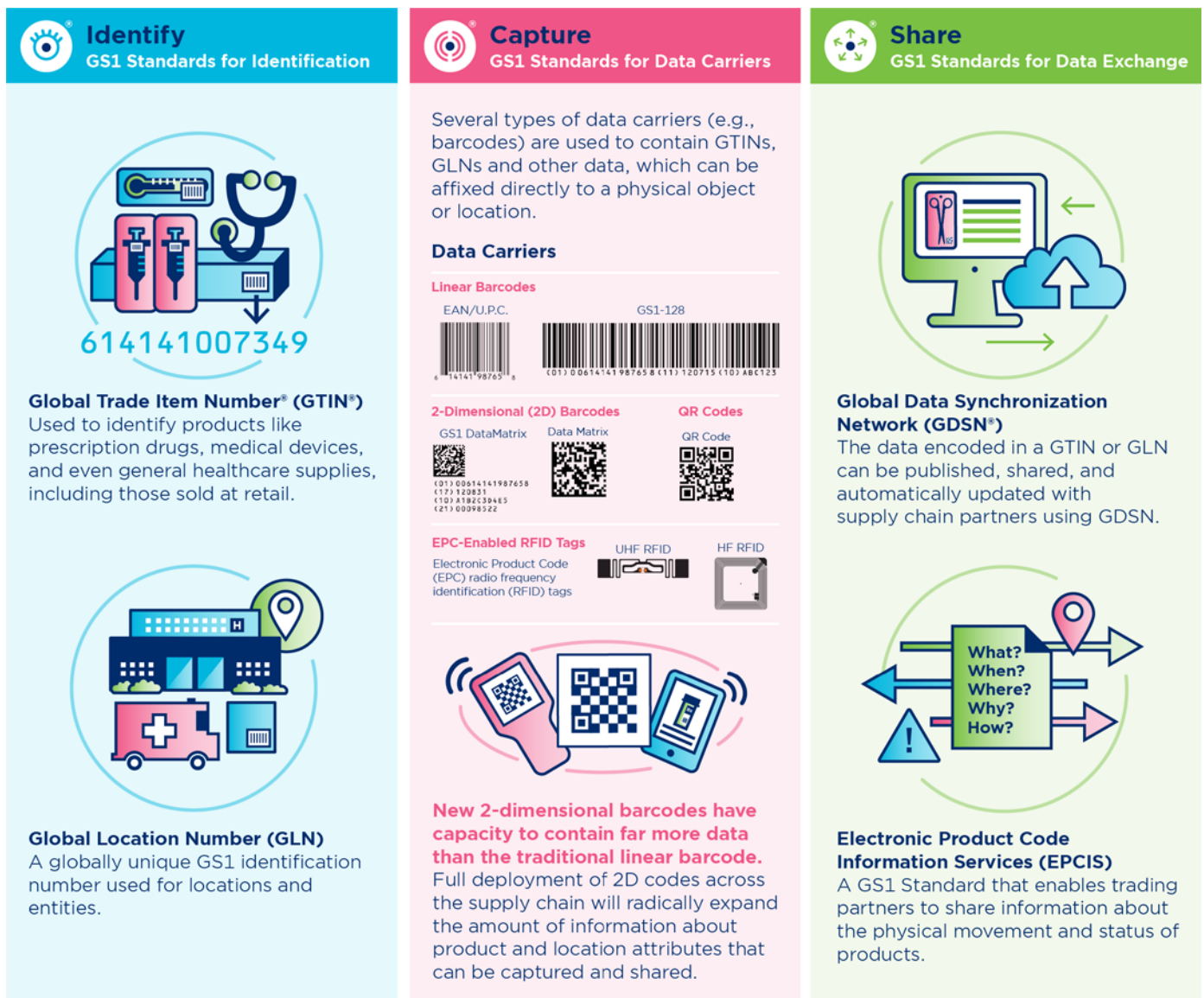
- Fewer medication or device errors
- More effective product recalls
- Efficient traceability of drugs and devices
- Inventory visibility
- Authentication to eliminate counterfeit products
- Rapid extraction of useful information to effectively address adverse events
- Cost reduction through increased supply-chain efficiency
- Improved processes for ordering, invoicing, receiving and inventory
- Support for regulatory compliance

3 About GS1 Standards

The GS1 System of Standards is an integrated suite of global standards for “unique identification” of companies, products, assets, services and locations, among other things. As in the U.S., GS1 Standards are recognized for unique product and location identification in hundreds of countries worldwide. For companies serving global markets, this means supply chain data can be interchangeably used everywhere they do business, and global integration of these standards will further enhance supply chain coherence and benefits. The GS1 Company Prefix, a unique number assigned and licensed by GS1, uniquely identifies your company and is needed to create GTINs, GLNs, Serial Shipping Container Codes (SSCC) and other GS1 identifiers. Two types of prefixes are provided by GS1 US under one licensing agreement – the GS1 Company Prefix and the U.P.C. Company Prefix.

Together, GS1 Standards create a common foundation for businesses to uniquely identify, accurately capture and automatically share vital information about products, locations, assets and more. Figure 3-1 highlights just a few of the key GS1 Standards for Healthcare.

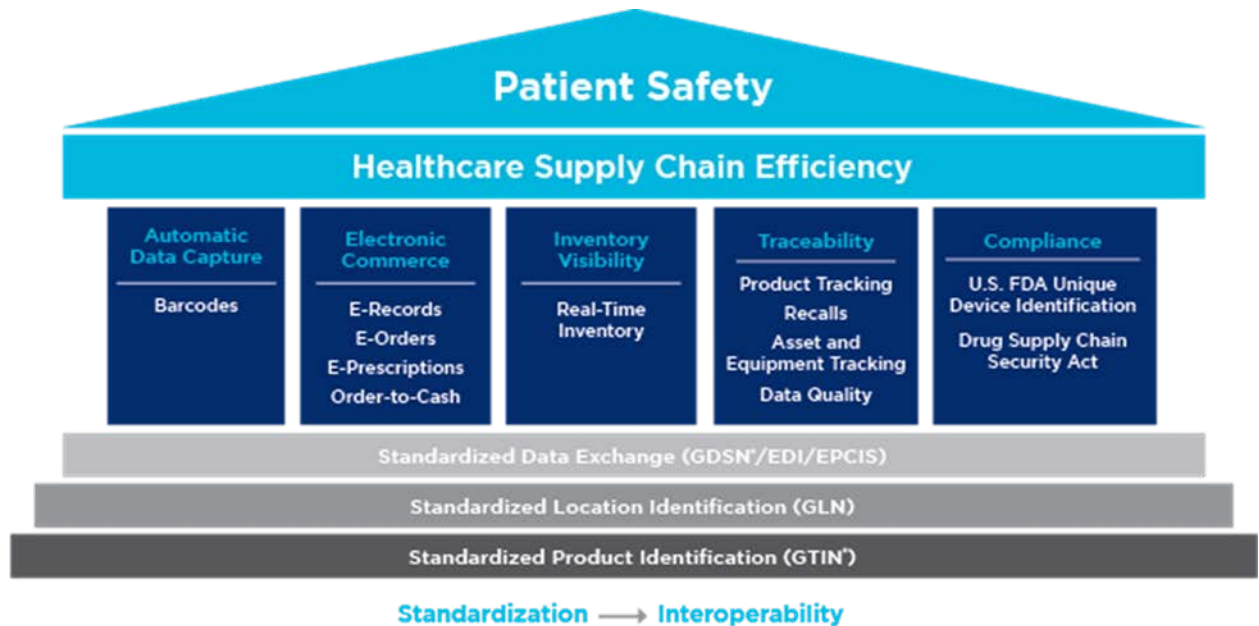
Figure 3-1 Key GS1 Standards for Healthcare



4 The Foundation of GS1 Standards

The “house” in Figure 4-1 represents the connection between the standards and how they support the healthcare supply chain. The roof of the house represents the ultimate goals: supply-chain efficiency and patient safety. To raise that roof and achieve those goals, the healthcare supply chain needs a strong foundation and pillars of support.

Figure 4-1: Healthcare Foundation



The *foundation* is the basis on which the pillars and the entire house are built. To achieve supply-chain efficiency and patient safety -- the ultimate goals in our house example -- a strong foundation is built with global standards that can be used by all supply-chain partners regardless of industry sector or location. Standardized product identification (GTINs), location information (GLNs) and data exchange platforms (GDSN/ EDI/ EPCIS) provide a solid foundation by fostering consistency and accuracy in supply-chain information.

Pillars are built on the foundation to raise the house and support the roof. The pillars in Figure 1 represent the numerous and ever-evolving tools and applications that healthcare supply chains can use to improve supply-chain management and patient safety. The foundation of global standards provides the basis for developing those tools. Only a house built on a strong foundation of global standards has the interoperability across all supply-chain partners to maximize safety and efficiency.

- The tools and applications represented in the pillars of Figure 1 advance the goals of supply-chain efficiency and patient safety by improving healthcare business processes.
- Automatic Data Capture (e.g., scanning a barcoded GTIN on a bottle of medication or hospital room) replaces manual data entry, reducing human error and expediting the process of recording information.
- E-Commerce replaces paperwork with automated transactions that are more efficient and accurate.
- Inventory visibility provides real-time access to inventory information across the supply chain.

- Traceability to support product tracking through the supply chain, asset and equipment tracking to quickly locate critical assets (e.g., IV pumps, blood pressure monitors, wheelchairs, etc.), reduce the risk of counterfeit goods and to support product recalls.
- Compliance applications relative to regulations such as the FDA Unique Device Identification requirements and the Drug Supply Chain Security Act (DSCSA) requirements and the Drug Supply Chain Security Act (DSCSA) Unique Device Identifiers.

In this document we dive into some of the details that make GTINs and GLNs for the unique identification of trade items and locations so useful in healthcare.

GS1 US and the Healthcare industry have published a significant level of detail on the topic of standards for sharing data about trade items and locations using GS1 sharing standards like Global Data Synchronization Network (GDSN) and Electronic Product Code Information Services (EPCIS) in separate documents. Please refer to the “References” Section at the end for a list and links to those resources.

4.1 The Global Trade Item Number (GTIN)

The GS1 GTIN is a globally unique identification number that refers unambiguously to a single product. Embedded in a barcode, the GTIN enables products to be accurately tracked, traced and specifically recognized by all trading partners throughout the supply chain.

GTINs can be assigned and used across business sectors anywhere in the world, so healthcare manufacturers can use the same identifier with all their customers regardless of region or sector.

The use of GTINs for product identification can solve a multitude of problems, benefiting the entire healthcare system, all the way to the patient.

Table 4-1: How GTINs Benefit Healthcare

Suppliers	Providers	Patients
<ul style="list-style-type: none"> ■ Improves accuracy in orders, invoices, returns and recalls ■ More accurate inventory management ■ Fewer mistakes and disputes ■ Improves efficiency ■ Reduces labor costs ■ Enhances customer satisfaction and competitive advantage ■ Interoperable across supply chains ■ Improves pricing accuracy ■ More efficient payment and reporting processes ■ Streamlines chargeback and rebate processing for better cash flow ■ Improved information quality ■ Compliance with regulations 	<ul style="list-style-type: none"> ■ More accurate, proactive inventory management ■ Sustainable, reliable ordering systems ■ Ability to leverage United Nations Standard Products and Services Code (UNSPSC) to establish ordering patterns ■ Improves accuracy in product returns, recalls and expirations ■ Enhances ability to identify costs and efficiently manage inventory ■ Eases cash flow issues and lowers supply chain costs ■ Allows more efficient use of clinical professionals’ time ■ Use of GTINs in BPOC systems facilitates identification of products used/ administered at bedside to ensure they are correct ■ Improves medical device reporting 	<ul style="list-style-type: none"> ■ Supports assurance of the 5 Patient Rights, enabling accurate identification of the right product for the right patient at the right time ■ Enables reliable tracking of products for patient use and follow-up ■ Helps ensure that recalled or expired products are not inadvertently used at point of care or sold to patients ■ Reduces medication errors

For details on assigning GTINs, please refer to these and other documents available from GS1 and GS1 US:

- [An Introduction to the Global Trade Item Number](#)
- [GS1 Healthcare GTIN Allocation Rules Standard](#)

4.2 The Global Location Number (GLN)

Locating products is just as important as understanding what they are. A GLN is a globally unique identification number assigned to a single entity (e.g., company) or location (e.g., distribution center, building, even a specific supply closet). It facilitates accurate tracking of products wherever they are in the supply chain or at point of use. The attributes defined for each GLN (e.g., name, address, location type) ensure that it is specific to one exact, unique location in the world. The GLN can be used to identify:

- A functional entity (e.g., a hospital pharmacy or accounting department)
- A physical entity (e.g., a warehouse or hospital wing or even a nursing station)
- A legal entity (e.g., a health system corporation)

When GTINs are captured at any point in the supply chain, the products can be positively located by the GLN assigned to that place.

GLNs are used whenever trading partners communicate business transactions. Here are some more specific examples of when it is used:

- Ordering products
- Processing supply-related order and invoicing inquiries
- Claiming manufacturer rebates
- Corresponding with suppliers
- For all other standard business transactions with manufacturers, distributors, group purchasing organizations, or any other stakeholder across the supply chain
- Using the supplier's GLNs as the standard supplier identification number within your purchasing, accounts payable, and in other systems where exact supplier information must be used is recommended. It will improve your pricing accuracy and revenue, eliminate the need to maintain thousands of proprietary supplier numbers, and improve the accuracy of your GPO sales reports.

Table 4-2: How GLNs Benefit Healthcare

Suppliers	Providers	Patients
<ul style="list-style-type: none"> ■ Enable healthcare suppliers to maintain and manage precise information for all of their various corporate identities and physical locations, as well as those of their customers and suppliers ■ Supports efficient exchange of accurate party/location information for supply chain communications, deliveries, rebates and claims ■ Enhances customer satisfaction ■ Promotes more efficient business practices and helps to drive down supply chain costs ■ Streamlines chargeback and rebate processing for better cash flow ■ More efficient payment and reporting processes ■ Reduced labor costs 	<ul style="list-style-type: none"> ■ Identifies locations like warehouses, ancillary facilities, even supply closets, and tie those locations to the products contained within (or moving through) them ■ Enables clinicians to more easily obtain and find necessary supplies ■ Improves ordering and inventory accuracy ■ Improves operational efficiencies ■ Enhances patient satisfaction and success rates. ■ Clear visibility on when to order more or move supplies from one facility to another to share resources. 	<ul style="list-style-type: none"> ■ Supports assurance of the 5 Patient Rights, enabling accurate identification of the right product for the right patient at the right time ■ Reduces medication errors

<ul style="list-style-type: none"> ■ Improves order accuracy ■ Facilitates contract pricing ■ Improved information quality ■ Enables identification of redundant business practices and inefficiencies 	<ul style="list-style-type: none"> ■ “Hoarding” of supplies is reduced as hospital staff understand they will be able to access what they need to deliver care, when they need it. ■ In the event of a recall or other problem, the products impacted can be quickly located and pulled from inventory, avoiding inadvertent use. 	
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For details on assigning and sharing GLNs, please refer to these and other documents available from GS1 and GS1 US:

- [An Introduction to the Global Location Number \(GLN\)](#)
- [GS1 GLN Allocation Rules](#)
- [GS1 US Data Hub Location](#)

4.3 Business and Financial Benefits of Standards in Healthcare

Improving quality of care and patient safety, operational efficiencies, and track-and-traceability of healthcare products are reasons enough to embrace full adoption of GS1 Standards. We now know these improvements are desperately needed, and regulatory requirements for unique identification of medical devices (UDI) and prescription drugs (DSCSA) add further urgency to the mission.

Beyond addressing these crisis points, full standards implementation will deliver even more benefits and contribute to your organization’s financial health in the following ways:

- Scanning product barcodes containing GTINs automates the data capture process and reduces errors. For example, inaccurate product information on a purchase order can cause the wrong product or quantity to be shipped; automated data capture assures accurate and complete product information for shipping, activity reports, returns and distribution accuracy.
- Standardized data helps eliminate incorrect or incomplete product information (e.g., unit of measure issues), supporting more efficient and accurate procurement. It improves completeness and accuracy of supplier information and eliminates confusion about product identification.
- The clarity offered by GS1 Standards reduces labor dedicated to tracking product identification numbers, handling product issues or errors, and clinical time related to monitoring products for patient charges and product reordering. Operational efficiencies improve with reduced staff time, improved and expedited recall processes, and improved ability to manage product lots and expirations.
- Using standards may also reduce cybersecurity vulnerabilities and introduction of counterfeit products, improves track and traceability and issue resolution rate, and importantly, it builds trading partner confidence, credibility and trust.
- Most importantly, using supply-chain data standards supports patient care and safety by allowing product information to be included in clinical records in a standardized, actionable manner. This enables quicker, more precise and efficient management of product recalls and expirations; follow-up evaluation of medical device efficacy; and better identification and correction of adverse events caused by devices and medications. All this information can be used to support strategic decisions about product sourcing, as well as patient monitoring and safety.

5 Implementing GS1 Standards in Your Organization

Implementing GTINs and GLNs provides the essential foundation for larger initiatives aimed at improving efficiency, as well as supporting patient safety, product efficacy and value-based analysis. The standards also support supply-chain management initiatives aimed at better visibility and cost management for both manufacturers and healthcare providers. It is crucial for all trading partners to begin with high-quality (accurate, complete and up-to-date) information – so a rigorous data management program is essential.

Using a project management approach, the implementation process should include the following twelve steps:

Table 5-1 Recommendations for Implementation

1.	Establish Executive support
2.	Form a standards management advisory group
3.	Establish a standards operational team
4.	Develop and initiate project communication
5.	Initiate education for advisory group and operational teams
6.	Assess information system issues and make necessary changes
7.	Identify / allocate GTINs and GLNs
8.	Establish implementation strategy
9.	Engage customer involvement
10.	Conduct transactional testing with trading partners
11.	Make adjustments to initial implementation plan
12.	Create standard operating procedures

Adoption and use of GTINs and GLNs is not a “once and done” effort. Collaboration and coordination with your customers and suppliers will be necessary. Detailed guidelines for implementation of GTINs and GLNs in healthcare are also available:

- GTIN Adoption and Usage Model – Implementation Roadmap for U.S. Healthcare
- GS1 GLN Allocation Rules

6 Conclusion

Healthcare is a dynamic, complicated, life and death business that relies on a vast and diverse network of suppliers, distributors and clinical organizations to fulfill its purpose. Full adoption of GS1 Standards across the healthcare supply chain will enable transformative improvements that support efficient operations and most importantly, help improve quality of care and patient safety.

It is time for healthcare organizations to prioritize adoption of standards toward these ends. For more information and assistance with GS1 Standards implementation, please visit www.gs1us.org or contact GS1 US at info@gs1us.org. Comprehensive resources are available – and our industry experts are here to help.

7 Glossary

Term	Definition
AI	Acronym for Application Identifier (defined below).
Application Identifier (AI)	The field of two or more digits at the beginning of an element string that uniquely identifies its format and meaning within the GS1 System.
Attribute	A piece of information reflecting a characteristic of the object to which an identification number (i.e., GLN, GTIN, etc.) relates.
Barcode	A precise arrangement of parallel lines (bars) and spaces that vary in width to represent data.
Company Number	A number allocated by the GS1 Numbering Organization. It is combined with the GS1 Prefix (for the GS1 Member Organization) to create the GS1 Company Prefix. The GS1 Company Prefix (i.e., the GS1 Prefix + the Company Number) uniquely identifies a healthcare provider or supplier.
Data Carrier	A physical or electronic mechanism that carries data (e.g., a barcode or RFID tag).
Data Format	Required structure for the numerical string of a GS1 Identifier (e.g., text, length, spacing, punctuation, etc.)
Data Standard	The entirety of all GS1 System data standardized in meaning and structure.
Data Structure	The GS1 System data structures defined in the various lengths required for the different identification purposes, which all share a hierarchical composition. Their composition blends the needs of international control with the needs of the user.
EDI	Acronym for Electronic Data Interchange (defined below).
Electronic Commerce	A method of business communications and management using electronic methods, such as electronic data interchange and automated data collection systems.
Electronic Data Interchange (EDI)	The computer-to-computer exchange of structured information, by agreed message standards, from one computer application to another by electronic means and with minimal human intervention.
GLN	Acronym for the GS1 Global Location Number (defined below).
Global Trade Item Number (GTIN)	The globally unique GS1 System identification number for products and services. A GTIN may be 8, 12, 13, or 14 digits in length, represented as GTIN-8, GTIN-12, GTIN-13, and GTIN-14 respectively.

Term	Definition
Global Location Number (GLN)	The globally unique GS1 System identification number for legal entities, functional entities, and physical locations. The GLN is 13 digits, comprised of a GS1 Company Prefix, Location Reference and Check Digit. Supply-side trading-partner locations generally include corporate headquarters, regional offices, warehouses, plants, and distribution centers. Demand-side trading-partner locations generally include corporate headquarters, divisional offices, stores and distribution centers.
GS1 Company Prefix	A globally unique number assigned to companies/organizations by GS1 Member Organizations to create the identification numbers of the GS1 System. It is comprised of a GS1 Prefix and a Company Number.
GS1 System	The specifications, standards, and guidelines administered by GS1. GS1, through the Global Standards Management Process, manages the GS1 System to maintain the most implemented standards in the world.
GS1-128 Barcode Symbol	A subset of the Code 128 Barcode Symbol that is utilized exclusively for GS1-defined data structures. UCC/EAN-128 symbols can be printed as stand-alone linear symbols or as a composite symbol with an accompanying 2D Composite Component printed directly above the GS1-128 linear component.
GTIN	Acronym for the GS1 Global Trade Item Number (defined above).
Identification Number (ID)	A numerical designation that uniquely identifies an object in the supply chain. Identification numbers are used to retrieve information previously exchanged between trading partners and stored in their computer database files.
Global Location Number	See GLN (defined above).
Location Reference	A number within a GLN assigned by various parties to identify a different entity.
Party	A Party (or location) is any legal, functional or physical entity involved at any point in any supply chain and for which there is a need to retrieve pre-defined information. A Party is uniquely identified by a Global Location Number (GLN).
Supply Chain Partner	A party to transactions in the supply chain, such as a supplier (seller) or a customer (buyer).
Trade item	Any item (product or service) from which there is a need to retrieve pre-defined information and that may be priced or ordered or invoiced at any point in any supply chain.
U.P.C. symbol	A barcode symbol that encodes the GTIN-12, Coupon-12, RCN-12, and VMN-12.
United Nations Standard Products and Services Code (UNSPSC)	An open, global, multi-sector standard for efficient, accurate classification of products and services, managed by GS1 US for the United Nations Development Programme. Companies and organizations use the UNSPSC to analyze various procurement and purchasing functions to reduce organizational costs and improve supply-chain efficiencies. The United Nations Standard Products and Services Code structure has four categories: Segment, Family, Class, and Commodity.
UNSPSC	Acronym for the United Nations Standard Products and Services Code (defined above).



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IAPMO

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