Healthcare Provider GS1 Standards Implementation Guidelines for Medical Device Use Cases

Release 1.1, April 2018
# Healthcare Provider GS1 Standards Implementation Guideline
## For Medical Device Use Cases

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1 Document Purpose

The use of global standards for supply chain management and care processes makes the healthcare system more efficient, accurate, and ultimately safer by linking the point of procurement to Electronic Medical Record (EMR or patient record) to claim adjudicators.

The purpose of this document is to provide guidance for the implementation of GS1 standards within common healthcare medical device business and clinical processes for use in the Canadian healthcare sector. Each healthcare organization is unique, therefore; technology and business processes vary across the healthcare sector. Healthcare organizations need to understand the implementation recommendations within this guide and translate these into steps that best suit their own individual requirements.

This document provides high level steps to enhance healthcare medical device business and clinical processes incorporating GS1 standards by:

- Enabling healthcare providers to accurately identify medical device products and locations throughout the healthcare value chain from the point of manufacturer to the patient’s Electronic Medical Record (EMR).
- Creating a sustainable foundation to support implementation of GS1 standards across multiple business processes.

2 About GS1 and GS1 Canada

2.1 About GS1 Global

GS1 is a neutral, not-for-profit, global organization that develops and maintains standards for supply chains across multiple sectors.

With local Member Organizations in over 112 countries, GS1 works with communities of trading partners, industry organizations, governments and technology providers and responds to their business and clinical needs through the adoption and implementation of global standards.

GS1 has over a million member companies across the world, executing more than five billion transactions daily using GS1 standards.

2.2 About GS1 Canada

GS1 Canada is a member organization of GS1 Global, and represents the interests of Canada in the continuing development of the global language of business. We enable our more than 20,000 subscribers – organizations of all sizes from over 20 sectors across Canada – to enhance their efficiency and cost effectiveness by adopting electronic supply chain best practices. We develop standards that improve the way that business is conducted and allow Canadian businesses to compete on a global scale. We deliver implementation services that enable businesses to apply standards to achieve supply chain efficiency. We educate industry on how to incorporate collaborative commerce tools and processes into their businesses through seminars, conferences, and published guides and standards.
3 **GS1 Standards**

The following is a summary of common GS1 standards topics that support the implementation of GS1 standards within healthcare medical device business and clinical processes:

### 3.1.1 What is a barcode?

A barcode is a combination of machine and human readable components. When using GS1 standards, the number below the barcode is the GS1 product identifier that is called the Global Trade Item Number (GTIN). The below illustration is an example of a GS1 data matrix barcode.

Barcodes are the transport mechanism for the GTIN and supplemental product information such as serial numbers, lot numbers and expiry date. For more information on barcoding visit: [http://www.gs1ca.org/pages/n/standards/Barcode_Standards.asp](http://www.gs1ca.org/pages/n/standards/Barcode_Standards.asp)

### 3.1.2 What is a Global Trade Item Number (GTIN)?

The Global Trade Item Number (GTIN) is a GS1 global standard that identifies products across various sectors. It is a unique and static identifier that is assigned to all packaging hierarchy of a product.

![Unique GTINs at each packaging level](image-url)

**Figure 1** Unique GTINs at each packaging level
Once the GTIN is assigned it does not change over time, and when it is used, it will enable processes such as traceability and recall.

Manufacturers assign the GTIN to the items they produce. Other identifiers (Brand, medical device class and license number, DIN, etc.) are pieces of information which can be linked to the GTIN in a data system through cross-referencing.

In healthcare and pharmacy, the rules for how GTINs are allocated to products and how they are used are slightly different compared to other sectors. Many products in healthcare and pharmacy are given what is known as a permanent GTIN, sometimes known as a non-reuse GTIN.

Visit http://www.gs1ca.org/pages/n/Permanent_GTIN/index.asp to learn more about permanent GTIN rule.

For more information about GTIN assignment go to: https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

3.1.3 What is a Global Location Number (GLN)?

The Global Location Number (GLN) is a 13-digit globally unique identification code that in Canada is assigned by GS1 Canada to identify:

- **Legal entities**: Whole companies, subsidiaries or divisions, such as manufacturers, hospitals, Shared Services Organizations.

- **Functions within legal entities**: Specific departments within a legal entity, such as, hospital pharmacy, hospital wards, accounting department, emergency department, purchasing departments, etc.

- **Physical locations**: Single points of access with a physical address, such as, hospital wing, nursing station, manufacturer’s warehouse, hospital unit, clinic, retail store, warehouse, manufacturing plant, loading dock, vending machine, cabinet, etc.

For more information about GLN allocation rules visit: https://www.gs1.org/gln.

To start implementing GLNs visit: http://www.gs1ca.org/pages/n/sectors/hc/get-a-gln.asp

3.1.4 What is Global Data Synchronization Network (GDSN)?

Data synchronization is the process by which a data source (e.g., supplier) and a data recipient (e.g. a retailer or a hospital) share data electronically. By eliminating manual transactions between trading partners, data synchronization is the foundation for effective modern data management.

The GS1 Global Data Synchronization Network (GDSN) is the infrastructure – the 'information highway' – that enables the automatic electronic exchange of product data between organizations, globally. Fully supported by GS1 Canada, the GDSN is comprised of a system of independent, interoperable data pools that enable GS1 standards-based product data to flow between trading partners using global business messaging standards.

For more information about GDSN visit: http://www.gs1ca.org/pages/n/gdsn/index.asp
3.1.5 What is Electronic Data Interchange (EDI)?

EDI is a standard format for computer-to-computer transmission of business information and transactions between trading partners, such as invoices and purchase orders.

The most recent version of the Electronic Data Interchange (EDI) standards used in Canada for the healthcare sector is X12 version 6020. It is strongly recommended that healthcare providers should be able to use EDI to obtain GTINs and GLN electronically.

For more information about EDI visit: http://www.gs1ca.org/pages/n/sectors/hc/standards-implementation-guidance.asp.

4 10-step guide for healthcare providers to implement GS1 standards

It is important to gather as much information as possible to understand options and opportunities for implementation of GS1 standards within an organisation's clinical or business processes. Simply put, this information is needed to define the business and/or clinical process you want to refine. The more information sourced, the more effective the implementation will be.

A general guide has been developed globally to support healthcare providers’ implementation of GS1 barcodes. This global guide provides supplemental information to healthcare providers.


4.1.1 Educate your team on GS1 Standards

Before starting to implement, you should educate your staff or project team on GS1 Standards. There are several ways that you can obtain this education:

a. You can leverage GS1 Canada Learning Module System (LMS) through https://learning.gs1.org/login/index.php
b. There is also a collection of case studies and implementation projects across the world as well as implementation guides and educational documents that are available to you via GS1 Canada healthcare web page. Visit http://www.gs1ca.org/pages/n/sectors/hc/index.asp
c. Representatives from GS1 Canada can provide your staff with standards education and support. For more information contact: healthcare@gs1ca.org
5 Healthcare Medical Device Business and Clinical Process Map High-Level Eco-System

Thousands of business and clinical processes occur in a hospital everyday with the goal of providing safe and efficient patient care. We refer to these processes as use cases whereby the sum of individual actions or event steps are completed to meet an end goal. The Healthcare Provider Deployment Committee and Healthcare Technical Work Group has identified high-level medical device use cases to be developed into generic implementation guidelines incorporating the use of GS1 global standards.

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6 Implementing GS1 Standards in New Item Introduction/Item Management (Item Setup) Business Process

6.1 What is New Item Introduction/Item Management (Item Setup) Business process?

A new product is introduced to the supply chain by adding a product record to the organization’s database. The database is typically referred to as the “item master”. Product records added to the item master are called “items.” The business process of creating a new item in a healthcare provider item master can be referred to as new item introduction (item setup).

Each new item master product record is assigned a unique code by the healthcare provider’s system, and stores all essential information about the product including the GTIN, vendor number, product description, units of measure, and other attributes that define or describe the product.

Accuracy of this information is crucial, as it controls how the item is identified in requisitioning, purchasing, inventory, accounting, and all other logistical and clinical aspects throughout the product’s life cycle.

6.2 Steps for Implementing GTINs and Product Attributes within the New Item Introduction (Item Setup) Business Process.

The following outlines the steps for introducing GS1 standards including GTIN and GLN within your item setup business process. These steps are provided at high level as each organization’s detailed processes will be unique.

For high-level technical guidance on implementing GS1 standards into healthcare provider systems refer to the section Technical Considerations and Recommendations contained in this guide.

Requests to add a new item to the item master may come from a variety of sources. The three most common item-add requests may be received from:

- a. A Requisitioner
- b. A Buyer
- c. The Contract Management Team

6.2.1 a) Requisitioner Initiates the Item Introduction Business Process

This is the process where a requisitioner (e.g. a nurse) creates and submits a request to add a new product to the item master. The following are recommendations on how to implement GS1 standards within this process.
1. The healthcare provider should modify their new item request form to include two fields:
   - One field that will be used to list the GTIN at each packaging level.
   - One field that will be used to capture the GLN of the manufacturer/supplier of the product.

2. Healthcare providers should update their Standard Operating Procedures (SOPs) to include the need for obtaining and storing GTINs and GLNs when adding product information to their item master.

   **Note:** Obtaining the GTIN, GLN and other related product attributes to be added to the item master can be done several ways:
   - **Good Practice** - manufacturer provides the GTIN, GLN and related product information in a table format (e.g. pdf, Excel) that can be entered manually into the healthcare provider’s system. Ideally, the manufacturer would provide this information in a standardized table format (e.g. Excel) that can be reviewed, modified or rejected and then automatically uploaded into the healthcare provider’s system.
   - **Best Practice** - providers can receive the GTIN, GLN and related product information using Electronic Data Interchange (EDI). This information can be exchanged via EDI Price/Sales Catalogue 832 transaction. Alternatively, the provider can receive the GTIN, GLN and related product information using the Global Data Synchronization Network (GDSN). Providers will need to invest in technology and resources or partner with a solution provider to develop either EDI or GDSN capabilities. For more information on EDI and GDSN standards visit www.gs1ca.org.

3. The Healthcare providers must ensure their internal system(s) (e.g. Enterprise Resource Planning (ERP)) can store and manage GTIN and GLN within different internal systems.

4. When the requisitioner submits the request to add products into the healthcare provider’s item master, the GTIN and GLN must be provided. The information provided is validated for accuracy and completeness by an internal team, such as Contract Management Team and Item Master Management Team.

5. The Contract Management Team using the GTIN as the product identifier and the GLN as the manufacturer/supplier identifier adds the product to an existing contract if required.

6. Item Master Management Team creates a new item record using the GTIN as the product identifier and the GLN as the manufacturer/supplier identifier in the materials management information system.

7. The Item Master Management Team notifies the Requisitioner and the Contract Management Team that the item has been setup on the material management information system.

8. After the new item is activated in the item master, the GTIN and GLN are available through the system for all stakeholders to view and have access too. The GTIN and GLN will be used for ordering products within the healthcare provider’s system.

6.2.2 b) Buyer Initiates the Item Introduction Business Process

This is the process where a Buyer creates and submits a request to add a new product to the Item Master. The following are recommendations on how to implement GS1 Standards within this process.

1. The healthcare provider should modify their new item request form to include two fields:
   - One field that will be used to list the GTIN at each packaging level.
   - One field that will be used to capture the GLN of the manufacturer/supplier of the product.
2. Healthcare providers should update their Standard Operating Procedures (SOPs) to include the need for obtaining and storing GTINs and GLNs when adding product information to their item master.

**Note:** Obtaining the GTIN, GLN and other related product attributes to be added to the item master can be done several ways:

- **Good Practice** - manufacturer provides the GTIN, GLN and related product information in a table format (e.g. pdf, Excel) that can be entered manually into the healthcare provider’s system. Ideally, the manufacturer would provide this information in a standardized table format (e.g. Excel) that can be reviewed, modified or rejected and then automatically uploaded into the healthcare provider’s system.

- **Best Practice** - providers can receive the GTIN, GLN and related product information using Electronic Data Interchange (EDI). This information can be exchanged via EDI Price/Sales Catalogue 832 transaction. Alternatively, the provider can receive the GTIN, GLN and related product information using the Global Data Synchronization Network (GDSN). Providers will need to invest in technology and resources or partner with a solution provider to develop either EDI or GDSN capabilities. For more information on EDI and GDSN standards visit [www.gs1ca.org](http://www.gs1ca.org).

3. Buyer completes internal documentation by entering all source and product information including the GTIN and GLN.

4. Buyer submits the documentation to the Purchasing Department.

5. Purchasing Department sources the product, identifies the vendor using the GLN, adds contract number (if applicable), GTIN, price, and other required product information.

6. The Purchasing Department submits the completed request that contains the GTIN for product identification and GLN for manufacturer/supplier identification to internal teams, such as the Contract Management Team and Item Master Management team for validation.

7. The Item Master Management Team validates the information provided.

8. The Contract Management Team follows their business rules for processing new products and validating the data and notifies the Item Master Management Team.

9. The Item Master Management Team creates a new Item record by entering the GTIN, GLN and other product related information into the materials management information system.

10. The Item Master Management Team sends the GTIN and the GLN to the Purchasing Department to confirm the product has been setup.

11. The Item Master Management Team notifies the Contract Management team of the new record.

12. After the new product is activated in the item master, it is available to authorized stakeholders.

6.2.3 c) The Contract Management Team Initiates the Item Introduction Business Process

This process outlines the steps taken when a contract has been granted to the winner of the bid process.

1. The healthcare provider should modify their new item request form to include two fields:
   - One field that will be used to list the GTIN at each packaging level.
   - One field that will be used to capture the GLN of the manufacturer/supplier of the product.
2. Healthcare providers should update their Standard Operating Procedures (SOPs) to include the need for obtaining and storing GTINs and GLNs when adding product information to their item master.

   **Note:** Obtaining the GTIN, GLN and other related product attributes to be added to the item master can be done several ways:

   - **Good Practice** - manufacturer provides the GTIN, GLN and related product information in a table format (e.g. pdf, Excel) that can be entered manually into the healthcare provider’s system. Ideally, the manufacturer would provide this information in a standardized table format (e.g. Excel) that can be reviewed, modified or rejected and then automatically uploaded into the healthcare provider’s system.

   - **Best Practice** - providers can receive the GTIN, GLN and related product information using Electronic Data Interchange (EDI). This information can be exchanged via EDI Price/Sales Catalogue 832 transaction. Alternatively, the provider can receive the GTIN, GLN and related product information using the Global Data Synchronization Network (GDSN). Providers will need to invest in technology and resources or partner with a solution provider to develop either EDI or GDSN capabilities. For more information on EDI and GDSN standards visit [www.gs1ca.org](http://www.gs1ca.org).

3. The Contract Management Team sends the vendor a list of attributes required for describing products and creating new item records in the item master. This list includes GTIN for product identification and GLN for manufacturer/supplier identification.

4. The vendor provides the required attributes to the Contract Management Team including the GTIN and the GLN. The vendor is responsible for providing accurate and complete data to the best of their knowledge.

5. The Contract Management Team reviews and validates the GTIN, GLN and other product attributes that is received from the vendor.

6. The Contract Management Team submits the GTIN, GLN and other product information to the Item Master Management Team to create the new item record(s).

7. The Item Master Management Team creates new item record(s) ensuring the GTIN and GLN have been entered into the materials management information system.

8. The Item Master Management Team notifies the Contract Management Team of the new record.

9. Once the new product is activated in the item master, it is available to authorized stakeholders.

### 7 How to Implement GS1 Standards in Contract Management Business Process

#### 7.1 What is Contract Management Business process?

The Contract Management process is the interaction between trading partners that ensures all parties meet their respective obligations in any procurement relationship. The purpose of this process is to meet the operational, functional and business objectives required by the contract and provide a profitable interaction.

In addition, The Contract Management process ensures the healthcare provider has the accurate and complete product information. The following outlines the steps of introducing the GTIN and GLN into to an organization’s contract management business process. These steps are provided at a high level as each organization’s detailed processes will be unique.
7.2 Steps to Implement GTIN, GLN and other Product Attributes within Contract Management Business Process.

The Contract Management business process starts when a contract has been signed. The vendor submits the attributes needed for each record to be created or updated in the healthcare provider’s item master.

The signed contract may contain either: a. New Item Record or b. Existing Item Record

7.2.1 a. New Item Record

1. The healthcare provider should modify their new item request form to include two fields:
   - One field that will be used to list the GTIN at each packaging level.
   - One field that will be used to capture the GLN of the manufacturer/supplier of the product.

2. Healthcare providers should update their Standard Operating Procedures (SOPs) to include the need for obtaining and storing GTINs and GLNs when adding product information to their item master.

   **Note:** Obtaining the GTIN, GLN and other related product attributes to be added to the item master can be done several ways:

   - **Good Practice** - manufacturer provides the GTIN, GLN and related product information in a table format (e.g. pdf, Excel) that can be entered manually into the healthcare provider’s system. Ideally, the manufacturer would provide this information in a standardized table format (e.g. Excel) that can be reviewed, modified or rejected and then automatically uploaded into the healthcare provider’s system.

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3. The healthcare provider sends the vendor a list of attributes required to create an item record in the item master. This list contains GTINs to identify product and the GLN to identify the vendor.

4. The vendor provides the required attributes including the GTINs and GLN(s) to the Healthcare Provider.
   - The vendor is responsible for providing accurate and complete data to the best of their knowledge.

5. The healthcare provider sends the information including GTINs and GLNs to The Contract Management Team.

6. The Contract Management Team reviews and validates the data that is received from the vendor.

7. The Contract Management Team submits the data including GTINs and GLNs to the Item Master Management Team to create the new item record(s).

8. The Item Master Management Team creates new item records including the GTINs and GLNs in the item master.

9. The Item Master Management Team notifies the Contract Management team and other internal teams of the new record.
10. After the new item is activated in the item master, it is available to authorized stakeholders.

7.2.2 Existing Item Record

1. The healthcare provider should modify their new item request form to include two fields:
   - One field that will be used to list the GTIN at each packaging level.
   - One field that will be used to capture the GLN of the manufacturer/supplier of the product.

2. Healthcare providers should update their Standard Operating Procedures (SOPs) to include the need for obtaining and storing GTINs and GLNs when adding product information to their item master.

   **Note:** Obtaining the GTIN, GLN and other related product attributes to be added to the item master can be done several ways:

   - **Good Practice** - manufacturer provides the GTIN, GLN and related product information in a table format (e.g. pdf, Excel) that can be entered manually into the healthcare provider’s system. Ideally, the manufacturer would provide this information in a standardized table format (e.g. Excel) that can be reviewed, modified or rejected and then automatically uploaded into the healthcare provider’s system.

   - **Best Practice** - providers can receive the GTIN, GLN and related product information using Electronic Data Interchange (EDI). This information can be exchanged via EDI Price/Sales Catalogue 832 transaction. Alternatively, the provider can receive the GTIN, GLN and related product information using the Global Data Synchronization Network (GDSN). Providers will need to invest in technology and resources or partner with a solution provider to develop either EDI or GDSN capabilities. For more information on EDI and GDSN standards visit [www.gs1ca.org](http://www.gs1ca.org).

3. The healthcare provider sends the vendor a list of attributes required to create an item record in the item master. This list contains GTIN to identify product and the GLN to identify the vendor.

4. The vendor provides the required attributes including the GTIN and GLN to the healthcare provider.
   - The vendor is responsible for providing accurate and complete data to the best of their knowledge.

5. The healthcare provider sends the information including GTIN and GLN to The Contract Management Team.

6. The Contract Management Team reviews and validates the data that is received from the vendor.

7. The Contract Management Team submits the data including GTIN and GLN to the Item Master Management Team to update the item records.

8. The Item Master Management Team updates new item records and ensures the GTIN and GLN have been recorded in the item master.

9. The Item Master Management Team notifies the Contract Management Team and other internal teams of the updated record.

10. After the updated item is activated in the item master, it is available to authorized stakeholders.
8 How to Implement GS1 Standards in Order Management Business Process

8.1 What is Order Management Business Process?
Order Management refers to the business process as it relates to ordering of goods or services. The scope of Order Management is broad and begins with the creation of an order. It includes tracking and fulfillment, invoicing and payment, reporting and handling of returned goods. Management and maintenance of all related systems are critical for the Order Management processes to run efficiently and with minimal errors.

8.2 Steps to Implement GTIN and GLN Within Order Management Business Process.
Guidance for the implementation of GTINs and GLNs within the Order Management business process is provided at a high level for the following three common types of orders:

a) Standard Orders
b) Blanket Orders
c) Consignment Orders

8.2.1 a. Standard Order
1. The healthcare provider should modify their new item request form to include two fields:
   - One field that will be used to list the GTIN at each packaging level.
   - One field that will be used to capture the GLN of the manufacturer/supplier of the product.
2. Healthcare providers should update their Standard Operating Procedures (SOPs) to include the need for obtaining and storing GTINs and GLNs when adding product information to their item master.

Note: Obtaining the GTIN, GLN and other related product attributes to be added to the item master can be done several ways:

- **Good Practice** - manufacturer provides the GTIN, GLN and related product information in a table format (e.g. pdf, Excel) that can be entered manually into the healthcare provider’s system. Ideally, the manufacturer would provide this information in a standardized table format (e.g. Excel) that can be reviewed, modified or rejected and then automatically uploaded into the healthcare provider’s system.

- **Best Practice** - providers can receive the GTIN, GLN and related product information using Electronic Data Interchange (EDI). This information can be exchanged via EDI Price/Sales Catalogue 832 transaction. Alternatively, the provider can receive the GTIN, GLN and related product information using the Global Data Synchronization Network (GDSN). Providers will need to invest in technology and resources or partner with a solution provider to develop either EDI or GDSN capabilities. For more information on EDI and GDSN standards visit [www.gs1ca.org](http://www.gs1ca.org).

3. An authorized user submits a requisition for goods and/or services using methods outlined by the healthcare provider. The requisition should contain GTIN and GLN as product and location identifiers.
4. The receiving healthcare provider may review the requisition for accuracy if there is reason for human intervention.
- There may be a requirement to validate signing authority, verify compliance to policy, review sales quotations, identify a supplier using the GLN, etc.

- The approved requisition is converted to a Purchase Order (PO) if items are not in inventory. The purchase order will contain the GTIN for each line item. GLNs should be included in the PO to identify the following:
  a. GLN for the party submitting the order (i.e. healthcare provider)
  b. GLN for the Ship To location for where the order is to be delivered
  c. GLN for the receiving party of the PO (i.e. vendor)
  d. GLN for the Bill To location to identify the billing party

- GTINs should be included in the PO for every line item to identify what product is being ordered.

5. The PO is sent to the vendor.

The healthcare provider can send the Purchase Order in several ways:

- Good Practice – Healthcare provider generates a manual purchase order (e.g. fax, email, vendor website) and sends to the vendor. Healthcare provider manually validates accuracy of purchase order including GLN, GTIN and related product attributes including vendor catalogue number, product description, unit of measure, order quantity, and pricing.

- Better Practice – Healthcare provider generates a standardized electronic purchase order (i.e. EDI 850 Purchase Order) from their material management information system and sends to the vendor. Healthcare provider manually validates accuracy of purchase order including GLN, GTIN and related product attributes including vendor catalogue number, product description, unit of measure, order quantity, and pricing. Healthcare providers will need to invest in technology and resources or partner with a solution provider to develop this capability. For more information on EDI, visit www.gs1ca.org.

- Best Practice – To support the perfect order, healthcare providers must maintain ongoing accuracy of GLN, GTIN, product attributes, and other related product information such as pricing. The recommended best practice for maintaining item master information is using Electronic Data Interchange (EDI) or the Global Data Synchronization Network (GDSN).

The healthcare provider generates a standardized electronic purchase order (i.e. EDI 850 Purchase Order) from their material management information system which is automatically validated for accuracy. Healthcare providers will need to invest in technology and resources or partner with a solution provider to develop this capability. For more information on EDI or GDSN, visit www.gs1ca.org.

6. The vendor receives the PO. The vendor’s systems process GTINs and GLNs and identify any discrepancies that may exist in the PO.

7. The vendor replies to the healthcare provider with a purchase order confirmation, often called the Purchase Order Acknowledgment (POA). The POA uses the GLN to accurately identify the vendor and the healthcare provider. The GTINs are used in the POA to identify the line items.

- This confirmation supports identification of discrepancies in the PO such as pricing, unit of measure, vendor catalog number, etc.
- As a best practice, the POA will also identify discrepancies in GTIN and GLN (i.e. incorrect or missing identifiers).

8. Healthcare provider receives, reviews and corrects the discrepancies on the POA using the GTIN to identify the correct product and apply the appropriate changes.

- Estimated time of delivery if provided in the POA will be entered in the system to support tracking by Healthcare Providers.

9. The vendor identifies the product to be picked using the GTIN and identifies the warehouse location (e.g. shelf or bin) where the product is stored using the GLN.

- The vendor picks and packs the products.
- The vendor applies the correct Serialized Shipping Container Code (SSCC) to the pallet ensuring the barcode is created based on GS1 standards and it is readable by a scanner.
- The vendor ships the products to the healthcare provider.

10. The vendor may send a shipment notification to the Healthcare Provider. If a shipment notification is sent, it should contain The SSCC of the shipment, the GLN to correctly identify the trading partners and the GTINs to identify products. The Healthcare Provider uses the information in the shipment notification to prepare for receiving deliveries.

- **Good Practice** – vendor submits a manual shipment notification (e.g. fax, email, phone) to the healthcare provider. Provider prepares to receive products.
- **Better Practice** – vendor generates a standardized EDI Advance Ship Notice (i.e. EDI 856 ASN) and sends to the healthcare provider. Healthcare provider receives the ASN and prepares to receive products. The ASN information is stored in the healthcare provider’s system for later use in the 3-way match business process. Healthcare providers will need to invest in technology and resources or partner with a solution provider to develop this capability. For more information on EDI, visit [www.gs1ca.org](http://www.gs1ca.org).

11. Healthcare provider receives the shipment.

- Orders may be received in full, or partially received if all items requested were not available at time of order.
- Partially-received orders are noted in the system and the back-orders are followed up until resolved.
- Receipt of products is captured in the system leveraging the GTIN to identify the correct product.

12. The received order is organized and re-packaged if applicable. Next the order is delivered to the healthcare providers’ internal locations identified by the GLN as per the requisition.

13. The vendor creates and submits the invoice. The invoice contains the GTIN for each product and the GLN to identify the issuer of the invoice (i.e. Remit To), receiver of the invoice (i.e. Bill To), and the GLN locations for where the product was shipped (i.e. Ship To).

- **Good Practice** – Vendor submits a manual invoice (e.g. fax, email, mail) and sends to the healthcare provider. Healthcare provider manually validates accuracy of invoice to the purchase order.
- **Better Practice** – Vendor generates a standardized electronic invoice (i.e. EDI 810 Invoice) and sends to the healthcare provider. Healthcare provider manually validates accuracy of invoice to the purchase order and the shipment notification (if received) against the vendor catalogue number, GLN, GTIN and other related product attributes including the unit of measure, order quantity, and pricing. Healthcare providers will need to invest in technology and resources or partner with a solution provider to develop this capability. For more information on EDI, visit [www.gs1ca.org](http://www.gs1ca.org).
- **Best Practice** – Vendor generates a standardized electronic invoice (i.e. EDI 810 Invoice) and sends to the healthcare provider. The healthcare provider’s system automatically conducts a 3-way match to validate accuracy of the invoice to the purchase order and Advance Ship Notice (i.e. EDI 856 ASN) against the vendor catalogue number, GLN, GTIN and other related product attributes including the unit of measure, order quantity, and pricing. Healthcare providers will need to invest in technology and resources or partner with a solution provider to develop this capability. For more information on EDI, visit [www.gs1ca.org](http://www.gs1ca.org).

14. The healthcare provider reviews, pays the invoice and closes the PO.

- **Good Practice** – healthcare provider issues a manual payment (i.e. cheque) to the vendor once the shipment has been received in full.
- **Better Practice** – healthcare provider sends payment by Electronic Funds Transfer (EFT) once the shipment has been received in full. Healthcare provider manually provides payment remittance information to the vendor. Healthcare providers will need to invest in technology and resources or partner with a solution provider or to develop this capability.
8.2.2 a. Blanket Order

Blanket order is a type of purchase order that allows for multiple delivery dates over a period. This type of order is often used when there is a frequent need for expendable goods. Releases against a blanket purchase order will be created as needed until one of the following are achieved:

a. the contract is fulfilled
b. the end of the order period is reached or
c. the pre-determined maximum order value is reached.

**General business process flow for blanket orders is the same as the standard order outlined above (section 8.2.1).**

When processing a blanket order, the following differences exist:

- An authorized user submits a requisition identifying the need for a blanket order for goods using methods outlined by the Healthcare Provider.
- Blanket Orders have a pre-determined dollar value limit and/or quantity limit.
- Blanket Orders usually have a defined scheduled shipment as well as multiple release dates.

8.2.3 a. Consignment Order

Consignment order is an initial order for all items to be delivered to the end user’s location, but at zero cost. This type of order is intended as a pay-as-consumed process.

1. The healthcare provider should modify their list of required attributes (requisition) to include two fields:
   - One field that will be used to list the GTIN at each packaging level.
   - One field that will be used to capture the GLN of the manufacturer/supplier of the product

2. Healthcare providers should update their Standard Operating Procedures (SOPs) to include the need for obtaining and storing GTINs and GLNs when managing contracts.

**Note:** Obtaining the GTIN, GLN and other related product attributes to be added to the item master can be done several ways:

- **Good Practice** - manufacturer provides the GTIN, GLN and related product information in a table format (e.g. pdf, Excel) that can be entered manually into the healthcare provider’s system. Ideally, the manufacturer would provide this information in a standardized table format (e.g. Excel) that can be reviewed, modified or rejected and then automatically uploaded into the healthcare provider’s system.

- **Best Practice** - providers can receive the GTIN, GLN and related product information using Electronic Data Interchange (EDI). This information can be exchanged via EDI Price/Sales Catalogue 832 transaction. Alternatively, the provider can receive the GTIN, GLN and related product information using the Global Data Synchronization Network (GDSN). Providers will need to invest in technology and resources or partner with a solution provider to develop either EDI or GDSN capabilities. For more information on EDI and GDSN standards visit [www.gs1ca.org](http://www.gs1ca.org).
3. The Healthcare providers must ensure their internal system(s) (e.g. ERP) can store, process and flow GTIN and GLN within different internal systems.

4. An authorized user submits a requisition for goods and/or services using methods outlined by the Healthcare Provider. The requisition should contain GTIN and GLN to as product and location identifiers.

   **Note:** The requisition follows the standard order process, but results in shipment & delivery of all goods to the healthcare provider's location for storage until needed. The invoice will be for zero dollars and lists all items on consignment that were shipped to the healthcare provider.

5. When an item is used, or consumed, the buyer is notified to create a purchase order.
   
a. If the item needs to be replaced, the buyer will create a bill-and-replace purchase order referencing the lot number, serial number and expiry date.

b. If the item does not need to be replaced, the buyer will create a bill-only purchase order.

c. The purchase order will contain the GTIN for each line item. Global Location Numbers (GLNs) should be included in the PO to identify the following:
   
   a. GLN for the party submitting the order (i.e. healthcare provider)
   b. GLN for the Ship To location for where the order is to be delivered
   c. GLN for the receiving party of the PO (i.e. vendor)
   d. GLN for the Bill To location to identify the billing party

d. Global Trade Item Numbers (GTINs) should be included in the PO for every line item to identify what product is being ordered.

6. The PO is sent to the vendor.

   The healthcare provider can send the Purchase Order in several ways:
   
   - **Good Practice** – provider generates a manual purchase order (e.g. fax, email, vendor website) from their material management information system and sends to the seller. Provider manually validates accuracy of purchase order including vendor number, GTIN and related product attributes including product description, unit of measure, order quantity, and pricing.
   
   - **Better Practice** - provider generates a standardized electronic purchase order (i.e. EDI 850 Purchase Order) from their material management information system and sends to the seller. Provider manually validates accuracy of purchase order including vendor catalogue number, GTIN and related product attributes including product description, unit of measure, order quantity, and pricing. Providers will need to invest in technology and resources or partner with a solution provider to develop this capability. For more information on EDI, visit [www.gs1ca.org](http://www.gs1ca.org).
   
   - **Best Practice** – To support the perfect order, providers maintain ongoing accuracy of GTIN, product attributes, and related product pricing information using Electronic Data Interchange (EDI) or via the Global Data Synchronization Network (GDSN). The provider generates a standardized electronic purchase order (i.e. EDI 850 Purchase Order) from their material management information system which is automatically validated for accuracy of purchase order details including vendor product number, GTIN, product description, unit of measure, order quantity, and pricing. Providers will need to invest in technology and resources or partner with a solution provider to develop this capability. For more information on EDI or GDSN, visit [www.gs1ca.org](http://www.gs1ca.org).

7. The vendor receives and process the PO. The vendor’s systems process GTINs and GLNs and identify any discrepancies that may exist in the PO.

8. The vendor replies to the Healthcare Provider with a purchase order confirmation, often called the Purchase Order Acknowledgment (POA). The POA uses the GLN to accurately
identify the vendor and the healthcare provider. The GTINs are used in the POA to identify the line items.

- This confirmation supports identification of discrepancies in the PO such as pricing, unit of measure, vendor catalog number, etc.
- As a best practice, the POA will also identify discrepancies in GTIN and GLN (i.e. incorrect or missing identifiers).

9. Healthcare Provider receives, reviews and corrects the discrepancies on the POA using the GTIN to identify the correct product to apply changes and using the GLN to identify the vendor.

- Estimated time of delivery if provided in the POA will be entered in the system to support tracking by Healthcare Providers.

10. The vendor picks the item using the GTIN to identify the items, and GLN to identify the warehouse location for each item. Then the vendor packs the items ensuring the barcode on the cases or pallets represent the correct GTIN for this packaging hierarchy. The vendor also ensures the bar code is created based on standards and it is readable by a scanner. The shipment is labelled with an SSCC and the items the are shipped to the Healthcare Provider.

11. The vendor may send an Advance Ship Notice (ASN) to the Healthcare Provider.

- The ASN will contain the SSCC to identify the shipment and the GLN to correctly identify the trading partner. It also must contain the GTIN(s) for item identification. The Healthcare Provider uses the information in the ASN to prepare for receiving deliveries.


- Orders may be received in full, or partially received if all items requested were not available at time of order.
- Partially-received orders are noted in the system and the back-orders are followed up until resolved.

13. The received order is organized, re-packaged if applicable, and delivered as requested. Receipt of goods is captured in the system leveraging the GTIN to identify the correct item.

14. The vendor creates and submits the invoice. The invoice contains the GTIN for each item and the GLN to identify the Bill To and Remit To locations.

- **Good Practice** – vendor submits a manual invoice (e.g. fax, email, mail) and sends to the healthcare provider. Provider manually validates accuracy of invoice to the purchase order.

- **Better Practice** – vendor generates a standardized electronic invoice (i.e. EDI 810 Invoice) from their system and sends to the healthcare provider. Healthcare provider manually validates accuracy of invoice to the purchase order such as vendor catalogue number, GLN, GTIN and related product attributes including product description, unit of measure, order quantity, and pricing. Healthcare providers will need to invest in technology and resources or partner with a solution provider to develop this capability. For more information on EDI, visit www.gs1ca.org.

- **Best Practice** – vendor generates a standardized electronic invoice (i.e. EDI 810 Invoice) from their system and sends to the healthcare provider. Healthcare provider’s system automatically conducts a 3-way match to validate accuracy of invoice to the purchase order and what was received such as vendor catalogue number, GLN, GTIN and related product attributes including product description, unit of measure, order quantity, and pricing. Providers will need to invest in technology and resources or partner with a solution provider to develop this capability. For more information on EDI, visit www.gs1ca.org.

15. The healthcare provider receives, reviews, pays the invoice and closes the PO.
Healthcare provider can perform a 3-way match between the PO, ASN, and the physical product by and scanning the GTIN.

- **Good Practice** – healthcare provider issues a manual payment (i.e. cheque) to the vendor once the shipment has been received in full.

- **Better Practice** – healthcare provider sends payment by Electronic Funds Transfer (EFT) from their system once the shipment has been received in full. Healthcare provider manually provides payment remittance information to the vendor. Healthcare providers will need to invest in technology and resources or partner with a solution provider or to develop this capability. For more information visit [www.gs1ca.org](http://www.gs1ca.org).

- **Best Practice** – healthcare provider sends payment by Electronic Funds Transfer (EFT) from their system once the shipment has been received in full. Additionally, the provider will automatically provide Electronic Payment Remittance information (i.e. EDI 820 Payment Order/Remittance Advice) to the vendor. Providers will need to invest in technology and resources or partner with a solution provider or to develop this capability. For more information visit [www.gs1ca.org](http://www.gs1ca.org).

### 9 Implementation Benefits

Some of the benefits of implementation of standards are:

- Supports automation of business processes
- Enables scanning at the patient bedside to support patient safety
- Reduces manual errors and improves accuracy of business processes (e.g. order management through Electronic Data Interchange or EDI)
- Fewer medication errors through efficient automated identification
- More effective and efficient product recalls
- Efficient traceability of supplies in the healthcare supply chain
- Clinical staff spend more time with patients, less time spent on manual documentation or looking for inventory.
- Cost reduction through increased supply chain efficiency
- Improved order and invoice processes
- Increased accuracy and control of inventory enabling reduced inventory costs
- Increased productivity in business processes
- Improved shelf management and cart management of supplies.

For more information visit [Safer, More Efficient Care Starts with a Simple Scan](http://example.com).

### 10 Implementation Risks

- Requesting to receive GTIN and GLNs from manufacturers may delay automation of the new item listing process by manufacturers who have not adopted GS1 standards.

- The upgrade of internal systems is dependant on your solution provider capabilities. Internal business and clinical systems must be able to store and process the standards (e.g. GTIN, GLN) to enable your organization’s implementation and use of global standards.

- Manufacturers that have not bar coded their product with a GTIN may provide the GTIN via an excel file. However, when the product arrives, healthcare providers will not be able to scan the barcode.
Implementation of GS1 standards involves change management for manufacturers. Some manufacturers may be resistant to loading and publishing their product catalogue in the GDSN.

11 Technical Considerations and Recommendations

- GTINs are assigned by product and packaging level, therefore; the item master file must be able to store a **14-digit GTIN** and related product attributes for each packaging level.
- It is recommended that healthcare providers **load and maintain GTINs for all available packaging levels** in their systems which can be used in downstream business and clinical processes.
- The GTINs should be stored in a separate field from other product identifiers within healthcare provider systems.
- GTINs can start with leading zeros therefore the **item master field that stores the GTIN must be a text field** to allow for storing the 14-digit GTIN without truncating the leading zeros.
- The GLNs should be stored in a separate field from other manufacturer/supplier identifiers within healthcare provider systems.
- GLNs can start with leading zeros therefore the **item master field that stores the GLN must be a text field** to allow for storing the 13-digit GLN without truncating the leading zeros.
- Both GTINs and GLNs should be easily accessible to the user. Therefore, staff should be able to easily search and retrieve GTINs and/or GLNs for items within their Materials Management Information and clinical systems.
- GTIN, GLN and other related product attribute information contained in the healthcare provider’s **Item Master should be synchronized with the Contract Management Solution**.
- GTIN and GLN and other related product attributes should be mapped and flow throughout all business and clinical systems to enable automation various business and clinical processes. This will ensure the same product information to be used throughout the organization while eliminating the risks associated with manually re-keying the information into each system.
- The most recent version of the **Electronic Data Interchange (EDI) standards** used in Canada for the healthcare sector is **X12 version 6020**. It is strongly recommended that healthcare providers should be able to use EDI to obtain GTINs and GLN electronically. The EDI 832 transaction is used to share product information including GTIN, GLN and pricing information to support new item listing. EDI transactions that support Order Management are:
  - EDI 832 Price Sales Catalogue.
  - EDI 850 Purchase Order
  - EDI 855 Purchase Order Acknowledgement
  - EDI 856 Advance Shipment Notification
  - EDI 997 Functional Acknowledgement
  - EDI 810 Invoice
  - EDI 820 Payment Order/Remittance Advice
Appendix A - Resources

Get a GTIN

GS1 Healthcare GTIN Allocation Rules

Permanent GTIN

Automatic Identification and Data Capture (AIDC) for Healthcare Implementation Guideline

The 10-step guide for healthcare providers to implement GS1 standards

GS1 General Specifications

GS1 Canada GDSN

Get a GLN

GLN Allocation Rules

Best Practice Guide: Building a GLN Hierarchy

Healthcare Implementation Guidelines for Electronic Data Interchange (EDI)
13 Appendix B - Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buyer</td>
<td>An individual that is authorized to make purchases on behalf of their organization.</td>
</tr>
<tr>
<td>Catalog Item</td>
<td>A product or service recorded in an organization’s item master file.</td>
</tr>
<tr>
<td>Contract Management Process</td>
<td>Contract management refers to the procedures and policies used in an organization to manage contract agreements between trading partners. It includes, but is not limited to, contract negotiation, execution, compliance, performance, maintenance and expiration of contracts.</td>
</tr>
<tr>
<td>Contract Management Team</td>
<td>Term used to generically identify the staff responsible for management, maintenance, compliance and reporting functions of contracts within an organization.</td>
</tr>
<tr>
<td>Distributor</td>
<td>An entity who supplies/resells goods to other organizations.</td>
</tr>
<tr>
<td>Enterprise Resource Planning (ERP) System</td>
<td>An ERP (Enterprise Resource Planning) system, refers to the internal system an organization is using to manage purchasing, inventory, marketing, finance and other business-related areas.</td>
</tr>
<tr>
<td>Group Purchasing Organization (GPO)</td>
<td>A group purchasing organization (GPO) is an entity that is created to leverage the purchasing power of a group of members.</td>
</tr>
<tr>
<td>Healthcare Provider</td>
<td>The term “Healthcare Provider” refers to Shared Service Organizations (SSOs), Group Purchasing Organizations (GPOs), Health Authorities (HAs) or hospitals in this document.</td>
</tr>
<tr>
<td>Item</td>
<td>A record in the Item Master. Each item record uniquely describes the item or service and defines how it will be handled throughout the supply chain. Item attributes may include, but are not limited to: description, model number, vendor item number, price, tax status, latex content, unit of measure, weight, dimensions, GTIN, UNSPSC etc.</td>
</tr>
<tr>
<td>Item Master</td>
<td>It is a collection of records that identifies the items and services available for use within the organization. Often referred to as the “catalog” of items.</td>
</tr>
<tr>
<td>Item Master Management Team</td>
<td>A group of people identified to work together in setting up and maintaining an organization’s repository of products or services.</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>The entity that makes, fabricates or produces goods.</td>
</tr>
<tr>
<td>Material Management Information System (MMIS)</td>
<td>A software suite packaged as an integrated offering to meet materials management, human-resources and back-office needs. Healthcare providers have implemented these systems to automate or facilitate functions such as purchasing, accounting, inventory management, and patient supply charges.</td>
</tr>
<tr>
<td>Member Hospital or Member Customer</td>
<td>Any entity that partners with a Shared Service Organization (SSO) or Group Purchasing (GPO) for goods or services. An example of a customer is Emergency Medical Services (EMS).</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-------------------------------</td>
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</tr>
<tr>
<td>New Item Request Form</td>
<td>An internal form used by a hospital or Shared Service Organization to request a new product or service.</td>
</tr>
<tr>
<td>Non-Catalog Item</td>
<td>A product or service NOT recorded in the organization’s item master file.</td>
</tr>
<tr>
<td>Purchasing Department</td>
<td>A team responsible for procuring goods and services on behalf of the organization.</td>
</tr>
<tr>
<td>Requisition</td>
<td>A formal request for the purchase of a good or service.</td>
</tr>
<tr>
<td>Requisitioner</td>
<td>A user of the healthcare supplier system that is authorized to submit formal requests on behalf of their business unit. Typical requests are for the purchase of goods and services, addition of new item records to the Item Master, and others as defined by each Healthcare Supplier.</td>
</tr>
<tr>
<td>Shared Service Organization (SSO)</td>
<td>An SSO is an entity that is resourced by its members. It is created to leverage the purchasing power of a group of members and may provide other services.</td>
</tr>
<tr>
<td>Trading Partner</td>
<td>A generic term used in this document to indicate the parties engaged in the business process.</td>
</tr>
</tbody>
</table>
| Vendor                        | A vendor is a trading partner in the supply chain who sells goods and services. In this document, the term Vendor is the organization selling to the Healthcare Provider.  
*Note: Vendor is interchangeable with Supplier or Seller.*  |