The Global Language of Business

GS1 Healthcare US

Creating the Case for Trusted Data

Attribute Lists and Implementation Insights for Pharmaceuticals under the Drug Supply Chain Security Act (DSCSA)

Release 1.0, August 17, 2022

Table of Contents

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.

Document Summary

Document Item	Current Value
Document Title	Creating the Case for Trusted Data: Attribute Lists and Implementation Insights for Pharmaceuticals under Drug Supply Chain Security Act (DSCSA)
Date Last Modified	August 17, 2022
Document Description	The goal of this document is to help the U.S. healthcare industry understand some of the core challenges that have been impeding the adoption of the GDSN and vital data attributes and help them start to address those challenges so they can experience the benefits of GDSN like other industries. To that end, this document provides a list of GDSN attributes to support their use case, guidance about key issues that arose during the GDSN implementation exercises and recommended next steps to help the industry leverage the GDSN to support their need for quality product information.

1 Executive Summary

Healthcare stakeholders are recognizing trusted product data as a vital asset and discovering that the benefits of consistent, quality data are real, including greater efficiencies, lower costs, and improved patient outcomes. Additionally, in order to achieve the Drug Supply Chain Security Act (DSCSA) requirement of interoperability at the serialized item-level, the structure and content of data must be able to be readily synchronized. All trading partners should be aligned on the format, structure, and content to be exchanged.

The GS1 Global Data Synchronization Network™ (GDSN®) is a standards-based solution that enables trading partners to share product master data in a fully automated way. With GDSN, stakeholders can establish an authoritative data source to align product information across their IT systems and with their trading partners. As many industries have already learned, the GDSN is a valuable tool for promoting and maintaining data quality. In fact, it is a core component of the GS1 US Data Quality Framework.

Nonetheless, implementation of data sharing tools like the GDSN lag across U.S. healthcare. GS1 Healthcare US® engaged with industry stakeholders to understand the dynamics inhibiting healthcare from fully leveraging GDSN to support their need for quality product information, especially for meeting the DSCSA requirements of interoperable traceability at the serialized item level. The first objective was to provide a list of GDSN attributes needed to support pharmaceutical Electronic Product Code Information Services (EPCIS) events for the DSCSA. The second objective was to conduct GDSN implementation exercises with industry members using those attributes.

Major conclusions:

- Lists of core attributes needed to support use cases for the industry to enable GDSN implementation.
  - ***Best Practice Guide for Sharing Vital Attributes for the Drug Supply Chain Security Act (DSCSA)***
  - ***GS1 Healthcare US: Best Practice Guide for Sharing Vital Attributes in Healthcare***
- The GDSN does provide the standardized attributes needed to support healthcare and can be an effective methodology for data sharing that can help promote data quality in healthcare.
- The key obstacle to widespread implementation of GDSN in healthcare specifically for organizations that have products governed by DSCSA is the lack of a clear value proposition for patient care and visibility of the benefits, avoided costs, and efficiency gain when using GDSN as many stakeholders are unaware of the current master data issues, resource consumption, and care of data and maintenance costs to support systems required for DSCSA regulations.

The goal of this document is to help the U.S. healthcare industry understand some of the core challenges that have been impeding the adoption of the GDSN and vital data attributes and help them start to address those challenges so they can experience the benefits of GDSN like other industries. To that end, this document provides a list of GDSN attributes to support their use case, guidance about key issues that arose during the GDSN implementation exercises and recommended next steps to help the industry leverage the GDSN to support their need for quality product information.

Note: As with all GS1 Standards and solutions, this compliance with the recommendations included in this document is voluntary, not mandatory. It should be noted that the use of the words “must” and “require” throughout this document relate exclusively to technical recommendations for the proper application of the standards to support the integrity of your implementation.

GS1 US is not offering legal services or advice on the Company’s compliance requirements with applicable law, nor providing any guarantee or warranty with respect to the Company’s compliance of the same. Each company is individually responsible for meeting all requirements of applicable law for its company and its products. Consult with your company’s legal counsel or compliance team for more specific information about requirements of applicable law.

2 Document Information

2.1 Purpose

The purpose of this document is to:

- Identify the GDSN attributes recommended to support the use case of pharmaceuticals under DSCSA
- Offer insight and recommendations about key topics for GDSN implementation
- Recommend next steps to help drive implementation of the GDSN in U.S. healthcare to support their need for quality product information

2.2 Audience

This document applies to members of the U.S. healthcare industry, including manufacturers, distributors/wholesalers, dispensers, and providers. This document does focus on elements specifically for trading partners managing and supporting products governed by DSCSA.

2.3 Cardinality Terminology for Attributes

For data synchronization, attributes have a characteristic that details whether the attribute must be populated. This characteristic is called “cardinality.” While the GDSN standards specify the baseline cardinality of the attributes overall, the GS1 Healthcare US Pharmaceutical GDSN Workgroup has analyzed and supplemented the cardinality of attributes over and above what is assigned by GDSN were appropriate for meeting the needs for the basic business use cases in scope for the healthcare industry specifically for pharmaceutical products governed by DSCSA. For example, the GDSN may specify an attribute as optional, but the Pharmaceutical GDSN Workgroup may have determined that the attribute should be populated for this specific use case. This determination does not prescribe any need or eliminate the ability to require the population of any attribute by a Data Recipient.

Cardinality term definition provided:

- **Pharma DSCSA Mandatory:** Attribute must be populated in order to load and/or share data via GDSN for products governed by DSCSA

2.4 Role terminology

In referencing various parties, this document uses terminology related to supply chain roles as well as terminology related to a party’s role in the GDSN. To promote clarity, the GDSN roles terminology are defined below:

- **Data Source:** GDSN term for a company loading and publishing data through the GDSN and managing response messages (from their data recipients) through the GDSN. This is usually the manufacturer, but distributors/wholesalers may also be data sources for their downstream partners.
- **Data Recipient:** GDSN term for a company receiving data and responding to the data through the GDSN. This can be a distributor, wholesaler, provider, pharmacy/dispenser, Group Purchasing Organization (GPO), etc.

3 Attribute List for the Use Case of Pharmaceuticals Under DSCSA

This section provides a list of attributes needed to support pharmaceutical traceability at the saleable unit level for the DSCSA (i.e., the use of GDSN to share attributes that would be needed to support an EPCIS event for DSCSA). This list was developed by industry stakeholders participating in the GS1 Healthcare US Pharmaceutical GDSN Workgroup. The Workgroup examined the attributes needed to support an EPCIS event for DSCSA and pharmaceutical traceability and identified 41 required attributes. The full list is provided in *Appendix A* of this document.

4 Lessons Learned During the GDSN Implementation Exercises

4.1 Findings

Drivers identified, from the input of industry leaders in the GS1 Healthcare US Pharmaceutical GDSN Workgroup, for GDSN implementation are:

- Automating the data flow of master data
- Simplifying the overall process
- Improving data quality

There is a dependency on the accuracy of master data to meet the DSCSA requirements for item-level traceability with an interoperable exchange of data. Master data errors can result in failed EPCIS events causing the quarantine of good products which ultimately will impact the patient in addition to organizational issues of complaints, resource consumption for problem resolution, and potential regulatory implications.

GS1 Healthcare US worked with these industry stakeholders to gain insight into the core issues hindering widespread adoption and use of GDSN within the U.S. healthcare industry. Even though there are strong drivers for the adoption of GSDN, barriers to implementation can be due to various factors. For data sources (e.g., manufacturers) the level of “upfront groundwork” required for the setup of master data and mapping of attributes is both critical and resource requiring. The level of accuracy of this master data has impacts downstream to the data recipient who is receiving a large volume of diverse data. Data recipients can experience difficulties consuming and operationalizing the data. Additionally, calculating the return on investment (ROI) and justifying the resource consumption can be hindered if there are issues with the quality of the data or if the anticipated benefit of the adoption is for a future need, such as a new regulatory requirement.

Overall findings of obstacles are:

- The awareness and understanding of the technical interfaces and advanced preparation needed to support a GDSN implementation. The need to connect all data sources to map attributes to GDSN.
- Expertise required in master data management (MDM), data governance, and the various technology systems that will use the data in their organization.
- Outdated versions of key systems and many manual processes still exist across the healthcare supply chain, and they inhibit stakeholders’ ability to seamlessly consume data in an automated way.
- Availability of resources and prioritization due to conflicting IT strategies.

4.2 Key Benefits and Considerations

The GS1 Healthcare US Pharmaceutical GDSN Workgroup identified key benefits and considerations for the adoption and implementation of GDSN.

Key Benefits:

- The trusted data source is the manufacturer.
- New Product Introduction (NPI) process is supported by GDSN through data sharing and product master listings.
- GDSN can manage hierarchies of product data, Global Trade Item Number® (GTIN®), and product data changes.
- GDSN enables data efficiency and data quality, as an example through validation rules established.
- Product changes at potentially near real-time.

Key Considerations:

- Resource planning and cross-functional procedures will need to be developed and updated.
- Time can occur between a data source change and when it is visible to the data recipient as the system(s) will need synchronization process time. This is also impacted by the method of connection.
- Attribute mapping alignment amongst trading partners is critical. This will require code changes, IT resources, and engagement with data management teams.
- Trading partners can request attributes beyond what is required due to their internal processes and systems.
- The enablers of GDSN are the identifiers required for setup.

4.3 Insights

- Organizations with multiple product divisions or target markets should look to ensure that their relationship with a GDSN-certified data pool covers all product divisions that have a need or want to share data with trading partners. Also, these organizations should assess and compare on-boarding requirements across these product divisions to leverage best practices and establish, as much as possible, one process for on-boarding of trading partners. For instance, one data source company in the exercise already had a data pool but discovered that their relationship was for a single product division of their organization. New capabilities and connections were required for the additional product division before data sharing could begin.
- Pre-implementation working sessions between an organization and its data pool are essential to understand what is involved in a GDSN implementation, and the tools, resources, and support that the data pool provides.
- Data recipients must focus on implementation readiness, particularly people, process, technology, and data management.
- GDSN implementation requires the support of system and master data experts from the organization.
- Prior to GDSN implementation, organizations need to perform a thorough review and assessment of their data (including data storage, data management, and data interfaces) and systems (including vendors, versions, and capabilities/functionalities).
- Knowledge of master data management and data quality best practices are key for obtaining the most benefits from a GDSN implementation.
    - Some organizations manage disconnected, independent databases for each system, and implement GDSN for one system's database. This limits the benefits to be achieved from GDSN.

  - The current best practice for master data management is to establish one authoritative database that houses all the product data the organization uses (e.g., the Enterprise Resource Planning (ERP) item master) and have the organization's other systems pull product data from that authoritative database. Implementing GDSN for the organization's authoritative database pushes the GDSN data throughout all the organization's systems, optimizing the benefit of the GDSN implementation.

- GDSN implementation requires the mapping of GDSN attributes to the organization's data fields. Data pools can assist in this effort.
- An interface between GDSN and the data recipient's item master is necessary to enable data from GDSN to be automatically uploaded without manual intervention. Data interfaces are also necessary to get data from the item master to the systems that will use it.
- Data recipient item masters need to be validated against and aligned with the GDSN metadata standards for each attribute to assure that the item master can receive the data (i.e., an item master that enforces non-standard metadata requirements could cause the system to reject the GDSN data).
  - Data recipient systems that will use GDSN data also need to be aligned with the GDSN metadata standards for each attribute.
- Trading partners should use a data recipient "test Global Location Number (GLN)" and a small subset of data to test GDSN publishing/subscribing and to test attributes for certain business functions. Once successful, the data source can then publish to an active GLN.
- Organizations wishing to test the use of GDSN data in business transactions should have a test environment or, at a minimum, a test Standard Operating Procedure (SOP) with which to conduct initial tests of data and process and identify a partner to pilot.
- Users need to define and follow GDSN Standard Operating Procedures to successfully maintain their GDSN continually. One participating data recipient was faced with receiving data for nearly 30,000 products at once because that data source publishes monthly, and the data recipient had not been pulling down data for several months due to changes in roles/responsibilities within their organization.
- Active and ongoing dialogue between implementation trading partners is critical to achieving an efficient and successful implementation of GDSN, and the use of GDSN attributes in key business processes.

5 Major Conclusions

5.1 GDSN can support healthcare

The business use case examined illustrated that the GDSN provides the standardized attributes needed to support healthcare trading partners meeting DSCSA requirements, and a methodology for data sharing that healthcare can use to promote data quality. The business use case examined also illustrated that manufacturers may effectively use GDSN to share product data for pharmaceuticals with any trading partner in the healthcare supply chain. Likewise, downstream partners needing product data about pharmaceuticals may leverage GDSN to obtain the data they need for core product set-up as well as transactional needs.

Moreover, GDSN is widely implemented across numerous industries and is a tool for sharing product data about non-healthcare-related products as well, like food, janitorial, textiles, etc. This enables large provider networks and Integrated Delivery Networks (IDNs) to leverage their GDSN implementation to obtain product data about all the products they use in their facilities and seamlessly integrate it into their material management information systems (MMIS).

5.2 Attribute list available

Providing a list of attributes for the use case was a key goal. It is provided in Appendix A of this document. The GS1 Healthcare US Pharmaceutical GDSN Workgroup identified 41 required attributes that are needed for pharmaceutical EPCIS events for DSCSA, and they are available to support the industry with GDSN implementation.

5.3 It's not the "what" - it's the "how"

To be successful in a GDSN sharing environment, trading partners need to make appropriate investments in process development, technology, and systems, as well as training and personnel to support GDSN. To assist in these areas, the workgroup agreed that a critical deliverable going forward is the development of a guidance document about GDSN implementation that clearly portrays the importance of such things as:

- Master data management,
- Attribute mapping and interfaces,
- Systems preparedness and mapping,
- Establishment of a cross-functional team,
- IT support, which is necessary and essential,
- Data quality and strong data validation and governance processes, and
- Trading partner collaboration.

5.4 Stakeholder best practices

While it certainly is not a comprehensive list of recommended best practices, the table below provides some of the best practices identified. Other best practices probably exist, and as more healthcare organizations begin to use GDSN as a means for sharing information about healthcare products, more recommendations will be identified and shared.

Figure 5.4-1 Stakeholder Best Practices

Industry Stakeholder	Recommended best practices to support the use of GDSN for sharing product data
Manufacturer/Data Source	▪ Understand the "voice of the customer" concerning data needs ▪ Establish Master Data Management (MDM) and data governance practices, including enterprise-wide information lifecycle policies and procedures ▪ Leverage the value of sharing complete and accurate data ▪ Engage IT resources and create a cross-functional team ▪ Establish SOPs for initiating data sharing with downstream business partners ▪ Establish a clear point of contact for GDSN or product synchronization efforts ▪ Alignment and agreement on data sharing through GDSN with direct and indirect customers
Provider/Data Recipient	▪ Understand what version of ERP or Electronic Health Record (EHR) software you are using and how it is equipped to handle identifiers and attributes associated with products and locations ▪ Map your internal data flow from data source to Item Master to various points of use, and understand the technology used to "move" the data ▪ Educate and engage IT resources in the effort ▪ Work with your ERP/EHR solution provider to leverage the functionality available in that system/version, and make whatever operational changes may be necessary to use the available functionality ▪ Establish Master Data Management (MDM) and data governance practices including enterprise-wide information lifecycle policies and procedures ▪ Assign a data steward and develop SOPs for accessing and integrating data into various internal systems ▪ Consider the use of GDSN "Send for Review" functionality to communicate data discrepancies with data owners ▪ Establish a technology test environment or a test SOP ▪ Identify a partner to pilot implementation
Industry Stakeholder	Recommended best practices to support the use of GDSN for sharing product data
Data Pool	▪ Publish/make available to the healthcare industry a list of data sources published to GDSN ▪ Define best practice guidance to share lessons learned by other verticals ▪ Make more inclusive to increase adoption through education of industry dynamics and impact
Solution Provider (ERP, EHR, MMIS, etc.)	▪ Engage with your customers on how your technology can support standards for specific business processes ▪ Ensure that your healthcare customers are using basic system capabilities (e.g., conversion factors for procurement) ▪ Develop standard interfaces to provide a solid starting point for critical attribute sharing across stakeholders

6 Next Steps

The goal of this document is to help the U.S. healthcare industry begin to understand some of the challenges that have been inhibiting their ability to experience the benefits of GDSN and chart a course for overcoming those challenges to promote more accurate, complete, and timely product data. The following next steps are to encourage the adoption and use of GDSN within the healthcare industry.

6.1 Develop a GDSN value proposition

In healthcare the "five rights": the right patient, the right drug, the right dose, the right route, and the right time are critical. To ensure the patient can receive the medicine they require, it needs to be available. With the DSCSA requirements of item-level serialized traceability that can be exchanged in an interoperable manner, GS1 US believes that the accuracy of the master data is crucial as errors can result in the inability of the product to progress through the supply chain which affects the patient.

Understanding GDSN in the context of master data management (MDM) and data quality is, therefore, essential for understanding the value proposition of GDSN. Accordingly, manufacturers, distributors, wholesalers, providers, and dispensers should consider advancing their understanding MDM and data quality, and the best practices of industries that excel in these areas and leverage GDSN for it. These best practices drive implementation strategies that derive the most benefits from GDSN.

6.2 Renew focus on education and implementation support

Misunderstandings of the basics of GDSN and a lack of readiness to consume and operationalize data are prevalent across the industry. To support and promote GDSN implementation, there is an apparent need for a renewed emphasis on getting started with GDSN and what implementation readiness means, including the essential steps that both data sources and data recipients need to take to prepare for implementation. This document and other resources (see Resource List) were developed to help educate and aid in the implementation of GDSN.

Additionally, Solution Providers play a key role in the advancement of GDSN as a trusted source of data for the healthcare industry.

- Data Pools should engage to develop an understanding of the basic needs of healthcare trading partners and define strategies to help fill the learning gaps that exist around core data elements.
- ERP Solution Providers should better communicate about the functions and features of their ERP systems that support GTINs, unit of measures, conversion factors, and other core data elements, and engage to assist healthcare providers in using them. They should also recommend ERP solutions that are capable to connect to GDSN to support an automated method of sharing master data.
- Middleware Solution Providers should better understand their client's technology footprint to help assure that their solutions do not become a bottleneck for data elements.

6.3 Drive implementation and use of GDSN in healthcare

Where the appropriate resources and investments are made to support GDSN as a data-sharing tool, GDSN communicates vital attributes between trading partners. It is important to raise awareness of these industry findings and emphasize that the benefits are cumulative as stakeholders begin to use GDSN. In addition, it is important to raise awareness that product attributes can have a starting point, a core set of data elements from which stakeholders can establish the data-sharing relationship. From this starting point, trading partners can establish the "how" of sharing data via GDSN. Once the systems, technology, and processes are in place, adding additional data elements to support additional business processes should become seamless with minimal effort.

Industry-wide agreement of the attributes identified as that “core” set of data elements is a key first step to driving adoption, implementation, and use. The GS1 Healthcare US Pharmaceutical GDSN Workgroup identified 41 required attributes that are needed for pharmaceutical EPCIS events for DSCSA, and these attributes are available to support the industry with GDSN implementation.

7 Resources List

For more guidance and updated references for these and other topics, please see the following additional resources:

Global Data Synchronization Network Resources

- *GDSN Quick Start Guide*
- *Healthcare GDSN Implementation Resources*
- *GS1 GDSN*
- *GS1 GDSN Standards*
- *GDSN Package Measurement Rules Standard Implementation Guideline*
- *Pharmaceutical Serialization and Traceability Use Case - Enable the sharing of pharmaceutical product information via the GDSN*
- *Healthcare Provider GDSN Tool Kit*
- *Healthcare Supplier GDSN Tool Kit*
- *GDSN Data Flow*
- *How to Choose a Data Pool*
- *GS1 Healthcare US® Getting Started with the GS1 Global Data Synchronization Network™ (GDSN®)*

Master Data Resources

- *GS1 Attribute Definitions for Business Standard*
- *Healthcare Provider GTIN Tool Kit*
- *Healthcare Supplier GTIN Tool Kit*
- *GTIN Adoption & Usage Model - Implementation Roadmap for U.S. Healthcare Supply Chain*

Appendix A

Attributes to Support U.S. Pharmaceutical EPCIS Events for DSCSA

(Note: "*" before Attribute Common Name indicates the element is "GDSN – Mandatory")

Attribute Common Name	GDSN Attribute Name	Description from Global Data Dictionary (GDD)	Traceability via EPCIS in the U.S. (Pharma)
*Unit GTIN	globalTradeItemNumber	Trade Item Identification for a TradeItem	*Required*
*Unit Descriptor	tradeItemUnitDescriptorCode	Describes the hierarchical level of the trade item. TradeItemUnitIndicator is mandatory. Examples: "CASE", PALLET	*Required*
Name of Information Provider	informationProviderOfTradeItem / NameOfInformationProvider	The party providing the information about the trade item (NAME)	*Required*
*GLN of Information Provider	informationProvider	The party providing the information about the trade item (GLN)	*Required*
*Target Market Code	targetMarketCountryCode	The code that identifies the target market. The target market is at country level or higher geographical definition and is where a trade-item is intended to be sold.	*Required*
*Brand Name	brandName	The recognizable name used by a brand owner to uniquely identify a line of trade item or services. This is recognizable by the consumer.	*Required, Proprietary Name should be provided here*
*Global Product Classification Code	gpcCategoryCode	Code specifying a product category according to the GS1 Global Product Classification (GPC) standard	*Required*
*Is Trade Item an Orderable Unit?	isTradeItemAnOrderableUnit	An indicator identifying that the information provider considers this trade item to be at a hierarchy level where they will accept orders from customers. This may be different from what the information provider identifies as a despatch unit. NOTE: This may be relationship dependent based on channel of trade or other point to point agreement	Required
*Is Trade Item a Base Unit?	isTradeItemABaseUnit	An indicator identifying the trade item as the base unit level of the trade item hierarchy.	Required

Identification Type Such as: Catalog or Model, HIBC, NDC, DIN(Canada), Buyer Assigned, etc. (Part 1)	additionalTradeItemIdentificationTypeCode	Code specifying an additional trade item identification type. Allowed code values are specified in GS1 Code List AdditionalTradeItemIdentificationTypeCode	*Required - NDC Code Type*
Number Such as: Catalogue or Model Number, HIBC, NDC11, DIN or Buyer assigned number (Part 2)	AdditionalTradeItemIdentification	Alternative means to the Global Trade Item Number to identify a trade item.	*Required - NDC Code*
Manufacturer Name (Part 1)	manufacturerOfTradeItem (partyName)	Party name and identification information for the manufacturer of the trade item	*Required*
Manufacturer GLN (Part 2)	manufacturerGLN	Party name and identification information for the manufacturer of the trade item	*Required*
Product Description	tradeItemdescription and additionalTradeItemDescription	Additional variants necessary to communicate to the industry to help define the product. Multiple variants can be established for each GTIN. This is a repeatable field, e.g., Style, Colour, and Fragrance. Allows for the representation of the same value in different languages but not for multiple values	*Required*
Trade Item/Package Depth	depth value	The depth of the unit load, as measured according to the GS1 Package Measurement Rules, including the shipping platform unless it is excluded according to the Pallet Type Code chosen	Required
DepthUOM	measurementUnitCode	Any standardized, reproducible unit that can be used to measure any physical property.	Required
Trade Item/Package Height	height value	The height of the unit load, as measured according to the GS1 Package Measurement Rules, including the shipping platform unless it is excluded according to the Pallet Type Code chosen	Required
HeightUOM	measurementUnitCode	Any standardized, reproducible unit that can be used to measure any physical property.	Required
Trade Item/Package Width	width value	The width of the unit load, as measured according to the GS1 Package Measurement Rules, including the shipping platform unless it is excluded according to the Pallet Type Code chosen	Required
WidthUOM	measurementUnitCode	Any standardized, reproducible unit that can be used to measure any physical property.	*Required*

Trade Item/Package Gross Weight	grossWeight value	Used to identify the gross weight of the trade item. The gross weight includes all packaging materials of the trade item. At pallet level the trade item, grossWeight includes the weight of the pallet itself. For example, "200 GRM", value - total pounds, total grams, etc. Has to be associated with a valid UOM	*Required*
GrossWeightUOM	measurementUnitCode	Any standardized, reproducible unit that can be used to measure any physical property.	*Required*
*Is Trade Item a Consumer Unit?	isTradeItemAConsumerUnit	Identifies whether the trade item to be taken possession of, or to be consumed or used by an end user or both, as determined by the manufacturer. The end user could be, but is not limited to, a consumer as in items sold at retail, or a patient/clinician/technician in a healthcare setting, or an operator for foodservice such as restaurants, airlines, cafeterias, etc.	*Required*
*Is Trade Item a Despatch Unit	isTradeItemADespatchUnit	An indicator identifying that the information provider considers the trade item as a despatch (shipping) unit. This may be relationship dependent based on channel of trade or other point to point agreement	*Required*
*Is Trade Item a Variable Unit?	isTradeItemAVariableUnit	Indicates that an article is not a fixed quantity, but that the quantity is variable. Can be weight, length, volume, trade item is used or traded in continuous rather than discrete quantities.	*Required*
Total Quantity of Units Contained	totalQuantityOfNextLowerLevelTradeItem	This represents the Total quantity of next lower level trade items that this trade item contains NOTE: Only applies if trade item contains unique GTIN(s) such as a kit containing multiple items.	*Required - Conditional*
Quantity of Next Lower Level GTIN	quantityOfNextLowerLevelTradeItem	This represents the Total quantity of next lower level trade items that this trade item contains. NOTE: Applies if a value is provided for "Next Lower Level GTIN"	*Required - Conditional*

Net Content	netContent value	The amount of the trade item contained by a package, usually as claimed on the label. For example, Water 750ml - net content = "750 MLT"; 20 count pack of diapers, net content = "20 ea.". In case of multi-pack, indicates the net content of the total trade item. For fixed value trade items use the value claimed on the package, to avoid variable fill rate issue that arises with some trade item which are sold by volume or weight, and whose actual content may vary slightly from batch to batch. In case of variable quantity trade items, indicates the average quantity. Allows for the representation of the same value in different units of measure but not multiple values.	*Required*
Net Content UOM	measurementUnitCode	Unit of Measure of the net content of the trade item. (netContent/@measurementUnitCode)	*Required*
*Effective Date	effectiveDateTIme	The date on which the information contents of the master data version are valid. This effective date can be used for initial trade item offering, or to mark a change in the in-formation related to an existing trade item. This date would mark when these changes take effect. (effectiveDateTime)	*Required*
End Availability Date Time	endAvailabilityDateTime	The date from which the trade item is no longer available from the information provider, including seasonal or temporary trade item and services.	*Required - Conditional*
Dosage Form Type	dosageFormTypeCodeReference	A dosage form is the physical form of a medication that identifies the form of the pharmaceutical item.	*Required*
Ingredient Name	nonfoodIngredientName	Intended to name each ingredient in a trade item to correspond with the ingredient strength. This is a repeatable attribute to enable multiple ingredients to be listed.	*Required*
Ingredient Strength	ingredientStrength (# and UoM)	Used to define the strength of each ingredient in a trade item or unit volume of non food and beverage the trade items.	*Required*
Data Carrier Type Code	dataCarrierTypeCode	A code indicating the type of data carrier physically present on the trade item. NOTE: In US for pharmaceuticals this is defined by regulation to be 2D DataMatrix. This attribute is therefore assumed for US target market but required for O-US.	*Required*

Serial Number	SerialNumberLocationCode	The location on the item or packaging of a serial number. A serial number is a code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime for example a Microscope model AC-2 with serial number 234568 and microscope model AC-2 with serial number 234569. NOTE: In US for pharmaceuticals this is defined by regulation to be 2D DataMatrix. This attribute is, therefore, assumed for the US target market but required for O-US.	*Required*
Batch/Lot	hasBatchNumber	Indication whether the base trade item is batch or lot number requested by law, not batch or lot number requested by law but batch or lot number allocated, or not batch or lot number allocated. A batch or lot number is a manufacturer assigned code used to identify a trade item's trade item on batch or lot. Differs from Serial Number which is a manufacturer assigned code during the trade item on cycle to identify a unique trade item NOTE: In US for pharmaceuticals this is defined by regulation to be 2D DataMatrix. This attribute is, therefore, assumed in the US target market but required for O-US.	*Required*
Expiry code	tradeItemDateOnPackagingTypeCode	Indicates the type of date marked on the packaging for example Best Before Date NOTE: In US for pharmaceuticals this is defined by regulation to be 2D DataMatrix. This attribute is, therefore, assumed for the US target market but required for O-US.	*Required*
Publication date	publicationDate	The date specified in the field. Mandatory in each occurrence of the composite, and non-repeating. May carry a dateformat attribute: if the attribute is missing, then indicates the format of the date; if both dateformat attribute and element are missing, the default format is YYYYMMDD.	*Required*
Trade Item Exempt	isTradeItemExemptFromSerialisation	This attribute will indicate to supply chain participants (wholesalers and dispensers) if a trade item is exempt from product identifier and traceability requirements.	*Required*

Proprietary Statement

This document contains proprietary information of GS1 US. Such proprietary information may not be changed for use with any other parties for any other purpose without the expressed written permission of GS1 US.

Improvements

Improvements and changes are periodically made to publications by GS1 US. All material is subject to change without notice. Please refer to GS1 US website for the most current publication available.

Disclaimer

Except as may be otherwise indicated in specific documents within this publication, you are authorized to view documents within this publication, subject to the following:

1. You agree to retain all copyright and other proprietary notices on every copy you make.
2. Some documents may contain other proprietary notices and copyright information relating to that document. You agree that GS1 US has not conferred by implication, estoppels, or otherwise any license or right under any patent, trademark, or copyright (except as expressly provided above) of GS1 US or of any third party.

This publication is provided “as is” without warranty of any kind, either express or implied, including, but not limited to, the implied warranties of merchantability, fitness for a particular purpose, or non-infringement. Any GS1 US publication may include technical inaccuracies or typographical errors. GS1 US assumes no responsibility for and disclaims all liability for any errors or omissions in this publication or in other documents which are referred to within or linked to this publication. Some jurisdictions do not allow the exclusion of implied warranties, so the above exclusion may not apply to you.

Several products and company names mentioned herein may be trademarks and/or registered trademarks of their respective companies. GS1 US does not, by promulgating this document on behalf of the parties involved in the creation of this document, represent that any methods, products, and/or systems discussed or recommended in the document do not violate the intellectual property rights of any third party. GS1 US has not performed a search to determine what intellectual property may be infringed by an implementation of any strategies or suggestions included in this document. GS1 US hereby disclaims any liability for any party’s infringement of intellectual property rights that arise as a result of any implementation of strategies or suggestions included in this document.

This publication may be distributed internationally and may contain references to GS1 US products, programs, and services that have not been announced in your country. These references do not imply that GS1 US intends to announce such products, programs, or services in your country.

GS1 US shall not be liable for any consequential, special, indirect, incidental, liquidated, exemplary, or punitive damages of any kind or nature whatsoever, or any lost income or profits, under any theory of liability, arising out of the use of this publication or any content herein, even if advised of the possibility of such loss or damage or if such loss or damage could have been reasonably foreseen.

GS1 US HEREBY DISCLAIMS, AND YOU HEREBY EXPRESSLY RELEASE GS1 US FROM, ANY AND ALL LIABILITY RELATING TO YOUR COMPLIANCE WITH REGULATORY STANDARDS AND LAWS, INCLUDING ALL RULES AND REGULATIONS PROMULGATED THEREUNDER. GS1 US MAKES NO WARRANTIES OF ANY KIND RELATING TO THE SUITABILITY OF THE GS1 STANDARDS AND THE SPECIFIC DOCUMENTS WITHIN THIS PUBLICATION TO COMPLY WITH ANY REGULATORY STANDARDS, LAWS, RULES AND REGULATIONS. ALL INFORMATION AND SERVICES ARE PROVIDED “AS IS.”

*GS1 US employees are not representatives or agents of the U.S. FDA, and the content of this publication has not been reviewed, approved, or authorized by the U.S. FDA. The following information contained herein is for informational purposes only as a convenience and is not legal advice or a substitute for legal counsel. GS1 US Inc. assumes no liability for the use or interpretation of the information contained herein.

No Liability for Consequential Damage

In no event shall GS1 US or anyone else involved in the creation, production, or delivery of the accompanying documentation be liable for any damages whatsoever (including, without limitation, damages for loss of business profits, business interruption, loss of business information, or other loss) arising out of the use of or the results of use of or inability to use such documentation, even if GS1 US has been advised of the possibility of such damages.

IAPMO

In this publication, the letters “U.P.C.” are used solely as an abbreviation for the “Universal Product Code” which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.

*If applicable

GS1 US Corporate Headquarters

Princeton South Corporate Center, 300 Charles Ewing Boulevard
Ewing, NJ 08628 USA
T +1 609.620.0200 | **E** info@gs1us.org

www.gs1us.org

Connect With Us