



# GS1 HEALTHCARE US

## IMPLEMENTATION GUIDELINE

Applying GS1 Standards to  
U.S. Pharmaceutical Supply Chain Business Processes  
TO SUPPORT PEDIGREE AND TRACK & TRACE

Release 1.0 (February, 2013)



THE GLOBAL LANGUAGE  
OF BUSINESS

## Future Versions

This document is a preliminary version of the implementation guideline. It is anticipated that it will undergo changes as the industry engages in pilots and implementations of product serialization, track and trace, and pedigree applications. Comments to this document should be sent to GS1 Healthcare US via [rceleste@gs1us.org](mailto:rceleste@gs1us.org). The document may be updated, replaced or made obsolete by other documents at any time. Please check the GS1 Healthcare US website frequently for the latest version of the document. <http://www.gs1us.org/healthcare>

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### **About GS1®**

GS1 is a neutral, not-for-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organizations in 111 countries, with the Global Office in Brussels, Belgium.

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GS1 US is the Member Organization of GS1 that serves companies in the United States. As such, it is the national implementation organization of the GS1 System dedicated to the adoption and implementation of standards-based, global supply chain solutions in the United States. GS1 US currently serves over 200,000 U.S. member companies -- 16,000 of which are in healthcare.

### **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 & 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 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 sixty-six local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

# Part 1: Preface

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# 1. Introduction

California state drug pedigree requirements become mandatory in 2015, marking the beginning of product serialization and visibility in the healthcare supply chain. In response, members of the United States pharmaceutical industry have been preparing their systems and business processes to meet those requirements. During this journey, the healthcare industry has rallied around the use of Electronic Product Code™ Information Services (EPCIS) for pedigree and track and trace. The EPCIS is a GS1 Standard that enables supply chain partners to capture event information about supply chain events (e.g., shipped; received; etc.), and to share that information with their trading partners securely and in near real-time.

The EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. There are numerous options for how the standards can be implemented in order to accommodate different applications and environments. Nonetheless, there still needs to be a certain level of consistency in terms of how the standards are implemented by individual trading partners in order to support collaborative supply chain solutions like pedigree and track and trace.

Therefore, members of the U.S. pharmaceutical industry joined forces to determine how the standards can best be applied to support pedigree and track and trace. Over fifty organizations from across the U.S. pharmaceutical supply chain participated. Leading manufacturers, wholesalers, retail pharmacies, healthcare providers, government agencies and industry associations all worked together to analyze business processes and post-2015 business requirements, consider the various options, and decide how the standards should be applied.

To support testing and analysis, they created a computerized model of the U.S. pharmaceutical supply chain that simulates forward logistics and reverse logistics processes using GS1 Standards for product serialization and visibility. All of their decisions about how the standards might be applied are embedded in that model, which is known as the Industry Reference Model for the U.S. Pharmaceutical Industry. The reference model provides an example of an implementation, reflecting the current wisdom in industry for how the standards can best be applied to support the needs of the U.S. pharmaceutical supply chain.

This document records all of the decisions points for how the standards are applied. By so doing, this document serves an implementation guideline that shows industry members how to apply the standards to their own business processes to support pedigree and track and trace.

## 2. Document Information

This implementation guideline was prepared by GS1 US and the Secure Supply Chain Task Force of the Traceability Adoption Workgroup to assist the U.S. pharmaceutical industry in implementing GS1 Standards to support pedigree and track and trace. It is based on the *GS1 General Specification*, the *EPC Tag Data Standard*, the *Tag Data Translation Standard*, and the *EPCIS Standard*. It was developed using information obtained from all members of the U.S. pharmaceutical supply chain from manufacturers to providers.

### 2.1. Purpose

This document identifies the GS1 Standards used and provides details about how they can be applied toward the purposes of product serialization, track and trace and pedigree. Included are all of the EPCIS *Business Step* and *Product Disposition* combinations used for each supply chain event. By so doing, this document serves an implementation guideline that directs industry members about how to apply the standards to their own business processes to support product serialization, pedigree and track and trace within the U.S. pharmaceutical supply chain.

### 2.2. Content Condition

This document is a working draft that reflects the current level of thought within industry. As such, it will undergo changes as the Traceability Adoption Workgroup deems necessary to reflect feedback from industry pilots, architecture work being conducted by GS1, and other industry efforts which advance the level of thought. The content may be of assistance as a resource for understanding current thinking or as an aid for pilot preparation. The reader should be aware that changes will be made frequently and should not expect any particular section of content to remain unchanged in the first release.

### 2.3. Version Updates

Version	Date	Update Notes	Reviewed by Team	Approved for Draft by Team
Release 1.0	02/01/2012	Initial release.		

Table A: Document Version History

## 2.4. Scope

This guideline presents the current wisdom in industry for how GS1 Standards can best be applied to U.S. pharmaceutical supply chain business processes to support pedigree and track and trace. It does not provide any guidance or advice regarding regulatory compliance.

- The content of a valid ePedigree is specified in pedigree regulations, and companies should consult those regulations for information, guidance and/or advice regarding regulatory compliance.
- The Drug Pedigree Messaging Standard (DPMS) defines an XML data format designed specifically to satisfy pedigree requirements.
- The DPMS complies with all known U.S. pedigree laws, and is currently the only pedigree format approved by regulators.
- The use of EPCIS events along with specific product and location master data provides a means for trading partners to accumulate the information that would be found in the *Drug Pedigree Messaging Standard (DPMS)*.

## 2.5. Normative References

This application guideline is based on the *GS1 General Specification*, the EPC Tag Data Standard, the Tag Data Translation Standard, and the EPCIS Standard. The specific standards referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- *GS1 General Specification* – Available in the Knowledge Center through the GS1 website at [www.gs1us.org/solutionscenter](http://www.gs1us.org/solutionscenter)
- EPC Tag Data Standard – Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/gsmc/kc/epcglobal>
- Tag Data Translation Standard – Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/gsmc/kc/epcglobal>
- EPCIS Standard – Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/gsmc/kc/epcglobal>
- Core Business Vocabulary Standard – Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/gsmc/kc/epcglobal>
- GTIN Allocation Rules
- GTIN Allocation Rules for Healthcare
- GLN Allocation Rules

## 2.6. Non-normative References

Material in this application guideline is based on a number of non-normative guidelines and references available from GS1 and GS1 US. The specific guidelines and documents referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- *GS1 RFID Bar Code Interoperability Guideline* - Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/gsmf/kc/barcodes>
- *Healthcare Provider GTIN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Supplier GTIN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Provider GLN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Supplier GLN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Provider GDSN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *Healthcare Supplier GDSN Tool Kit* – Available on the GS1 US website at <http://www.gs1us.org/hctoolkit>
- *The Practice of Inference in the U.S. Pharmaceutical Supply Chain* - Available on the GS1 US website at [www.gs1us.org/hctools](http://www.gs1us.org/hctools)

## 2.7. Additional Considerations & Resources

- GS1 DataMatrix requires camera-based scanners. Traditional laser barcode scanners cannot read the GS1 DataMatrix. As a result, it is important for supply chain partners to communicate prior to implementing GS1 DataMatrix to ensure that the appropriate scanners are in place.
- Prior to purchasing barcode scanning equipment, it is recommended that you consult the *Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria* (see the Resources page in the Appendix for the link). This document was prepared by GS1 US to assist members of the U.S. healthcare supply chain in evaluating the various barcode scanning equipment options on the market, and selecting the equipment that best fits their needs.
- There are many reasons why a barcode may not scan. Many times it is not the barcode, but the scanner itself. For example, the lens could be dirty or the batteries discharged. GS1 US prepared another document entitled *Procedure for Responding to Troublesome Barcodes* (see the Resources page in the Appendix for the link) to help resolve barcode scanning issues. This document offers a simplified process to rectify barcode scanning issues based on the experiences of healthcare users. It is recommended that you download this document as a reference to help you respond if a barcode does not scan.

## 3. Overview of the GS1 Standards Used

This chapter provides a brief definition of each GS1 Standard used in the industry reference model. (Refer to the [Appendix](#) of this document for more information about GS1 Standards that support pedigree and track and trace.)

### 3.1. Global Location Number (GLN)

The Global Location Number (GLN) is the globally unique GS1 Identification Number for locations and supply chain partners. The GLN can be used to identify a *functional entity* (like a hospital pharmacy or accounting department), a *physical entity* (like a warehouse or hospital wing or even a nursing station), or a *legal entity* (like a health system corporation). The attributes defined for each GLN [e.g., name, address, location type (e.g., ship to, bill to, deliver to, etc.)] help users to ensure that each GLN is specific to one unique location within the world.

### 3.2. Global Trade Item Number® (GTIN®)

The Global Trade Item Number (GTIN) is the globally unique GS1 Identification Number used to identify “trade items” (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The GTIN uniquely identifies a product at each packaging level (e.g., a bottle of 100 aspirin tablets; a case of 200 bottles of aspirin tablets, etc.).

### 3.3. Serial Shipping Container Code (SSCC)

The Serial Shipping Container Code (SSCC) is the globally unique GS1 Identification Number used to identify individual logistic units (i.e., an item of any composition established for transport and/or storage which needs to be tracked individually and managed through the supply chain). The SSCC is assigned for the lifetime of the transport item and is a mandatory element on the GS1 Logistic Label. SSCCs serve as “license plates” from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

### 3.4. GS1 Data Carriers

GS1 Data Carriers provide *machine-readable representations* of GS1 Identification Numbers that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports eight data carriers: six barcode symbologies (i.e., GS1 Barcodes) and two RFID tags [i.e., GS1 Electronic Product Code / Radio Frequency Identification Tags (EPC/RFID Tags)].

### 3.5. GS1 Application Identifiers

GS1 Application Identifiers (AIs) are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two, three, or four digit numeric code. (When rendered in human-readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode’s encoded data.) Each data element in a barcode is preceded by its AI. For example, the AI for GTIN is 01. Thus, when “01” appears in the encoded content of a barcode, it means the next 14 digits comprise a GTIN. There are approximately 100 AIs. There is an AI for each GS1 Identification Number. In addition, there are AIs for various types of secondary information to enable supply

chain partners to communicate item-specific information wherever the barcode is scanned (e.g., expiration date; lot number; batch number). GS1 AI's commonly used in healthcare include AI (10) for Lot/Batch Number, AI (17) for Expiration Date, and AI (21) for Serial Number.

### 3.6. EPC Information Service (EPCIS)

The EPC Information Service (EPCIS) standard defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain. The EPCIS specification provides technical standards, as well as a standardized set of service operations and associated data elements. In addition, the EPCIS standard also incorporates data standards for how to populate EPCIS data elements. (See Core Business Vocabulary below.)

### 3.7. Core Business Vocabulary (CBV)

The Core Business Vocabulary (CBV) provides data standards for populating EPCIS data elements. The CBV provides lists of acceptable values for how to express what business process was operating on an object and the status of the object upon exiting the process. It includes syntaxes, vocabularies, and element values (with definitions).

### 3.8. GLN Registry

The GLN Registry is the single source of truth for healthcare location information, offering a comprehensive list of healthcare and healthcare-related facilities in the United States with corresponding Global Location Numbers (GLNs). The GLN is the globally recognized identification number used in the GS1 System to uniquely identify legal entities, trading partners, and locations in electronic commerce transactions. The GLN Registry enables subscribers to access up-to-date, reliable location information, validated by the U.S. Postal Service, for manufacturers, distributors, retailers, hospitals, clinics, as well as retail and mail-order pharmacies in order to improve the accuracy of their supply chain activities.

### 3.9. Global Data Synchronization Network™ (GDSN®)

The Global Data Synchronization Network (GDSN) provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly defined and formatted, and (3) sharing that information with supply chain partners. The GDSN is a network of interoperable data pools connected by the GS1 Global Registry®. The GDSN-certified Data Pools store and manage supply chain information for their users, and the GS1 Global Registry connects those data pools together. The GDSN offers a continuous, automated approach to data management that ensures that supply chain information is identical among trading partners, increasing data accuracy and driving costs out of the supply chain.

## 4. Background Concepts

### 4.1. Relationship between NDC – GTIN – SGTIN

The FDA National Drug Code (NDC) is a U.S. regulatory identifier used to identify pharmaceutical products for regulatory purposes. The GTIN is a supply chain identifier used to identify *products* for supply chain purposes. The SGTIN is a supply chain identifier used to identify *individual instances of a product* for supply chain purposes. There is a cohesive, hierarchical relationship between these identifiers. As illustrated in Figure 1, NDCs can be embedded into GTINs so that identification of pharmaceutical products for supply chain purposes is consistent with identification of pharmaceutical products for regulatory purposes. GTINs can then be supplemented with serial numbers to identify individual instances of the pharmaceutical product.



Figure 1: Relationship of the NDC, GTIN and SGTIN

### 4.2. NDC Labeler Code & GS1 Company Prefix

The NDC is a 10-digit identifier comprising two segments: a *Labeler Code* assigned by the FDA and a *Product/Package Code* assigned by the manufacturer. The *Labeler Code* is a variable length identifier assigned by the FDA (and encoded into NDCs) to identify a company that manufactures a drug (including repackers or relabelers) or distributes a drug (under its own name).

GS1 US has reserved a placeholder in the GS1 Company Prefix numbering system that enables the NDC *Labeler Code* to be integrated into the GS1 Company Prefix for pharmaceutical companies. The placeholder (named the “GS1 Prefix”) is **03**, and the GS1 Company Prefix for a pharmaceutical company is simply its *Labeler Code* with “03” appended in front. For example:

GS1 Prefix	<b>03</b>
FDA-assigned <i>Labeler Code</i>	<b>61414</b>
GS1 Company Prefix	<b>0361414</b>

**i** In order to use a *Labeler Code* as a GS1 Company Prefix, manufacturers must first contact GS1 US to have a GS1 Company Prefix that embeds their *Labeler Code* assigned to the company.

Pharmaceutical companies may have more than one GS1 Company Prefix (e.g., one GS1 Company Prefix that integrates their NDC *Labeler Code*, and other GS1 Company Prefixes that do not). Those companies will need to use the GS1 Company Prefix that integrates their *Labeler Code* when assigning GTINs that embed NDCs (discussed below). However, they may use whichever GS1 Company Prefix they prefer to generate SSCCs and GLNs.

### 4.3. Integrating NDCs into GTINs

As noted above, NDCs can be integrated into GTINs. Figure 2 illustrates how the two NDC segments (i.e., *Labeler Code* and *Product/Package Code*) are integrated into the segments of a GTIN-14. The NDC *Labeler Code* is integrated into a GS1 Company Prefix (as described above). The NDC *Product/Package Code* is used to populate the Item Reference segment of the GTIN.

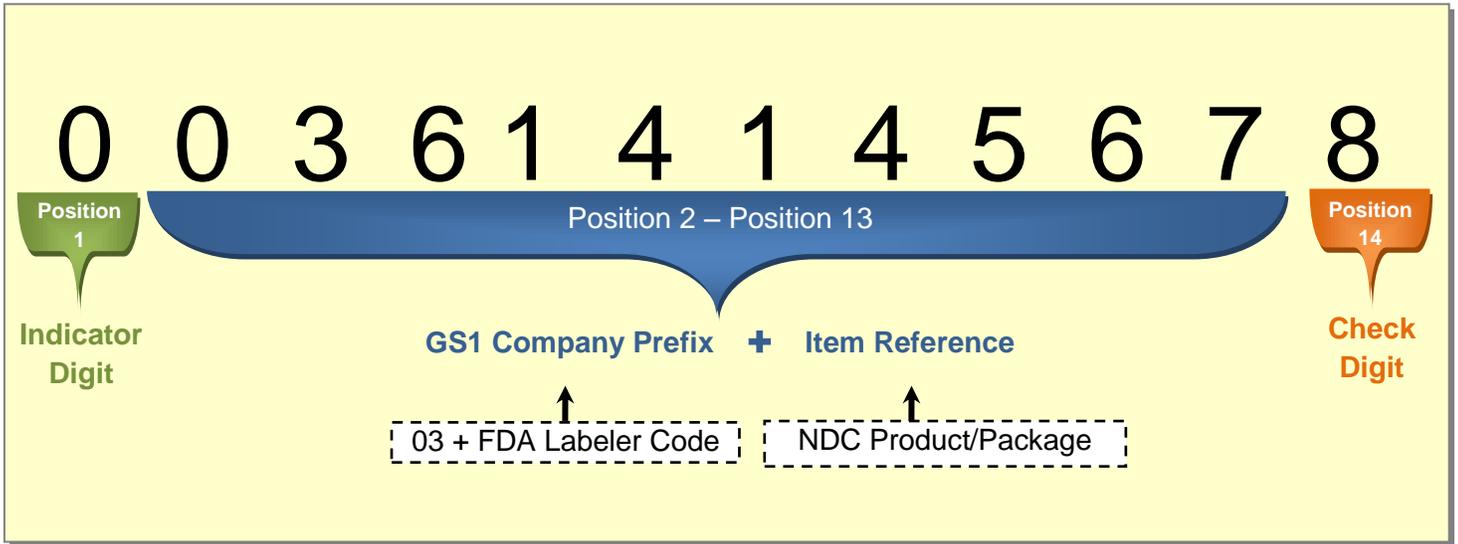


Figure 2: Segments of a GTIN-14 that embeds an NDC (based on the hypothetical GTIN “00361414567894”)

### 4.4. Assigning vs. Storing vs. Encoding GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length. Within the U.S. pharmaceutical supply chain, the 12-digit GTIN (“GTIN-12”) and the 14-digit GTIN (“GTIN-14”) are predominantly used. Regardless of how they are assigned, it is important to understand that GTINs are always encoded in barcodes<sup>①</sup> and stored in databases in 14-digit format.

Assigning GTINs	Storing GTINs	Encoding GTINs
<b>GTIN-12 <u>or</u> GTIN-14</b>	<b>14-digit format</b>  (i.e. GTIN-14 <u>or</u> GTIN-12 in 14-digit format using leading zeros)	<b>14-digit format<sup>①</sup></b>  (i.e. GTIN-14 <u>or</u> GTIN-12 in 14-digit format using leading zeros)

Table B: Key to Assigning, Storing and Encoding GTINs

<sup>①</sup> The exception is the UPC-A, which is the only barcode in which GTINs are encoded as 12 digits.

## 4.5. Marking Products with Both UPC-A and GS1 DataMatrix

As of this writing, FDA regulations require pharmaceutical products to be marked with a linear barcode that carries their NDC. Serialization requirements and pedigree regulations typically require pharmaceutical products to be marked with a barcode that carries their NDC, a serial number, and possibly other secondary information such as lot/batch or expiration date. To satisfy these requirements, many pharmaceutical manufacturers are marking products that move through a Point of Sale (POS) with both a UPC-A (to satisfy the FDA linear barcode requirement) and a GS1 DataMatrix (to satisfy serialization/pedigree requirements). (See the [note in Section 8.1.1](#) for more information.) The UPC-A holds a maximum of 12 digits, but the GS1 DataMatrix requires the GTIN to be in a format that is 14 digits long. In order to ensure that the GTIN encoded in both barcodes is the same, manufacturers should follow the recommendations below for all products that will be marked with both a UPC-A and a GS1 DataMatrix:

- assign a GTIN-12 to identify the product at the lowest saleable level (i.e., the bottle or pack)
- create the UPC-A linear barcode using the GTIN-12
- pad the GTIN-12 with two leading zeros to create a “GTIN-12 in 14-digit format” ⓘ

**GTIN-12**

**31414 199999 5**

**GTIN-12 in 14-digit format**

**0 031414 199999 5**

- when storing GTIN-12s in databases, store them in the 14-digit format
- use the “GTIN-12 in 14-digit format” when encoding the GS1 DataMatrix (along with Expiration Date, Lot Number and Serial Number for serialization purposes)

**ⓘ THIS SHOULD NOT BE DONE IN THE OPPOSITE DIRECTION** (i.e., assign a GTIN-14 and remove the first two digits in an attempt to create a GTIN-14 in a 12-digit format). A true GTIN-14 (one with digits other than “00” in the 1<sup>st</sup> and 2<sup>nd</sup> positions) cannot be converted to a 12-digit format because, among other reasons, the check digit (which is calculated using the value and position of each digit) would not match.

A GTIN-12 remains a GTIN-12 whether it is in its original 12-digit format or represented in a 14-digit format using leading zeros. Technically speaking, the padded GTIN-12 is called a “GTIN-12 in a 14-digit format.” It is not a GTIN-14. Therefore, when a product needs to be marked with a UPC-A, it should be assigned a GTIN-12 (not a GTIN-14) in order to preserve the manufacturer’s ability to represent the GTIN in a 12-digit U.P.C. as well as any barcode that requires a 14-digit format.

## 4.6. Case Identification

Cases can be identified using GTIN + serial number or using SSCC, depending on how the case is being used:

- **Use GTIN + serial number if the case is orderable and if your customer is expecting to identify the contents from the case barcode or EPC/RFID tag**
- **Use SSCC if the case is to be treated as a logistics unit**

## 4.7. Location Identification: Data Capture vs. Data Reporting

The reference model includes a table that provides a reference between a business location (i.e., a building with an address) and internal locations (e.g., loading dock; doorway; etc.). The model captures EPCIS events at the internal location level, and produces EPCIS events for trading partners at the business location level. For example, a manufacturer may capture the location of a palletizer as cases are aggregated or packed onto a pallet. The EPCIS event that is generated for trading partners will include the location of the manufacturing site, not the palletizer itself. The manufacturer may decide to store the lower level location (palletizer) for their own purposes and report a higher level location (the production plant) for the purposes of external track and trace.

## 4.8. EPCIS & the URI

EPCIS stores identifiers (e.g., GTIN + serial number; SSCC; GLN; etc.) in URI format. "URI" stands for Uniform Resource Identifier, which is used in many Internet-based software systems to refer to any resource on the network. There are two types of URIs: Uniform Resource Names (URNs) and Uniform Resource Locator (URLs). The EPCIS data format standard is a URN which takes the following form:

`urn:epc:id:scheme:component1.component2....`

*Scheme* names an EPC scheme, and the content and format of the remainder of the URI string (i.e., *component1*, *component2*, etc.) depends on which EPC scheme is being used. Each EPC scheme provides a namespace of identifiers that can be used to identify physical objects of a particular type. There are seven EPC schemes that correspond to GS1 keys. For example, the EPC scheme for SGTIN is provided below:

**General syntax:** `urn:epc:id:sgtin:CompanyPrefix.ItemReference.SerialNumber`

**Example:** `urn:epc:id:sgtin:0614141.112345.400806`

The URI scheme to be used for GTIN + serial number, SSCC and GLN are provided in the relevant sections of this manual.

## 4.9. Determining the Length of GS1 Company Prefixes for URIs

When translating data from URI formats, it is necessary to indicate the length of the GS1 Company Prefix (i.e., how many digits within the GS1 Key belong to the GS1 Company Prefix). Because GS1 Company Prefixes are issued in varying lengths, you will need to obtain the length of each GS1 Company Prefix you expect to encounter in your EPCIS events. To facilitate this, GS1 US has published a list of U.S. GS1 Company Prefixes that you can download and use ([www.gs1us.org/gcplist](http://www.gs1us.org/gcplist)). Alternatively, you can ask your trading partners for the length of their GS1 Company Prefixes and create your own table. (You can even make this part of your on-boarding process for vendors.)

## 4.10. Inference

*Inference* is the process a supply chain partner uses to ensure there is enough evidence to infer the serialized number without physically reading ALL serialized numbers. Inference applies in instances where a collection is moved through the supply chain in an outer container (e.g., pallets; cases; totes; etc.), and less than 100% of data carriers in that collection are read by recipients. In such circumstances, inference enables the recipient of the collection to leave the outer container intact (un-opened) so as not to undermine tamper-evident security features. To gain a more complete understanding of what is contained in the entire collection, the recipient reads the serialized identifiers for the visible items, cross-checks them with the shipping documents for the collection and outer container bundle, and verifies the integrity of the outer container bundle and its security features. If all three conditions are confirmed, the rest of the items in the collection can be inferred to be present.

*Inference* is a mechanism that enables supply chain partners to leverage strong supply chain practices to meet the potential challenges associated with the receiving/shipping of serialized items. For more information, see the GS1 US white paper entitled *The Practice of Inference in the U.S. Pharmaceutical Supply Chain* (see References above for link).

### **Use of Inference in examples:**

For internal levels of packaging where either barcodes are used or EPC/RFID devices are unreadable, the trading partner in possession of the object is said to have inferred the existence of internal layers of packaging that cannot be read at the time of the event and may exercise an inference SOP for that purpose.

## 4.11. Use of Inference

For internal levels of packaging where either barcodes are used or RFID devices are unreadable, the trading partner in possession of the object is said to have inferred the existence of internal layers of packaging that cannot be read at the time of the event and may exercise an inference SOP for that purpose.

## 4.12. Drug Pedigree Messaging Standard (DPMS)

The content of a valid ePedigree is specified in pedigree regulations. At the time of publication, the DPMS complied with all known U.S. pedigree laws. The present guideline makes use of GS1 Visibility standards including Global Data Synchronization Network (GDSN), EPCIS, Core Business Vocabulary and the Tag Data Standard to manage, share and assemble pedigree data.

The documented EPCIS events and Master Data Management architecture provides for reporting capabilities that provide all of the information that would be found in the DPMS.

## Part 2: Identify

GS1 Identification Numbers globally and uniquely identify supply chain objects (e.g., products, assets, logistic units, etc.), as well as supply chain partners and physical locations. Table 3 lists the GS1 identification standards used in this guideline to support pedigree and track and trace.

Supply Chain Object or Location	Corresponding GS1 Identifier	Instance
Companies and warehouses	GLN	
Specific locations within companies & warehouses	GLN + extension	
Item	GTIN	GTIN + serial number
Kit	GTIN	GTIN + serial number
Homogeneous Case	GTIN	GTIN + serial number, SSCC
Mixed / Partial Case		SSCC
Pallet		SSCC
Tote		SSCC

Table C: GS1 Identifiers<sup>1</sup>

<sup>1</sup> There may be other layers of packaging that are not specified here.

## 5. Identifying Trade Units (Products, Cases and Kits): GTIN

In the GS1 System, products, cases and kits<sup>2</sup> are identified with the Global Trade Item Number (GTIN). GTIN is a globally unique, standards-based, identification number for trade items. When a manufacturer assigns (“allocates”) a GTIN, they define a prescribed set of data about the product to which that GTIN relates. These *product description attributes* define master data that is consistent across all instances of the product (e.g., size; color; brand information; etc.). GS1 Standards specify the list of attributes that must be defined for each GTIN, as well as the permissible values. Once the GTIN is allocated and the attributes are defined, the GTIN and its associated attributes are then saved in a database (like a GDSN-certified Data Pool) and shared among supply chain partners. (The section of this guideline entitled “[Master Data Management](#)” explains how this information can be combined with EPCIS event information to obtain supply chain visibility.)

(NOTE: GS1 US provides an online tool, known as Data Driver®, to support users in allocating GTINs and defining the associated attributes. Visit <http://www.gs1us.org/resources/tools/data-driver> for more information.)

### 5.1. Assigning GTINs

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length (known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14, respectively). However, within the U.S. pharmaceutical supply chain, the GTIN-12 and the GTIN-14 are predominantly used. The choice of format is related to point of sale:

- **Assign a GTIN-12 to pharmaceuticals products that will be scanned at point of sale** (see [Section 4.5](#) for more information)
- **Assign a GTIN-14 to pharmaceuticals that will not be scanned at point of sale**

#### 5.1.1. Creating a GTIN-12

Each GTIN-12 is a numerical string comprising three distinct segments. The three segments within a GTIN-12 are:

- **U.P.C. Company Prefix:** A specific representation of a GS1 Company Prefix that serves as the foundation for generating GTIN-12 identifiers. U.P.C. Company Prefixes vary in length depending on the company/organization’s needs. In a GTIN-12 that embeds an NDC, the U.P.C. Company Prefix segment is populated with the NDC Labeler Code with a “3” appended in front.
- **Item Reference:** A number assigned by the holder of the U.P.C. Company Prefix to uniquely identify a trade item. The *Item Reference* varies in length as a function of the U.P.C. Company Prefix length. (Refer to the *GS1 General Specifications* and the *GTIN Allocation Rules for the Healthcare Sector* for additional information.) In a GTIN-12 that embeds an NDC, the *Item Reference* segment is populated with the NDC Product/Package Code.
- **Check Digit:** A one-digit number calculated from the first 11 digits of the GTIN-12 used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at <http://www.gs1us.org/resources/tools-and-services/check-digit-calculator>.

<sup>2</sup> Consult the FDA UDI (Unique Device Identification) Rule for Kits that include a medical device.

Although the length of the U.P.C. Company Prefix and the length of the *Item Reference* vary, they will always be a combined total of 11 digits in a GTIN-12. The addition of the *Check Digit* completes the 12 digits of the GTIN-12. Figure 3 provides a color-coded example of a hypothetical GTIN-12 that embeds an NDC, and a key explaining how each digit is populated. (Figure 3 uses hypothetical GTIN **312345678906**.)

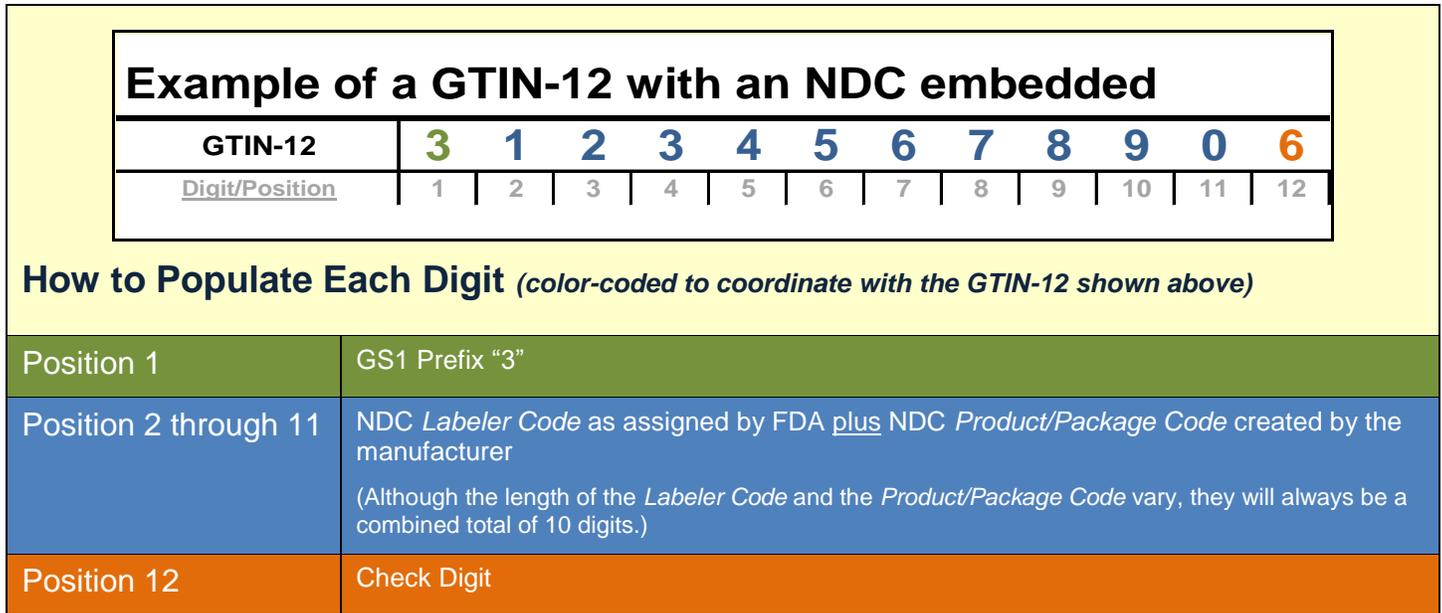


Figure 3: Populating the 12 digits of a GTIN-12 with an NDC embedded

### 5.1.2. Creating a GTIN-14

Each GTIN-14 is a numerical string comprising four distinct segments. The four segments in a GTIN-14 are:

- **GS1 Indicator Digit:** The indicator digit identifies packaging level. The field consists of a numeric value from 1 to 8. (The number “0” is used in this position as a fill character when a GTIN-12 or GTIN-13 is written in 14-digit format.)
  - ① *Packaging specialists must review the Indicators used on all other packaging levels prior to incorporating a new packaging level for a product. This ensures that there is a unique GTIN on every packaging level, which is imperative to preserve the uniqueness of each GTIN.*
- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization’s needs. In a GTIN-14 that embeds an NDC, the GS1 Company Prefix segment is populated with the NDC Labeler Code with a “03” appended in front.
- **Item Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a trade item. The *Item Reference* varies in length as a function of the GS1 Company Prefix length. (Refer to the *GS1 General Specifications* and the *GTIN Allocation Rules for the Healthcare Sector* for additional information.) In a GTIN-14 that embeds an NDC, the *Item Reference* segment is populated with the NDC Product/Package Code.
- **Check Digit:** A one-digit number calculated from the first 13 digits of the GTIN used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at <http://www.gs1us.org/resources/tools-and-services/check-digit-calculator>.

Although the length of the GS1 Company Prefix and the length of the Item Reference vary, they will always be a combined total of 12 digits in a GTIN-14. The *Indicator Digit* and the *Check Digit* comprise the remaining 2 digits of the GTIN-14. Figure 4 provides a color-coded example of a hypothetical GTIN-14 that embeds an NDC, and a key explaining how each digit is populated. (Figure 4 uses hypothetical GTIN **00361414567894**.)

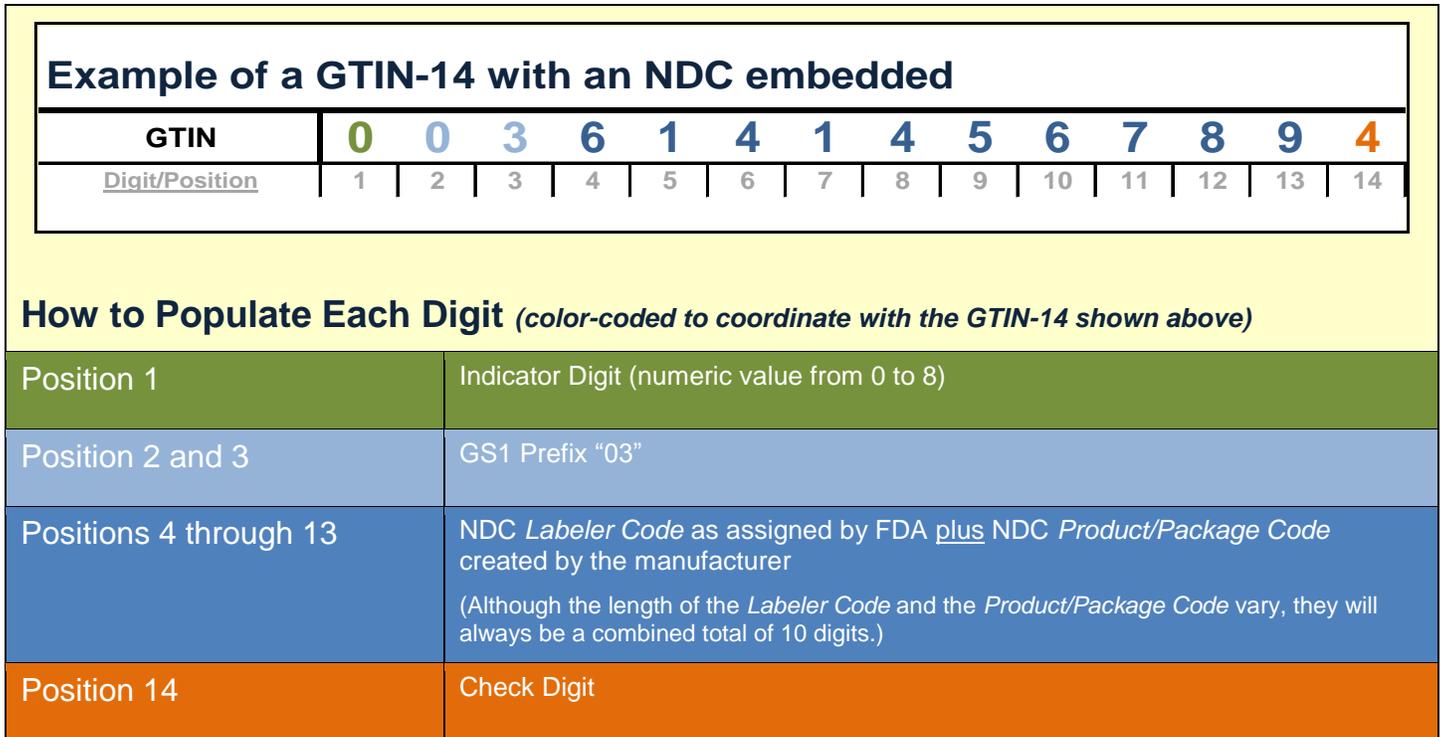


Figure 4: Populating the 14 digits of a GTIN-14 with an NDC embedded

## 5.2. Assigning/Allocating Serial Numbers

The combination of a GTIN plus a unique serial number is used to identify a specific instance of a trade item. For example, if hypothetical GTIN 00361414567894 is assigned to identify a 100-count bottle of XYZ tablets, then the combination of GTIN 00361414567894 plus a serial number would identify a *specific* 100-count bottle of XYZ tablets. All bottles of XYZ tablets would have the same GTIN, but each bottle would be assigned a unique serial number.

The *GS1 General Specifications* define a serial number for use with a GTIN as an alphanumeric string whose length is variable between one and 20 characters (*the specific characters allowed are defined in the GS1 General Specifications*). Therefore, databases and messages that need to contain a GTIN plus serial number should be designed to accommodate any serial number consisting of 1-20 characters. "Zero" characters in serial numbers are treated as any other alphanumeric character such that serial numbers 7, 07, and 007 are all *different* serial numbers according to the standard. Databases should treat the serial number as a text field so that leading zeros are not inadvertently stripped off.

In GS1 barcodes, serial numbers are represented using AI (21). Any serial number consisting of 1-20 characters may be used in a GS1 barcode per the standard. Although barcodes can accommodate any 1-20 character serial number, the size of the barcode may vary depending on how many characters are used. However, many production systems prefer a consistent barcode size in order to conform to package artwork

constraints and to simplify the quality assurance process. For this reason, manufacturers often adopt a consistent serial number length rather than allow their serial numbers to vary between 1 and 20 characters.

When using EPC/RFID tags, however, certain limitations apply. As with barcodes, EPC/RFID tags having at least 198 bits of EPC memory capacity can accommodate any 1-20 character serial number. However, EPC/RFID tags having 96-197 bits of EPC memory capacity use a 96-bit encoding format (called SGTIN-96) that places limitations on the serial numbers that can be encoded. When using the SGTIN-96 encoding, the serial number must be numeric only (that is, the only characters permitted are the digits '0' through '9'), must not have any leading zeros, and must have a numeric value that is less than or equal to 274877906943.

The following Best Practices have been defined to accommodate all of the considerations described above:

- Business applications, messages, and databases should be designed to accept data from any data carrier. Specifically, this means that applications and databases should be designed to accept the full range of data values defined by GS1 Standards, including a full 14-digit GTIN and a serial number between one and 20 alphanumeric characters. The restrictions on data values that certain data carriers impose (e.g., 96-bit EPC/RFID tags) should not be carried through to this level.
- Applications must not add or remove leading zeros to serial numbers.
- While the standards support serial numbers beginning with "0", applications that assign serial numbers for use with GTIN should avoid serial numbers that begin with a "0" character in order to avoid errors associated with incorrect implementations.
- If 96-bit EPC/RFID tags are to be used, serial numbers must fit within the encoding constraints of the 96-bit SGTIN format as defined by the GS1 EPC Tag Data standard (described above).
- In order to support both barcodes and 96-bit EPC/RFID tags, and to achieve a consistent barcode size, a good policy would be to assign either 11-digit numeric serial numbers within the range 10000000000 – 99999999999, or 12-digit numeric serial numbers within the range 100000000000 – 274877906943.
- The GTIN and serial number identifies a unique instance of a product. Therefore, reuse of serial numbers for a given GTIN is not a best practice at this time. The subject of reuse has been submitted to GS1 for review.

## 5.3. Data Formats for Databases

### 5.3.1. GTIN Fields

Although the U.S. pharmaceutical supply chain uses both GTIN-14 and GTIN-12, EPCIS requires GTINs to be in a 14-digit format. Therefore, a GTIN should always be represented in software applications as 14 digits by adding leading zeros as necessary to make 14 digits. In order to preserve any leading zeros that may be present, the GTIN field should be represented in a database as a text field (not numeric). This is especially important for manufacturers who currently have many GTIN-12s in their systems due to the Barcode Rule.

### 5.3.2. Serial Number Fields

As described above, the industry best practice is for manufacturers to assign all numeric serial numbers of only 11-12 digits in length in order to ensure compatibility of serial numbers across bar codes and 96-bit EPD/EPC/RFID tags. Regardless, serial numbers should always be stored in a text field (not numeric) that is

capable of handling from one to 20 characters. Leading zeros should *never* be added or removed from serial numbers.

### 5.4. Data Format for EPCIS: URI Format

Within the EPCIS, GTIN + serial number must be stored in EPC URI format. The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (SGTIN EPC).

*ⓘ The SGTIN EPC is based on a 14-digit GTIN. Therefore, GTIN-12s will first need to be converted to a 14-digit number by adding two leading zeros. (An example of the conversion is provided below.)*

**General syntax:**

urn:epc:id:sgtin:*CompanyPrefix.ItemReference.SerialNumber*

**Example:**

urn:epc:id:sgtin:0614141.112345.400806

**Grammar:**

SGTIN-URI ::= “urn:epc:id:sgtin:” SGTINURIBody

SGTINURIBody ::= 2\*(PaddedNumericComponent “.”)GS3A3Component

The number of characters in the two PaddedNumericComponent fields must total 13 (not including any of the dot characters). The Serial Number field of the SGTIN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the (AI) 21 Serial Number according to the *GS1 General Specifications*. Figure 5 depicts how the element string of a GTIN + serial number corresponds to the element string of a SGTIN EPC URI:

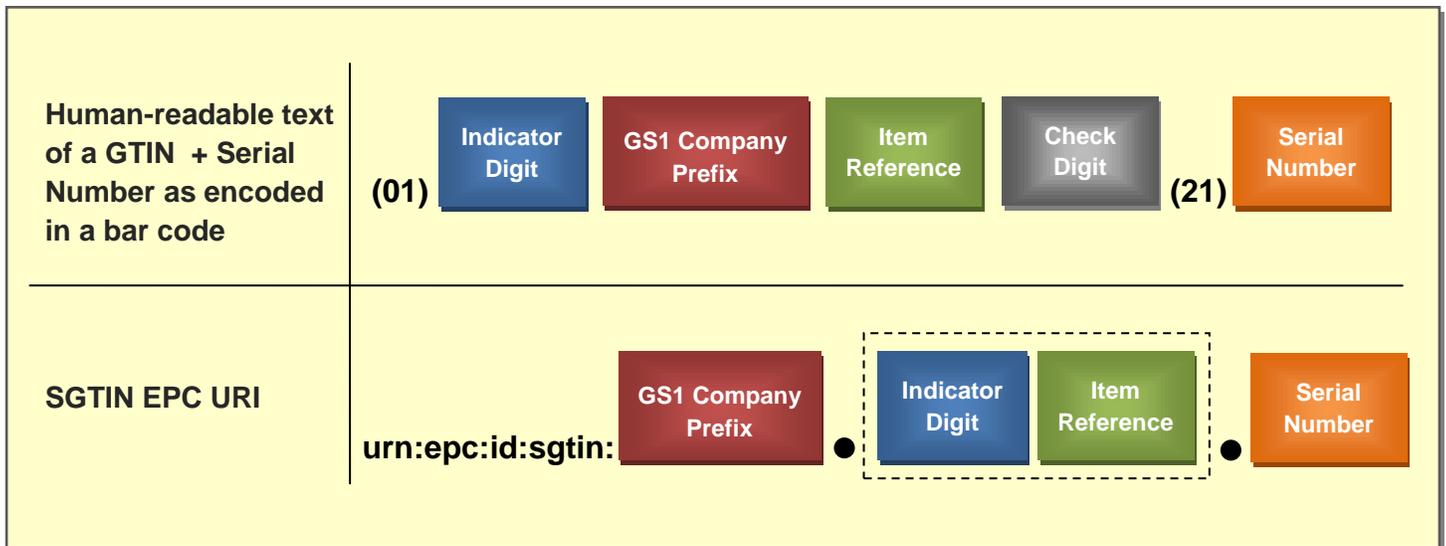


Figure 5: How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GTIN key.
- The *Item Reference* as it appears in the SGTIN EPC URI is derived from the GTIN key by concatenating the Indicator Digit of the GTIN and the Item Reference digits, and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.
- The *Serial Number* is the equivalent of AI(21).

### **Example – Converting a GTIN-14 + serial number into EPC URI Format:**

GTIN-14	2 030001 123498 7
Serial Number	123456789012
Corresponding Barcode Human Readable Text	(01) 2 030001 123498 7 (21)123456789012
Corresponding SGTIN-EPC URI	urn:epc:id:sgtin: 030001 . 2 123498 . 123456789012

**i** The spaces in the example above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.

### **Example – Converting a GTIN-12 + serial number into EPC URI Format:**

To find the EPC URI corresponding to the combination of a GTIN-12 and a serial number, first convert the GTIN-12 to a 14-digit number by adding two leading zero characters. The first leading zero will serve as the Indicator Digit, and the second leading zero will serve as the first place of the U.P.C. Company Prefix as shown below:

GTIN-12	31234 567890 6
GTIN-12 in 14-digit format	0 031234 567890 6
Serial Number	123456789012
Corresponding Barcode Human Readable Text	(01) 0 031234 567890 6 (21)123456789012
Corresponding SGTIN-EPC URI	urn:epc:id:sgtin: 031234 . 0 567890 . 123456789012

**i** The spaces in the example above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.

## 5.5. Data Storage Options

GTIN and serial number are assigned as separate data elements, but are saved together as an SGTIN in EPCIS. Users have several options for how to store GTIN + serial number in databases: (1) GTINs and serial numbers can be saved in their own fields; (2) saved together in the SGTIN EPC URI format (to be parsed by backend systems as needed), or (3) saved as both.

Thus, there are three options for storing GTINs and serial numbers in databases:

- 2 fields = GTIN field and Serial Number field
- 1 field = One field containing serialized GTIN in EPC URI format
- 3 fields = GTIN field, Serial Number field, and field containing serialized GTIN in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 4 below:

Field	Data Format
GTIN	<ul style="list-style-type: none"> <li>▪ 14 digits</li> <li>▪ text field (not numeric)</li> </ul>
Serial Number	<ul style="list-style-type: none"> <li>▪ 1-20 characters</li> <li>▪ text field (not numeric)</li> </ul>
Serialized GTIN EPC URI	<ul style="list-style-type: none"> <li>▪ 33-52 characters:               <ul style="list-style-type: none"> <li>▪ 17 characters for "urn:epc:id:sgtin:"</li> <li>▪ 13 characters for the GTIN (without the Check Digit)</li> <li>▪ 1-20 characters for the serial number</li> <li>▪ 2 periods (".")</li> </ul> </li> <li>▪ text field (not numeric)</li> </ul>

Table D: Data Formats for GTIN Fields

## 6. Identifying Logistics Units (Cases, Pallets and Totes): SSCC

In the GS1 System, logistics units such as cases, pallets and totes are identified with the Serial Shipping Container Code (SSCC). The SSCC is an 18-digit, globally unique, standards-based, identification number for logistics units. SSCCs serve as "license plates" from the carton level to the trailer load level to facilitate simple tracking of goods and reliable look up of complex load detail.

### 6.1. Assigning SSCCs

Suppliers are responsible for assigning (*allocating*) SSCCs to their logistics units. Each SSCC is a numerical string comprising four distinct segments. The four segments within an SSCC are:

- **Extension Digit:** The Extension Digit has no defined logic. It is available to the company to increase the capacity of the *Serial Reference*. The field consists of a numeric value from 0 to 9.
- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs; SSCCs; etc.). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization's needs.
- **Serial Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a logistic unit. This segment is the "serial" part of the number assigned one-by-one by the company to create a globally unique SSCC. The *Serial Reference* varies in length as a function of the GS1 Company Prefix length.
- **Check Digit:** A one-digit number calculated from the first 17 digits of the SSCC used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at [http://www.gs1us.org/solutions\\_services/tools/check\\_digit\\_calculator](http://www.gs1us.org/solutions_services/tools/check_digit_calculator).

Although the length of the GS1 Company Prefix and the length of the Serial Reference vary, they will always be a combined total of 16 digits in an SSCC. Figure 6 provides a color-coded example of a hypothetical SSCC, and a key explaining how each digit is populated. (Figure 6 uses hypothetical SSCC **03345678912345604**.)

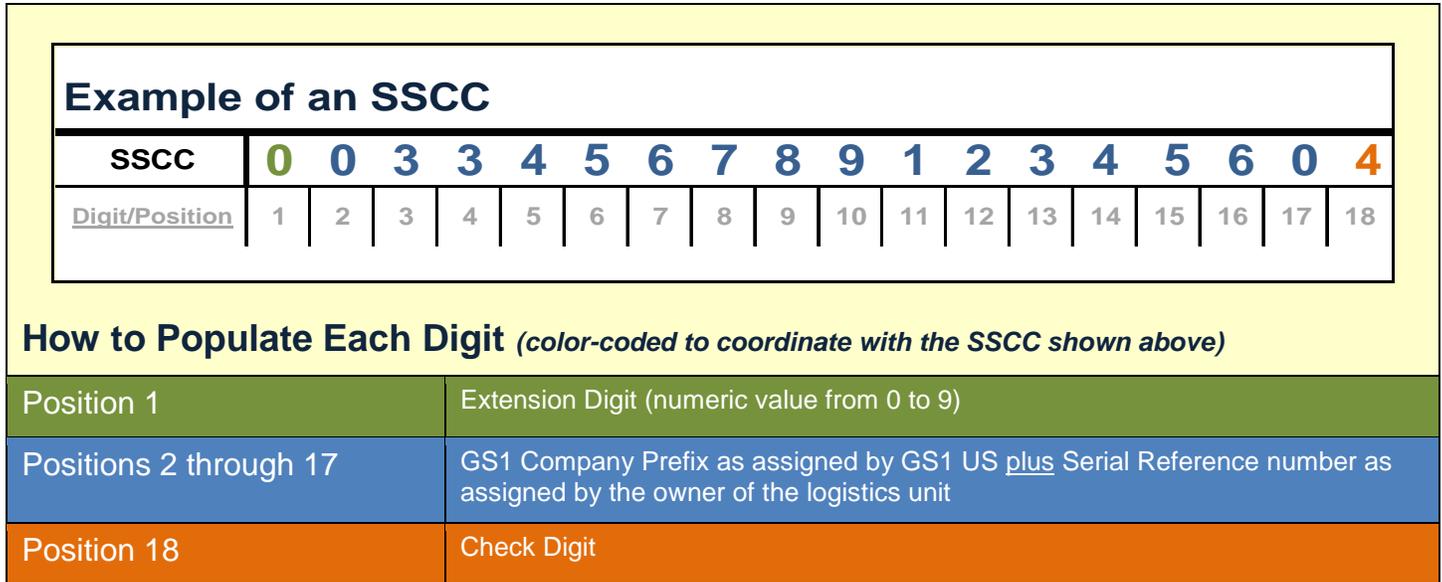


Figure 6: Populating the 18 digits of an SSCC

## 6.2. Data Format for Databases

In databases, SSCC fields should be 18 characters in length. The SSCC should be represented in a database as a text field (not numeric), so that leading zeros are not inadvertently dropped.

## 6.3. Data Format for EPCIS: URI Format

Within the EPCIS, SSCCs must be stored in EPC URI format. The EPC URI format for an SSCC is the SSCC EPC.

### **General syntax:**

urn:epc:id:sscc:*CompanyPrefix.SerialReference*

### **Example:**

urn:epc:id:sscc:0614141.1234567890

### **Grammar:**

SSCC-URI ::= "urn:epc:id:sscc:" SSCCURIBody

SSCCURIBody ::= PaddedNumericComponent "."PaddedNumericComponent

The number of characters in the two PaddedNumericComponent fields must total 17 (not including any of the dot characters). Figure 7 depicts how the element string of an SSCC corresponds to the element string of a SSCC EPC URI:

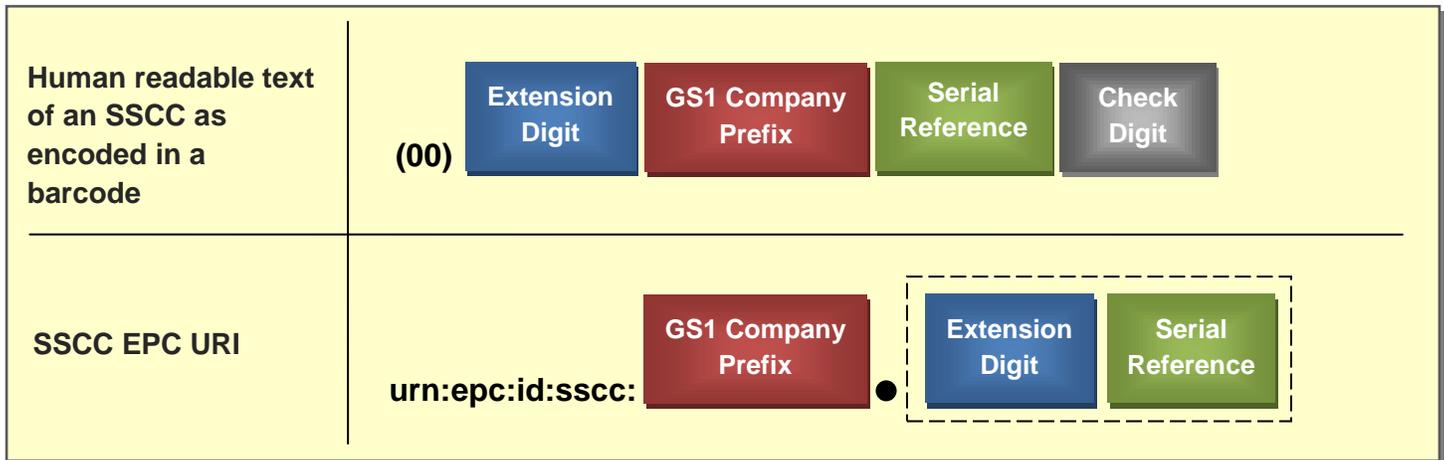


Figure 7: How the segments of an SSCC are represented in the SSCC EPC URI format

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 SSCC key.
- The *Serial Reference* as it appears in the SSCC EPC URI is derived from the SSCC key by concatenating the Extension Digit of the SSCC and the Serial Reference digits, and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.

### 6.4. Data Storage Options

When storing SSCCs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing SSCC in databases:

- 1 field = SSCC
- 1 field = SSCC in EPC URI format
- 2 fields = SSCC field and a field containing SSCC in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 5 below:

Field	Data Format
SSCC	<ul style="list-style-type: none"> <li>▪ 18 digits</li> <li>▪ text field (not numeric, to avoid dropping leading zeros)</li> </ul>
SSCC URI	<ul style="list-style-type: none"> <li>▪ 34 characters</li> <li>▪ text field</li> </ul>

Table E: Data Formats for SSCC Fields

## 7. Identifying Parties & Locations: GLN

In the GS1 System, parties and locations are identified with the Global Location Number (GLN). The GLN is a 13-digit, globally unique, standards-based, identification number for legal entities, functional entities, and physical locations. Each company is responsible for assigning (*allocating*) GLNs to its own parties and locations. When a user assigns a GLN, they define a prescribed set of data about the party/location to which that GLN relates (e.g., street address, floor, etc.). These GLN attributes define master data about the party/location (e.g., name, address, class of trade, etc.), which help to ensure that each GLN is specific to one, very precise location within the world. The GLN and its associated attributes are then saved in a database (like the GLN Registry for Healthcare) and shared among supply chain partners.

**i** GS1 US offers an annual GLN subscription program for companies that are not members of GS1 US and need only one or a few GLNs (e.g., wholesalers, distributors, and retailers without private label products). Subscribers to the GLN Registry for Healthcare have the option of acquiring GLNs using this GS1 US subscription program instead of allocating them as described above. Please call GS1 US Customer Service for more information about this program at +1 937.610.4222.

### 7.1. Assigning GLNs

Each GLN is a numerical string comprising three distinct segments. The three segments within a GLN are:

- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs; SSCCs; etc.). GS1 Company Prefixes are assigned in varying lengths depending on the company/organization’s needs.
- **Location Reference:** A number assigned by the holder of the GS1 Company Prefix to uniquely identify a location within the company. The length of the *Location Reference* varies as a function of the GS1 Company Prefix length.
- **Check Digit:** A one-digit number calculated from the first 12 digits of the GLN used to ensure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you. The check digit calculator can be found at <http://www.gs1us.org/resources/tools-and-services/check-digit-calculator> . (Check digits can also be calculated manually.)

Although the length of the GS1 Company Prefix and the length of the Location Reference vary, they will always be a combined total of 12 digits in a GLN. The addition of the *Check Digit* completes the 13 digits of the GLN. Figure 8 provides a color-coded example of a hypothetical GLN, and a key explaining how each digit is populated. (Figure 8 uses hypothetical GLN **0321012345676**.)

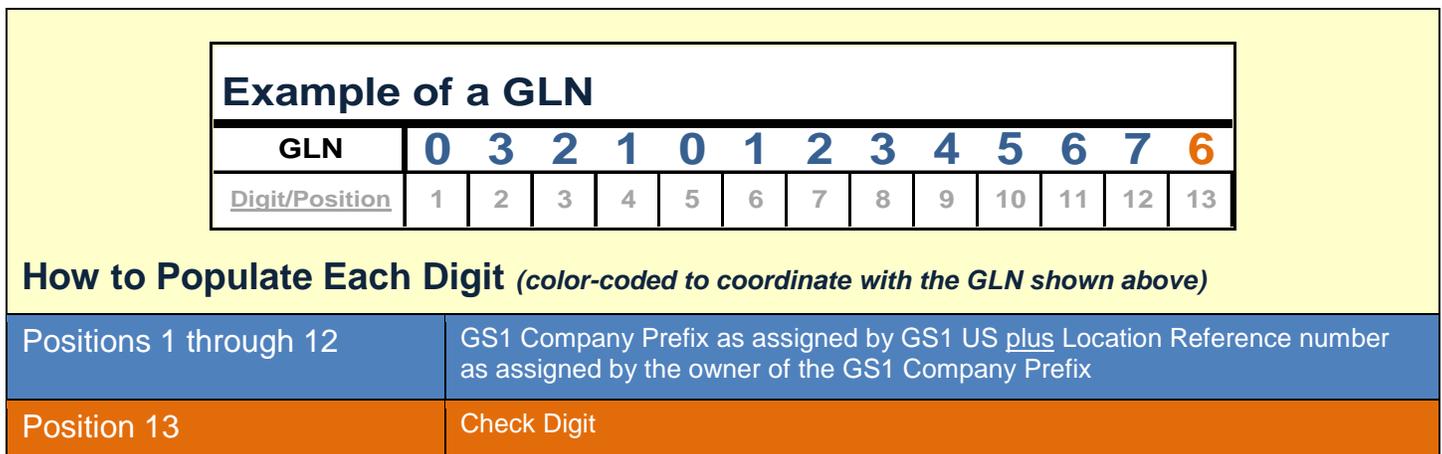


Figure 8: Populating the 13 digits of a GLN

## 7.2. Assigning GLN Extensions

GLN Extensions are used to identify internal physical locations within a location that is identified with a GLN. Locations that currently have a GLN may use GLN Extensions to distinguish unique sub-locations within that GLN location (e.g., production line, RFID tunnel, loading dock, etc.) GLN Extensions are represented by AI(254). The GS1 General Specifications define a GLN Extension as an alphanumeric string whose length is variable between one and 20 characters (the specific characters allowed are defined in the GS1 General Specifications). GLN Extensions can be encoded in GS1 DataBar, GS1-128 and EPC/RFID tags. AI(254) may only be used in conjunction with AI(414) [i.e., GLN of a physical location].

Use of GLN Extensions is optional. Sub-locations can be identified by assigning a unique GLN to the sub-location, or by using a GLN Extension with the location's GLN. There is no rule for when to assign a new GLN versus when to use a GLN Extension. However, the GLN Workgroup has identified the following Best Practices to assist companies in making this decision:

- For sub-locations that will never be used as an address (e.g., shelf, door, etc.), use GLN Extensions in order to conserve GLNs.
- For sub-locations where the identifier will be used for purposes other than EPCIS events (e.g., EDI), assign a unique top-level GLN to that sub-location.

(For additional information, consult the GLN Workgroup materials.)

## 7.3. Data Format for Databases

In databases, GLN fields should be 13 digits in length. The GLN should be represented in a database as a text field (not numeric). The GLN extension should be represented in a database as a text field capable of handling from one to 20 characters.

## 7.4. Data Format for EPCIS: URI Format

Within the EPCIS, GLNs must be stored in EPC URI format. The EPC URI format for a GLN (with or without Extension) is the Serialized Global Location Number EPC (SGLN EPC).

### **General syntax:**

urn:epc:id:sgln:*CompanyPrefix.LocationReference.Extension*

### **Example:**

urn:epc:id:sgln:0614141.12345.400

### **Grammar:**

SGLN-URI ::= "urn:epc:id:sgln:" SGLNURIBody

SGLNURIBody ::= PaddedNumericComponent "."

PaddedNumericComponentOrEmpty ::= GS3A3Component

The number of characters in the two PaddedNumericComponent fields must total 12 (not including any of the dot characters). The Extension field of the SGLN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the AI (254) Extension according to the GS1 General Specifications. Figure 9 depicts how the element string of a GLN corresponds to the element string of an SGLN EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 GLN key.
- The *Location Reference* is the same as it appears in the GLN key.
- The *Check Digit* is not used in the EPC URI format.
- The *Extension* is the same as the *GLN Extension* assigned by the managing entity to an individual unique location. If there is no GLN Extension for this location, enter a single zero digit to indicate that the SGLN stands for a GLN without an extension.

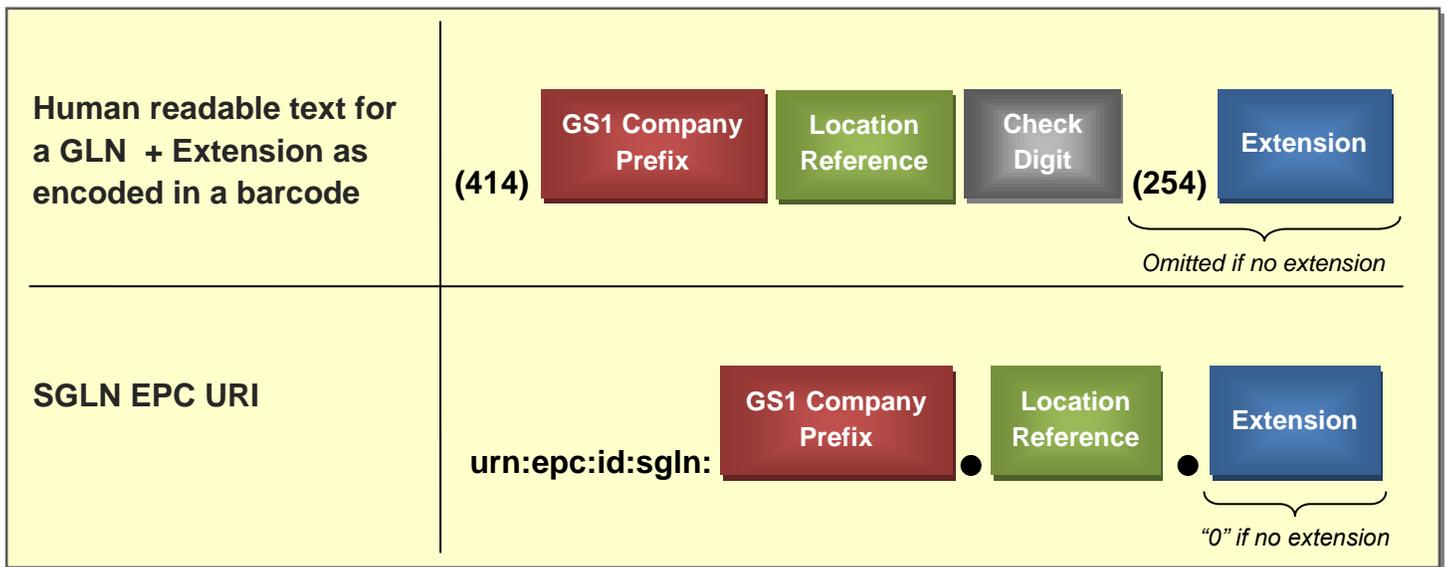


Figure 9: How the segments of a GLN (with or without extension) are represented in the SGLN EPC URI format

## 7.5. Data Storage Options

When storing SGLNs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing a GLN with extension in databases:

- 2 fields = GLN field and GLN Extension field
- 1 field = One field containing GLN + extension in EPC URI format
- 3 fields = GLN field, GLN Extension field, and field containing GLN + extension in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 6 below:

Field	Data Format
GLN	<ul style="list-style-type: none"> <li>▪ 13 digits</li> <li>▪ text field (not numeric)</li> </ul>
GLN Extension	<ul style="list-style-type: none"> <li>▪ 1-20 characters</li> <li>▪ text field (not numeric)</li> </ul>
SGLN EPC URI	<ul style="list-style-type: none"> <li>▪ 31-50 characters:               <ul style="list-style-type: none"> <li>▪ 16 characters for “urn:epc:id:sgln:”</li> <li>▪ 12 characters for the GLN (no Check Digit)</li> <li>▪ 1-20 characters for the GLN extension</li> <li>▪ 2 periods (‘.’)</li> </ul> </li> <li>▪ text field (not numeric)</li> </ul>

Table F: Data Formats for GLN Fields

## Part 3: Capture

GS1 Data Carriers provide *machine-readable representations* of GS1 Identification Numbers that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports eight data carriers: six barcode symbologies (i.e., GS1 Barcodes) and two RFID tags (i.e., GS1 EPC/RFID Tags).

Table 7 lists the GS1 data carriers used in this guideline to support pedigree and track and trace. Because this guideline documents a specific application of the standards to support serialization and pedigree, only data carriers that can carry serial numbers are shown.

Supply Chain Object	GS1 Data Carrier Options
TRADE ITEMS: Products, Cases & Kits	GS1 DataMatrix
	GS1-128
	EPC/RFID Tag
LOGISTICS UNITS: Cases, Pallets & Totes	GS1-128
	GS1 DataMatrix
	EPC/RFID Tag

Table G: GS1 Data Carriers Used in this Guideline

## 8. Encoding GS1 Data Carriers

Examples in this guideline use four GS1 Data Carriers: three GS1 barcodes and one EPC/RFID tag. Guidance for encoding those data carriers is provided in this chapter.

### 8.1. Barcodes

The data elements within a barcode are demarcated through the use of GS1 Application Identifiers (AIs). GS1 AIs are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two, three, or four digit numeric code. (When rendered in human-readable form, the AI is usually shown in parentheses. However, the parentheses are not part of the barcode's encoded data.) Each data element in a barcode is preceded by its AI. There are approximately 100 AIs, including one AI for each GS1 identifier (e.g., GTIN, GLN, SSCC, etc.) as well as numerous AIs for secondary information. The AI's that are relevant to this guideline are:

AI (01)	GTIN	AI (21)	Serial Number
AI (00)	SSCC	AI (10)	Batch/Lot Number
AI (414)	GLN (physical location)	AI (17)	Expiration Date
AI (254)	GLN Extension		

More than one AI can be carried in one barcode. Table 8 presents some high-level concepts and principles that should be followed when encoding barcodes.

Principle	Example/Illustration										
Each barcode data element has a two- to four-digit AI that defines data type and field size.	<table border="1"> <tbody> <tr> <td>GTIN</td> <td><b>AI(01)</b></td> </tr> <tr> <td>Serial Number</td> <td><b>AI(21)</b></td> </tr> <tr> <td>Batch/Lot Number</td> <td><b>AI(10)</b></td> </tr> <tr> <td>Expiration Date</td> <td><b>AI(17)</b></td> </tr> <tr> <td>SSCC</td> <td><b>AI (00)</b></td> </tr> </tbody> </table>	GTIN	<b>AI(01)</b>	Serial Number	<b>AI(21)</b>	Batch/Lot Number	<b>AI(10)</b>	Expiration Date	<b>AI(17)</b>	SSCC	<b>AI (00)</b>
GTIN	<b>AI(01)</b>										
Serial Number	<b>AI(21)</b>										
Batch/Lot Number	<b>AI(10)</b>										
Expiration Date	<b>AI(17)</b>										
SSCC	<b>AI (00)</b>										
When encoding, each data element is preceded by its corresponding AI.	<table border="1"> <tbody> <tr> <td>GTIN</td> <td><b>(01)00314141999995</b></td> </tr> <tr> <td>Expiration Date</td> <td><b>(17)101231</b></td> </tr> <tr> <td>Batch/Lot Number</td> <td><b>(10)987654321GFEDCBA</b></td> </tr> <tr> <td>Serial Number</td> <td><b>(21)ABCDEFGH123456789</b></td> </tr> <tr> <td>SSCC</td> <td><b>(00)003345678912345604</b></td> </tr> </tbody> </table>	GTIN	<b>(01)00314141999995</b>	Expiration Date	<b>(17)101231</b>	Batch/Lot Number	<b>(10)987654321GFEDCBA</b>	Serial Number	<b>(21)ABCDEFGH123456789</b>	SSCC	<b>(00)003345678912345604</b>
GTIN	<b>(01)00314141999995</b>										
Expiration Date	<b>(17)101231</b>										
Batch/Lot Number	<b>(10)987654321GFEDCBA</b>										
Serial Number	<b>(21)ABCDEFGH123456789</b>										
SSCC	<b>(00)003345678912345604</b>										
Encode the GS1 Identifier (GTIN or SSCC) first. Encode any optional data (such as batch/lot number, expiration date, serial number, etc.) following the identifier.  <i>NOTE: Although parentheses and spaces appear in the human readable text accompanying the barcode, these characters are not encoded in the barcode itself.</i>											
For the most efficient encoding, ensure that fixed-length AI's precede variable-length AI's.	<table border="1"> <tbody> <tr> <td>GTIN</td> <td><i>fixed</i></td> </tr> <tr> <td>Expiration Date</td> <td><i>fixed</i></td> </tr> <tr> <td>Batch/Lot Number</td> <td><i>variable</i></td> </tr> <tr> <td>Serial Number</td> <td><i>variable</i></td> </tr> </tbody> </table>	GTIN	<i>fixed</i>	Expiration Date	<i>fixed</i>	Batch/Lot Number	<i>variable</i>	Serial Number	<i>variable</i>		
GTIN	<i>fixed</i>										
Expiration Date	<i>fixed</i>										
Batch/Lot Number	<i>variable</i>										
Serial Number	<i>variable</i>										

Table H: Encoding Principles

**i Human Understandable Text Below A Barcode:** Many pharmaceutical companies are including text below the barcode that is more readily understandable by healthcare clinicians and supply chain personnel. Here are some examples:



GTIN 00314141999995  
 SN 10000000234  
 LOT 987654321GFEDCBA  
 EXP 01/2015



GTIN 00314141999995  
 SN 10000000234  
 EXP JAN 2015  
 LOT 987654321GFEDCBA



GTIN 00314141999995  
 SN 10000000234  
 EXP 25 JAN 2015  
 LOT 987654321GFEDCBA

### 8.1.1. Trade Items: Products, Cases & Kits

As a way of gaining uniformity throughout the supply chain, this guideline includes two best practice barcode options for products, cases and kits: GS1 DataMatrix and GS1-128. There are two required data elements to be encoded: GTIN and Serial Number.

## Barcodes for Products, Cases & Kits

Required Identification Information	Data Element	Corresponding GS1 AI
	GTIN	AI (01)
	Serial Number	AI 21)
GS1 Barcode Options	GS1 DataMatrix GS1-128	

Table I: Barcodes for Products, Cases & Kits

### Encoding Principles:

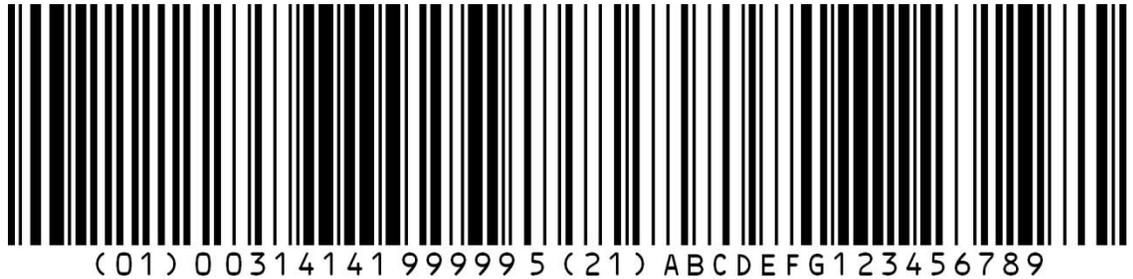
GTIN	<ul style="list-style-type: none"> <li>Begin with the two-digit AI (01) to indicate GTIN.</li> <li>A fixed-length field comprising the 14 numeric characters of a GTIN data follows the AI.                             <ul style="list-style-type: none"> <li><b>i</b> For GTIN-12: encode in 14-digit format using two leading zeros</li> </ul> </li> <li>The data syntax for the GTIN component is n2 + n14.</li> <li><b>EXAMPLE:</b> <b>0100312345678906</b></li> </ul>
Serial Number	<ul style="list-style-type: none"> <li>The two-digit AI (<b>21</b>) is used to indicate the <i>Serial Number</i>.</li> <li>A variable-length field of up to 20 alphanumeric characters of <i>Serial Number</i> data follows the AI.                             <ul style="list-style-type: none"> <li><b>i</b> If using a barcode with a 96-bit EPC/RFID tag: see <a href="#">Section 5.2</a> for limitations on serial number</li> </ul> </li> <li>The data syntax for the <i>Serial Number</i> component is n2 + a1..20.</li> <li><b>EXAMPLE:</b> <b>21ABCDEFGH123456789</b></li> </ul>

**Examples:**

Figure 10: GTIN with Serial Number Encoded in a GS1 DataMatrix



Figure 11: GTIN with Serial Number Encoded in a GS1-128



**① Marking Products with Both UPC-A and GS1 DataMatrix**

Many pharmaceutical manufacturers are marking products that move through a Point of Sale (POS) with both a UPC-A and a GS1 DataMatrix:

- Any item that passes through a POS is typically marked with a UPC-A. The UPC-A is a linear barcode that holds a maximum of 12 digits, which promotes readability by traditional POS systems. The UPC-A can be used to satisfy the FDA’s linear barcode requirement. However, because it is limited to 12 digits, the UPC-A cannot carry the information needed to satisfy serialization and/or pedigree requirements.
- The GS1 DataMatrix is a 2D barcode that can carry more data (e.g., GTIN, serial number, expiration date, etc.) in a smaller space. Most manufacturers are choosing to use the GS1 DataMatrix to satisfy serialization and/or pedigree requirements. However, as a 2D barcode, the GS1 DataMatrix does not satisfy the FDA’s linear barcode requirement.

Marking pharmaceutical products that cross POS with both barcodes satisfies both types of requirements (i.e., the UPC-A for the FDA linear barcode requirement, and the GS1 DataMatrix for serialization/pedigree requirements). To ensure that the GTIN encoded in both barcodes is the same, manufacturers should follow the recommendations outlined in [Section 4.5](#) for all products that will be marked with both a UPC-A and a GS1 DataMatrix.



GTIN-12 encoded in a UPC-A



GTIN-12 encoded in a GS1 DataMatrix

### 8.1.2. Logistics Units: Pallets, Cases & Totes

This guideline includes two barcode options for pallets, cases and totes: GS1-128 and GS1 DataMatrix. There one required data element to be encoded: SSCC.

Cases Pallets & Totes		
Required Identification Information	Data Element	Corresponding GS1 Standard
		SSCC
GS1 Barcode Options	GS1-128	
	GS1 DataMatrix	

Table J: Barcodes for Pallets, Cases & Totes

#### Encoding Principles:

- SSCC
  - The two-digit AI (00) is used to indicate SSCC.
  - A fixed-length field comprising the 18 numeric characters of SSCC data follows the AI.
  - The data syntax for the SSCC component is n2 + n18.
  - EXAMPLE: 00003345678912345604**

#### Examples:

Figure 12: SSCC Encoded in a GS1-128



Figure 13: SSCC Encoded in a GS1 DataMatrix



## 8.2. EPC/RFID Tags

EPC/RFID tags use a specialized binary encoding to hold data equivalent to barcode data. Software that reads and writes EPC/RFID tags translates between this binary encoded form and the barcode form (and/or the EPC URI form). See the *EPC Tag Data Standard* for details about how the translations are performed.

## 9. Translating Captured Data

The EPCIS stores identifiers (e.g., GTIN + serial number; SSCC; GLN; etc.) in EPC URI format, which differs from both the AI-based format used in GS1 barcodes and the binary encoding used in EPC/RFID tags. Therefore, identification information read from either barcodes or EPC/RFID tags must first be translated into EPC URI format in order to be stored in the EPCIS.

Most commercial RFID and/or EPCIS products already have the translation technology integrated into their software so that data read from either barcodes or EPC/RFID tags is automatically translated into EPC URI format when an EPCIS event is created. However, if a company is implementing their own software, they can either write their own translation module or license one of the commercially-available software libraries on the market.

In order to translate barcode data into EPC URI format, it is necessary to know the length of the GS1 Company Prefix (i.e., what is the length of the GS1 Company Prefix in this barcoded GTIN?). To facilitate this, GS1 US has published a table of U.S. GS1 Company Prefixes ([www.gs1us.org/gcplist](http://www.gs1us.org/gcplist)) that you can download and link to your translator/EPCIS to enable your system to access GS1 Company Prefix lengths automatically instead of prompting the user for the information. Alternatively, you can ask your trading partners for the length of their GS1 Company Prefixes and create your own table. (NOTE: EPC/RFID tags already include the length of the GS1 Company Prefix in the encoded binary form. Therefore, no additional lookup is needed to translate binary data from EPC/RFID tags into EPC URI format.)

### 9.1. EPC URI Format for GTIN + serial number

The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (SGTIN EPC).

#### **General syntax:**

`urn:epc:id:sgtin:CompanyPrefix.ItemReference.SerialNumber`

#### **Example:**

`urn:epc:id:sgtin:0614141.112345.400806`

#### **Grammar:**

`SGTIN-URI ::= "urn:epc:id:sgtin:" SGTINURIBody`

`SGTINURIBody ::= 2*(PaddedNumericComponent ".") GS3A3Component`

The number of characters in the two PaddedNumericComponent fields must total 13 (not including any of the dot characters). The Serial Number field of the SGTIN-URI is expressed as a GS3A3Component, which permits the representation of all characters permitted in the (AI) 21 Serial Number according to the GS1 General Specifications. Figure 14 depicts how the element string of a GTIN + serial number corresponds to the element string of a SGTIN EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GTIN key.
- The *Item Reference* as it appears in the SGTIN EPC URI is derived from the GTIN key by concatenating the Indicator Digit of the GTIN and the Item Reference digits, and treating the result as a single numeric string.

- The *Check Digit* is not used in the EPC URI format.
- The *Serial Number* is the equivalent of AI(21).

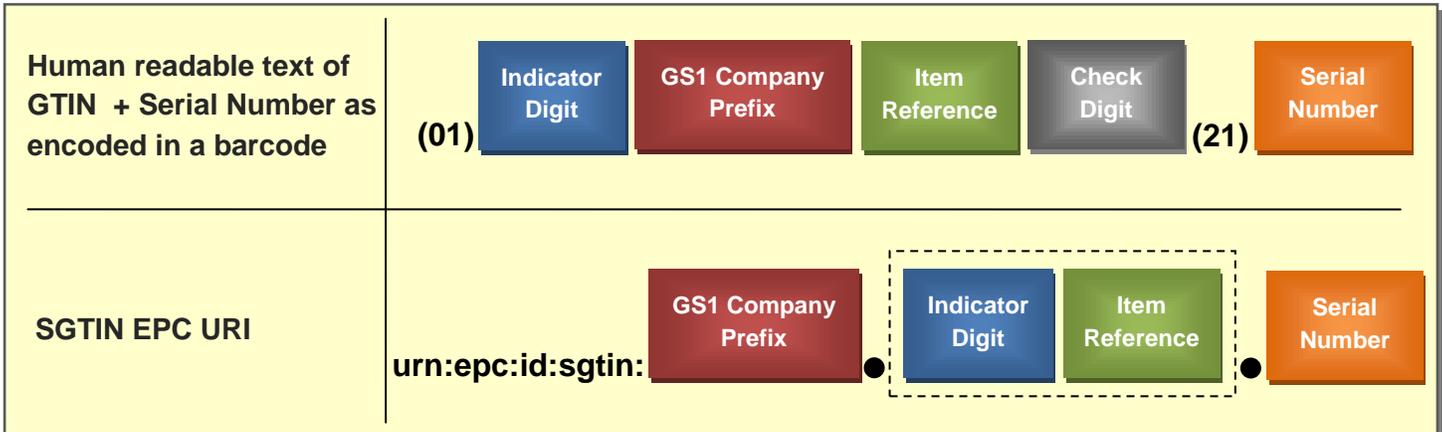


Figure 14: How the segments of a GTIN + serial number are represented in the SGTIN EPC URI format

**Example – Converting a GTIN-14 + Serial Number into EPC URI Format:**

GTIN-14	2 030001 123498 7
Serial Number	123456789012
Corresponding Barcode human readable text	(01) 2 030001 123498 7 (21) 123456789012
Corresponding SGTIN EPC URI	urn:epc:id:sgtin: 030001 . 2 123498 . 123456789012

*ⓘ The spaces in the examples above have been inserted for visual clarity. Those spaces are not included in either the GTIN-14 or the SGTIN EPC URI actually used within a computer system.*

**9.2. EPC URI Format for SSCC**

**General syntax:**

urn:epc:id:sscc: *CompanyPrefix.SerialReference*

**Example:**

urn:epc:id:sscc:0614141.1234567890

**Grammar:**

SSCC-URI ::= “urn:epc:id:sscc:” SSCCURIBody

SSCCURIBody ::= PaddedNumericComponent “.”PaddedNumericComponent

The number of characters in the two PaddedNumericComponent fields must total 17 (not including any of the dot characters).

Figure 15 depicts how the element string of an SSCC corresponds to the element string of a SSCC EPC URI:

- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within a GS1 SSCC key.
- The *Serial Reference* as it appears in the SSCC EPC URI is derived from the SSCC key by concatenating the Extension Digit of the SSCC and the Serial Reference digits, and treating the result as a single numeric string.
- The *Check Digit* is not used in the EPC URI format.

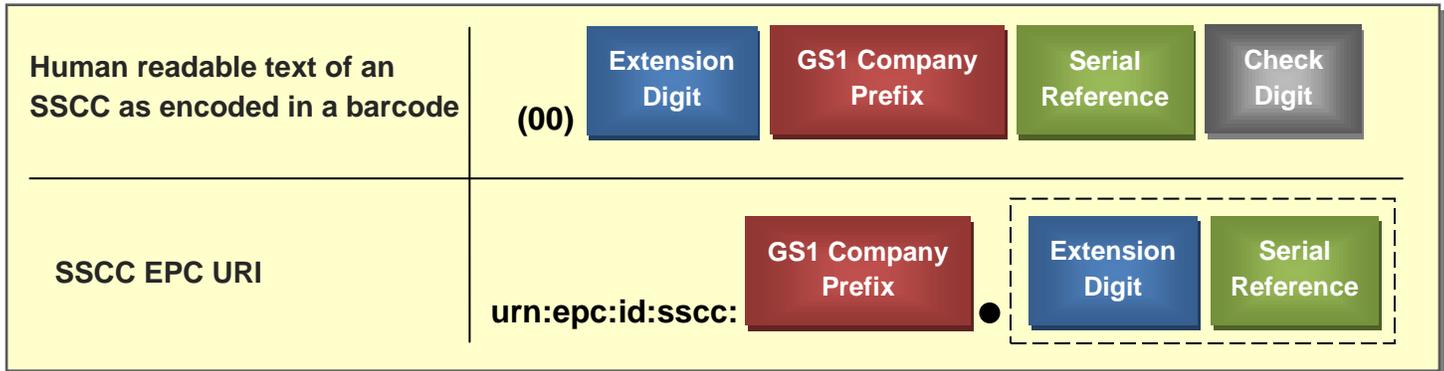


Figure 15: How the segments of an SSCC are represented in the SSCC EPC URI format

### 9.3. Data Storage Options

When storing GTIN + serial number in databases, GTINs and serial numbers can be saved in their own fields, saved together in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing GTINs and serial numbers in databases:

- 2 fields = GTIN field and Serial Number field
- 1 field = One field containing serialized GTIN in EPC URI format
- 3 fields = GTIN field, Serial Number field, and field containing serialized GTIN in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 11 below:

Field	Data Format
GTIN	<ul style="list-style-type: none"> <li>▪ 14 digits</li> <li>▪ text field (not numeric)</li> </ul>
Serial Number	<ul style="list-style-type: none"> <li>▪ 1-20 characters</li> <li>▪ text field (not numeric)</li> </ul>
Serialized GTIN EPC URI	<ul style="list-style-type: none"> <li>▪ 33-52 characters:               <ul style="list-style-type: none"> <li>▪ 17 characters for “urn:epc:id:sgtin:”</li> <li>▪ 13 characters for the GTIN (without the Check Digit)</li> <li>▪ 1-20 characters for the serial number</li> <li>▪ 2 periods (“.”)</li> </ul> </li> <li>▪ text field (not numeric)</li> </ul>

Table K: GTIN+ serial number Data Formats

When storing SSCCs in databases, they can be saved in their regular format, saved in the EPC URI format (to be parsed by backend systems as needed), or saved as both. Thus, there are three options for storing SSCC in databases:

- 1 field = SSCC
- 1 field = SSCC in EPC URI format
- 2 fields = SSCC and a field containing SSCC in EPC URI format

Select whichever method best serves your data storage strategies. The data format for each of those fields is provided in Table 12 below:

Field	Data Format
SSCC	<ul style="list-style-type: none"><li>▪ 18 digits</li><li>▪ text field (not numeric, to avoid dropping leading zeros)</li></ul>
SSCC EPC URI	<ul style="list-style-type: none"><li>▪ 34 characters</li><li>▪ text field (not numeric)</li></ul>

Table L: SSCC Data Formats

## Part 4: Share Concepts

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## 10. Master Data

When users assign a GS1 Identification Number, they define a set of standardized information (known as *attributes*) about the object to which that identifier relates. The GS1 System specifies the list of attributes that must be defined for each GS1 Identifier, and provides a precise definition as well as acceptable values and data formats for each attribute. This set of attributes constitutes the “master data” about the object. For example:

- The GTIN is the globally unique GS1 Identification Number used to identify products. Standardized GTIN attributes about products include selling unit, item dimensions, and product classification. Once defined by the user, those attributes are then stored in a GDSN-certified Data Pool and shared with supply chain partners using the Global Data Synchronization Network (GDSN).
- The GLN is the globally unique GS1 Identification Number for locations and supply chain partners. Standardized GLN data about locations include name, street address, location type, etc. Once defined by the user, those attributes are then stored in a database and shared with supply chain partners using the GLN Registry.

From there, GS1 Identification Numbers can be encoded into GS1 Data Carriers for identification and automatic data capture, and used in supply chain transactions. Because of this, master data, transaction data, and event data related to supply chain objects are all connected by their GS1 Identification Number.

GS1 Identification Numbers provide a link to information, and GS1 Standards for data sharing enable supply chain partners to share data and link it up in their systems to avoid re-entering it for every application that needs the data:

### Sharing Master Data

Products = GDSN, RxNorm, Prime Vendor Database  
Locations = GLN Registry for Healthcare

### Sharing Event & Disposition

EPCIS

### Item Event Locator

Discovery Services

This is especially important for EPCIS applications like pedigree where trading partners capture and share information about numerous supply chain events for each product. Use of GS1 Identifiers minimizes the data collected for each event, and maximizes the data that can be linked to the event. This enables trading partners to avoid massive duplication of data in their systems by managing master data separately from pedigree data. For example, a distributor records a Pedigree Event. The *Object ID* (i.e., GTIN) provides the link to finding master data about the product:

**Name:** Product X, 50 Tabs

The *BizLocation* (i.e., GLN) provides the link to master data about the location using the GLN Registry:

**LocationName:** Smithfield Distribution Center

**Address:** 123 Main Street

**City:** Lawrenceville

**State:** NJ

**Zip Code:** 08648

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## Best Practices:

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- Because master data is managed separately from event/pedigree data, it is essential to archive the original/previous version of master data whenever master data about products or locations is updated or changed. This will ensure that the historic master data is still available if ever needed after the update.
  - Need to validate and establish the source and governance of your master data.
- 

**i** The following documents provide an in depth discussion of Master Data Management concepts (see [Section 2.6](#) for links):

- *Healthcare Provider GTIN Tool Kit*
- *Healthcare Supplier GTIN Tool Kit*
- *Healthcare Provider GLN Tool Kit*
- *Healthcare Supplier GLN Tool Kit*
- *Healthcare Provider GDSN Tool Kit*
- *Healthcare Supplier GDSN Tool Kit*

## 11. Event Data

Electronic Product Code Information Services (EPCIS) is a GS1 Standard for capturing and communicating data about the movement and status of objects in the supply chain (e.g., products; logistics units; returnable assets; etc.). It enables supply chain partners to capture event information about objects as they move through the supply chain (e.g., shipped; received; etc.), and to share that information with their trading partners securely and in near real-time. EPCIS defines technical standards for a data-sharing interface between applications that capture EPC-related data and those that need access to it. EPCIS also provides data standards for how to express what business process was operating on the object and the status of the object upon exiting the process. For the data standards, EPCIS makes use of a second standard named the Core Business Vocabulary (CBV), which offers a pre-defined vocabulary for a large set of business events and scenarios.

The data elements captured and recorded for each EPCIS event are grouped into four dimensions: *what*, *when*, *where*, and *why*. The GS1 General Specifications and the GS1 EPC Tag Data Standard define identifiers for physical objects used in the “*what*” dimension, and identifiers for locations used in the “*where*” dimension. The GS1 EPC Core Business Vocabulary provides lists of acceptable values for *Business Step*, *Disposition*, and *Business Transaction Type* used in the *why* dimension, as well as the format for the business transaction identifiers used in the *why* dimension. Beyond the four dimensions of *what*, *where*, *when*, and *why* defined in the EPCIS standard, this guideline defines extension fields used to provide additional business data for ePedigree in certain EPCIS events.

The data elements captured and recorded for each EPCIS are presented in Table 13 below.

Dimension	Data	Definition	Examples
	<b>Event Type Action</b>	the event type and the action together define the type of EPCIS event; e.g., object creation, object observation, aggregation, disaggregation, etc	Object Event with Action = ADD Aggregation Event with Action = DELETE etc.
<b>What</b>	<b>EPC List</b>	the item's GS1 Identification Key, expressed as an EPC Pure Identity URI. Depending on the event type, this will either be a list of EPCs, or the combination of a Parent ID and a list of child EPCs	GTIN, SSCC, GRAI, etc.
	<b>Parent ID</b>		
	<b>Child EPCs</b>		
<b>When</b>	<b>Event Time</b>	the moment in time at which the event occurred	March 15, 2010 at 10:07am UTC
	<b>Event Timezone Offset</b>	indicates the local time zone in effect at the place where the event occurred. This is not needed to interpret Event Time (which carries its own timezone indicator) but instead helps software display data to users in local time	UTC -05:00
<b>Where</b>	<b>Read Point</b>	the location at which the event took place, expressed as an EPC Pure Identity URI	GLN or GLN with extension
	<b>Business Location</b>	the location at which the objects are presumed to be following the event until a subsequent event says otherwise, expressed as an EPC Pure Identity URI	GLN or GLN with extension
<b>Why</b>	<b>Business Step</b>	the business process taking place at the time of this event	Shipping, Receiving, Picking, etc.
	<b>Disposition</b>	business condition of the objects named in the <i>what</i> dimension that is presumed to hold until a subsequent event occurs	Saleable, Recalled, etc.
	<b>Business Transaction</b>	one or more references to associated business transactions, each comprised of a business transaction type (e.g., purchase order, invoice, etc) and a globally unique reference to a specific transaction of that type	Acme Corp Purchase Order #1234

Table M: EPCIS Data

EPCIS is a flexible standard that can be leveraged for a wide variety of business needs. To serve the needs of a particular business application, supply chain partners must come to an agreement with regard to the EPCIS events and data that will be shared. Therefore, members of the U.S. pharmaceutical industry joined forces to determine how the EPCIS shall be applied to support pedigree and track and trace.

The remainder of this document specifies how the EPCIS standard is applied to support pedigree and track and trace for the US pharmaceutical industry.

## Part 5: Application of EPCIS for Serialized Product Pedigree

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EPCIS events consist of data captured by each party in the supply chain as they handle a product in the course of the product's lifecycle. As such, EPCIS events provide visibility of handling operations for either internal business applications (i.e., if the EPCIS events are consumed internally), or across the supply chain (i.e., if the events are shared with trading partners). Visibility data in the form of EPCIS events may be used to automate a variety of business processes, including track and trace, pedigree, recall, etc.

This section specifies the minimum set of EPCIS events required to support the pedigree business process. A set of EPCIS events pertaining to a specific instance or instances of a product, inclusive of all events from the point of origin (i.e., commissioning) to the present, and conforming to this section provides all of the data content in a drug pedigree. Certain pedigree laws consider product and location data to be part of the pedigree. Companies that have implemented the best practice of a [Master Data Management](#) architecture, may wish to obtain and manage product and location master data separate from the EPCIS events themselves. For example, a drug pedigree includes both the unique identifier for a pharmaceutical product (i.e., the NDC and/or GTIN), as well as its dose and strength information. When using EPCIS events to provide pedigree content, the NDC and/or GTIN is present in the EPCIS event data itself, while the dose and strength information is obtained from the master data associated with the NDC/GTIN. Those companies will use the product and location identifiers (GTIN and GLN, respectively) found in the EPCIS events as keys to "look up" the previously synchronized master data and assemble the full drug pedigree content.

Other trading partners who are unable to, or have yet to adopt a master data management strategy may require the product and location master data be provided as part of the EPCIS events. To support both scenarios, product and location master data attributes are shown as "optional" in the EPCIS events.

Supply chain parties may collect additional EPCIS events not required for pedigree but used for other business applications. These events are discussed in a [Part 7](#) of this guideline.

## 12. Overview of EPCIS Events for Serialized Product Pedigree

For purposes of pedigree, each party in the supply chain must capture and share a certain set of EPCIS events. The EPCIS events that need to be captured and shared by each party depend on that party's position in the supply chain. An overview of EPCIS events for pedigree is provided below. Detailed definitions of each EPCIS event are specified in subsequent subsections.

### **Events captured and shared by the party at the beginning of the supply chain (e.g., manufacturer):**

- **Commissioning Events (Section 17.1)** declaring that specified serial numbers have been introduced into the supply chain and providing information about the corresponding products.
- **Packing Events (Section 17.2)** providing the hierarchical relationships (e.g., item-to-case, case-to-pallet) between objects as they exist at the point of shipping. The beginning party does not need to reflect any internal unpacking and packing activity that may have taken place, as long as the events that are shared fully account for the hierarchy as shipped.
- **Shipping Events (Section 17.3)** indicating that objects have been shipped to a downstream trading partner and providing pedigree information governing the shipment. The shipping events only reference the outermost (i.e., top-level) products in the packaging hierarchy. The full hierarchy is specified by inference from the prior packing events.

### **Events captured and shared by intermediate parties (e.g., distributor):**

- **Receiving Events (Section 17.4)** indicating that objects have been received from an upstream trading partner and providing pedigree information governing the receipt. The receiving party may only verify the identifiers of the outermost (i.e., top-level) products in the packaging hierarchy, in which case the full hierarchy inferred from prior packing events is inferred to have been received. Alternatively, the receiving party may verify one or more inner levels of hierarchy (*in which case the verified levels are declared explicitly in the receiving event, and inference is only used for inner levels not declared explicitly or not at all if all levels are declared explicitly*).
- **Unpacking Events (Section 17.5), Commissioning Events (Section 17.1), and Packing Events (Section 17.2)** as needed to reflect changes in the packaging hierarchy that have occurred prior to shipment. Commissioning events in this instance are only used to introduce new identifiers for logistic units (e.g., new SSCCs for pallets packed to order), *not to introduce new products*. The intermediate party does not need to reflect all internal unpacking, commissioning, and packing activity that may have taken place, as long as the events that are shared fully account for all changes in hierarchy between receiving and shipping.
- **Shipping Events (Section 17.3)** indicating that objects have been shipped to a downstream trading partner and providing pedigree information governing the shipment. The shipping events only reference the outermost (i.e., top-level) products in the packaging hierarchy. The full hierarchy is specified by inference from the prior unpacking and packing events (possibly including unpacking and packing events from prior supply chain parties).

**Events captured and shared by the party at the end of the supply chain (e.g., Hospital, Pharmacy, etc):**

- **Receiving Events (Section 17.4)** indicating that objects have been received from an upstream trading partner and providing pedigree information governing the receipt. The receiving party may only verify the identifiers of the outermost (i.e., top-level) products in the packaging hierarchy, in which case the full hierarchy inferred from prior packing events is inferred to have been received. Alternatively, the receiving party may verify one or more inner levels of hierarchy (*in which case the verified levels are declared explicitly in the receiving event, and inference is only used for inner levels not declared explicitly or not at all if all levels are declared explicitly*).
- **Unpacking Events (Section 17.5) and Packing Events (Section 17.2)** as needed to reflect changes in the packaging hierarchy that have occurred prior to end-of-life events. The final party does not need to reflect all internal unpacking and packing activity that may have taken place, as long as the unpacking and packing events that are shared fully account for all changes in hierarchy between receiving and end-of-life events.
- **End-of-life events including Dispensing (Section 17.6.1), Destroying (Section 17.6.3), and Decommissioning (Section 17.6.4)** indicating that specific products have been removed from the supply chain

### 13. Pedigree Data Elements

Drug pedigree data elements are derived from both the data in the EPCIS events themselves, as well as certain product and location master data that is referenced by product and location identifiers found in the EPCIS event. For example, a drug pedigree includes both the unique identifier for a pharmaceutical product (i.e., the NDC and/or GTIN), as well as its dose and strength information. When using EPCIS events to provide pedigree content, the NDC and/or GTIN is present in the EPCIS event data itself, while the dose and strength information is obtained from the master data associated with the NDC/GTIN.

A list of the pedigree data elements (from GS1 / EPCglobal Pedigree Ratified Standard v1.0) with the expected source for that data is provided in Table 14 below.

Type of Information	Data Attribute	Expected Source (EPCIS Event, Master Data, etc.)
<b>Document Information</b>	Pedigree serial number	Event ID
<b>Item Information</b>	Item serial number(s) of product(s) (if available)	EPCIS epcList
	Lot number	EPCIS ObjectEvent event where bizStep is "commissioning"
	Expiration date	EPCIS ObjectEvent event where bizStep is "commissioning"
	Quantity of saleable units in transaction	EPCIS ObjectEvent event where bizStep is "shipping"

Type of Information	Data Attribute	Expected Source (EPCIS Event, Master Data, etc.)
<b>Product Information</b>	Drug name	Product Master Data
	Manufacturer	Product Master Data
	Product code (e.g., the NDC number)	EPCIS epcList and as part of the additionalTradeltemIdentification
	Dosage form	EPCIS ObjectEvent event where bizStep is "commissioning"
	Strength	EPCIS ObjectEvent event where bizStep is "commissioning"
	Container size	EPCIS ObjectEvent event where bizStep is "commissioning"
<b>Transaction Information</b>	Transaction identifier (for example, invoice or purchase order number)	EPCIS ObjectEvent event where bizStep is "shipping"
	Transaction document type (e.g., Invoice, Purchase order, Return authorization)	EPCIS ObjectEvent event where bizStep is "shipping"
	Date of transaction	EPCIS eventTime and eventTimeOffset
	Transaction type (e.g., sale, transfer, return)	EPCIS ObjectEvent event where bizStep is "shipping"
<b>Seller and Recipient Information</b>	Business Address (see below)	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Shipping Address (see below; used only if different than Business Address)	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	License number	EPCIS ObjectEvent event where bizStep is "shipping"
	License state or region	EPCIS ObjectEvent event where bizStep is "shipping"
	License agency	EPCIS ObjectEvent event where bizStep is "shipping"
	Contact Information for seller used for authentication of transaction (see below)	EPCIS ObjectEvent event where bizStep is "shipping"
<b>Business and Shipping Address</b>	Business name	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Street1	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Street 2	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	City	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	State or Region	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Postal Code	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"
	Country	Location Master Data, or EPCIS ObjectEvent event where bizStep is "shipping" or "receiving"

Type of Information	Data Attribute	Expected Source (EPCIS Event, Master Data, etc.)
<b>Contact Information1</b>	Contact Name	EPCIS ObjectEvent event where bizStep is “shipping”
	Contact Title	EPCIS ObjectEvent event where bizStep is “shipping”
	Contact Email	EPCIS ObjectEvent event where bizStep is “shipping”
	Contact Telephone	EPCIS ObjectEvent event where bizStep is “shipping”
	Contact URL (for automated authentication)	EPCIS ObjectEvent event where bizStep is “shipping”
<b>Receiving Information</b>	Date received	EPCIS ObjectEvent event where bizStep is “receiving”
	Item Information (e.g., Lot, Quantity, Serial Numbers) for items in partial receipt2	EPCIS ObjectEvent event where bizStep is “commissioning”
<b>Signer Information</b>	Name of signer	EPCIS ObjectEvent event where bizStep is “receiving”
	Title of signer	EPCIS ObjectEvent event where bizStep is “receiving”
	Date of signature	EPCIS ObjectEvent event where bizStep is “receiving”
	Signature meaning (defines certification context such as certified outbound, received and authenticated inbound)	EPCIS ObjectEvent event where bizStep is “receiving”
		EPCIS ObjectEvent event where bizStep is “receiving”
<b>Digital Signature Information3</b>	SignedInfo	N/A
	SignatureValue	N/A
	KeyInfo	N/A
	SignatureProperties	N/A

Table N: Pedigree Data Elements

## 14. Pedigree Data Rules

### 14.1. EPCIS Event Time

The *Event Time* data element in an EPCIS event is defined as the moment in time when the event occurred. When sharing EPCIS events with trading partners for pedigree purposes, it is permissible for the *Event Time* to be different from the actual moment in time when the event occurred, provided that the rules in this section are followed. These rules are designed to give freedom to supply chain parties to capture the *Event Time* in a manner that is not overly burdensome and to hide certain internal business details from trading partners (e.g., the lag in time between packing a shipment and dispatching the shipment through the door), while at the same time ensuring that applications receiving EPCIS events will see a “reasonable” sequence of *Event Times*. When a party shares EPCIS events with a trading partner, the *Event Time* in those events shall conform to the following rules.

**①** Note that the *Event Time* shared with trading partners may differ from the *Event Time* captured internally, so long as the rules are followed; that is, a party may keep more detailed *Event Time* for internal use, but modify the *Event Time* to obscure certain details not appropriate to share with trading partners.

**Rules:**

- The *Event Time* shared with trading partners may differ from the *Event Time* captured internally. However, for any given event, the *Event Time* shared with trading partners shall be the same across all trading partners.
- EPCIS provides for millisecond precision in the *Event Time*. The *Event Time* shared with trading partners may be expressed with less precision, provided that the reported *Event Time* is within one minute of the actual *Event Time*.
- Business processes such as packing and shipping may take place over a span of time rather than a moment in time. Normally, the *Event Time* shared with trading partners should correspond to the time of completion of the process. However, any time within the span may be used as long as the other rules are adhered to.
- The diagram below shows the chronological sequence of *Event Times* that shall hold between events that refer to the same object identifier:
  - The *Event Time* reported for Shipping, Receiving, and end-of-life events shall reflect the true time of those events (subject to the rules above).
  - The *Event Time* for other events (e.g., commissioning, packing, unpacking) as shared with trading partners may be advanced in time up to (but not equal to) the time of the subsequent shipping or end-of-life event as long as the relationships in the diagram continue to hold.
  - Only the *Event Times* for Shipping, Receiving, and end-of-life events are relevant for pedigree purposes. The *Event Times* for other events may be advanced in order to obscure internal business details not relevant to trading partners.

Figure 16 below shows the relationships of *Event Times*. The “<” symbol indicates that the first *Event Time* must be strictly less than the second *Event Time*.

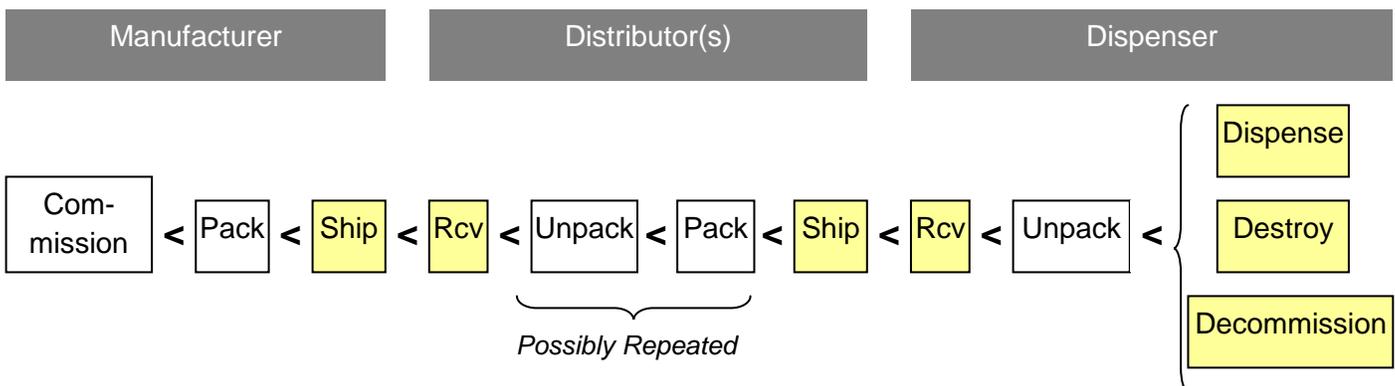


Figure 16: Event Time Relationships for Pedigree Purposes

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## Best Practice:

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- For change of ownership situations where the process does not provide a natural change in time difference between shipping and receiving (consignment inventory), Receiving times Shall be created with a time greater than the related Shipping events (when used). When creating events to share with a trading partner, the timing of events should reflect the sequence of events that naturally would occur.
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## 14.2. EPCIS Read Points and Business Locations

The EPCIS standard defines two data elements that provide the *where* dimension for an EPCIS event: *Read Point* and *Business Location*. The *Read Point* is an EPC URI that identifies the location where the event took place. The *Business Location* is an EPC URI that identifies the location where the object named in the event is presumed to be until a subsequent event says otherwise. The *Business Location* is useful for answering questions about where objects are right now (or at any prior moment between events).

Supply chain parties may capture *Read Points* and *Business Locations* at a coarse level (e.g., identifying a site or campus) or at a granular level (e.g., identifying a specific area or door within a building). A supply chain party may also choose to share location information with trading partners at a coarser level of granularity than it captures for internal purposes. For example, a supply chain party may capture the specific loading dock door where a shipping event took place for internal purposes. However, when sharing data with a trading partner, that party may only share the site without providing information about which dock door was used.

### Rules:

EPCIS events shared for pedigree purposes shall conform to the following rules for *Business Locations* and *Read Points*:

- The *Business Location* for an event shall be a site-level GLN (without extension) expressed as an EPC URI. Such a URI begins with “**urn:epc:id:sgln:**” and ends with “.0.”. (Note that *Business Location* is omitted from a Shipping event. See section [17.3](#).)
- The *Read Point* for an event shall be one of the following:
  - A site-level GLN (without extension) expressed as an EPC URI. . Such a URI begins with “**urn:epc:id:sgln:**” and ends with “.0.”.
  - A GLN with extension denoting a more granular location within a site, expressed as an EPC URI. Such a URI begins with “**urn:epc:id:sgln:**” and ends with a dot followed by the GLN extension value. In this case, the base GLN shall be the same as the site-level GLN in which the more granular location is located.
    - For example, if you have used a GLN (GLN of: **urn:epc:id:sgln:0354321654923.0**) to identify a warehouse location and want to identify a location in the warehouse, use the warehouse’s GLN and add an extension (**urn:epc:id:sgln:0354321654923.1234**).

**i** GS1 Standards allow more granular locations within a site to be given individual GLNs without extension. However, the above rule requires that extensions be used in this case so that applications to ascertain the GLN for the site-level location can be accomplished by simply disregarding the extension.

### 14.3. EPCIS Business Transactions

The *Business Transaction* list in EPCIS events is used for purchase order and invoice information to be included in shipping and receiving events. The EPCIS standard specifies that *Business Transactions* be globally unique identifiers expressed in URI syntax.

#### **Rules:**

*Business Transactions* in EPCIS events shall conform to the following rules:

- The *Business Transaction type* shall be one of the URIs defined in Section 7.3 of the GS1 EPC Core Business Vocabulary. Typically, this is either **urn:epcglobal:cbv:btt:po** denoting a purchase order or **urn:epcglobal:cbv:btt:inv** denoting an invoice.
- The *Business Transaction identifier* shall conform to the syntax defined in Section 8.4.2 of the GS1 EPC Core Business Vocabulary. This syntax constructs a globally unique identifier in URI syntax by combining the transaction identifier (e.g., purchase order number) with a GLN that identifies the party that issued the transaction identifier. This combined identifier is globally unique and leaves no ambiguity about the system from which a transaction identifier comes. For example, urn:epcglobal:cbv:bt:0614141123452:A123 identifies a transaction whose native identifier (e.g., purchase order number) is A123 and which comes from a party identified by GLN 0614141123452.
- The GLN used in a *Business Transaction* identifier as specified above shall match the GLN provided in the **transferredById** or **transferredTold** extension to a shipping or receiving event (whichever party created the transaction). Namely, the *Business Transaction* identifier shall match the **transferredById** for an invoice, and the **transferredTold** for a purchase order. (See Section 17.3 for the definition of [transferredById](#) and [transferredTold](#).)

### 14.4. Checking EPCIS Event Contents

The following are suggested rules for verifying matching Receiving events and Shipping events.

- Pay attention to the dates. Dates should match your business expectations. Your systems should alert you to events outside of your normal business practice.
- The GTIN in the barcode should match the GTIN in the Shipping event.
- NDC in Receiving should match the Shipping NDC.
- All events SHALL conform to the attributes / extensions that are outlined in this guideline.
- Mandatory attributes SHALL exist.
- Location Identifier should belong to the expected party.

## 15. EPCIS Extension Elements

The EPCIS standard provides for data elements not specified in the standard to be included in EPCIS events as extensions. This is done by including additional XML elements just before the closing tag for an event, where those XML elements are in an XML namespace other than the EPCIS namespace.

**All extension elements defined in this guideline are defined in the following XML namespace:**

<http://epcis.gs1us.org/hc/ns>

**All XML illustrations in this guideline use the prefix “gs1ushc” to denote this XML namespace. This means that an extension would look like this:**

```
<epcis:EPCISDocument xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" ...>
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>...</eventTime>
        ...
        <bizTransactionList>
          ...
        </bizTransactionList>
        <gs1ushc:lotNumber>ABC123</gs1ushc:lotNumber>
        <gs1ushc:itemExpirationDate>2011-03-15</gs1ushc:itemExpirationDate>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

**i** The EPCIS standard XML schema defines an element `<extension>`. This is reserved for use by future versions of the EPCIS standard to introduce new standard data elements in a forward-compatible way, and may not be used to define extensions outside of the EPCIS standard. Extensions outside the standard are defined as illustrated above (i.e., in a different XML namespace and not enclosed in the `<extension>` element).

## 16. Core Business Vocabulary (CBV) Extensions

The EPCIS standard specifies that the *Business Step*, *Disposition*, and *Business Transaction Type* fields of EPCIS events shall be populated with URI strings (each denoting a specific business step, disposition, or business transaction type, respectively). The GS1 EPC Core Business Vocabulary (CBV) standard provides standardized URI strings for a variety of commonly-occurring *Business Steps*, *Dispositions*, and *Business Transaction Types*.

This guideline has identified the need for additional *Business Steps* and *Dispositions* in pedigree EPCIS events for which the CBV does not provide a suitable standardized identifier. This guideline specifies URI strings to use in these situations. All such URI strings have the following form:

### For business steps:

<http://epcis.gs1us.org/hc/bizstep/new-bizstep-name>

### For dispositions:

<http://epcis.gs1us.org/hc/disp/new-bizstep-name>

The specific names are specified in the sections documenting the events in which they are used.

**i** All vocabulary values beginning with `urn:epcglobal:cbv:` are reserved for use by the CBV standard, and this prefix may not be used to define vocabulary outside the CBV. New vocabulary elements outside the CBV standard are defined by using a private URI space as illustrated above, not by using `urn:epcglobal:cbv:.`

## 17. EPCIS Event Details for Pedigree

This remainder of section defines individual EPCIS events for different steps in the pharmaceutical supply chain process for pedigree purposes. The EPCIS standard defines many fields of EPCIS events to be optional. In the context of a specific event defined in this guideline, a field that is optional in the EPCIS standard may be required to be present (or required to be omitted) for pedigree purposes. For clarity, the EPCIS event details tables throughout this section use the following notations to indicate what is required for pedigree purposes:

<b>Required</b>	The field is required in the context of this specific event. (This is always the case if the field is specified as required in the EPCIS standard.)
<b>Optional</b>	The field may or may not be included in the context of this specific event.
<b>Conditional</b>	In the context of this specific event, the field may be required, optional, or omitted depending on circumstances. The circumstances are specified in the description.
<b>Omitted</b>	The field is always omitted in the context of this specific event.

## 17.1. Commissioning

*Commissioning* is the process of associating an object (e.g., bottle, case, tote, pallet, etc.) with an EPC (i.e., an identifier representing a GTIN / Serial Number, SSCC, etc.). The EPC may be encoded in a data carrier (i.e., a barcode or EPC/ RFID tag) and applied to the object during this step, or the data carrier may have been previously encoded.

❖ **A Commissioning event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
<b>eventTime</b>	Required	Timestamp	Date and time of event (see Section <a href="#">14.1</a> ).	EPCIS standard definition
<b>recordTime</b>	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
<b>eventTimeZoneOffset</b>	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
<b>epcList</b>	Required	List of URI	EPC(s) of the commissioned item in EPC Pure Identity URI format. If more than one EPC is included, they shall all have the same value for extensions defined below, or shall all require these extensions to be omitted. EPCs having different values for these extensions must be shared in different Commissioning events.	Because the extensions below are <i>event-level</i> extensions, they must be the same for all EPCs in the event.
<b>action</b>	Required	String	ADD	EPCIS standard definition
<b>bizStep</b>	Required	URI	urn:epcglobal:cbv:bizstep:commissioning	CBV standard definition
<b>disposition</b>	Required	URI	urn:epcglobal:cbv:disp:active	CBV standard definition: the <i>Disposition</i> value "active" is always used with the <i>Business Step</i> "commissioning."
<b>readPoint</b>	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section <a href="#">14.2</a> ).	EPCIS standard definition
<b>bizLocation</b>	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section <a href="#">14.2</a> ).	EPCIS standard definition
<b>bizTransactionList</b>	Omitted	List of biz transactions (each represented as a pair of URIs)		Omitted in Commissioning events as there are no relevant business transactions to share.

### ❖ Extensions used in Commissioning Events:

In addition to the EPCIS standard fields shown above, the following extensions are also included in a Commissioning event. (See Section [15](#) for general notes about extensions.)

Element	Usage	Type	Value
<b>eventID</b>	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>
<b>additionalTradeItemIdentification</b>	Conditional	AdditionalTradeIdentificationType (see below)	The product code associated with all of the EPCs in the epcList of the ObjectEvent.
<b>tradeItemMasterData</b>	Conditional	Complex Type tradeItemMasterData (see below)	Used for trading partners who do not employ a master data management strategy
<b>lotNumber</b>	Conditional (see notes below)	String	The lot or batch number for all of the EPCs in the epcList of the ObjectEvent.
<b>itemExpirationDate</b>	Conditional (see notes below)	Date	The expiration date for all of the EPCs in the epcList of the ObjectEvent, formatted as an xsd:date. *

**\* Special Notes:**

The GS1 General Specification states that, for Expiration Date (AI 17) in a barcode, if only year and month are available, the day portion of the date must be filled with two zeroes (ex: January 2013 would be represented as “130100”). The itemExpirationDate attribute uses the W3C standard date format which does not allow “00” as a day. The GS1 US Secure Supply Chain Task Force is considering options to address this in an amendment to this guideline or in a future version. In the interim, certain manufacturers have elected to use the last day of the month in the itemExpirationDate attribute, please communicate to your trading partners how you plan on addressing this so that they can understand how to interpret the expiration date they receive in your barcoded product and EPCIS Commissioning events.

**2011 HDMA Barcode Guidelines:** The application identifier for expiration date, AI(17), requires the “YYMMDD” (Year, Year, Month, Month, Day, Day) format. No other expiration date format is supported or allowed in the GS1 System. Yet some suppliers do not designate a day of the month as part of their expiration date. In this case “00” is used in the GS1 System as a place holder for the “DD” date segment when no day of the month is specified. The last day of the month is analogous to using 00 and is also perfectly acceptable. Whatever the human-readable format, HDMA recommends that the human-readable year always be represented in its complete “CCYY” (Century, Century, Year, Year) four-digit format.

It also is important to note that the lack of a specified day of the month in the expiration date can cause confusion as to which day of the month is the expiration date. HDMA recognizes the following excerpt from the United States Pharmacopeia\* (USP) as authoritative on the subject of the date format:

USP 34–NF 29 through Second Supplement 10.40.100. Expiration Date and Beyond-Use Date:

The label of an official drug product or nutritional or dietary supplement product shall bear an expiration date. The expiration date identifies the time during which the article may be expected to meet the requirements of the compendial monograph, provided it is kept under the prescribed storage conditions. The expiration date limits the time during which the article may be dispensed or used. Where an expiration date is stated only in terms of the month and the year, it is a representation that the intended expiration date is the last day of the stated month

\* The USP is a non-governmental, official public standards-setting authority for prescription and over-the-counter medicines and other healthcare products manufactured or sold in the United States.

**❖ The AdditionalTradeltemIdentificationType elements are:**

Element	Usage	Type	Value
<b>additionalTradeltemIdentificationValue</b>	Required	String	The product code associated with all of the EPCs in the epcList.of the ObjectEvent For NDC, do not include dashes.
<b>additionalTradeltemIdentificationType</b>	Required	Additional Tradeltem Identification ListType (enum list)	(Mandatory) The product code type.  Valid values are: NDC442, NDC541, NDC532, NDC542

❖ **The TradeItemMasterData elements are:**

Element	Usage	Type	Value
<b>drugName</b>	Required	String	The name of the drug as it appears on the product label.
<b>manufacturer</b>	Required	String	The name of the manufacturer or repackager of the drug as it appears on the product label.
<b>dosageForm</b>	Required	String	Standard forms of drugs (AEROSOL, CAPSULE, GEL, PILL, TABLET) as defined by the FDA. The FDA currently defines 143 dosage forms.
<b>strength</b>	Required	String	The strength or potency of the product, including the unit of measure (for example, 60 mg, 25 ml).
<b>containerSize</b>	Required	String	The number of units contained in a package of the product (for example, 60, 100). This is also known as pack size.

❖ **Commissioning ObjectEvent Rules:**

- ObjectEvents for commissioning item serial numbers SHALL include the extension elements to define the product code, lot and expiration date.
- ObjectEvents for commissioning homogenous containers (e.g., cases and pallets of the same object) MAY include the extension elements to define the product code, lot and expiration date.
- ObjectEvents for commissioning non-homogenous containers (e.g., cases and pallets of different items, lots, etc.) SHALL NOT include the extension elements to define the product code, lot and expiration date.
- All of the EPCs within a single Commissioning event must belong to only one of the categories defined in the previous three rules Multiple Commissioning events must be used for EPCs belonging to different categories.

## ❖ Commissioning Event Example:

```

<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gs1us.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000002</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000003</epc>
          <epc>urn:epc:id:sgtin:030001.1012345.22222222222</epc>
        </epcList>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:active</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </bizLocation>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>

        <gslushc:additionalTradeItemIdentification>

        <gslushc:additionalTradeItemIdentificationValue>0001012345</gslushc:additionalTradeItemIdentificationValue>

        <gslushc:additionalTradeItemIdentificationType>NDC442</gslushc:additionalTradeItemIdentificationType>
        </gslushc:additionalTradeItemIdentification>
        <gslushc:tradeItemMasterData>
          <gslushc:drugName>Epcistra</gslushc:drugName>
          <gslushc:manufacturer>GS1 Pharma LLC</gslushc:manufacturer>
          <gslushc:dosageForm>PILL</gslushc:dosageForm>
          <gslushc:strength>100mg</gslushc:strength>
          <gslushc:containerSize>500</gslushc:containerSize>
        </gslushc:tradeItemMasterData>
        <gslushc:lotNumber>A123</gslushc:lotNumber>
        <gslushc:itemExpirationDate>2015-03-15</gslushc:itemExpirationDate>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
  
```

## 17.2. Packing

*Packing* denotes a specific activity within a business process that includes putting an object (e.g., individuals, inners, cases, pallets, etc.) into a larger container (e.g., cases, totes, pallets, etc.) usually for the purposes of storing or shipping. Aggregation of one unit to another occurs at this point.

❖ **A Packing event shall be an EPCIS Aggregation Event populated as follows:**

Element	Usage	Type	Value	Reason
<b>eventTime</b>	Required	Timestamp	Date and time of event (see Section <a href="#">14.1</a> ).	EPCIS standard definition
<b>recordTime</b>	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
<b>eventTimeZoneOffset</b>	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
<b>parentID</b>	Required	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition
<b>childEPCs</b>	Required	List of URI	EPC(s) of the item(s) being packed into the parent in EPC Pure Identity URI format.	EPCIS standard definition
<b>action</b>	Required	String	ADD	EPCIS standard definition
<b>bizStep</b>	Required	URI	urn:epcglobal:cbv:bizstep:packing	CBV standard definition
<b>disposition</b>	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
<b>readPoint</b>	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section <a href="#">14.2</a> ).	EPCIS standard definition
<b>bizLocation</b>	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section <a href="#">14.2</a> ).	EPCIS standard definition
<b>bizTransactionList</b>	Omitted	List of biz transactions (with each represented as a pair of URIs)		Omitted in the packing event as there are no relevant business transactions to share.

## ❖ Extensions used in Packing Events:

In addition to the EPCIS standard fields shown above, the following extensions are also included in a Packing event. (See Section [15](#) for general notes about extensions.)

Element	Usage	Type	Value
<b>eventID</b>	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

## ❖ Packing Event Example:

```

<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gs1us.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <AggregationEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <parentID>urn:epc:id:sgtin:030001.1012345.2222223333</parentID>
        <childEPCs>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001003</epc>
        </childEPCs>
        <action>ADD</action>
        <bizStep>urn:epcglobal:cbv:bizstep:packing</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </bizLocation>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </AggregationEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
    
```

## 17.3. Shipping

*Shipping* is the process of initiating the transfer an object from one trading partner to another. A data carrier (i.e., a bar code or EPC/RFID tag) may have been read during this process. Only the outermost containers in the packaging hierarchy are included.

❖ **A Shipping event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
<b>eventTime</b>	Required	Timestamp	Date and time of event (see Section <a href="#">14.1</a> ).	EPCIS standard definition
<b>recordTime</b>	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
<b>eventTimeZoneOffset</b>	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
<b>epcList</b>	Required	List of URI	EPC(s) of the shipped item(s) in EPC Pure Identity URI format. Only the outermost containers in the packaging hierarchy are included.	For pedigree purposes, the Shipping event only needs the outermost identifiers because separate Packing events are used to indicate the hierarchy.
<b>action</b>	Required	String	OBSERVE	EPCIS standard definition
<b>bizStep</b>	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
<b>disposition</b>	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The <i>Disposition</i> value "in_transit" is always paired with the <i>Business Step</i> "shipping" for forward logistics.
<b>readPoint</b>	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section <a href="#">14.2</a> ).	EPCIS standard definition
<b>bizLocation</b>	Optional	URI		The <i>Business Location</i> is the location where the objects are presumed to be following the event. For a Shipping event, this is unknown until a Receiving event occurs. Therefore, <i>Business Location</i> is always omitted for a Shipping event. (Note that extension elements in this event provide "Ship from" and "Ship to" information.
<b>bizTransactionList</b>	Optional	List of biz transactions (each represented as a pair of URIs)	Business transactions governing this Shipping event, which may include a purchase order or an invoice (see Section <a href="#">14.3</a> for details).	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for P.O., Invoice or other ID's.

## ❖ Extensions used in Shipping Events

In addition to the EPCIS standard fields listed above, the following extensions are also included in a Shipping event. (See Section [15](#) for general notes about extensions.)

Element	Usage	Type	Value
<b>eventID</b>	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>
<b>transferredById</b>	Required	String	The identifier of the party that transferred the goods (in the format implied by the accompanying @type attribute)
<b>@type</b>	Required	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
<b>shipFromLocationId</b>	Conditional	String	The identifier of the location where the goods are shipped from (in the format implied by the accompanying @type attribute). Only included if different from transferredById.
<b>@type</b>	Conditional	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
<b>shipFromLocationAddress</b>	Optional	AddressType	Fully enumerated address.
<b>transferredToId</b>	Required	String	The identifier of the party that the goods were transferred to (in the format implied by the accompanying @type attribute). Indicates the change of ownership. Previous owner (transferredById) has transferred ownership to this party.
<b>@type</b>	Required	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
<b>shipToLocationId</b>	Conditional	String	The identifier of the location where the goods were shipped to (in the format implied by the accompanying @type attribute). Only included if different from transferredToId.
<b>@type</b>	Conditional	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
<b>shipToLocationAddress</b>	Optional	AddressType	Fully enumerated address.

Element	Usage	Type	Value
<b>shipFromLicenseList</b>	Conditional	List of LicenseListType. Multiple LicenseListType instances may be included to express as many licenses as needed.	(Mandatory for compliance with CA, but may not be needed in other states.) A list of one or more state or federal license numbers for the party that sold the goods.  <i>(See the list of values in the sections following this table.)</i>
<b>shipToLicenseList</b>	Conditional	List of LicenseListType. Multiple LicenseListType instances may be included to express as many licenses as needed.	(Mandatory for compliance with CA, but may not be needed in other states.) A list of one or more state or federal license numbers for the party that the goods were shipped to.  <i>(See the list of values in the sections following this table.)</i>
<b>soldFromContact</b>	Optional	ContactType	Contact information for the seller

❖ **The PartyIdQualifierEnum code list values are:**

- GLN**                      GS1 GLN for the company, expressed as a 13-digit string
- SGLN**                    GS1 GLN for the facility, expressed in SGLN EPC Pure Identity URI format, ending in ".0" to indicate the lack of a GLN extension. (See Sections 6.3.3 and 7.3 of the EPC Tag Data Standard.)
- DEA**                      Drug Enforcement Agency Number
- HIN**                        HIBCC Health Industry Number

**i** *GS1 Healthcare US recommends the use of GLN and/or SGLN as they maintain alignment with the GS1 System of Standards. GS1 Healthcare US discourages the use of identifiers from outside the GS1 System because they may not be global, and/or because issuing agencies for some identifiers do not approve of the use of their identifiers beyond the specific application for which they were issued.*

❖ **The AddressType elements are:**

Element	Usage	Type	Value
<b>street1</b>	Required	String	The first line of the street address.
<b>street2</b>	Optional	String	The second line of the street address.
<b>city</b>	Required	String	The city.
<b>stateOrRegion</b>	Required	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
<b>postalCode</b>	Required	String	The ZIP or other postal code.
<b>country</b>	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

❖ **The LicenseListType elements are:**

Element	Usage	Type	Value
<b>licenseNumber</b>	Required	String	A list of one or more state or federal license numbers for the trading partner.
<b>@state</b>	Optional	String	The state or region in which the trading partner is licensed, using the standard two letter abbreviation specified in ISO 3166-2:1998 country sub-division code. This attribute is used to give additional context to the license number.
<b>@agency</b>	Optional	String	The agency that granted the license (e.g., Florida DOH, NABP). This attribute is used to give additional context to the license number.

❖ **The ContactType elements are:**

Element	Usage	Type	Value
<b>name</b>	Optional	String	The name of the contact department or individual at the company.
<b>title</b>	Optional	String	The title of the individual.
<b>telephone</b>	Optional	String	The phone number of the contact department or individual at the company. This SHALL begin with the "+" character followed by the Country Calling Code.
<b>email</b>	Optional	String	The email address of the contact department or individual at the company.
<b>url</b>	Optional	String	The Web address to facilitate authentication.

## ❖ Shipping Event Example:

```

<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gslus.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:030001.01234567890</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:shipping</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_transit</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:030001.111111.0</id>
        </readPoint>
        <bizTransactionList>
          <bizTransaction
            type="urn:epcglobal:cbv:btt:inv">urn:epcglobal:cbv:bt:0300011111116:A123</bizTransaction>
          <bizTransaction
            type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:
0399999999991:XYZ567</bizTransaction>
          </bizTransactionList>
          <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
          <gslushc:transferredById
            type="GLN">0300011111116</gslushc:transferredById>
          <gslushc:shipFromLocationId
            type="GLN">0300011111116</gslushc:shipFromLocationId>
          <gslushc:shipFromLocationAddress>
            <gslushc:street1>1295 S George Ave</gslushc:street1>
            <gslushc:street2>Room 378</gslushc:street2>
            <gslushc:city>Washington</gslushc:city>
            <gslushc:stateOrRegion>DC</gslushc:stateOrRegion>
            <gslushc:postalCode>12345-6789</gslushc:postalCode>
            <gslushc:country>US</gslushc:country>
          </gslushc:shipFromLocationAddress>
          <gslushc:transferredToId
            type="GLN">0399999999991</gslushc:transferredToId>
          <gslushc:shipToLocationId
            type="GLN">0399999999991</gslushc:shipToLocationId>
          <gslushc:shipToLocationAddress>
            <gslushc:street1>230 Park Ave S</gslushc:street1>
            <gslushc:city>New York</gslushc:city>
            <gslushc:stateOrRegion>NY</gslushc:stateOrRegion>
            <gslushc:postalCode>10003-1502</gslushc:postalCode>
            <gslushc:country>US</gslushc:country>
          </gslushc:shipToLocationAddress>
          <gslushc:shipFromLicenseList>
            <gslushc:licenseNumber
              state="TN"
              agency="SLN">0000001013</gslushc:licenseNumber>
          </gslushc:shipFromLicenseList>
          <gslushc:soldFromContact>
            <gslushc:name>CONTACT NAME</gslushc:name>
            <gslushc:telephone>+1-212-555-5624</gslushc:telephone>
            <gslushc:email>contact.name@example.com</gslushc:email>
          </gslushc:soldFromContact>
        </ObjectEvent>
      </EventList>
    </EPCISBody>
  </epcis:EPCISDocument>
  
```

## 17.4. Receiving

*Receiving* is the process of completing the transfer of an object from one trading partner to another. Receiving may be recorded in one of two ways:

- 1: Only the outermost containers in the packaging hierarchy are included in the Receiving event, in which case the full hierarchy inferred from prior Packing events is inferred to have been received, or
- 2: One or more inner levels of hierarchy are declared explicitly in one or more Receiving events, in which case inference is only used for inner levels not declared explicitly (or not at all if all levels are declared explicitly)

If the Receiving event is to be recorded using the first method (i.e., where only the outermost containers are included in the Receiving event), the Receiving event shall be an EPCIS Object Event populated as specified below. If the Receiving event is to be recorded using the second method (i.e., where hierarchy is declared explicitly), share as many Receiving Events as needed to express the hierarchy. Each event shall be an EPCIS Aggregation Event where the *Parent ID* and *Child EPC List* fields express the hierarchy and all other fields (including the action and the extensions) are as specified below.

Element	Usage	Type	Value	Reason
<b>eventTime</b>	Required	Timestamp	Date and time of event (see Section <a href="#">14.1</a> ).	EPCIS standard definition
<b>recordTime</b>	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
<b>eventTimeZoneOffset</b>	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
<b>epcList</b>	Required	List of URI	EPC(s) of the received item(s) in EPC Pure Identity URI format. *If an <i>Object Event</i> is used, only the outermost containers in the packaging hierarchy are included. * If <i>Aggregation Events</i> are used, the event contains parentID and childEPCs fields (instead of the epcList field) for expressing the observed hierarchy.	See the discussion above regarding receiving options.
<b>action</b>	Required	String	OBSERVE	EPCIS standard definition
<b>bizStep</b>	Required	URI	urn:epcglobal:cbv:bizstep:receiving	CBV standard definition
<b>disposition</b>	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
<b>readPoint</b>	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section <a href="#">14.2</a> .)	EPCIS standard definition
<b>bizLocation</b>	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section <a href="#">14.2</a> .)	EPCIS standard definition
<b>bizTransactionList</b>	Optional	List of biz transactions, (each represented as a pair of URIs)	Business transactions governing this shipping event, which may include a purchase order or an invoice. (See Section <a href="#">14.3</a> for details.)	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for P.O., Invoice or other ID's.

## ❖ Extensions used in Receiving Events

In addition to the EPCIS standard fields, the following extensions are included in a Receiving event. (See Section [15](#) for general notes about extensions.)

Element	Usage	Type	Value
<b>eventID</b>	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>
<b>transferredById</b>	Required	String	The identifier of the party that transferred the goods (in the format implied by the accompanying @type attribute)
<b>@type</b>	Required	PartyIdQualifierEnum (enum list)	(See the list of values in the section following this table.)
<b>transferredToId</b>	Required	String	The identifier of the party that the goods were transferred to (in the format implied by the accompanying @type attribute). Indicates the change of ownership. Previous owner (transferredById) has transferred ownership to this party.
<b>@type</b>	Required	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
<b>shipToLocationId</b>	Conditional	String	The identifier of the location where the goods were shipped to, in the format implied by the accompanying @type attribute. Only included if different from transferredToId
<b>@type</b>	Conditional	PartyIdQualifierEnum (enum list)	(See the list of values in the sections following this table.)
<b>shipToLocationAddress</b>	Optional	AddressType	Fully enumerated address.
<b>receivedByContact</b>	Optional	ContactType (see Section <a href="#">13</a> )	Contact information for the receiver

### Best Practice:

- To help in later matching Shipping and Receiving events, if possible, use the same values found in your trading partner's "Shipping" event for transferredById and transferredToId in your "Receiving" event.

❖ **The PartyIdQualifierEnum code list values are:**

- GLN**                      GS1 GLN for the company, expressed as a 13-digit string
- SGLN**                    GS1 GLN for the facility, expressed in SGLN EPC Pure Identity URI format, ending in “.0” to indicate the lack of a GLN extension. (See Sections 6.3.3 and 7.3 of the EPC Tag Data Standard.)
- DEA**                      Drug Enforcement Agency Number
- HIN**                        HIBCC Health Industry Number

**i** *GS1 Healthcare US recommends the use of GLN and/or SGLN as they maintain alignment with the GS1 System of Standards. GS1 Healthcare US discourages the use of identifiers from outside the GS1 System because they may not be global, and/or because issuing agencies for some identifiers do not approve of the use of their identifiers beyond the specific application for which they were issued.*

❖ **The AddressType elements are:**

Element	R/O	Type	Value
<b>street1</b>	Required	String	The first line of the street address.
<b>street2</b>	Optional	String	The second line of the street address.
<b>city</b>	Required	String	The city.
<b>stateOrRegion</b>	Required	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
<b>postalCode</b>	Required	String	The ZIP or other postal code.
<b>country</b>	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

## ❖ Receiving Event Example:

```

<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gs1us.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sscc:030001.01234567890</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </bizLocation>
        <bizTransactionList>
          <bizTransaction
            type="urn:epcglobal:cbv:btt:inv">urn:epcglobal:cbv:bt:0300011111116:A123</bizTransaction>
          <bizTransaction type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:
0399999999991:XYZ567</bizTransaction>
          </bizTransactionList>
          <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
          <gslushc:transferredById type="GLN">0300011111116</gslushc:transferredById>
          <gslushc:transferredToId type="GLN">0399999999991</gslushc:transferredToId>
          <gslushc:shipToLocationId type="GLN">0399999999991</gslushc:shipToLocationId>
          <gslushc:shipToLocationAddress>
            <gslushc:street1>230 Park Ave S</gslushc:street1>
            <gslushc:city>New York</gslushc:city>
            <gslushc:stateOrRegion>NY</gslushc:stateOrRegion>
            <gslushc:postalCode>10003-1502</gslushc:postalCode>
            <gslushc:country>US</gslushc:country>
          </gslushc:shipToLocationAddress>
          <gslushc:receivedByContact>
            <gslushc:name>CONTACT NAME</gslushc:name>
            <gslushc:telephone>+1-212-555-5624</gslushc:telephone>
            <gslushc:email>contact.name@example.com</gslushc:email>
          </gslushc:receivedByContact>
        </ObjectEvent>
      </EventList>
    </EPCISBody>
  </epcis:EPCISDocument>
  
```

## 17.5. Unpacking

*Unpacking* denotes a specific activity within a business process that includes removing an object (e.g., individuals, inners, cases, pallets, etc.) from a larger container (e.g., cases, totes, pallets, etc.) – usually for the purposes of storing or shipping. Unpacking is the reverse of Packing, and the Unpacking EPCIS event disaggregates specific aggregation relationships created by Packing events.

❖ **An Unpacking event shall be an EPCIS Aggregation Event populated as follows:**

Element	Usage	Type	Value	Reason
<b>eventTime</b>	Required	Timestamp	Date and time of event. (See Section <a href="#">14.</a> )	EPCIS standard definition
<b>recordTime</b>	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
<b>eventTimeZoneOffset</b>	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
<b>parentID</b>	Required	URI	EPC of the outer container in EPC Pure Identity URI format	EPCIS standard definition
<b>childEPCs</b>	Required	List of URI	EPC(s) of the item(s) unpacked from the parent in EPC Pure Identity URI format	EPCIS standard definition. [Although the EPCIS standard permits childEPCs to be omitted to indicate that all children are disaggregated from the parent, this usage is <u>not</u> permitted for this guideline.]
<b>action</b>	Required	String	DELETE	EPCIS standard definition
<b>bizStep</b>	Required	URI	<a href="http://epcis.gs1us.org/hc/bizstep/unpacking">http://epcis.gs1us.org/hc/bizstep/unpacking</a>	Extension vocabulary element introduced in this guideline
<b>disposition</b>	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
<b>readPoint</b>	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section <a href="#">14.2.</a> )	EPCIS standard definition
<b>bizLocation</b>	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section <a href="#">14.2.</a> )	EPCIS standard definition
<b>bizTransactionList</b>	Omitted	List of biz transactions (each represented as a pair of URIs)		Omitted in the packing event as there are no relevant business transactions to share

## ❖ Extensions used in Unpacking Events

In addition to the EPCIS standard fields, the following extensions are included in an Unpacking event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

## ❖ Unpacking Event Example:

```
<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gs1us.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <AggregationEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <parentID>urn:epc:id:sgtin:030001.1012345.2222223333</parentID>
        <childEPCs>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
          <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
        </childEPCs>
        <action>DELETE</action>
        <bizStep>http://epcis.gs1us.org/hc/bizstep/unpacking</bizStep>
        <disposition>urn:epcglobal:cbv:disp:in_progress</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:039999.999999.0</id>
        </bizLocation>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </AggregationEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

## 17.6. End of Useful Life EPCIS Events

The following EPCIS events represent business processes that occur at the end of the supply chain, typically at a hospital or pharmacy.

### 17.6.1. Dispensing

*Dispensing* is the process of removing a portion of a product for use while retaining the remainder for subsequent dispensing, such as when individual tablets are removed from a bottle to fill a prescription. The EPCIS event indicates the item from which the portion was dispensed. Unlike destroying or decommissioning, the item continues to exist after dispensing, but a special disposition value is used to indicate that the item is no longer in its original state. After all portions have been dispensed from an item, it is subsequently destroyed.

❖ **A Dispensing event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
<b>eventTime</b>	Required	Timestamp	Date and time of event. (See Section <a href="#">14.</a> )	EPCIS standard definition
<b>recordTime</b>	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
<b>eventTimeZoneOffset</b>	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
<b>epcList</b>	Required	List of URI	EPC of the dispensed item in EPC Pure Identity URI format.	EPCIS standard definition
<b>action</b>	Required	String	OBSERVE	EPCIS standard definition
<b>bizStep</b>	Required	URI	<a href="http://epcis.gs1us.org/hc/bizstep/dispensing">http://epcis.gs1us.org/hc/bizstep/dispensing</a>	Extension vocabulary element introduced in this guideline
<b>disposition</b>	Required	URI	<a href="http://epcis.gs1us.org/hc/disp/partial">http://epcis.gs1us.org/hc/disp/partial</a>	Extension vocabulary element introduced in this guideline. "Partial" denotes that the item being dispensed from is no longer the same as originally packaged.
<b>readPoint</b>	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section <a href="#">14.2.</a> )	EPCIS standard definition
<b>bizLocation</b>	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section <a href="#">14.2.</a> )	EPCIS standard definition
<b>bizTransactionList</b>	Optional	List of biz transactions (each represented as a pair of URIs)		<i>The pharmacy could choose to insert the prescription ID if they wanted to extend traceability to the patient. (There may already be this type of function in the pharmacy system).</i>

## ❖ Extensions used in Dispensing Events

In addition to the EPCIS standard fields, the following extensions are included in a Dispensing event. (See Section [15](#) for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

## ❖ Dispensing Event Example:

```
<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gslus.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>http://epcis.gslus.org/hc/bizstep/dispensing</bizStep>
        <disposition>http://epcis.gslus.org/hc/disp/partial</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </bizLocation>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

## 17.6.2. Destroying

Destroying is the process of destroying a product so that it no longer exists, as opposed to decommissioning which implies that the item may still exist even though it no longer carries serialized identification. Destroying occurs when a party at the end of the supply chain physically destroys a product.

❖ **A Destroying event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
<b>eventTime</b>	Required	Timestamp	Date and time of event. (See Section <a href="#">14.1.</a> )	EPCIS standard definition
<b>recordTime</b>	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
<b>eventTimeZoneOffset</b>	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
<b>epcList</b>	Required	List of URI	EPC(s) of the destroyed item(s) in EPC Pure Identity URI format	EPCIS standard definition
<b>action</b>	Required	String	DELETE	EPCIS standard definition. (Action DELETE in an Object Event indicates that the EPCs no longer exist.)
<b>bizStep</b>	Required	URI	urn:epcglobal:cbv:bizstep:destroying	CBV standard definition
<b>disposition</b>	Required	URI	urn:epcglobal:cbv:disp:destroyed	CBV standard definition
<b>readPoint</b>	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section <a href="#">14.2.</a> )	EPCIS standard definition
<b>bizLocation</b>	Omitted	URI		The Business Location is the location where the object is presumed to be following the event. For a Destroying event, the object no longer exists following the event. Therefore, Business Location is always omitted for a Destroying event.
<b>bizTransactionList</b>	Omitted	List of biz transactions (each represented as a pair of URIs)		Omitted in the Destroying event as there are no relevant business transactions to share.

## ❖ Extensions used in Destroying Events

In addition to the EPCIS standard fields, the following extensions are included in a Destroying event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
eventID	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

## ❖ Destroying Event Example:

```
<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gs1us.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>DELETE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:destroying</bizStep>
        <disposition>urn:epcglobal:cbv:disp:destroyed</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

### 17.6.3. Decommissioning

*Decommissioning* is the process of removing the EPC from the item so that it is no longer tracked. Unlike the Destroying business process, the item may still physically exist after decommissioning even though it no longer carries serialized identification. Decommissioning occurs when a party at the end of the supply chain removes the serialized identification (i.e., at point of sale).

❖ **A Decommissioning event shall be an EPCIS Object Event populated as follows:**

Element	Usage	Type	Value	Reason
<b>eventTime</b>	Required	Timestamp	Date and time of event. See Section <a href="#">14.1</a> .	EPCIS standard definition
<b>recordTime</b>	Optional	Timestamp	(Optional) Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
<b>eventTimeZoneOffset</b>	Required	String	Time zone offset in effect at the at the time and place where the event occurred.	EPCIS standard definition
<b>epcList</b>	Required	List of URI	EPC(s) of the decommissioned item(s) (EPC Pure Identity URI format)	EPCIS standard definition
<b>action</b>	Required	String	DELETE	EPCIS standard definition. Action DELETE in an Object Event indicates that the EPCs no longer exist
<b>bizStep</b>	Required	URI	urn:epcglobal:cbv:bizstep:decommissioning	CBV standard definition
<b>disposition</b>	Required	URI	urn:epcglobal:cbv:disp:inactive	CBV standard definition
<b>readPoint</b>	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section <a href="#">14.2</a> .)	EPCIS standard definition
<b>bizLocation</b>	Omitted	URI		The Business Location is the location where the objects are presumed to be following the event. For a decommissioning event, the location of objects can no longer be tracked following the event and so Business Location is always omitted for a Decommissioning event.
<b>bizTransactionList</b>	Omitted	List of biz transactions, each a pair of URIs		Omitted in the Decommissioning event as there are no relevant business transactions to share

## ❖ Extensions used in Decommissioning Events

In addition to the EPCIS standard fields, the following extensions are included in a Decommissioning event. (See Section [15](#) for general notes about extensions.)

Element	Usage	Type	Value
<b>eventID</b>	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc.).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>

## ❖ Decommissioning Event Example:

```

<epcis:EPCISDocument
  xmlns:gslushc="http://epcis.gs1us.org/hc/ns"
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  schemaVersion="1.0"
  creationDate="2012-03-25T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-25T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>DELETE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:decommissioning</bizStep>
        <disposition>urn:epcglobal:cbv:disp:inactive</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <gslushc:eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</gslushc:eventID>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
    
```

## Part 6: Sample Supply Chain Event Choreographies for Pedigree

---

## 18. Model & Key for EPCIS Event Choreographies

In order to understand and hold conversations about EPCIS events supporting pedigree or other processes, it is helpful to use diagrams to show the choreography (or full set of events) that take place among a given set of trading partners. The following diagram was developed as the model to use for depicting the choreography of messages between trading partners in a specific scenario.

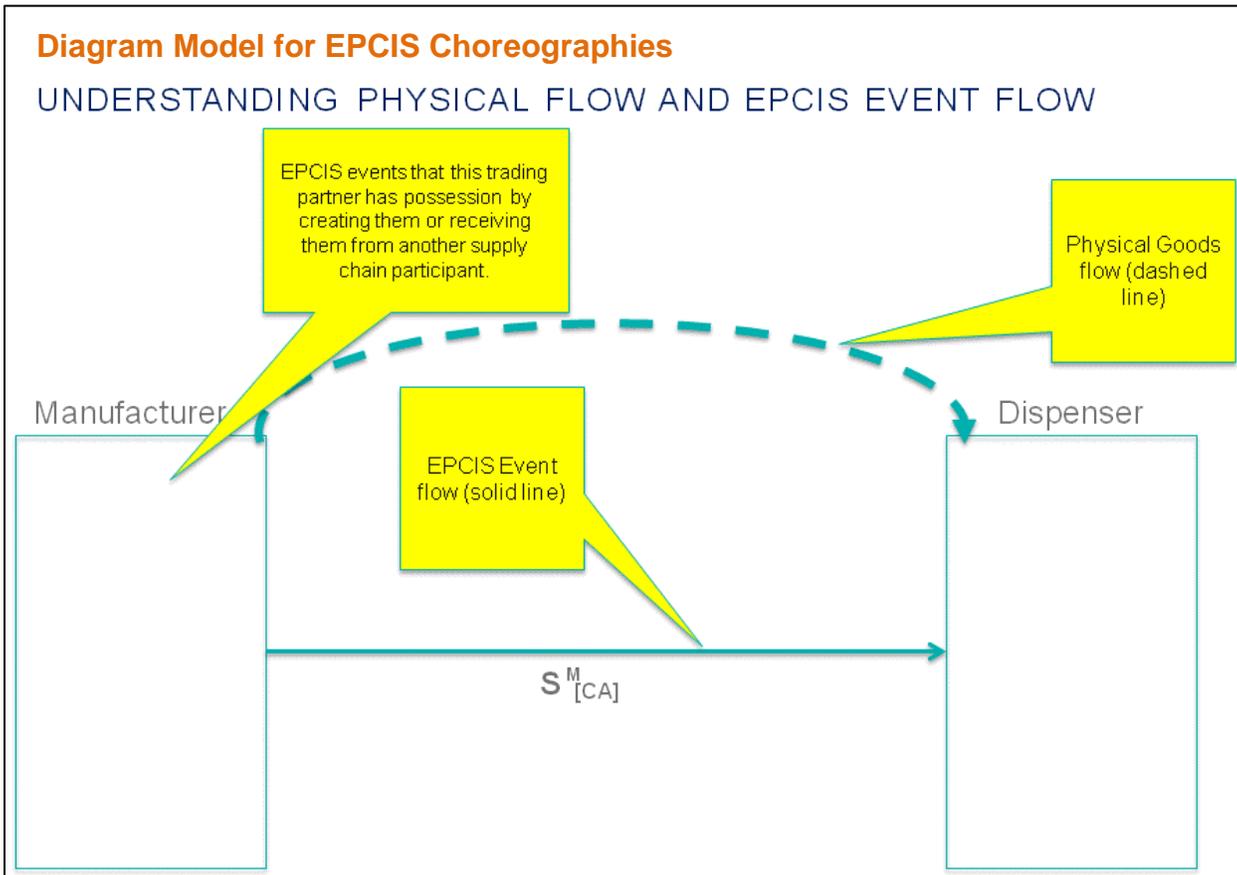


Figure 17: Model for EPCIS Choreography Diagrams

The diagram model shows the trading partners involved in the scenario, the physical flow of product (dashed line), and the EPCIS events transacted in the scenario (solid line). The EPCIS events within each trading partner's box are events that the trading partner has created themselves or received from their trading partner. Choreography diagrams help users to understand the interaction of trading partners as business processes that consume or produce EPCIS events are discussed, and as business and regulatory rules are applied. In addition, the diagrams make clear what information each trading partner has access to as the scenario progresses.

As documented in Part 5 of this guideline, each EPCIS event includes a defined set of data attributes. The following shorthand notation was developed to help communicate event data efficiently within diagrams. The shorthand notation uses an icon that represents the EPCIS event with the relevant information that is needed to understand the business and regulatory rules and constraints in the scenario.

Figure 18 provides the key to the shorthand notation used to represent EPCIS events in the choreography diagrams.

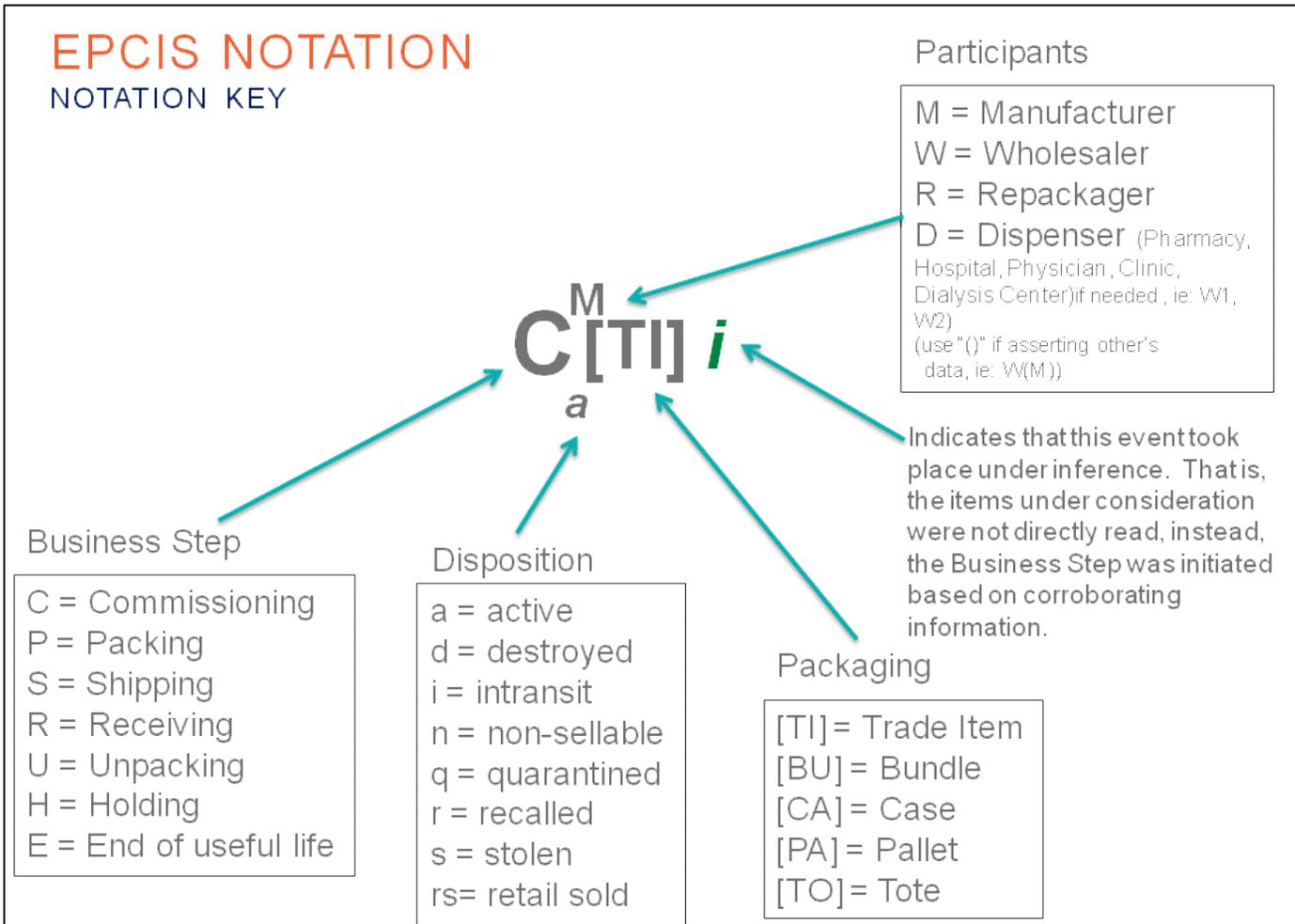


Figure 18: Shorthand Notation for Depicting EPCIS Events

**i** The full lists of Business Steps and Dispositions can be found in the Core Business Vocabulary Standard.

## 19. Forward Logistics Choreographies

The following diagrams provide examples of various scenarios that can take place as products move forward through the supply chain. This version of the guideline focuses on basic forward logistics supporting a one-up-one-down model. Future releases of this guideline will provide examples for additional forward logistics scenarios (e.g., drop shipments, repackaging, kitting, etc.), reverse logistics (e.g., recalls, returns, withdrawals, refusals, etc.) and exceptions (e.g., shortages, overages, data discrepancy, etc.).

### 19.1. Basic Forward Logistics

The following examples show how EPCIS events can be used to support basic forward logistics scenarios for product moving through the supply chain.

#### 19.1.1. Ship a full case through the supply chain

The following examples depict a Manufacturer shipping a pallet of cases to a Wholesaler who then breaks the pallet down to its cases and ships a full case to the Dispenser warehouse.

In the Figure 19 scenario, each trading partner captures the correct EPCIS events; however, they only share the *Shipping* event with each other. (If necessary, each trading partner could collect the remaining events from their trading partners to assemble the full history of events for a particular trade item.)

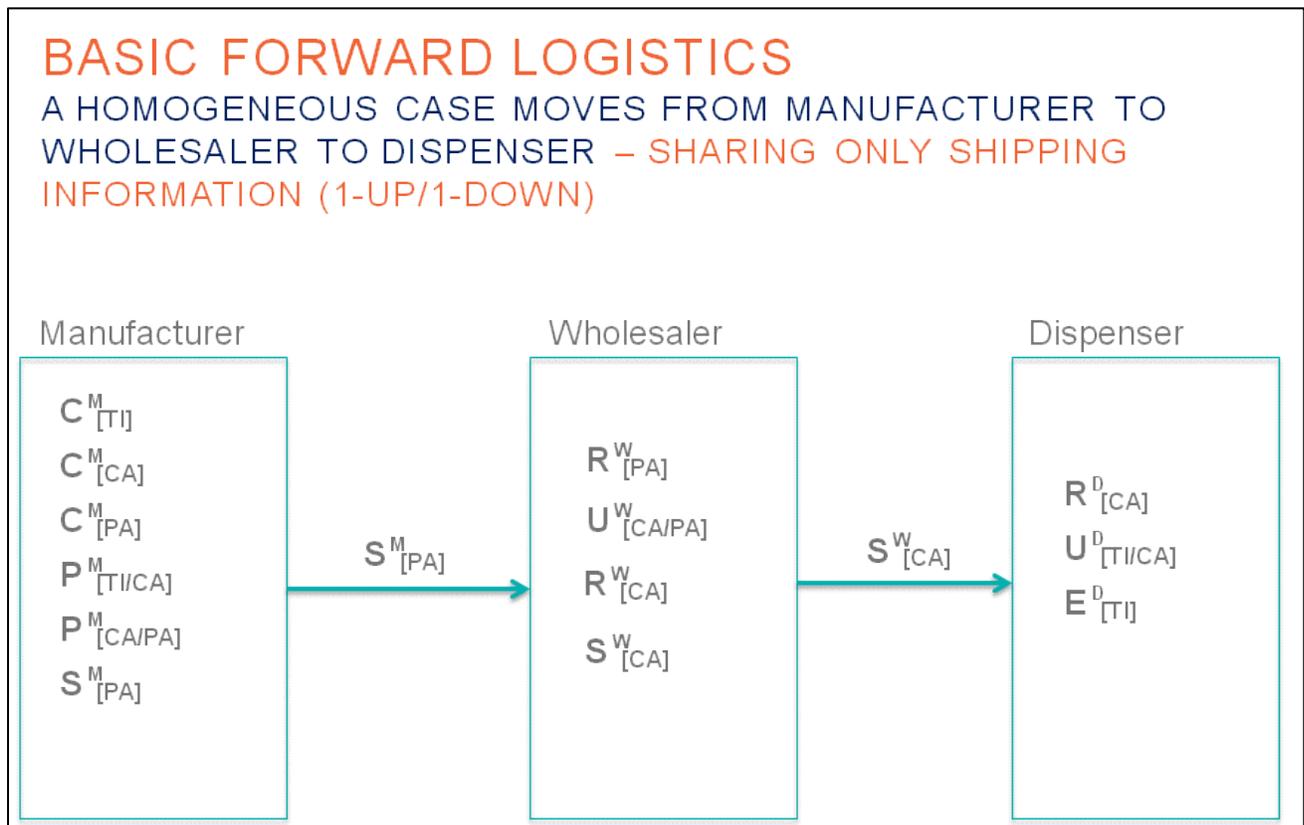


Figure 19: Ship full case through supply chain -- sharing *Shipping* events only

In the Figure 20 scenario, each trading partner captures the correct EPCIS events; however, they only share certain *pedigree events* to fulfill a one-up/one-down model. Note that the Wholesaler is shown to be asserting that the Manufacturer commissioned the trade item that the Wholesaler has shipped to the Dispenser.

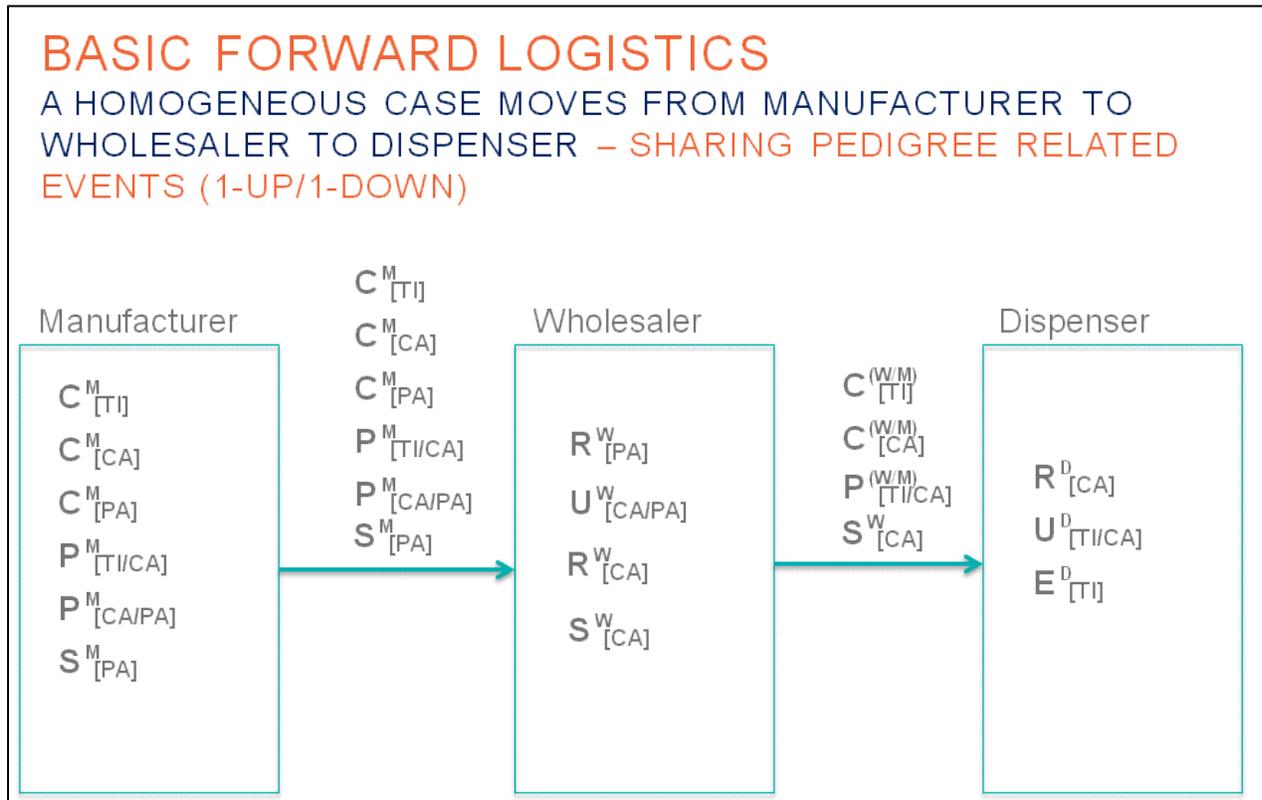


Figure 20: Ship full case through supply chain -- sharing *pedigree-related* events

### 19.1.2. Ship a pallet, break-down to trade items, pack and ship tote

The following examples depict a Manufacturer shipping a pallet of cases to a Wholesaler who then breaks the pallet down into cases and then to the individual trade items. The Wholesaler then packs the trade items into a tote and ships the tote to the Dispenser.

In the Figure 21 scenario each trading partner captures the correct EPCIS events; however, they only share the *Shipping* event with each other. (If necessary, each trading partner could collect the remaining events from their trading partners to assemble the full history of events for a particular trade item.)

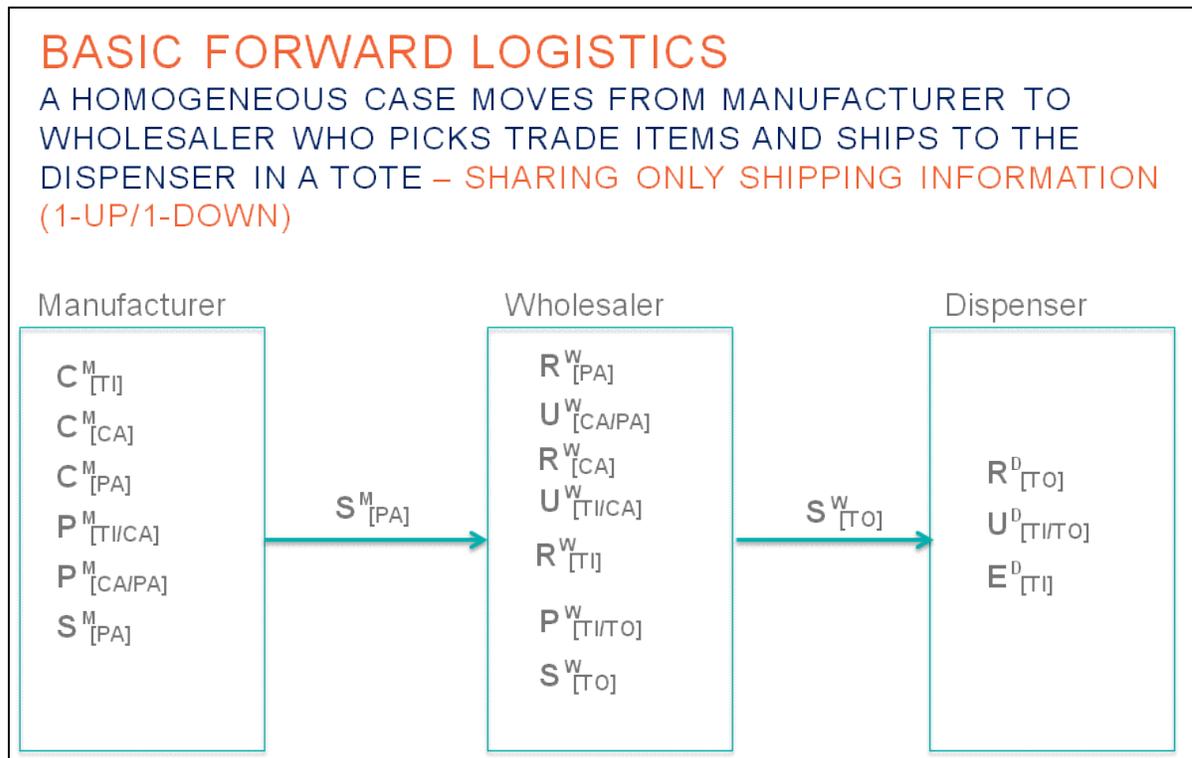


Figure 21: Ship pallet, break down to trade items, pack/ship totes -- sharing *Shipping* events only

In the Figure 22 scenario, each trading partner captures the correct EPCIS events; however, they only share certain *pedigree events* to fulfill a one-up/one-down model. Note that the Wholesaler is shown to be asserting that the Manufacturer commissioned the trade item that the Wholesaler has shipped to the Dispenser.

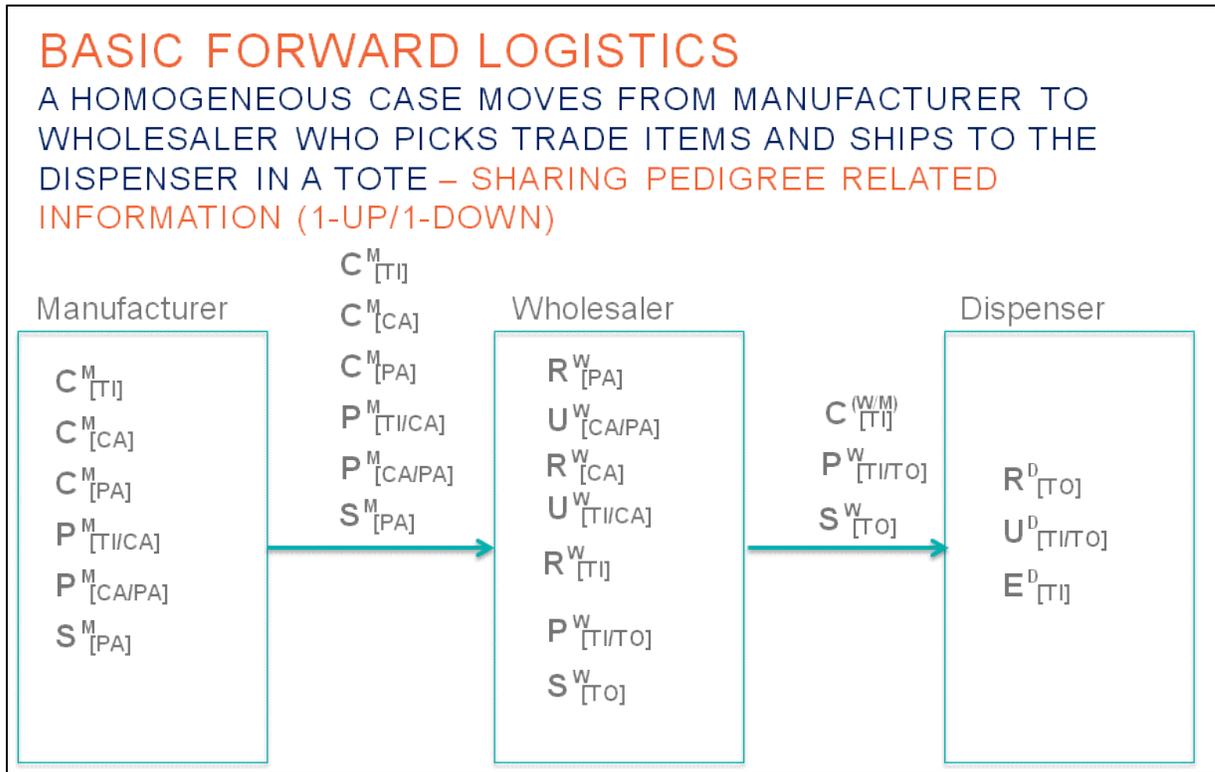


Figure 22: Ship pallet, break down to trade items, pack/ship totes -- sharing *pedigree-related* events

## Part 7: Exceptions Processing

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This section was developed by the GS1 Healthcare US Secure Supply Chain Task Force as a means to start assessing how supply chain partners might further leverage the EPCIS standard to address exceptions within supply chain business processes that impact serialization and visibility.

## 20. Overview

Managing serialized products throughout the supply chain is an order of magnitude change for trading partners. As the industry prepares to manage serialized products while simultaneously tracking pedigree data for each and every saleable unit, it is likely that exceptions regarding pedigree-related data will occur early on. This section was developed by the GS1 Healthcare US Secure Supply Chain Task Force as a means to start assessing how supply chain partners might further leverage the EPCIS standard to address exceptions within supply chain business processes that impact serialization and visibility. It will be updated with additional insights into exception processing from actual implementations, pilots and healthcare visibility programs. The primary goal is to address those exceptions that are likely to occur during the transition to serialized products.

This section identifies each known exception, defines the impact on the trading partners, and depicts how the trading partners could use EPCIS to notify each other that an exception had occurred. Later versions of this document may go further to define the full choreography of messages or EPCIS events needed to resolve the exceptions. While this section provides examples of exception processing using the EPCIS standard, it is recognized that there are other methods [e.g., Electronic Data Interchange (EDI), etc.] that may be used by individual trading partners.

It is anticipated that future versions of this guideline will provide detailed guidance on how companies may manage exceptions that can occur in a serialized, pedigreed world. The goal is to enable company systems to resolve exceptions with minimal human interaction by specifying EPCIS event choreographies that are aligned with the company's business rules and processes.

## 21. List of Exceptions

To date, the GS1 Healthcare US Secure Supply Chain Task Force has identified the following list of exceptions that could occur. As these exceptions and their resolutions are documented, it may be that some have the same root cause and will be consolidated. Likewise, as pilots and implementations continue to inform the content of this guideline, other exceptions may be uncovered and documented in this section in future releases.

### **Exception List:**

- 1: Overage
- 2: Shortage
- 3: Pedigree Serial Number discrepancy
- 4: Pedigree Lot Number discrepancy
- 5: Pedigree Serial Number and Lot Number incorrect
- 6: Product inference problem
- 7: Quantity inference problem
- 8: Physical inventory overage
- 9: Physical inventory overage (concealed)

- 10: Physical inventory shortage (concealed)
- 11: Pedigree contains incorrect customer or location information
- 12: Pedigree contains incorrect product information
- 13: Pedigree contains incorrect reference number information
- 14: Pedigree (or EPCIS Ship Business Step) not received by customer
- 15: Undelivered shipment
- 16: Lost shipment
- 17: Received physical product from an unidentified sender
- 18: *Resolved (number maintained as placeholder)*
- 19: Could not read pedigree data due to security mismatch
- 20: Pedigree data not in correct format
- 21: Good product - damaged barcode or RFID
- 22: Damaged product - good barcode or RFID
- 23: Damaged product - damaged barcode or RFID
- 24: Damaged shipment
- 25: *Resolved – accounted for in other exceptions*
- 26: *Resolved – accounted for in other exceptions*
- 27: No parent – child aggregation
- 28: Pedigree data incomplete
- 29: Pedigree data has broken chain
- 30: Shipped product to wrong customer and pedigree data to correct customer
- 31: Customer refuses order
- 32: Unauthorized return
- 33: Shipment for Wholesaler “Y” arrives at Wholesaler “X”

## Part 8: Appendices

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## 22. Converting an 11-digit NDC to a 10-digit NDC

This section is provided for the benefit of billing system suppliers and users. Many National Drug Codes (NDCs) are displayed on drug packaging in a 10-digit format. Many billing systems require an 11-digit NDC number in a 5-4-2 format. The following table shows common 10-digit NDC formats indicated on packaging and the appropriate conversion to an 11-digit format for billing systems.

In the table below:

- The additional "0" in the 11-digit converted example is shown in **bold** and underlined.
- Hyphens have been inserted for visual clarity to illustrate the various formatting examples of NDCs. Do not use hyphens when entering the NDC in your claim.

10-Digit Format on Package	10-Digit Format Example	11-Digit Format	11-Digit Converted Example
<b>4 - 4 - 2</b>	0002-7597-01 Zyprexa 10mg vial	<b>5 - 4 - 2</b>	<b><u>0</u>0002-7597-01</b>
<b>5 - 3 - 2</b>	50242-040-62 Xolair 150mg vial	<b>5 - 4 - 2</b>	50242- <b><u>0</u></b> 040-62
<b>5 - 4 - 1</b>	60575-4112-1 Synagis 50mg vial	<b>5 - 4 - 2</b>	60575-4112- <b><u>0</u></b> 1

Table O: Key to Assigning, Storing and Encoding GTINs

## 23. GS1 Standards

From an information management point of view, supply chain applications like pedigree and track and trace require all parties to systematically associate the physical flow of products with the flow of information about them. This is best attained by deploying a common business language within the framework of a comprehensive standards system. The GS1 System is such a system, providing a comprehensive platform for companies to identify products and other business entities, capture supply chain data, and share data with trading partners.

The GS1 System encompasses identification standards, data standards, automatic identification data capture (AIDC) standards, and data communication standards. Table 16 below summarizes some of the GS1 Standards that support pedigree and track and trace.

GS1 Standards Supporting Pedigree and Track & Trace			
<b>Identification Standards</b>	<b>Trade Items</b>	Global Trade Item Number (GTIN)	
	<b>Locations &amp; Trading Partners</b>	Global Location Number (GLN)	
	<b>Logistics Units</b>	Serial Shipping Container Code (SSCC)	
	<b>Individual Assets</b>	Global Individual Asset Identifier (GIAI)	
	<b>Returnable Assets</b>	Global Returnable Asset Identifier (GRAI)	
<b>AIDC Standards</b>	<b>GS1 Barcodes</b>	GS1-128 GS1 DataMatrix RSS EAN/UPC ITF-14 Composite Component	
	<b>GS1 EPC/RFID</b>		
<b>Data Standards</b>	<b>Master Data:</b> Global Data Dictionary Item Business Messaging Standard Party Business Messaging Standard	<b>Transactional Data:</b> eCom/EDI	<b>Event Data:</b> EPCIS Schema EPCIS Core Business Vocabulary
<b>Sharing &amp; Communication Standards</b>	<b>Master Data:</b> GDSN GLN Registry EPCIS Master Data	<b>Transactional Data:</b> AS2	<b>Event Data:</b> EPCIS Capture EPCIS Query Discovery Services

Table P: Overview of GS1 Standards to Support Pedigree and Track & Trace

## 24. Resource Links

- GS1 Healthcare US Website: <http://www.gs1us.org/healthcare>
- GS1 Healthcare US Tools and Resources: <http://www.gs1us.org/hctools>
- GLN Registry: <http://www.gs1us.org/glnregistry>
- *Healthcare Provider Tool Kit for GS1 Standards*: <http://www.gs1us.org/hctoolkit>
- *Healthcare Supplier Tool Kit for GS1 Standards*: <http://www.gs1us.org/hctoolkit>
- GS1 Healthcare US 2015 Readiness Program Report - Phase 1: Basic Forward Logistics: <http://www.gs1us.org/hctools>
- GS1 Healthcare US 2015 Readiness Program Report - Phase 2: Additional Forward Logistics: <http://www.gs1us.org/hctools>
- 2015 Readiness Pilot Reports: <http://www.gs1us.org/hctools>
- *The Practice of Inference in the U.S. Pharmaceutical Supply Chain*: <http://www.gs1us.org/hctools>
- *GS1 US Visibility Framework White Paper*: <http://www.gs1us.org/visibility>
- *Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria* – Available on the GS1 US website at [www.gs1us.org/hctools](http://www.gs1us.org/hctools)
- *Procedure for Responding to Troublesome Barcodes* – Available on the GS1 US website at [www.gs1us.org/hctools](http://www.gs1us.org/hctools)
- *GS1 RFID Bar Code Interoperability Guideline* - Available in the Knowledge Center through the GS1 website at <http://www.gs1.org/gsmf/kc/barcodes>

## 25. Acronyms

AI	Application Identifier
CBV	Core Business Vocabulary
DPMS	Drug Pedigree Messaging Standard
EPC/RIFD	Electronic Product Code / Radio Frequency Identification
EPCIS	Electronic Product Code Information Services
XML	eXtensible Markup Language
GDSN	Global Data Synchronization Network
GLN	Global Location Number
GTIN	Global Trade Item Number
NDC	National Drug Code
RFID	Radio Frequency Identification
SSCC	Serial Shipping Container Code
SGLN	Serialized Global Location Number (GLN)
SGTIN	Serialized Global Trade Item Number (GTIN)
U.P.C.	Universal Product Code (U.P.C.)
URI	Uniform Resource Identifier
URN	Uniform Resource Name

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