Healthcare Quick Start Guide

For implementing the GS1 Global Data Synchronization Network (GDSN) in Healthcare

If your company is looking to access and improve your trading partner data and share accurate, reliable, complete and timely data about the products that you trade or use, this Quick Start Guide will help you get started today.

It provides a brief overview of the steps and resources needed for a successful implementation of the GS1 Global Data Synchronization Network™ (GDSN®) for medical device and/or pharmaceutical products. This Quick Start Guide serves as a starting point to other GS1 Healthcare US GDSN documents.

Implementation Steps for GDSN in Healthcare

1. Document Your Use Case

Manufacturers, labelers, wholesale distributors, and healthcare providers can all benefit from accurate, complete, and timely data across a myriad of supply chain business processes. It is important to understand the opportunities that can be addressed by implementing GDSN as a trusted source of healthcare product data. All core business processes require at least some basic information about the healthcare products being traded and used throughout the supply chain. From new product setup, through order-to-cash, through patient use and, ultimately, for analytics and decision making, information about healthcare products is required. And what specific information is required will vary based on the process being undertaken. Establishing baseline metrics in the areas where improvement could be gained is essential. These baselines will help an organization identify areas of need and develop a roadmap for product data requirements.

Once there is a business process roadmap then each use case becomes an opportunity to access those pieces of data about healthcare products that are required to support the use case.
2. Establish a Project Team

A cross-functional project team is crucial for successfully implementing GDSN in healthcare. Consider representation from the following organizational areas:

- Supply Chain
- Information Technology
- Data Governance, Master Data Management
- Operations and Business Process Experts
- Office of Information Security
- Customer Service
- Quality Assurance
- Public Relations
- Sales and Sales Operations
- R & D, Packaging, and Product Development
- Specs and Labeling
- Legal — Service Contracts, System Integrity, etc.
- Regulatory
- Clinical
- Product Management
- Marketing

Inform other trading partners of the effort you are undertaking. Manufacturers, group purchasing organizations (GPOs), distributors/wholesalers, providers/end users, and solution providers all need to be aware of, and potentially involved in, the effort as they will likely be impacted by it.

3. Engage Your Data Pool Provider

Choosing a data pool provider, if your organization doesn’t already have one, is an important decision. In many instances other areas of your organization may already be providing, or sourcing data, via GDSN. Areas such as housekeeping or foodservice within a hospital provider, for example, may already have established GDSN relationships with their trading partners. Manufacturers that have a strong retail presence within certain product divisions may already be sharing product data via GDSN to their retail trading partners.

It’s a great time to find out if these relationships already exist and to leverage the experiences of these colleagues.

If you are a member of a GPO, then consider that they may also be able to provide assistance or direction on choosing a data pool. It is important to consider your long-term strategy for sharing data with your trading partners. Do not limit your evaluation of data pool services to just those that support one aspect of your transactional or operational areas.

GDSN data pools must be certified and capable of the sharing of data via all GDSN-certified data pools. There is no requirement for you to select the same data pool that your key trading partners are using. All certified data pools are able to interact with all other certified data pools through GDSN. However, most data pool providers offer services or tools that add industry-specific value to the base GDSN service, so, it is important to understand your needs and develop a request for proposal (RFP) that can be presented to interested parties. This will help establish a common baseline for the services your organization requires. If you are unsure of what to ask, consider the How to Select a GDSN-certified Data Pool resource.

4. Understand and Define Required Attributes

Part of your business process roadmap from Step 1 above should include an assessment of each business process. For each business process, your project team will need to identify and define the data elements necessary to support that process. You will probably see that there is a core set of product attributes, which cross many of your roadmap processes. It is also likely that these common data elements will be part of the recommended “core” set of data elements for U.S. healthcare trading partners. (See Creating the Case for Trusted Data - Attribute Lists and Implementation Insights from Three Healthcare Business Process Cases Using GDSN.)

It is the recommendation of the GS1 Healthcare US GDSN Vital Attributes Workgroup that everyone who reads this Quick Start Guide also review this complementary resource as well as the other resources cited.

5. Understand and Define Technology Mapping Requirements

Determine your organization’s technology “readiness” for implementation and use of GS1 Global Trade Item Numbers (GTINs) and their associated data elements, including the existence and accurate definitions of placeholders in item master files and downstream business systems.

Your organization, as the initiating entity, should provide a recommended process map to the trading partners with whom you intend to engage. Trading partners should agree on the basic outline of the process and data before GTINs and associated attributes are shared. Multiple maps should be considered, including:

- Business process maps (see examples of process maps at the end of this guide)
- List of the products in play and the required data elements, including the product hierarchies
- Understand how data is moved internally between technology systems (Item Masters, Enterprise Resource Planning (ERP), Clinical Inventory Systems, Electronic Health Records (EHRs), Billing Systems, and Supply Chain/Inventory Systems)
Maps of the flow of information between trading partners throughout the impacted business process including any forms of automated data sharing, such as Electronic Data Interchange (EDI) or GDSN (Manufacturer, Wholesaler/Distributor, Healthcare Provider, Ambulatory Facilities, and GPO).

The degree of detail associated with each map can vary and should be discussed during the project initiation phase.

6. Identify and Connect: Data Source and Data Recipient Global Location Number (GLN) “Handshake”

Identify the key trading partners with whom your organization will want to share data initially. This may be your largest trading partner or you may choose to start with a smaller, lower volume trading partner first. The choice is yours. To share data via GDSN both the data source and the data recipient will need to establish and communicate each organization’s GLN, which serves as the entity identifier for the data messages from the “publisher” (data source) to the “subscriber” (data recipient). The GLN uniquely identifies the data source and the data recipient and forms the basis for “opening the door” to the data to be shared between the two entities.

Share GLNs with your trading partners and with your data pools so that a messaging “handshake” can be done to ensure the flow of data.

7. Publish and Subscribe With Test Data

Synchronization between trading partners is essential for using GDSN to share data. It is recommended that trading partners start out by sharing a minimum set of products in a test environment* to work out any bugs on a limited basis before sharing large files.

- Experiment on a single business process with one or two business partners.
- Start small to avoid disrupting your day-to-day process.

8. Establish Steady State—SOPs for Data Sharing and Maintenance

Synchronizing data sharing via GDSN is not a “once and done” exercise. Standard Operating Procedures (SOPs) should be established for the ongoing maintenance and timely sharing of product information. SOPs should include periodic audits of data to ensure that internal data management practices are resulting in complete and accurate data being shared with trading partners or internally across various systems.

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Key Resources

How to Choose a Data Pool - https://www.gs1us.org/documents?Command=Core_Download&EntryId=161

Healthcare Supplier Toolkit for GDSN - https://www.gs1us.org/documents?Command=Core_Download&EntryId=311


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*Since test environments are sometimes not full “copies” of true production environments, not all data pool test environments are “linked.” It is suggested that you confirm the compatibility and use of test environments across the data sharing partners during this step.
These business process flow diagrams are meant to be sample illustrations of a process map. They are not meant to be interpreted as exact instructions.
### Device/Product Recall Notices to Users

<table>
<thead>
<tr>
<th>Supplier/Manufacturer</th>
<th>Notation</th>
<th>Evaluation/Documentation</th>
<th>Response</th>
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<tbody>
<tr>
<td>Suppliers issue Recall Notice. Identifiers include manufacturer number, lot, and serial numbers.</td>
<td>Note: Recall notices generated by Manufacturers and Third Party Recall Services. Sent simultaneously to many departments of HCO to assure communication.</td>
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<tr>
<td>Does review of HCO system and paper purchase orders (PO) show confirmation of PO to manufacturer?</td>
<td>Notify HCO Risk Management and legal services</td>
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<td>Does review of paper requisitions or excel show a match of recall to HCO records?</td>
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<td>Most HCO purchasing and materials information systems do not include information for Lot and Serial number for non-stock products so physical review is required following confirmation of PO from manufacturer.</td>
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<tr>
<td>Does review of system receipts show confirmation of receipt from manufacturer?</td>
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<td>Identify item locations for stocked items</td>
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<td>Yes, stocked item</td>
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<td>Entry in EHR and follow recall instructions</td>
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<tr>
<td>Yes, non-stocked item</td>
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<td>Notify departments potentially affected</td>
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<td>Clinical and support staff pull from identified locations and follow recall instructions</td>
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<td>Nurses often send supplies home with patients without documentation of product identifiers; Recall cannot be pursued</td>
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*If applicable