

Improving Patient Safety and Supply Chain Efficiency with GS1 Standards in

HEALTHCARE



THE GLOBAL LANGUAGE OF BUSINESS



Together, we're making it possible to follow drugs and medical devices from the manufacturer to the patient, improving efficiency, safety, and patient care.

GS1 STANDARDS IN HEALTHCARE

Challenges Facing the Industry Today

IMPROVING QUALITY AND PERFORMANCE

In today's changing landscape, U.S. healthcare providers must transform their delivery systems to provide value, quality, and safe care; eliminate waste and inefficiencies; achieve financial sustainability; and leverage information technologies to improve performance. Hospitals are using GS1 Standards to ensure the reliability of data and optimize processes to reduce preventable errors, enhance Electronic Health Record management, support outcome-based medicine and comparative effectiveness, and provide transparency for better clinical and supply chain margin management.

ENSURING REGULATORY COMPLIANCE

The Drug Supply Chain Security Act is top of mind for the pharmaceutical industry. The new FDA Unique Device Identification (UDI) regulation is at the forefront in the medical device arena as companies need to transform disparate medical identification methods into a standardized UDI system. GS1 is an FDA-Accredited Issuing Agency for UDI and GS1 Standards are authorized for use by manufacturers for UDI implementation. On both fronts, the industry is leveraging GS1 Standards and the support of GS1 Healthcare US* to prepare for these new requirements and assist with regulatory compliance.



GS1 STANDARDS IN HEALTHCARE

Moving Forward Together with GS1 Healthcare US

Since 2008, GS1 Healthcare US members have been driving the adoption and implementation of GS1 Standards to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the industry to address the supply chain issues that most impact healthcare in the United States using GS1 Standards as the foundation for improved business and care delivery processes.

KEY FOCUS AREAS

- Location identification using GS1 Global Location Numbers (GLNs)
- Product identification using GS1 Global Trade Item Numbers (GTINs)
- Product data sharing with GS1 Global Data Synchronization Network™ (GDSN*)
- Unique device identification for medical devices
- Product serialization, track and trace, and drug pedigree processes using GS1 Visibility standards

KEY BENEFITS

- Improving patient safety
- Lowering costs through increased efficiency
- Reducing medication errors
- Enabling supply chain visibility
- · Facilitating effective product recalls
- Tracking of pharmaceutical products/medical devices
- Reducing introduction of counterfeit products
- Enhancing inventory management
- Linking critical product data to the patient record
- Supporting regulatory compliance
- Optimizing order, invoice, sales reporting, and chargeback/rebate processes

Patient Safety

Healthcare Supply Chain Efficiency

CAPTURE
Barcodes
RFID

E-COMMERCE EDI/XML Transactions ELECTRONIC RECORD
MANAGEMENT
e-Records
e-Prescriptions

COMPLIANCE
FDA Unique Device
Identification (UDI)
Drug Supply Chain
Security Act

TRACEABILITY
E-Pedigree
Recalls
Assets &
Equipment
Tracking

STANDARDIZED PRODUCT DEFINITION (GDSN')

STANDARDIZED LOCATION IDENTIFICATION (GLN)

STANDARDIZED PRODUCT IDENTIFICATION (GTIN')



STANDARDIZATION ····· INTEROPERABILITY







GS1 Standards for identifying, capturing, and sharing information —

about products, business locations, and more—

make it possible for companies to speak the same language, connect with each other, and move their business forward.



IDENTIFY **GS1 IDENTIFICATION NUMBERS**

GS1 Standards begin with GS1 Identification Numbers used to uniquely distinguish all products (trade items), logistic units, locations, assets, and relationships across the supply chain from manufacturer to consumer.

These numbers provide the link between the item and the information pertaining to it.

GS1 STANDARDS IN HEALTHCARE

COMPANY

Global GS1 Company Prefix

GLN

Global Location Number

PRODUCT

GTIN®

Global Trade Item Number®

EPC®/SGTIN

Serialized Global Trade Item Number

ASSETS

GIAI

Global Individual Asset Identifier

GRAI

Global Returnable Asset Identifier

LOCATION

GLN

Global Location Number

LOGISTICS

SSCC

Serial Shipping Container Code

GSIN

Global Shipment Identification Number

SERVICES AND OTHER

GSRN

Global Service Relation Number

GDTI

Global Document Type Identifier

GLN

GTIN

GTIN SSCC SSCC

GLN

SSCC

GLN

GTIN

GTIN

GLN



























MANUFACTURER

ITEM

CASE

PALLET

TRANSPORT

DISTRIBUTOR/ WHOLESALER TRANSPORT

PALLET

DISTRIBUTION CENTER

TRANSPORT

CASE

ITEM

PROVIDER



CAPTURE GS1 DATA CARRIERS

GS1 Data Carriers are capable of holding varying amounts of data to accommodate different needs for different products.

The data encoded in GS1 Data Carriers not only uniquely identifies products at every level of packaging, it provides access to product information and visibility of product movement through the supply chain.

GS1 STANDARDS IN HEALTHCARE



ITEM

BARCODES

Carries a Global Trade Item Number (GTIN)

EAN/UPC*







(21)00098522



*For products that are also sold at retail.

AND (optional)

EPC-ENABLED RFID

Carries a Serialized GTIN (SGTIN)

UHF RFID



HF RFID





Radio Frequency Identification (RFID) tags are read quickly and easily without requiring a point of sight and carry data that can be added to or modified as the tagged item moves.

The EPC (Electronic Product Code) encodes GS1 Identification Numbers like GTINs, GLNs, and SSCCs and allows them to be carried on RFID tags.

The appearance of the EPCglobal* Seal is to inform that an EPC-Enabled RFID tag is present on or within the packaging of the product(s).



CASE

ITF-14

Carries a GTIN



Used to uniquely identify bulk units such as cartons, cases, or pallets and help manage fast and accurate tracking of inventory. This barcode only encodes a GTIN and is not intended to pass through retail point of sale.

OR

GS1-128

Carries a GTIN with extended data or a Serial Shipping Container Code (SSCC)



This barcode enables the encoding of data in addition to a GTIN including Expiration Date, Batch/Lot and Serial Number, Weight, etc.

AND (optional)

EPC-ENABLED RFID

Carries an SGTIN or an SSCC

UHF RFID



HF RFID



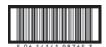
The appearance of the EPCglobal Seal is to inform that an EPC-Enabled RFID tag is present on or within the packaging of the product(s).



PALLET

ITF-14

Carries a GTIN



OR

GS1-128

Carries a GTIN or an SSCC



AND (optional)

EPC-ENABLED RFID

Carries an SGTIN or an SSCC

UHF RFID







The appearance of the EPCglobal Seal is to inform that an EPC-Enabled RFID tag is present on or within the packaging of the product(s).



MASTER DATA

GDSN

Global Data Synchronization Network

The GDSN connects trading partners to the GS1 Global Registry* via GS1-certified data pools, enabling the immediate electronic sharing of standardized, up-to-date, accurate product information.

GLN REGISTRY

The GLN Registry is the single source of truth for accurate and up-to-date location information for healthcare and healthcare-related facilities in the U.S. with corresponding GLNs.

WHAT GOES INTO IT

GTINs

Product Descriptions
Product Classification
GLN of Brand Owner

GLNs for:

- Ship-To/From
- Bill-To
- Deliver-To

GS1 STANDARDS IN HEALTHCARE

TRANSACTIONAL DATA

EDI

Electronic Data Interchange

EDI enables the computer-to-computer exchange of business documents between companies using a standardized format.

WHAT GOES INTO IT

GTIN GLN SSCC

EDI DOCUMENT TYPES

Purchase Order Advance Ship Notice Invoice Payment

PHYSICAL EVENT DATA

EPCIS

Electronic Product Code Information Services

EPCIS is the standard for sharing information about the movement and status of goods in the physical world.

WHAT GOES INTO IT

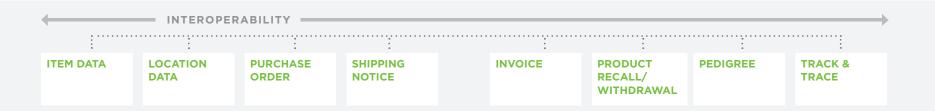
Who GLN

What GTIN or SSCC

Where GLN

When Date & Time Stamp
Why Business Step &

Product Disposition





Across the supply chain, trading partners are connecting with each other and leveraging the power of information by using GS1 Standards as the foundation of their business processes.



Manufacturer Headquarters

IDENTIFY

- GTINs are created for each product (Each level, Shelf-pack level, and Case level)
- · Product master data is defined, created, and managed
- · Company GLNs are assigned and managed
- Validated customer GLNs are collected and stored.

SHARE

- EDI processes are synchronized with GLN and GTIN
- Entity/Location data is shared through the GLN Registry
- Product data is shared through the GDSN
- Orders are managed
- Data is stored in Enterprise Resource Planning (ERP) system
- GTINs are used for recall process at every level of packaging

BENEFITS

Improves order, inventory, and invoice accuracy Enables compliance with contractual requirements of customers



GLN Global Location Number 0614141000029



CASE LEVEL IDENTIFICATION

GTIN and Extended Data









PALLET LEVEL IDENTIFICATION

SSCC



Manufacturer Factory

IDENTIFY

- · Pallet makeup is defined, created, and managed
- · SSCCs are created for each pallet shipped

CAPTURE

- GTINs with extended data (e.g., lot number, expiration date, serial number) are printed on products (barcode and human readable) or tagged for Each level, Shelf-pack level, and Case level
- SSCCs are printed on shipping labels
- GTINs are used to track products during manufacturing for internal processes
- GTINs and SSCCs are used to track contents of shipments

SHARE

- Production order and GTINs are pulled from ERP system
- Manufacturing data (GTIN and extended data) is stored in ERP system

BENEFITS

Provides the foundation for patient safety, product traceability, and recalls

Facilitates accurate tracking of inventory



Manufacturer Distribution Center

IDENTIFY

• Shipping unit content is barcoded and tracked with SSCC (pallet license plate)

CAPTURE

INBOUND

 GTINs/SSCCs and Advance Ship Notices (ASNs) are used for receipt verification

OUTBOUND

- GTINs are used to assure accuracy of picked products
- GTINs with extended data or SSCCs are used to track shipping unit

SHARE

- ASNs containing GTINs, SSCCs, and GLNs are sent to customers
- Inventory and delivery information is stored in ERP system
- GTINs are used for recall process at every level of packaging

BENEFITS

Facilitates accurate tracking of sales

Ensures delivery of the right products to the right locations

Initiates pedigree

LOCATION IDENTIFICATION **GLN** Global Location Number 1100003974533

Healthcare Distributor

IDENTIFY

- · Company GLNs are assigned and managed
- · Validated customer GLNs are collected and stored

OUTBOUND

• Distributor's SSCCs are created for each pallet shipped

CAPTURE

INBOUND

- GTINs/SSCCs and ASNs are used for receipt verification
- GTINs are used to put products into inventory

OUTBOUND

- Manufacturer-assigned GTINs with extended data are used to rotate inventory for quality control processes
- GTINs are used to ensure accuracy of picked products
- SSCCs are used to track shipping unit

SHARE

- Entity/Location data is shared through the GLN Registry
- Product data is shared through the GDSN
- EDI processes are synchronized with GLN and GTIN
- ASNs containing GTINs, SSCCs, and GLNs are sent to customers
- Inventory and delivery information is stored in ERP system
- GTINs are used for recall process at every level of packaging

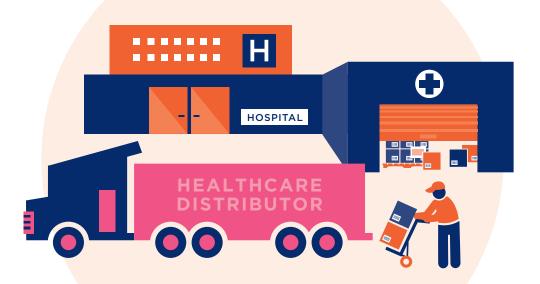
BENEFITS

Ensures delivery of the right products to the right locations Improves throughput efficiencies

Facilitates accurate tracking of sales

LOCATION IDENTIFICATION

GLN Global Location Number 0123456000001



Hospital Receiving

IDENTIFY

- GLNs are assigned and managed at Corporate
- Validated supplier and internal hospital GLNs are collected and stored

CAPTURE

- GTINs/SSCCs are used at the point of receipt to validate delivery accuracy
- GTINs and internal hospital GLNs are used to put products into inventory

SHARE

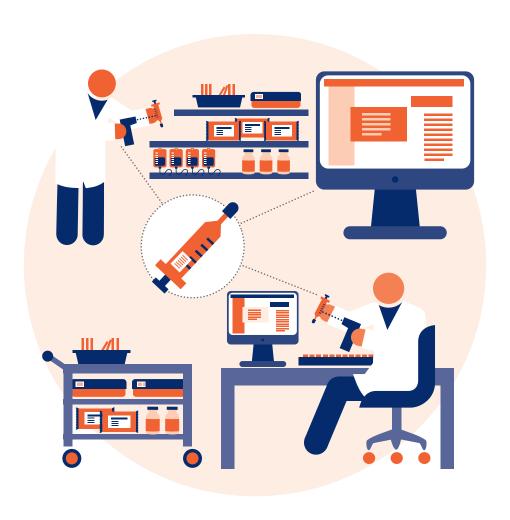
- · ASN is received from supplier
- Inventory and delivery information is stored in ERP system
- GTINs are used for recall process at every level of packaging

BENEFITS

Improves internal distribution processes

Reduces accounting costs

Maintains chain of custody through automated processes Provides accurate contract pricing and rebate processing



Hospital Store Room

CAPTURE

INBOUND

- GTINs are used at the point of receipt to validate delivery accuracy
- GTINs are used to put products into inventory

OUTBOUND

- Manufacturer assigned GTINs with extended data are used to rotate inventory, for quality control processes, and to help search for products in hospital's MMIS system
- GTINs are used to pick products for various departments throughout the hospital system

SHARE

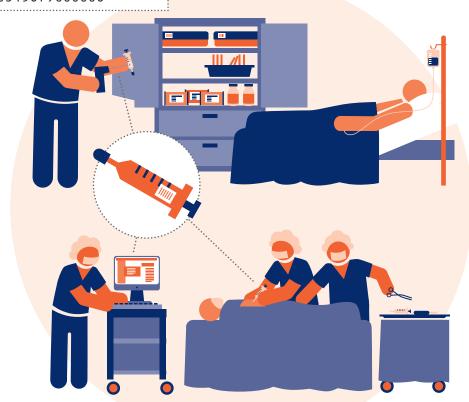
- GTINs are used to order and track medical devices for use in labs, pharmacies, storage locations, and in-patient care
- GDSN product data is used to populate the item master file
- GTINs are used to drive inventory replenishment via EDI or paper transactions
- GTINs are used for recall process at every level of packaging

BENEFITS

Reduces unnecessary inventory levels Enhances equipment and instrument tracking Improves service levels/fill rates

LOCATION IDENTIFICATION

GLN Global Location Number 0345679000006



LOCATION IDENTIFICATION

GLN Global Location Number 0345678000007

Hospital Patient Room/Operating Room

CAPTURE

- Patient/Operating Room GLN is captured
- GTINs with extended data on product packaging are scanned at point of care capturing critical information to enable patient safety, clinical, financial, and supply chain processes
- Products (GTINs with extended data) used in the operating room during the procedure are documented on the patient's chart

SHARE

- Data is shared across hospital information systems:
 - Inventory Management and Replenishment
 - Patient Charge Records
 - Electronic Health Record
 - Accounting
- GTIN data is tracked from the point of order to the patient
- Allows for final check of recalls, expiration, etc.

BENEFITS

Improves management of the Electronic Health Record Increases accuracy of charge capturing

Supports patient rights

GS1 STANDARDS IN HEALTHCARE

GS1 Healthcare US Now is the time to get involved!

Become a Member of GS1 Healthcare US

As a member of GS1 Healthcare US, you will play an active role in driving adoption and use of GS1 Standards in the U.S. by working with other industry members through community groups, workgroups, and task groups to improve patient safety and supply chain efficiency.

GS1 Healthcare US Community Groups

The GS1 Healthcare US Community Groups provide a member-only forum to facilitate standards-related discussions and address the impact of standards on specific communities, business practices, legislation or regulation, and opportunities for standards usage.

- Healthcare Provider Community Group
- Medical Device Community Group
- Pharmaceutical Community Group

GS1 Healthcare US Workgroups And Task Forces

Members may also participate in our targeted workgroups and task forces to develop implementation guidelines, business cases, roadmaps, best practice guides, and education to enable industry-wide adoption.



GET STARTED TODAY

Visit the GS1 US website for:

- Industry Sunrise Dates and Scorecards
- Information about GS1 Standards
- FDA UDI and Drug Supply Chain Security Act Support
- Tools and Resources: Tool Kits, Implementation Resources, and Case Studies
- Education: Webinars and Industry Calls
- Members, Advocates, and Partners
- Events: Workshops and Workgroup Forums

www.gs1us.org/healthcare

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CONTACT US TO FIND OUT HOW GS1 US CAN HELP MOVE YOUR BUSINESS FORWARD.



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