The Global Language of Business

Healthcare

Implementation Guideline:

Applying GS1 Standards for DSCSA and Traceability

Release 1.2, Nov 07 2016

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GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers, and distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US® in the United States.

About GS1 Healthcare US

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

Part I: Foundational Concepts

1 Preface

1.1 Introduction

Federal Drug Supply Chain Security Act (DSCSA) traceability requirements became mandatory in 2015, marking the beginning of the journey to lot-level management, product serialization, and finally item-level traceability 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 lot-level management and item-level traceability. 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 standard 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 such as lot-level management and item-level traceability. Therefore, members of the U.S. pharmaceutical industry have joined forces to determine how the standards can best be applied to support these applications. Over fifty organizations from across the U.S. pharmaceutical supply chain have participated in this on-going effort. Leading manufacturers, wholesalers, retail pharmacies, healthcare providers, government agencies and industry associations have all been working together to analyze business processes and business requirements, consider the various options, and decide how the standards could best be applied. This guideline records all of the decisions points from that effort, defining each event and data element needed to support serialization, pedigree and track and trace, and showing industry members how to apply the standards to their own business processes.

Release 1.0 of this guideline was developed around item-level serialization requirements provided by the industry to satisfy California pedigree regulations. With the passage of the DSCSA, industry worked to develop and publish Release 1.1 to align with DSCSA requirements for lot-level management. Release 1.1 included a new means to share Lot-Level Management data for DSCSA lot-level requirements (including Transaction Information, Transaction History and Transaction Statement), and updated all of the Version 1.0 events (which were originally developed around California serialization requirements) to align with the DSCSA requirements for item-level traceability commencing in 2023.

This document, Release 1.2, has been updated to align with the updated GS1 EPCIS standard (Version 1.2) and the updated GS1 Core Business Vocabulary (CBV) standard (Version 1.2). In addition, it provides additional choreographies for item-level serialization and updates the lot-level management events to align with Version 1.2 of EPCIS and CBV.

1.2 Document Information

This implementation guideline was prepared by GS1 US® and the Secure Supply Chain Workgroup to assist the U.S. pharmaceutical industry in implementing GS1 Standards to support traceability. It is based on the *GS1 General Specifications*, the *EPC Tag Data Standard* (Version 1.9), the *EPCIS Standard* (Version 1.2), and the *Core Business Vocabulary Standard* (Version 1.2). It was developed using information obtained from a wide variety of members of the U.S. pharmaceutical supply chain from manufacturers to providers.

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

1.2.1 Contributors

This guideline was developed through the commitment and dedication of the Secure Supply Chain Workgroup over the past two years, in preparation for applying GS1 Standards in support of the requirements of DSCSA.

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1.2.2 Purpose

This document identifies the GS1 Standards used and provides details about how they can be applied to support product serialization, lot-level management, and item-level traceability. It includes the EPCIS *Business Step* and *Product Disposition* combinations to handle each identified supply chain event. By so doing, this document serves as a voluntary implementation guideline that provides guidance to industry members about how to apply the standards to their own business processes to support product serialization, lot-level management, and item-level traceability.

1.2.3 Future Releases

This guideline presents the current wisdom in industry for how GS1 Standards can be applied to U.S. pharmaceutical supply chain business processes to support lot-level management and item-level traceability. It will be updated as 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 and should not expect any particular section of content to remain unchanged. **Future publications of the guideline will address alternative methods within the structure of the model, additional exceptions, and inference/aggregation resolution.**

1.2.4 Scope

This guideline defines the EPCIS events (XML data format) to support DSCSA requirements for lot-level information and item-level information. **It does not provide any guidance or advice regarding regulatory compliance.** Federal requirements for traceability in the pharmaceutical supply chain are specified in the 2013 Drug Supply Chain Security Act (DSCSA) and subsequent FDA Guidance(s).

This guideline reflects current industry understanding of the DSCSA traceability requirements. Those requirements, and the statutes and regulations affecting them, are subject to change and may evolve in a manner this guideline cannot anticipate.

This implementation guideline was prepared by GS1 US and the Secure Supply Chain Workgroup to assist the U.S. pharmaceutical industry in implementing GS1 Standards to support traceability for the purpose of compliance with the DSCSA traceability requirements. This guideline does not address other considerations or factors, apart from DSCSA compliance, that might impact or inform the adoption of optimal traceability processes or procedures for any particular company or product.

Important: Each company is individually responsible for meeting all statutory and/or regulatory requirements for their company and their products. Consult with your company's legal counsel or compliance team (regulatory or quality) for more specific information about current statutory and regulatory requirements applicable to your company and products.

1.2.5 Normative References

This implementation guideline is based on the *GS1 General Specifications*, the *EPC Tag Data Standard*, the *Tag Data Translation Standard*, the *EPCIS Standard*, and the *Core Business Vocabulary 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 Specifications*
- *EPC Tag Data Standard (TDS) 1.9*
- *EPCIS 1.2 Standard*
- *Core Business Vocabulary (CBV) 1.2 Standard*
- *GTIN Management Standard* (formerly known as the GTIN Allocation Rules)
- *Healthcare GTIN Allocation Rules*

1.2.6 Non-Normative References

Material in this implementation 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.

- *GS1 RFID Bar Code Interoperability Guideline*
- *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*
- *The Practice of Inference in the U.S. Pharmaceutical Supply Chain*

1.2.7 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*. 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* 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.

1.3 The GS1 US DSCSA Implementation Suite

To promote ease of use, the content for applying GS1 Standards to DSCSA and traceability has been split into four documents. All of these documents are available in the GS1 US DSCSA Implementation Suite. The four documents in that suite are:

- *Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability*
- *Addendum: Guidance and XML Examples for Supply Chain Choreographies in Lot-Level Management*
- *Addendum: Diagrams and XML Examples for Lot-Level Management Exceptions Processing*
- *Addendum: Diagrams and XML Examples for Serialized Exceptions Processing*

1.4 Summary of Changes from Release 1.1

The following changes have been made in this Release 1.2 of the guideline as compared to Release 1.1:

- EPCIS event specifications for lot-level management have been updated to take advantage of new features in EPCIS 1.2 and CBV 1.2. In Release 1.1 of the guideline, only features of EPCIS 1.1 and CBV 1.1 were used, requiring the use of custom extensions. See *Section 1.4.1* for more details.
- EPCIS event specifications for serialized item traceability have been updated to provide for all data requirements of DSCSA, and to take advantage of new features in EPCIS 1.2 and CBV 1.2. In Release 1.1 of the guideline, EPCIS event specifications for serialized traceability were based on data requirements of the 2015 California drug pedigree law, and only features of EPCIS 1.1 and CBV 1.1 were used, requiring the use of custom extensions. See *Section 1.4.2* for more details.
- For both lot-level management and serialized item traceability, exception scenarios have been added, including detailed flowcharts and XML examples. Additional EPCIS event specifications have been added as necessary to cover the exception scenarios. (Note: Lot-level management and

serialized item traceability exceptions are provided in addendums documents in the GS1 US DSCSA Suite.)

- For DSCSA lot-level management, an EPCIS event specification for a *Transformation* event is added to address repackaging scenarios.
- Additional clarification has been added regarding the handling of expiration dates, including the need to synchronize the expiration date printed on the label, encoded in the barcode, and reported in EPCIS, as well as strongly recommending that a day of month always be included.
- Additional clarification has been added regarding EPCIS event times.
- Guidance has been added regarding best practices when a party notifies a trading partner of an exception condition.
- The section numbering and document formatting have been updated for better readability.

1.4.1 Changes to EPCIS Event Specifications for Lot-Level Management

EPCIS event specifications for lot-level management have been updated to take advantage of new features in EPCIS 1.2 and CBV 1.2. In Release 1.1 of the guideline, only features of EPCIS 1.1 and CBV 1.1 were used, requiring the use of custom extensions.

The following summarizes the changes to EPCIS event specifications for lot-level management:

- Changes to the *Shipping* event:
  - The **sourceLicenseList** and **destinationLicenseList** extensions have been removed. DSCSA does not require reporting of license information.
  - The **eventID** extension is removed. In the rare instances where an event ID is used (for the corrective event referenced by an error declaration), the standard **eventID** field defined in EPCIS 1.2 is used instead.
  - The **purchasedItemDirectlyFromManufacturerOrRepackager** extension is renamed to **directPurchase**.
- A new event is introduced for repackaging scenarios, using the EPCIS *Transformation* event.
- Changes to the EPCIS document header:
  - The **masterData** extension is replaced by the standard **VocabularyList** element, new in EPCIS 1.2.
  - All product, lot, and company master data elements are changed to use standard master data elements introduced in CBV 1.2. This implies that the namespace of master data elements has changed from `http://epcis.gs1us.org/hc/ns` to `urn:epcglobal:cbv:mda`, and the name of each element has changed according to the *Changes to Master Data Element Names and Namespace* table below.

1.4.2 Changes to EPCIS Event Specifications for Serialized Item Traceability

EPCIS event specifications for serialized item traceability have been updated to provide for all data requirements of DSCSA, and to take advantage of new features in EPCIS 1.2 and CBV 1.2. In Release 1.1 of the guideline, EPCIS event specifications for serialized traceability were based on data requirements of the 2015 California drug pedigree law, and only features of EPCIS 1.1 and CBV 1.1 were used, requiring the use of custom extensions.

The following summarizes the changes to EPCIS event specifications for serialized item traceability:

- Changes affecting all events:
  - The **eventID** extension is removed. In the rare instances where an event ID is used (for the corrective event referenced by an error declaration), the standard **eventID** field defined in EPCIS 1.2 is used instead.

- Changes to the *Commissioning* event:
  - The **lotNumber** and **itemExpirationDate** instance-level master data elements are now in the CBV standard namespace `urn:epcglobal:cbv:mda`, instead of the GS1US extension namespace `http://epcis.gs1us.org/hc/ns`.
  - The **tradeItemMasterData** instance-level master data element has been removed. Instead, product master data is carried in the EPCIS header rather than the Item/Lot Master Data (ILMD) section of the *Commissioning* event. This avoids repetition when the same trade item appears in multiple *Commissioning* events within the same EPCIS document. In addition, product master data element names have changed; see the *Changes to Master Data Element Names and Namespace* table below.
- Changes to the *Packing* event:
  - The cardinality of **childEPCs** is corrected to say "required." In Release 1.1 of this guideline, it was incorrectly noted as "optional."
- Changes to the *Shipping* event:
  - The cardinality of **epcList** is corrected to say "required." In Release 1.1 of this guideline, it was incorrectly noted as "optional."
  - The **companyMasterData** extension element has been removed. Instead, company master data is carried in the EPCIS header rather than as an event-level extension of the *Shipping* event. This avoids repetition when the same company appears in multiple *Shipping* events within the same EPCIS document. In addition, company master data element names have changed; see the *Changes to Master Data Element Names and Namespace* table below.
  - The **sourceLicenseList** and **destinationLicenseList** extensions have been removed. DSCSA does not require reporting of license information.
  - Event extensions **transactionDate** and **directPurchase** are added for DSCSA data requirements.
- Changes to the *Receiving* event:
  - The **companyMasterData** extension element has been removed. Instead, company master data is carried in the EPCIS header rather than as an event-level extension of the *Shipping* event. This avoids repetition when the same company appears in multiple *Shipping* events within the same EPCIS document. In addition, company master data element names have changed; see the *Changes to Master Data Element Names and Namespace* table below.
- Changes to the *Unpacking* event:
  - The cardinality of **childEPCs** is corrected to say "required." In Release 1.1 of this guideline, it was incorrectly noted as "optional."
- Changes to the *Dispensing* event:
  - The value of **bizStep** and **disposition** are changed to the CBV 1.2 standard values `urn:epcglobal:cbv:bizstep:dispensing` and `urn:epcglobal:cbv:disp:partially_dispensed`.
- Changes to the *Destroying* event:
  - The cardinality of **epcList** is corrected to say "required." In Release 1.1 of this guideline, it was incorrectly noted as "optional."
- Two new event specifications are added: *Void Shipping* and *Shipping Business Transaction Detail*.
- The use of the EPCIS 1.2 Error Declaration event/mechanism is illustrated for certain exception conditions.

- Extension elements for the EPCIS header have been specified to meet DSCSA Transaction Statement requirements.

1.4.3 Changes to Master Data Element Names and Namespace

All master data elements have been updated to use standard master data element names defined in CBV 1.2. All attributes are now in the CBV standard namespace `urn:epcglobal:cbv:mda`, instead of the GS1US extension namespace `http://epcis.gs1us.org/hc/ns`.

Table 1-1 Changes in the names of master data elements

Master data type	Attribute name in Version 1.2 of this guideline	Attribute name in Version 1.1 of this guideline
Product	**additionalTradeItemIdentification** (in Release 1.2, this is always an NDC in 11-digit format)	**additionalTradeItemIdentification** (in Release 1.1, several different formats were allowed)
	additionalTradeItemIdentificationTypeCode (in Release 1.2, this always has the value `FDA_NDC_11`)	**additionalTradeItemIdentificationType** (in Release 1.1, a different set of code values were used)
	regulatedProductName	**drugName**
	manufacturerOfTradeItemPartyName	**manufacturerName**
	dosageFormType	**dosageForm**
	strengthDescription	**strength**
	netContentDescription	**containerSize**
Company	**name**	**companyName**
	streetAddressOne	**street1**
	streetAddressTwo	**street2**
	streetAddressThree	[new in Version 1.2 of this guideline]
	city	**city**
	state	**stateOrRegion**
	postalCode	**postalCode**
	countryCode	**country**
Lot	**itemExpirationDate**	**itemExpirationDate**

2 Application to the Drug Supply Chain Security Act (DSCSA)

For the purposes of this guideline, the DSCSA law can be viewed as a three-phase implementation over ten years.

- The first phase, started on January 1, 2015 and ending November 2023, requires that supply chain participants share chain-of-ownership data. The use of EPCIS events for lot-level management is covered in *Part II* of this document.
- The second phase of DSCSA, starting no later than November 2017, requires that pharmaceutical products be marked with a National Drug Code (NDC)*, Serial Number, Lot Number, and Expiration Date in both machine-readable and human-readable format. The use of GS1 Identification Numbers, Application Identifiers, and Data Carriers (barcodes and RFID tags) are covered in Part I *Chapter 5* and *Chapter 6* of this guideline. (* In the GS1 System, the GS1 Global Trade Item Number® (GTIN®) is used to represent the NDC.)
- The third phase of DSCSA requires that trading partners share chain-of-ownership data in a manner that allows for serialized item traceability back to the product origin (usually the manufacturer). The expanded use of EPCIS events for serialized item traceability are covered in *Part III* of this document.

Although the DSCSA law specifies 2023 as the year when serialized item traceability is required, many trading partners have already made significant investments in serializing product lines and implementing serialized item traceability systems. And as more and more trading partners start to transition from lot-level management to serialized item traceability, it is reasonable to expect that the U.S. pharmaceutical industry will experience a mixed environment of lot-based and serialized item information throughout the 2015 – 2023 timeframe. This current release of the guideline (Version 1.2) provides the basics on how to identify and mark products, as well as how to share change-of-ownership information at the lot-level, as well as the serialized item-level.

2.1 EPCIS Approach to DSCSA Phase 1: Lot-Level Management

Phase 1 of the DSCSA involves the exchange of lot-level Transaction Information, Transaction History, and Transaction Statement at each sale/transfer of ownership. Using EPCIS, the *Shipping* event is used to record a transfer of ownership. Therefore, this guideline integrates DSCSA lot-level transaction requirements (including Transaction Information, Transaction History, and Transaction Statement) into the EPCIS *Shipping* event. Trading partners can use this event to record and exchange DSCSA lot-level information for each sale/transfer of ownership. In addition to the EPCIS *Shipping* event, repackaging scenarios will also use the EPCIS *Transformation* event to record the relationship between the original product and the repackaged product.

Part II of this guideline presents the application of EPCIS for lot-level management pursuant to Phase 1 of the DSCSA. Key points:

- The EPCIS *Shipping* event is used to record and exchange DSCSA lot-level information for each sale/transfer of ownership. Each trading partner records and exchanges this *Shipping* event for each sale/transfer of ownership.
  - *Shipping* events will be captured at the individual saleable unit.
  - Product identifier (GTIN) and lot number are data elements in the *Shipping* event per DSCSA Transaction Information requirements. These data elements relate to the products contained in the shipment.
- In addition to the *Shipping* event, the EPCIS *Transformation* event is also used in repackaging scenarios to record the relationship between the original product and the repackaged product.
- Phase 1 of the DSCSA does not require the product identifier (GTIN) and lot number of the products contained in the case to be marked on the case. Companies will determine for themselves how they will capture/enter that data into their *Shipping* events (e.g., have system prompt shipping staff to

enter that data manually; create a product identifier/lot number barcode for each lot and have shipping staff scan that barcode for each case in the lot to record the data electronically; etc.).

2.2 GS1 Standards for DSCSA Phase 2: Item-Level Identification & Marking

Phase 2 of the DSCSA involves item-level identification and marking. Supply chain participants will be identifying pharmaceutical products with an NDC (GTIN in GS1 Standards), Serial Number, Lot Number, and Expiration Date, and marking product identifiers on products in both machine-readable (e.g., barcode) and human-readable format.

Part I *Chapter 5* and *Chapter 6* of this guideline present the application of GS1 Standards for item-level identification for Phase 2 of the DSCSA.

2.3 EPCIS Approach to DSCSA Phase 3: Item-Level Traceability

Phase 3 of the DSCSA establishes package level requirements for the interoperable, electronic tracing of products. This will involve sharing chain-of-ownership data in a manner that allows for serialized item traceability back to the product origin (usually the manufacturer), including the electronic exchange of transaction information for each sale of certain prescription drugs and verification of product identifiers at the package level.

Using EPCIS, *Commissioning* events declare that specified serial numbers have been introduced into the supply chain, *Packing* events convey the hierarchical relationships (e.g., item-to-case, case-to-pallet) between objects as they exist at the point of shipping, and *Shipping* events indicate that objects have been shipped to a downstream trading partner and provide serialized item-level traceability information governing the shipment. The *Shipping* events only reference the outermost (i.e., top-level) products in the packaging hierarchy. For any given transaction, a collection of *Shipping* events, *Packing* events (if applicable), and *Commissioning* events (if applicable), together with master data and Transaction Statement data, comprise the DSCSA Transaction Information and Transaction Statement.

Part III of this guideline presents the application of EPCIS for item-level traceability for Phase 3 of the DSCSA.

2.4 Industry Transitions to DSCSA

As described above, the DSCSA law can be viewed as a three-phase implementation over ten years. Companies will likely be working to transition their systems and implement the various requirements throughout the entire period. For example, although the DSCSA law specifies 2023 as the year when serialized item traceability is required, many trading partners have already made significant investments in serializing product lines and implementing serialized item traceability systems. And as more and more trading partners start to transition from lot-level management to serialized item traceability, it is reasonable to expect that the U.S. pharmaceutical industry will experience a mixed environment of lot-based and serialized item-based product marking and information sharing throughout the 2015 – 2023 timeframe.

- **Product Marking Transition:** Phase 1 of the DSCSA does not require lot information to be marked on products in machine-readable form. Phase 2 of the DSCSA requires pharmaceutical products to be marked with a product identifier (GTIN/NDC), Serial Number, Lot Number, and Expiration Date starting in 2017. For the purposes of DSCSA, pharmaceutical products will migrate from being marked with only a product identifier (GTIN/NDC) to being marked with a product identifier (GTIN/NDC), Serial Number, Lot Number, and Expiration Date. Therefore, as industry works to implement Phase 2 item-level marking requirements, the supply chain will likely experience a mixed environment in which products will be marked with product identifier (GTIN/NDC) only and/or marked with a product identifier (GTIN/NDC), Serial Number, Lot Number, and Expiration Date.
- **Information Sharing Transition:** Phase 1 of the DSCSA calls for trading partners to share change of ownership information at the lot-level. Starting in 2023, Phase 3 of the DSCSA requires

trading partners to share change of ownership information at the item-level. Therefore, as industry implements Phase 1 lot-level sharing in 2015 and works to implement Phase 3 item-level sharing by 2023, the supply chain will likely experience a mixed environment in which change of ownership data will be shared at the lot-level and/or the item level.

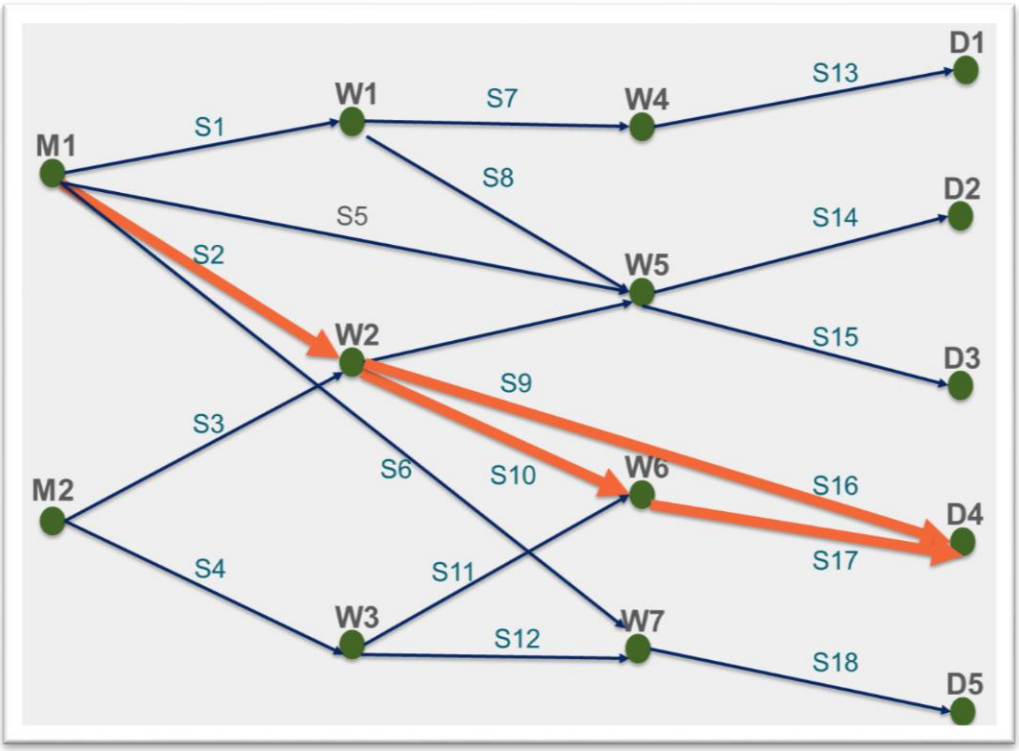
2.5 Lot-Level Management & Serialized Item-Level Traceability

The DSCSA law calls for supply chain participants to share chain-of-ownership information with trading partners first at the lot-level (Product ID + Lot Number), and then at the serialized item-level (Product ID + Serial Number). It is important to understand the different level of visibility provided by each.

Lot-level information does not provide for item-level traceability. Lot-level information conveys the product identifier and lot number. The combination of Product ID and Lot Number does not produce a unique identifier for each and every instance of a product. Instead, each and every item in a lot will carry the exact same identifier. A lot may conceivably contain thousands of individual products. All products from the same lot would have the same identification information (same Product ID + same Lot Number), making them indistinguishable from one another in a traceability system. Although there may be cases where a lot-based item can be traced back to the original manufacturer, if items from the same lot cross paths in the supply chain, it would be impossible to determine the exact path through the supply chain that each item traveled.

Consider the diagram below as an example: Manufacturer 1 (M1) sells Product X to Wholesaler 2 (W2), and Wholesaler 2 sells to Wholesaler 6 (W6), then Dispenser 4 (D4) purchases Product X from W2 and W6. In a lot-based information sharing system, it is impossible to determine which bottle of Product X was purchased from W2 or W6 after they have been placed in D4's inventory.

Figure 2-1 Understanding Lot-Level Visibility



Nonetheless, it would still be possible to report the various paths back to the manufacturer that an item could have taken. Because this is quite different from item-level traceability, this guideline refers to this as "lot-level management."

In contrast, serialized product identification does provide for item-level traceability. Item-level information conveys the product identifier and serial number. The combination of Product ID and Serial Number produces a unique identifier for each and every instance of a product. This enables each individual product to be identified both physically (through a barcode or RFID tag) and within company systems. As a result, it is possible to determine the exact path through the supply chain that any serialized item traveled, and to trace each item back to its source. Using a serialized item-level information sharing system in the example above, the different Product ID + Serial Number on each product would allow us to distinguish one bottle from the other and identify their separate paths through the supply chain. This is referred to as "serialized item-level traceability."

3 Overview of the GS1 Standards Used

This Section provides a brief definition of each GS1 Standard used in this guideline. (Refer to the *Appendices* of this document for more information about GS1 Standards that support lot-level management and item-level traceability.)

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 assure 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 is used to uniquely identify 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 (EPC®)-enabled 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 Services (EPCIS)

The EPC Information Services (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 GS1 US DataHub | Location

Data Hub | Location provides a single source for healthcare location information and how they are related, offering a comprehensive list of healthcare and healthcare-related facilities in the United States with corresponding 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. Data Hub | Location enables subscribers to view, create, manage, and share 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)

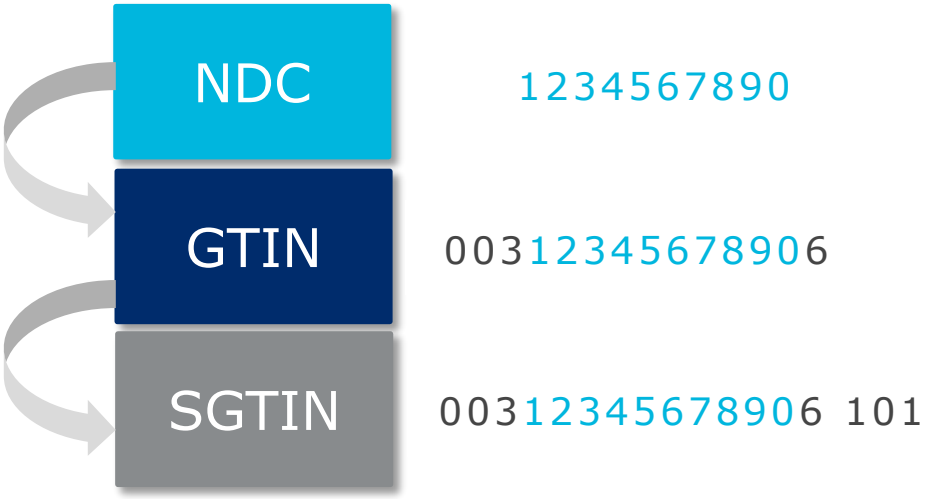
The Global Data Synchronization Network™ (GDSN®) provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly formatted, and (3) sharing that information with supply chain partners. 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 promotes alignment of supply chain information 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 the figure below, 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 4-1 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 or distributes a drug under its own name (including repackagers or relabelers).

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	**03**
FDA-assigned *Labeler Code*	**61414**
GS1 Company Prefix	**0361414**

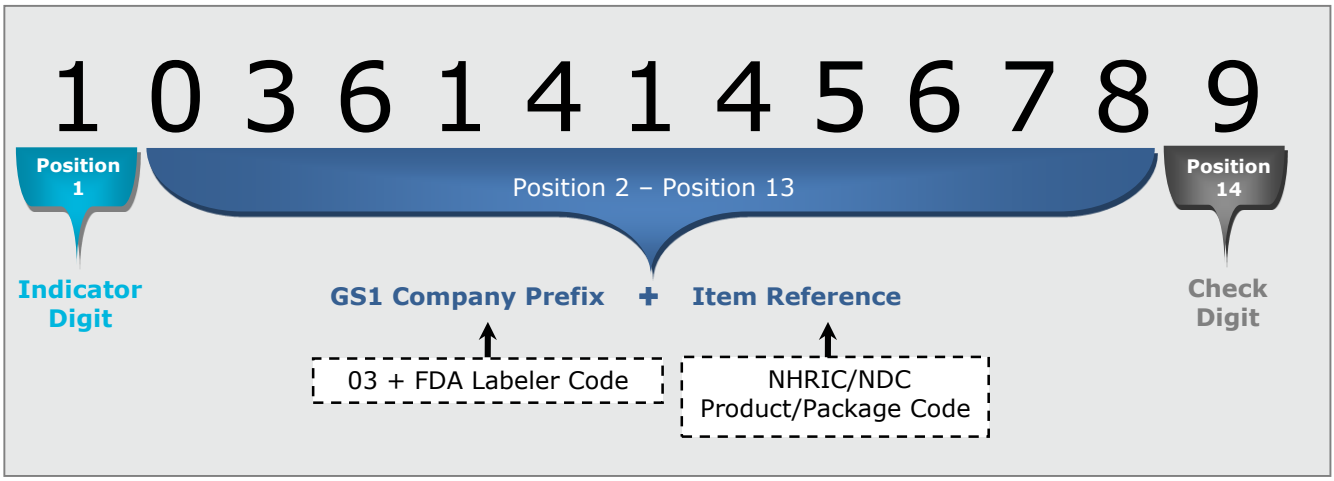
Important: In order to use a Labeler Code as a GS1 Company Prefix, manufacturers must first contact GS1 US to have a GS1 Company Prefix that embeds their Labeler Code assigned to the company.

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. The figure below 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 4-2 Segments of a GTIN-14 that embeds an NDC (based on the hypothetical GTIN "1036141456789")



4.4 "GTIN-12" vs. "GTIN-14" vs. "GTIN-12 in 14-digit format"

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 (known as the "GTIN-12") and the 14-digit GTIN (known as the "GTIN-14") are predominantly used. Nonetheless, most barcodes require GTINs to be encoded in a 14-digit format. To accommodate that requirement, GTINs of less than 14-digits can be padded with leading zeros for encoding. For example, to encode a GTIN-12 in a barcode that requires GTINs in 14-digit format (e.g., GS1 DataMatrix), two leading zeros are added to the GTIN-12 as shown below:

GTIN-12	**314141999995**
GTIN-12 in 14-digit format	**00314141999995**

Note that 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 14-digit format."

Important: PER THE GS1 GENERAL SPECIFICATIONS, THIS MUST 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 1st and 2nd positions) cannot be converted to a 12-digit format because, among other reasons, removing these non-zero digits creates an entirely different GTIN.

4.5 Assigning vs. Storing vs. Encoding GTINs

As discussed above, GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length. Regardless of how they are assigned, it is important to understand that GTINs are always stored in databases and encoded in barcodes* in 14-digit format. (* *The only exceptions are U.P.C. and EAN-13 barcodes, which are the only GS1 barcodes in which GTINs are encoded as 12 or 13 digits.)*

Table 4-1 Key to Assigning, Storing and Encoding GTINs

Assigning GTINs	Storing GTINs	Encoding GTINs
GTIN-12 or GTIN-14	**14-digit format** (i.e. GTIN-14 or GTIN-12 in 14-digit format using leading zeros)	**14-digit format *** (i.e. GTIN-14 or GTIN-12 in 14-digit format using leading zeros)

* *The only exceptions are U.P.C. and EAN-13 barcodes, which are the only GS1 barcodes in which GTINs are encoded as 12 or 13 digits.*

4.6 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. However, DSCSA requires pharmaceutical products to be marked with a barcode that carries their NDC, serial number, lot number, and 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 DSCSA serialization/traceability requirements)*. (See the section entitled *Marking Products with Both UPC-A and GS1 DataMatrix* 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 assure 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	**00 31414 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 DSCSA purposes)

Important: **PER THE GS1 GENERAL SPECIFICATIONS, THIS MUST 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 1st and 2nd positions) cannot be converted to a 12-digit format because, among other reasons, removing these non-zero digits creates an entirely different GTIN.

Important: 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.

4.7 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

4.8 Location Identification: Data Capture vs. Data Reporting

The guideline 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.

4.9 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 identifiers. For example, the EPC scheme for SGTIN and LGTIN are provided below:

SGTIN:

General syntax: urn:epc:id:sgtin:*CompanyPrefix*.*ItemRefAndIndicator*.*SerialNumber*

Example: urn:epc:id:sgtin:0614141.112345.400806

LGTIN:

General syntax: urn:epc:class:lgtin:*CompanyPrefix*.*ItemRefAndIndicator*.*Lot*

Example: urn:epc:class:lgtin:030001.2123498.A1B2C3

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

4.10 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 Identification Number 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. 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.)

4.11 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*.

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.

5 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. The table below lists the GS1 identification standards used in this guideline to support lot-level management and item-level traceability.

Table 5-1 GS1 Identifiers[1]

Supply Chain Object or Location	Lot-Level	Serialized Item-Level
Companies & warehouses	GLN	GLN
Specific locations within companies & warehouses	GLN + extension	GLN + extension
Item	GTIN + lot number	GTIN + serial number
Kit	GTIN + lot number	GTIN + serial number
Homogeneous Case	GTIN + lot number, or SSCC	GTIN + serial number, or SSCC
Mixed / Partial Case	SSCC	SSCC
Pallet	SSCC	SSCC
Tote	SSCC	SSCC
Companies & warehouses	GLN	GLN

5.1 Identifying Trade Units (Products, Cases & Kits): GTIN

In the GS1 System, products, cases and kits[2] 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 to 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 *Master Data* section of this guideline explains how this information can be combined with EPCIS event information to obtain efficient supply chain visibility.)

Note: GS1 US provides an online tool, known as GS1 US Data Hub®, to support users in allocating GTINs and defining the associated attributes. Visit http://www.gs1us.org/resources/tools/gs1-us-data-hub for more information.

5.1.1 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 *Marking Products with Both UPC-A and GS1 DataMatrix* for more information)
- **Assign a GTIN-14** to pharmaceuticals that will not be scanned at point of sale

[1] There may be other layers of packaging that are not specified here.
[2] Consult the FDA UDI (Unique Device Identification) Rule for Kits that include a medical device.

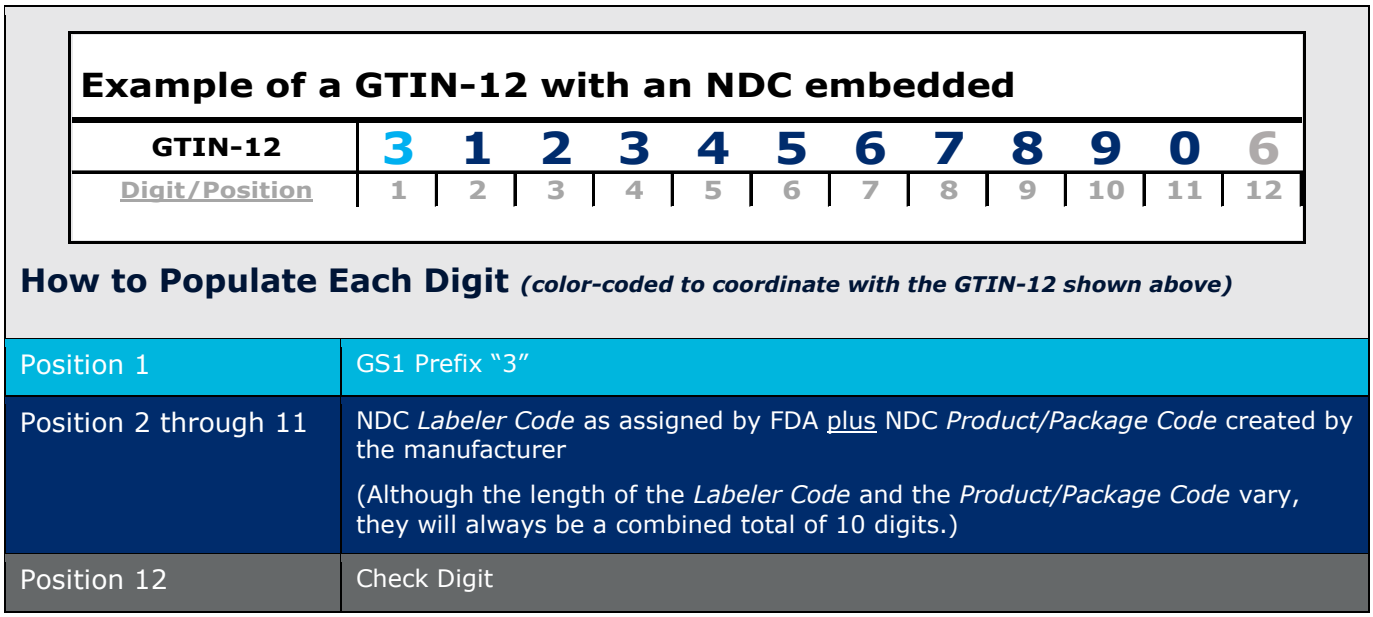
5.1.1.1 Creating a GTIN-12

Each GTIN-12 is a numerical string comprising three distinct segments. The 3 segments within a GTIN-12 are:

- **U.P.C. 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., GTIN). The U.P.C. Company Prefix is 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.

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. The figure below provides a color-coded example of a hypothetical GTIN-12 that embeds an NDC, and a key explaining how each digit is populated.

Figure 5-1 Populating the 12 digits of a GTIN-12 with an NDC embedded



5.1.1.2 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.

  Note: Packaging specialists should review the Indicators used on all other packaging levels prior to incorporating a new packaging level for a product to assure that there is a unique GTIN on every packaging level. This 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 assure data integrity. GS1 US provides a check digit calculator to automatically calculate check digits for you.

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. The figure below provides a color-coded example of a hypothetical GTIN-14 that embeds an NDC, and a key explaining how each digit is populated.

Figure 5-2 Populating the 14 digits of a GTIN-14 with an NDC embedded

Example of a GTIN-14 with an NDC embedded

GTIN	2	0	3	6	1	4	1	4	5	6	7	8	9	8
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14

How to Populate Each Digit ***(color-coded to coordinate with the GTIN-14 shown above)***

Position 1	Indicator Digit (numeric value from 0 to 8)
Position 2 and 3	GS1 Prefix "03"
Positions 4 through 13	NDC *Labeler Code* as assigned by FDA plus NDC *Product/Package Code* created by the manufacturer (Although the length of the *Labeler Code* and the *Product/Package Code* vary, they will always be a combined total of 10 digits.)
Position 14	Check Digit

5.1.1.3 Data Format for Databases & Applications

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.**

5.1.1.4 Data Format for EPCIS

Within the EPCIS, GTIN is stored either with a batch/lot number or a serial number in EPC URI format.

- The EPC URI format for a GTIN + batch/lot is the *LGTIN EPC*.
- The EPC URI format for a GTIN + serial number is the Serialized Global Trade Item Number EPC (*SGTIN EPC*).

Each is discussed in detailed in the *batch/lot section* and *serial number section* below.

5.1.2 Batch / Lot Numbers

5.1.2.1 Assigning Batch/Lot Numbers

The *GS1 General Specifications* define a batch/lot number as an alphanumeric string whose length is variable between one and 20 characters *(the specific characters allowed are defined in the GS1 General Specifications)*. In GS1 BarCodes, batch/lot numbers are represented using AI (10). Any batch/lot number consisting of 1-20 alphanumeric characters may be used in a GS1 BarCode per the standard. Although barcodes can accommodate any 1-20 character batch/lot number, the size of the barcode may vary depending on how many characters are used. 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 batch/lot number length rather than allow their batch/lot numbers to vary between 1 and 20 characters.

5.1.2.2 Data Formats for Databases & Applications

Databases, applications and messages that need to contain a batch/lot number should be designed to accommodate any batch/lot number consisting of 1-20 alphanumeric characters. "Zero" characters in batch/lot numbers are treated as any other alphanumeric character such that batch/lot numbers 7, 07, and 007 are all *different* batch/lot numbers according to the standard. Databases and applications should treat the batch/lot number as a text field so that leading zeros are not inadvertently stripped off.

5.1.2.3 Data Format for EPCIS: LGTIN URI

Within the EPCIS, GTIN + batch/lot are stored in EPC URI format. The EPC URI format for a GTIN + batch/lot is the LGTIN EPC.

Note: The LGTIN 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:

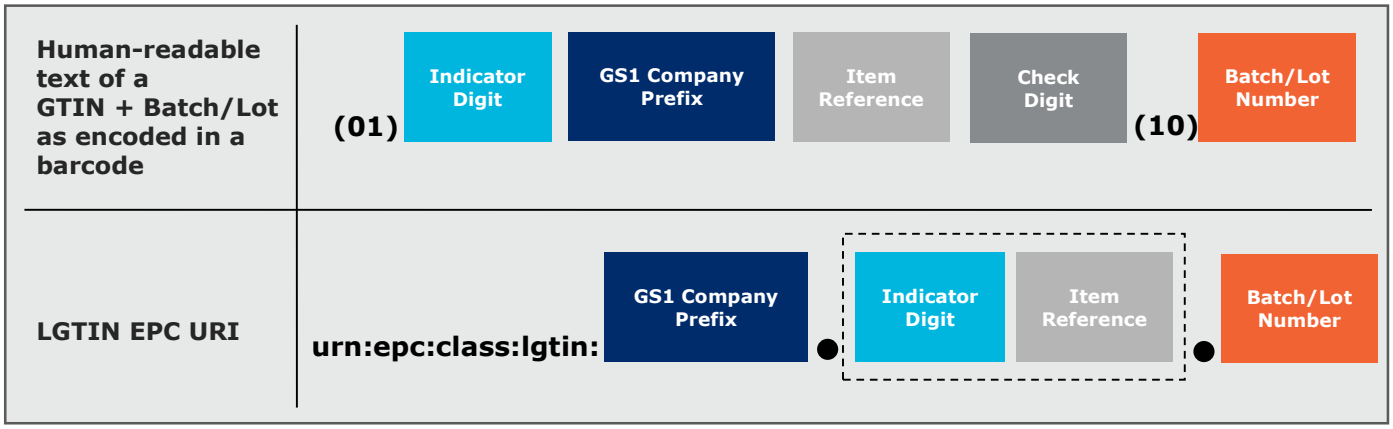
`urn:epc:class:lgtin:`*`CompanyPrefix.ItemRefAndIndicator.Lot`*

Example:

`urn:epc:class:lgtin:030001.2123498.A1B2C3`

The figure below depicts how the element string of a GTIN + batch/lot corresponds to the element string of a LGTIN EPC URI.

Figure 5-3 How the segments of a GTIN + batch/lot are represented in the LGTIN 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 LGTIN 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 *Batch/Lot Number* is the equivalent of AI (10).

Example – Converting a GTIN-14 + batch/lot into EPC URI Format:

GTIN-14	**2 030001 123498 7**
Batch/Lot Number	**A1B2C3**
Corresponding Barcode Human Readable Text	**(01) 2 030001 123498 7 (10) A1B2C3**
Corresponding LGTIN-EPC URI	**urn:epc:class:lgtin: 030001 . 2 123498 . A1B2C3**

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

Example – Converting a GTIN-12 + batch/lot into EPC URI Format:

To find the EPC URI corresponding to the combination of a GTIN-12 and a batch/lot 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	**00 31234 567890 6**
Batch/Lot Number	**D4E5F6**
Corresponding Barcode Human Readable Text	**(01) 00 31234 567890 6 (10) D4E5F6**
Corresponding LGTIN-EPC URI	**urn:epc:class:lgtin: 031234 . 0 567890 . D4E5F6**

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

5.1.2.4 Data Storage Options for GTIN + Batch/Lot Number

GTIN and batch/lot number are assigned as separate data elements, but are saved together as an LGTIN in EPCIS. Users have several options for how to store GTIN + batch/lot number in databases and applications: (1) GTINs and batch/lot numbers can be saved in their own fields; (2) saved together in the LGTIN 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 batch/lot numbers in databases:

2 fields = GTIN field and Batch/Lot Number field

1 field = One field containing GTIN + batch/lot number in EPC URI format (i.e., LGTIN URI)

3 fields = GTIN field, Batch/Lot Number field, and field containing GTIN + batch/lot number in EPC URI format (i.e., LGTIN URI)

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

Table 5-2 Data Formats for GTIN + Batch/Lot Number Fields

Field	Data Format
GTIN	▪ 14 digits ▪ text field (not numeric)
Batch/Lot Number	▪ 1-20 characters ▪ text field (not numeric)

LGTIN EPC URI	▪ 36-55 characters:
	  ▪ 20 characters for "urn:epc:class:lgtin:"
	  ▪ 13 characters for the GTIN (without the Check Digit)
	  ▪ 1-20 characters for the batch/lot number
	  ▪ 2 periods (".")
	▪ text field (not numeric)

5.1.3 Serial Numbers

5.1.3.1 Assigning 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 Specification*s 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)*. 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 should 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 permitted under the standards.

5.1.3.2 Data Format for Databases & Applications

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 barcodes and 96-bit EPC/RFID tags. Nonetheless, databases and messages that need to contain a serial number should be designed to accept the full range of data values defined by GS1 Standards. Therefore, serial

numbers should always be stored in a text field (not numeric) that is capable of handling between one and 20 alphanumeric characters.

Important: "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. Leading zeros should never be added or removed from serial numbers.

5.1.3.3 Data Format for EPCIS: SGTIN URI

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

Important: 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.ItemRefAndIndicator.SerialNumber`*

Example:

`urn:epc:id:sgtin:0614141.112345.400806`

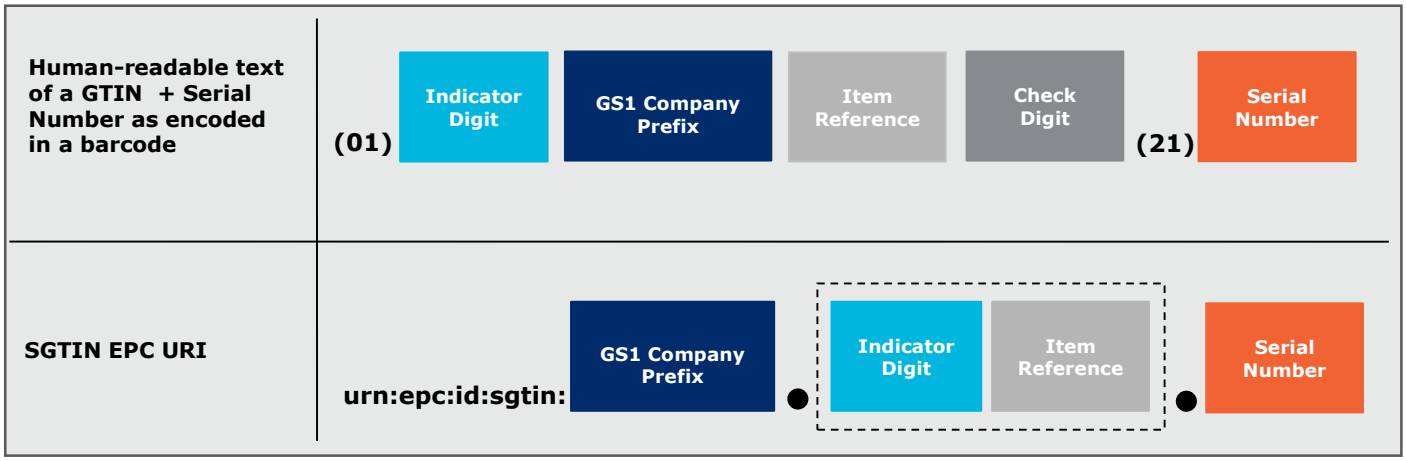
Grammar:

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

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

The number of characters in the two PaddedNumericComponent fields should 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. The figure below depicts how the element string of a GTIN + serial number corresponds to the element string of a SGTIN EPC URI:

Figure 5-4 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**

Note: 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	**00 31234 567890 6**
Serial Number	**123456789012**
Corresponding Barcode Human Readable Text	**(01) 00 31234 567890 6 (21)123456789012**
Corresponding SGTIN-EPC URI	**urn:epc:id:sgtin: 031234 . 0 567890 . 123456789012**

Note: 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.

5.1.3.4 Data Storage Options for GTIN + Serial Number

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 and applications: (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 the table below.

Table 5-3 Data Formats for GTIN + Serial Number Fields

Field	Data Format
GTIN	▪ 14 digits ▪ text field (not numeric)
Serial Number	▪ 1-20 characters ▪ text field (not numeric)

Serialized GTIN EPC URI	▪ 33-52 characters:
	  ▪ 17 characters for "urn:epc:id:sgtin:"
	  ▪ 13 characters for the GTIN (without the Check Digit)
	  ▪ 1-20 characters for the serial number
	  ▪ 2 periods (".")
	▪ text field (not numeric)

5.2 Identifying Logistics Units (Cases, Pallets & 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.

5.2.1 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.

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. The figure below provides a color-coded example of a hypothetical SSCC, and a key explaining how each digit is populated.

Figure 5-5 Populating the 18 digits of an SSCC

Example of an SSCC

SSCC	0	0	3	3	4	5	6	7	8	9	1	2	3	4	5	6	0	4
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18

How to Populate Each Digit ***(color-coded to coordinate with the SSCC shown above)***

Position 1	Extension Digit (numeric value from 0 to 9)
Positions 2 through 17	GS1 Company Prefix as assigned by GS1 US plus Serial Reference number as assigned by the owner of the logistics unit
Position 18	Check Digit

5.2.2 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.

5.2.3 Data Format for EPCIS: SSCC URI Format

Within the EPCIS, SSCCs are 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
```

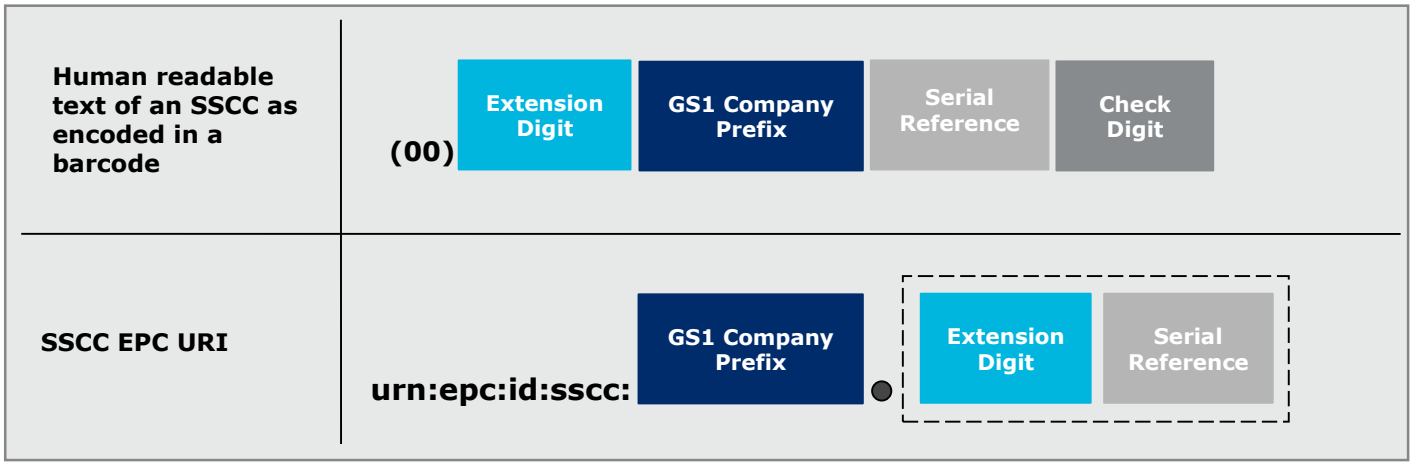
Grammar:

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

SSCCURIBody ::= PaddedNumericComponent "." PaddedNumericComponent

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

Figure 5-6 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.

5.2.4 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 the table below.

Table 5-4 Data Formats for SSCC Fields

Field	Data Format
SSCC	▪ 18 digits ▪ text field (not numeric, to avoid dropping leading zeros)

SSCC URI	▪ 34 characters:
	  ▪ 16 characters for "urn:epc:id:sscc:"
	  ▪ 17 characters for the SSCC (without the Check Digit)
	  ▪ 1 period (".")
	▪ text field (not numeric)

5.3 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 GS1 US DataHub | Location) and shared among supply chain partners.

5.3.1 Assigning GLNs

Each GLN is a numerical string comprising three distinct segments. The three segments in 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.

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. The figure below provides a color-coded example of a hypothetical GLN, and a key explaining how each digit is populated.

Figure 5-7 Populating the 13 digits of a GLN

Example of a GLN

GLN	0	3	2	1	0	1	2	3	4	5	6	7	6
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13

How to Populate Each Digit ***(color-coded to coordinate with the GLN shown above)***

Positions 1 through 12	GS1 Company Prefix as assigned by GS1 US plus Location Reference number as assigned by the owner of the GS1 Company Prefix
Position 13	Check Digit

5.3.2 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.

5.3.3 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.

5.3.4 Data Format for EPCIS: SGLN URI Format

Within EPCIS, GLNs are 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 "."

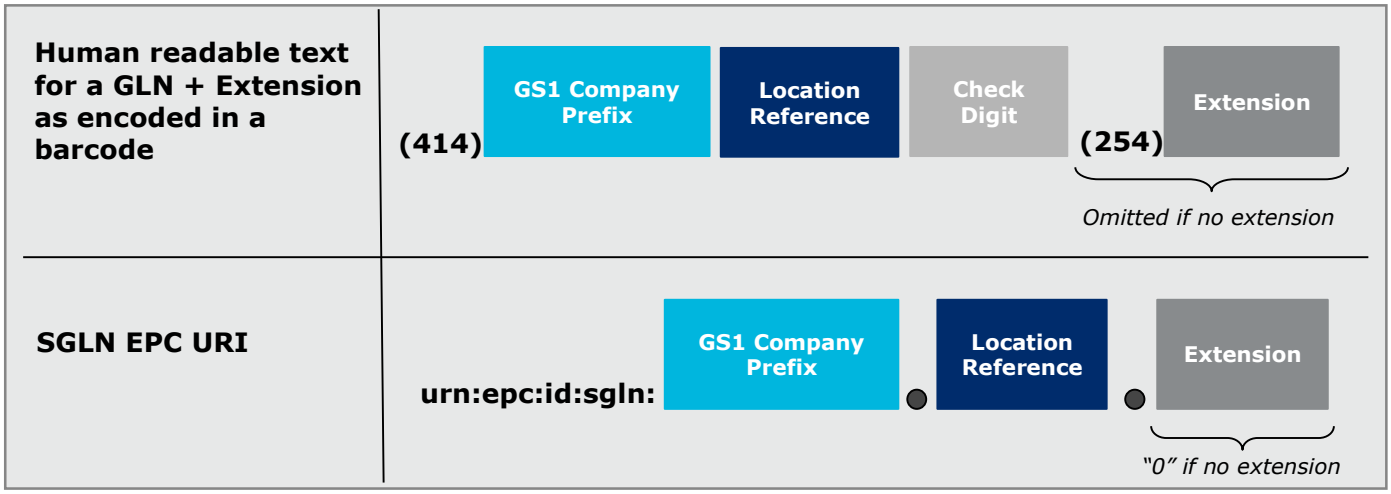
PaddedNumericComponentOrEmpty "." GS3A3Component

The number of characters in the two PaddedNumericComponent fields should 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.

The figure below 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 5-8 How the segments of a GLN (with or without extension) are represented in the SGLN EPC URI format



5.3.5 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 the table below.

Table 5-5 Data Formats for GLN Fields

Field	Data Format
GLN	▪ 13 digits ▪ text field (not numeric)
GLN Extension	▪ 1-20 characters ▪ text field (not numeric)

SGLN EPC URI	▪ 31-50 characters:
	  ▪ 16 characters for "urn:epc:id:sgln:"
	  ▪ 12 characters for the GLN (no Check Digit)
	  ▪ 1-20 characters for the GLN extension
	  ▪ 2 periods ('.')
	▪ text field (not numeric)

5.3.6 Alternate Party Identifier: DEA Number

In some cases, a party to a transaction does not have a GLN number, but does have a DEA number. In those cases, the following URI form may be used.

DEA Number URI Form:

`http://epcis.gs1us.org/hc/dea/loc/DEANumber`

Example:

`http://epcis.gs1us.org/hc/dea/loc/12345678`

6 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).

The table below lists the GS1 data carriers used in this guideline to support lot-level management and item-level traceability. Because this guideline documents a specific application of the standards to support serialized item-level traceability, only data carriers that can carry serial numbers are shown.

Table 6-1 GS1 Data Carriers Used in this Guideline

Supply Chain Object	GS1 Data Carrier Options
TRADE ITEMS: Products, Cases & Kits	GS1 DataMatrix
	GS1-128
	EPC/RFID Tag *(serialized trade items only)*
LOGISTICS UNITS: Cases, Pallets & Totes	GS1-128
	GS1 DataMatrix
	EPC/RFID Tag

Note: Phase 1 of the DSCSA does not require lot information to be marked on products in machine-readable form. Phase 2 of the DSCSA requires pharmaceutical products to be marked with a product identifier (GTIN/NDC), Serial Number, Lot Number, and Expiration Date starting in 2017. Therefore, as industry works to implement Phase 2 item-level marking requirements, the supply chain will likely experience a mixed environment in which products will be marked with product identifier (GTIN/NDC) only and/or marked with a product identifier (GTIN/NDC), Serial Number, Lot Number, and Expiration Date.

6.1 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 section.

6.1.1 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. The table below presents some high-level concepts and principles that should be followed when encoding barcodes.

Table 6-2 Encoding Principles

Principle	Example / Illustration	
Each barcode data element has a two- to four-digit AI that defines data type and field size.	GTIN	**AI (01)**
	Serial Number	**AI (21)**
	Batch/Lot Number	**AI (10)**
	Expiration Date	**AI (17)**
	SSCC	**AI (00)**
When encoding, each data element is preceded by its corresponding AI.	GTIN	**0100314141999995**
	Serial Number	**21ABCDEFG123456789**
	Batch/Lot Number	**10987654321GFEDCBA**
	Expiration Date	**17150331**
	SSCC	**00003345678912345604**
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. *NOTE: Although parentheses and spaces appear in the human readable text below the barcode, these characters are not encoded in the barcode itself.*	 (01) 00314141999995 (10) 987654321GFEDCBA	
For the most efficient encoding, ensure that fixed- length AI's precede variable-length AI's.	 (01) 20887511 00734 6 (17) 150331 (10) A1B2C3D4E5 (21) 123456789	GTIN ***fixed*** Expiration Date ***fixed*** Batch/Lot Number ***variable*** Serial Number ***variable***

Note: ***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
EXP 25 JAN 2015
LOT 987654321GFEDCBA

6.1.1.1 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. DSCSA requirements commencing in 2017 include the marking of pharmaceutical products with a product identifier, serial number, batch/lot number, and expiration date.

Table 6-3 Barcodes for Products, Cases & Kits

Barcodes for Products, Cases & Kits		
Required Identification Information	GTIN	AI (01)
	Serial Number	AI (21)
	Batch/Lot Number	AI (10)
	Expiration Date	AI (17)
GS1 Barcode Options	GS1 DataMatrix GS1-128	

6.1.1.1.1 Encoding Principles

GTIN

- Begin with the two-digit AI "**01**" to indicate GTIN.
- A fixed-length field comprising the 14 numeric characters of a GTIN data follows the AI.
  - *For GTIN-12: encode in 14-digit format using two leading zeros*
- The data syntax for the GTIN component is n2 + n14 (where n2 is the AI and a14 is the GTIN).
- EXAMPLE: **0100312345678906**

Serial Number

- Begin with two-digit AI "**21**" to indicate the *Serial Number*.
- A variable-length field of up to 20 alphanumeric characters of *Serial Number* data follows the AI.
  - *If using a barcode with a 96-bit EPC/RFID tag: be sure to note the associated limitations on serial number*
- The data syntax for the *Serial Number* component is n2 + a1..20 (where n2 is the AI and a1..20 is the *Serial Number*).
- EXAMPLE: **21ABCDEFG123456789**

Batch/Lot Number

- Begin with the two-digit AI "**10**" to indicate *Batch/Lot Number*.
- A variable-length field of up to 20 alphanumeric characters representing the *Batch/Lot Number* follows the AI.
- The data syntax for the *Batch/Lot Number* component is n2 + a1..20 (where n2 is the AI and a1..20 is the *Batch/Lot Number*).
- EXAMPLE: **10987654321gfedcba**

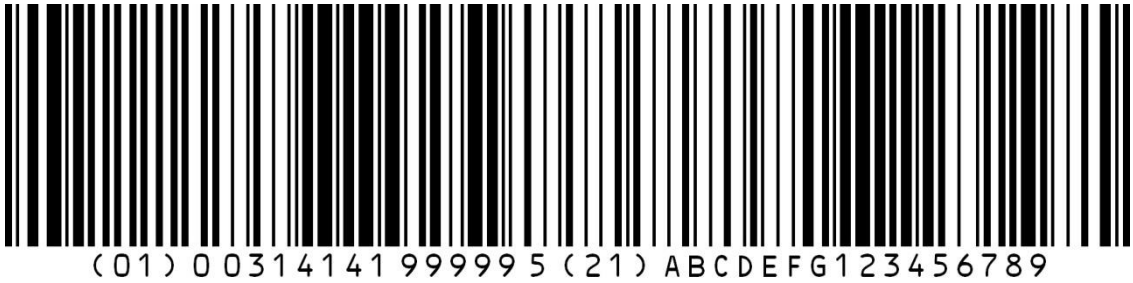
Expiration Date

- The two-digit AI "**17**" is used to indicate *Expiration Date*.
- A fixed-length field of six numeric characters representing the *Expiration Date* as **YYMMDD** follows the AI.
  - YY = the tens and units of the year (e.g., 2015 = 15).
  - MM = the number of the month (e.g., March = 03).
  - DD = the number of the day of the relevant month (e.g., second day = 02).
- The data syntax for *Expiration Date* is n2 + n6 (where n2 is the AI and n6 is the *Expiration Date*).
- EXAMPLE: **17180331**
  - *See Rules for Expressing Expiration Date for more information*

6.1.1.1.2 Examples

Figure 6-1 GTIN with Serial Number Encoded in a GS1 DataMatrix

Figure 6-2 GTIN with Serial Number Encoded in a GS1-128



6.1.1.1.3 Marking Products with Both UPC-A and GS1 DataMatrix

The FDA 2004 Pharmaceutical Barcode Rule (updated in 2006), requires prescription drug products to carry the NDC in one of two standard linear barcode formats. However, starting in 2017, the DSCSA law requires items to be marked with a 2D data matrix barcode. The industry and GS1 have asked the FDA whether the requirement to use linear barcodes will be sunset in light of the DSCSA law in order to reduce duplicate data, free label space, and lessen ambiguity for clinicians determining which barcode to read. Until there is guidance from the FDA, manufacturers and repackagers will need to encode both linear and 2D DataMatrix barcodes on products that are serialized. Many pharmaceutical manufacturers are marking products that move through a Point of Sale 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 lot-level management or serialized item-level traceability 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 traceability 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/traceability requirements). To ensure that the GTIN encoded in both barcodes is the same, manufacturers should follow the *recommendations* outlined for all products that will be marked with both a UPC-A and a GS1 DataMatrix.

Figure 6-3 GTIN-12 in a UPC-A and GS1 DataMatrix

GTIN-12 encoded in a UPC-A

GTIN-12 encoded in a GS1 DataMatrix

6.1.1.1.4 Rules for Expressing Expiration Date

The following rules specify how the expiration date is expressed in a barcode, in human readable text, and in EPCIS events pursuant to the standards.

1. EPCIS data SHALL contain an expiration date that includes a year, month, and non-zero day, in YYYY-MM-DD format as required by XML standards.
2. It is STRONGLY RECOMMENDED that the barcode contain an expiration date that includes a year, month, and non-zero day, in YYMMDD format according to the *GS1 General Specifications*. While the *GS1 General Specifications* permit a day of 00, it is NOT RECOMMENDED that this be used.
3. The human readable text on the package SHOULD include an expiration date that includes a year, month, and non-zero day, but the human readable text MAY, if necessary, only include a year and month.
4. The expiration dates as expressed in EPCIS, all barcodes, and human readable text, SHALL be consistent with each other. "Consistent" means that all three have an identical year, month, and non-zero day; or if one or more forms do not specify a day of the month (omitted from human readable and/or 00 in the bar code) that the remaining forms, specify the last day of the month. This is in keeping with United States Pharmacopeia (USP) guidance which specifies that an expiration date on a label lacking a day, should be understood to refer to the last day of the month.

The following examples illustrate the application of these standards rules.

Example 1: **CONFORMING** -- all three specify an identical year, month, and non-zero day

EPCIS: `<cbvmda:itemExpirationDate>2017-03-15</cbvmda:itemExpirationDate>`
Barcode: (17)170315
HR: 2017-03-15

Example 2: CONFORMING (though not preferred) -- all three specify an identical year and month, HR omits the day, and the others have end of month

EPCIS: `<cbvmda:itemExpirationDate>2017-03-31</cbvmda:itemExpirationDate>`
Barcode: (17)170331
HR: 2017-03

Example 3: CONFORMING (though NOT RECOMMENDED) -- all three specify an identical year and month, HR and barcode omits the day, and EPCIS has end of month

EPCIS: `<cbvmda:itemExpirationDate>2017-03-31</cbvmda:itemExpirationDate>`
Barcode: (17)170300
HR: 2017-03

Example 4: NOT CONFORMING -- they do not match

EPCIS: `<cbvmda:itemExpirationDate>2017-03-15</cbvmda:itemExpirationDate>`
Barcode: (17)170331
HR: 2017-02

Example 5: NOT CONFORMING -- omitted day in HR does not match EPCIS/barcode which specify something other than end of month. Under USP guidance, the HR would be understood to mean 2017-03-31 which is different than what EPCIS and barcode say

EPCIS: `<cbvmda:itemExpirationDate>2017-03-15</cbvmda:itemExpirationDate>`
Barcode: (17)170315
HR: 2017-03

Example 6: NOT CONFORMING -- omitted day in HR and barcode does not match EPCIS which specifies something other than end of month. Under USP guidance, the HR or barcode would be understood to mean 2017-03-31 which is different than what EPCIS says.

EPCIS: `<cbvmda:itemExpirationDate>2017-03-15</cbvmda:itemExpirationDate>`
Barcode: (17)170300
HR: 2017-03

Example 7: NOT CONFORMING -- omitted day in HR does not match EPCIS and barcode which specify something other than end of month. Under USP guidance, the HR would be understood to mean 2017-02-28 which is different than what EPCIS and the barcode say.

EPCIS: `<cbvmda:itemExpirationDate>2017-03-15</cbvmda:itemExpirationDate>`
Barcode: (17)170315
HR: 2017-02

Example 8: NOT CONFORMING – because of leap years. It would be conforming if EPCIS and barcode had Feb 29, instead of 28.

EPCIS: `<cbvmda:itemExpirationDate>2020-02-28</cbvmda:itemExpirationDate>`
Barcode: (17)200228
HR: 2020-02

6.1.1.2 Logistics Units: Pallets, Cases & Totes

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

Table 6-4 Barcodes for Pallets, Cases & Totes

Barcodes for Cases Pallets & Totes		
Required Identification Information	SSCC	AI (00)
GS1 Barcode Options	GS1-128 GS1 DataMatrix	

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 6-4 SSCC Encoded in a GS1-128

Figure 6-5 SSCC Encoded in a GS1 DataMatrix

6.1.2 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.

6.2 Translating Captured Data

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 need to first be translated into EPC URI format in order to be stored in 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 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.)

6.2.1 GTIN + Batch/Lot Number

6.2.1.1 EPC URI Format

The EPC URI format for a GTIN + batch/lot is the LGTIN EPC.

General syntax:

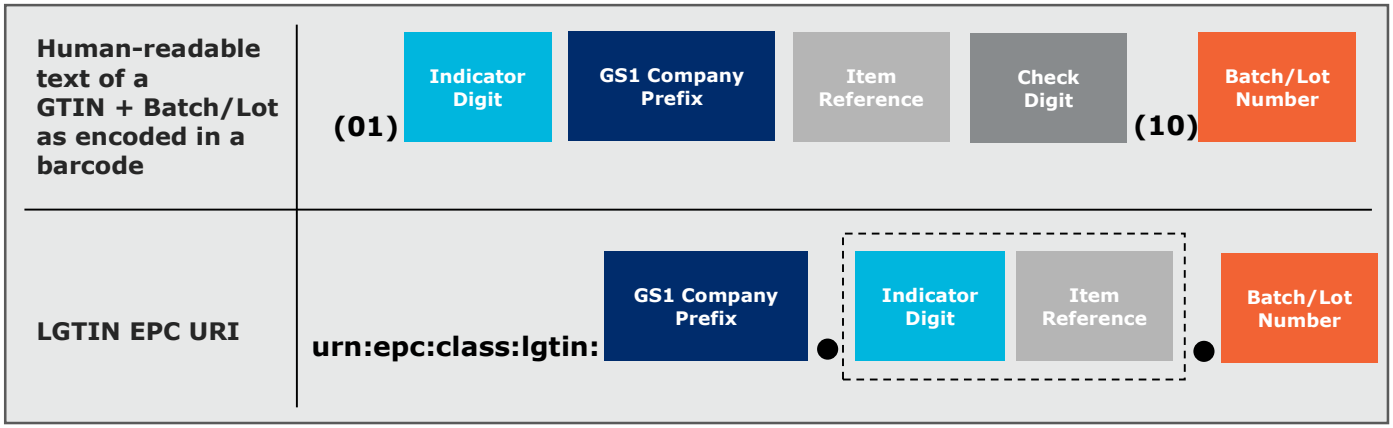
`urn:epc:class:lgtin:`*`CompanyPrefix.ItemRefAndIndicator.Lot`*

Example:

`urn:epc:class:lgtin:030001.2123498.A1B2C3`

The figure below depicts how the element string of a GTIN + batch/lot corresponds to the element string of a LGTIN EPC URI.

Figure 6-6 How the segments of a GTIN + batch/lot are represented in the LGTIN 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 LGTIN 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 *Batch/Lot Number* is the equivalent of AI(10).

Example – Converting a GTIN-14 + batch/lot into EPC URI Format:

GTIN-14	**2 030001 123498 7**
Batch/Lot Number	**A1B2C3**
Corresponding Barcode Human Readable Text	**(01) 2 030001 123498 7 (10) A1B2C3**
Corresponding LGTIN-EPC URI	**urn:epc:class:lgtin: 030001 . 2 123498 . A1B2C3**

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

6.2.1.2 Data Storage Options for GTIN + Batch/Lot Number

GTIN and batch/lot number are assigned as separate data elements, but are saved together as an LGTIN in EPCIS. Users have several options for how to store GTIN + batch/lot number in databases and applications: (1) GTINs and batch/lot numbers can be saved in their own fields; (2) saved together in the LGTIN 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 batch/lot numbers in databases:

2 fields = GTIN field and Batch/Lot Number field

1 field = One field containing GTIN + batch/lot number in EPC URI format (i.e., LGTIN URI)

3 fields = GTIN field, Batch/Lot Number field, and field containing GTIN + batch/lot number in EPC URI format (i.e., LGTIN URI)

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

Table 6-5 Data Formats for GTIN + Batch/Lot Number Fields

Field	Data Format
GTIN	▪ 14 digits ▪ text field (not numeric)
Batch/Lot Number	▪ 1-20 characters ▪ text field (not numeric)

LGTIN EPC URI	▪ 36-55 characters:
	  ▪ 20 characters for "urn:epc:class:lgtin:"
	  ▪ 13 characters for the GTIN (without the Check Digit)
	  ▪ 1-20 characters for the batch/lot number
	  ▪ 2 periods (".")
	▪ text field (not numeric)

6.2.2 GTIN + Serial Number

6.2.2.1 EPC URI Format

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.ItemRefAndIndicator.SerialNumber`*

Example:

`urn:epc:id:sgtin:0614141.112345.400806`

Grammar:

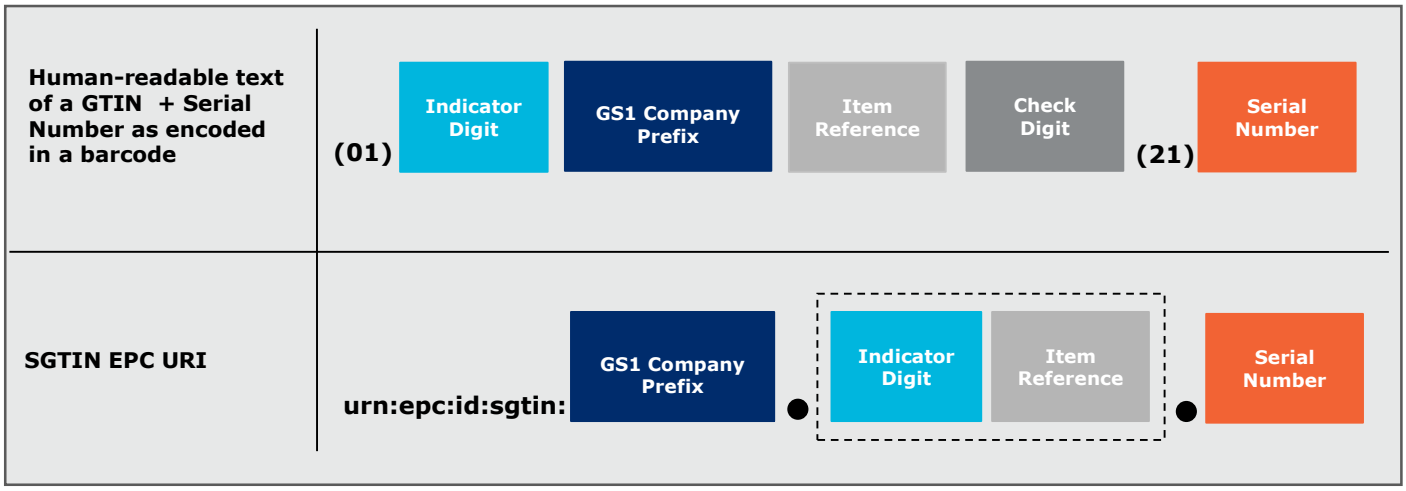
SGTIN-URI ::= "urn:epc:id:sgtin:" SGTINURIBody

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

The number of characters in the two PaddedNumericComponent fields should 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. The figure below 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 6-7 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**

Note: 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.

6.2.2.2 Data Storage Options for GTIN + Serial Number

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 the table below.

Table 6-6 Data Formats for GTIN + Serial Number Fields

Field	Data Format
GTIN	▪ 14 digits ▪ text field (not numeric)
Serial Number	▪ 1-20 characters ▪ text field (not numeric)

Serialized GTIN EPC URI	▪ 33-52 characters:
	  ▪ 17 characters for "urn:epc:id:sgtin:"
	  ▪ 13 characters for the GTIN (without the Check Digit)
	  ▪ 1-20 characters for the serial number
	  ▪ 2 periods (".")
	▪ text field (not numeric)

6.2.3 SSCC

6.2.3.1 EPC URI Format

Within EPCIS, SSCCs are 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

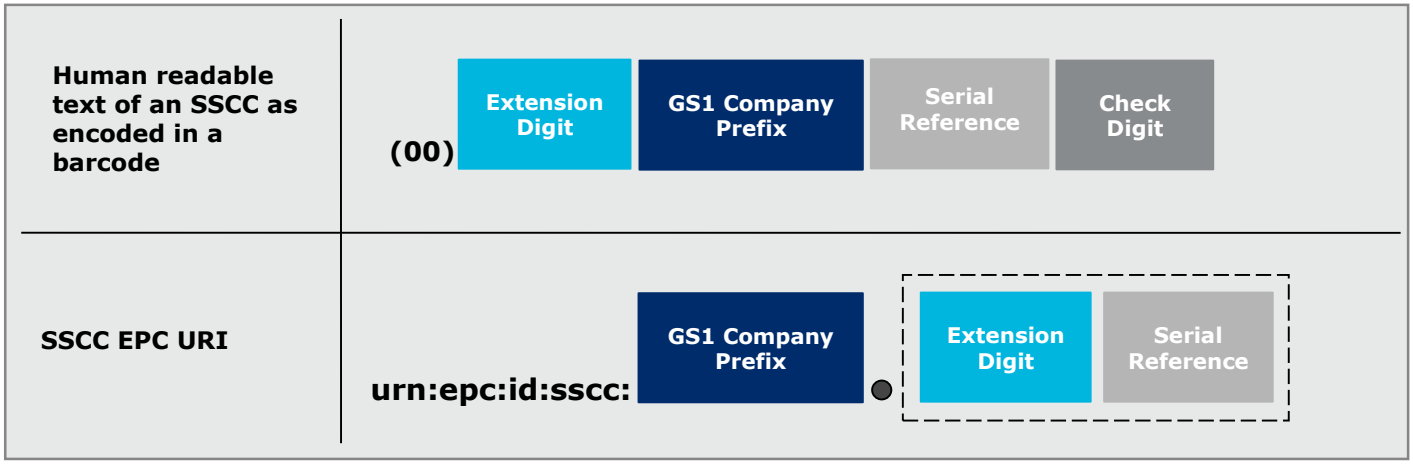
SSCCURIBody ::= PaddedNumericComponent "." PaddedNumericComponent

The number of characters in the two PaddedNumericComponent fields should total 17 (not including any of the dot characters). The figure below 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 6-8 How the segments of an SSCC are represented in the SSCC EPC URI format



6.2.3.2 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 the table below.

Table 6-7 Data Formats for SSCC Fields

Field	Data Format
SSCC	▪ 18 digits ▪ text field (not numeric, to avoid dropping leading zeros)

SSCC URI	▪ 34 characters:
	  ▪ 16 characters for "urn:epc:id:sscc:"
	  ▪ 17 characters for the SSCC (without the Check Digit)
	  ▪ 1 period (".")
	▪ text field (not numeric)

7 Share Concepts

7.1 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 to 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 GS1 US DataHub | Location.

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, EPCIS Locations = GS1 US DataHub | Location, EPCIS
Sharing Event & Disposition	EPCIS
Item Event Locator	Discovery Services or Checking Service (future)

This is especially important for EPCIS applications like traceability 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 traceability data. For example, a distributor records a traceability 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 GS1 US DataHub | Location:

LocationName: Smithfield Distribution Center
Address: 123 Main Street
City: Lawrenceville
State: NJ
Zip Code: 08648

Best Practices:

- Because master data is managed separately from event/traceability 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.

7.2 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 lot-level management and serialized item-level traceability in certain EPCIS events. The data elements captured and recorded for each EPCIS are presented in the table below.

Table 7-1 EPCIS Data Elements

Dimension	Data	Definition	Examples
	Event Type Action	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.
What	EPC List	the item's unique identifier, 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.
	Parent ID		
	Child EPCs		
When	Event Time	the moment in time at which the event occurred	March 15, 2010 at 10:07am UTC
	Event Timezone Offset	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 time zone indicator) but instead helps software to display data to users in local time	UTC -05:00
Where	Read Point	the location at which the event took place expressed as an EPC Pure Identity URI	GLN or GLN with extension
	Business Location	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
Why	Business Step	the business process taking place at the time of this event	*Shipping*, *Receiving*, *Picking*, etc.
	Disposition	business condition of the objects named in the *what* dimension that is presumed to hold until a subsequent event occurs	Saleable, Recalled, etc.
	Business Transaction	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
	Source	transferring entity expressed as an EPC Pure Identity URI	GLN
	Destination	transferred-to entity expressed as an EPC Pure Identity URI	GLN

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 EPCIS can best be applied to support lot-level management and item-level traceability.

The remainder of this document specifies how the EPCIS standard is applied to support lot-level management and item-level traceability for the US pharmaceutical industry.

8 EPCIS Principles for this Guideline

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 lot-level management, serialized item-level traceability, recall, etc. This section presents information and concepts related to the application of EPCIS for DSCSA requirements within this guideline.

8.1 Master Data in EPCIS Events for DSCSA

Initial stages of the DSCSA consider product and location data to be part of the lot-level management data set. 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, the DSCSA lot-level management data set includes both the unique identifier for a pharmaceutical product (i.e., the GTIN), as well as its dose and strength information. When using EPCIS events to assemble DSCSA content, companies that use master data management strategies will obtain the GTIN from the EPCIS event data itself, and obtain the dose and strength information from the master data associated with that GTIN to assemble the full DSCSA data set. In contrast, 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 in the EPCIS Header that accompanies the EPCIS events. To support both scenarios, product and location master data attributes are shown as "optional" in the EPCIS Header.

8.2 Data Rules for this Guideline

8.2.1 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 lot-level management or serialized item traceability 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 should conform to the following rules.

Note: 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.

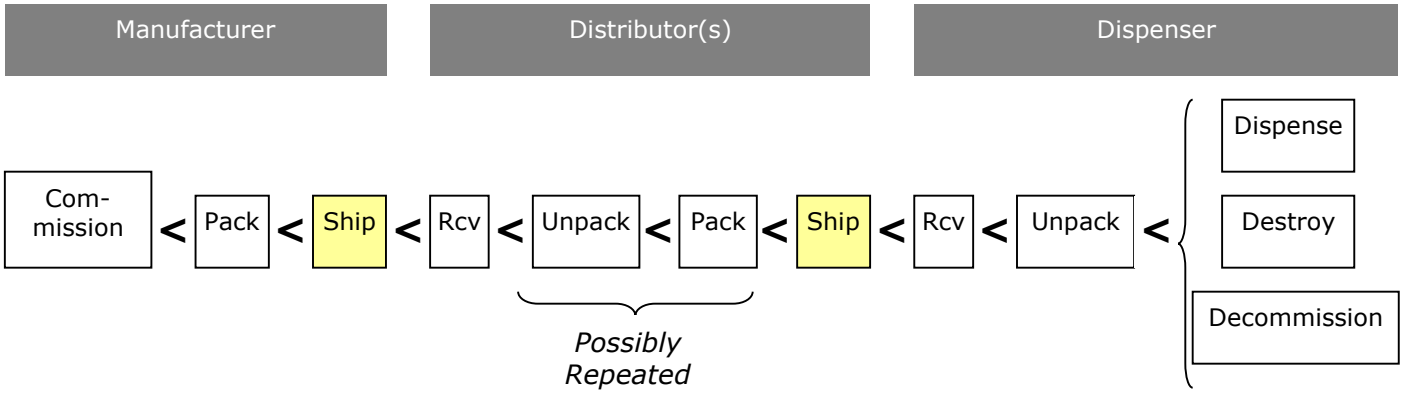
Rules for this Guideline:

- 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 should 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* (except for event times that are artificially advanced, as specified below).

- 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 should hold between events that refer to the same object identifier:
  - The *Event Time* reported for *Shipping*, *Receiving*, and end-of-life events should 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 as long as the relationships in the diagram continue to hold between events that pertain to the same physical objects.
  - The order in which EPCIS events are listed in an EPCIS document has no significance. Applications that receive EPCIS events use *Event Time* or other data within the events to understand the sequence in which they occurred.

The figure below shows the relationships of Event Times. The " < " symbol indicates that the first Event Time must be strictly less than the second Event Time. ***These relationships only apply to pairs of events that pertain to the same physical objects*** (e.g., a given *Commissioning* event needs to have an earlier event time than a given *Packing* event if one or more of the objects in that *Commissioning* event is part of that *Packing* event. The *Commissioning* event does not need to have an earlier event time if none of the objects are part of the *Packing* event).

Figure 8-1 Event Time Relationships for Lot Level Management Purposes



Best Practice:

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 should 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.

8.2.2 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 choose to only share the site without providing information about which dock door was used.

Rules for this Guideline:

EPCIS events shared for lot-level management or serialized item traceability purposes should conform to the following rules for *Business Locations* and *Read Points*:

- The *Business Location* for an event should 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 section4.8.)
- The *Read Point* for an event should 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 should be the same as the site-level GLN in which the more granular location is located.
    - For example, if you have used a GLN (EPC URI: `urn:epc:id:sgln:0614141.00000.0`) 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:0614141.00000.12345`).

Important: 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 may ascertain the GLN for the site-level location by simply disregarding the extension.

8.2.3 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 for this Guideline:

Business Transactions in EPCIS events should conform to the following rules:

- The *Business Transaction* type should 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 should 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 should match the GLN provided in the *Source* or *Destination* attributes in a *Shipping* event. For example, in normal forward logistics, the GLN in the *Business Transaction* identifier for an invoice would match the *Source*, and the GLN in the *Destination* for a purchase order would match the *Destination*. (See *Table 7-1 EPCIS Data Elements* for the definition of *Source* and *Destination*.)

8.2.4 EPCIS Expiration Date

See *Rules for Expressing Expiration* Date regarding the synchronization of the expiration date as represented in EPCIS with the expiration date as marked on the package.

8.2.5 Checking EPCIS Event Contents

The following are recommended approaches 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.
- The GTIN in the *Receiving* event should match the *Shipping* event GTIN.
- All events should conform to the attributes / extensions that are outlined in this guideline.
- Mandatory attributes should exist.
- Location identifier should belong to the expected party.

8.3 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:directPurchase value="true" />
```

```
        </ObjectEvent>
      </EventList>
    </EPCISBody>
</epcis:EPCISDocument>
```

Note: 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).

8.4 Core Business Vocabulary (CBV) Extensions

The EPCIS standard specifies that the *Business Step*, *Disposition*, and *Business Transaction Type* fields of EPCIS events should 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*.

In this version of the guideline, only CBV standard *Business Step*, *Disposition*, and *Business Transaction Type* values are used, so no CBV extensions are defined.

8.5 EPCIS Event Fields

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 lot-level management or serialized item traceability purposes. For clarity, the EPCIS event details tables throughout this section use the following notations to indicate what is required for lot-level management or serialized item traceability purposes:

Required	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.)
Optional	The field may or may not be included in the context of this specific event.
Conditional	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.
Omitted	The field is always omitted in the context of this specific event.

Part II: Application of EPCIS for Lot-Level Management

Phase 1 of the DSCSA involves the exchange of lot-level Transaction Information, Transaction History, and Transaction Statement at each sale/transfer of ownership. Using EPCIS, the *Shipping* event is used to record a transfer of ownership. Therefore, this guideline integrates DSCSA lot-level transaction requirements (including Transaction Information, Transaction History, and Transaction Statement) into the EPCIS *Shipping* event. Trading partners can use this event to record and exchange DSCSA lot-level information for each sale/transfer of ownership. In addition to the EPCIS *Shipping* event, repackaging scenarios will also use the EPCIS *Transformation* event to record the relationship between the original product and the repackaged product.

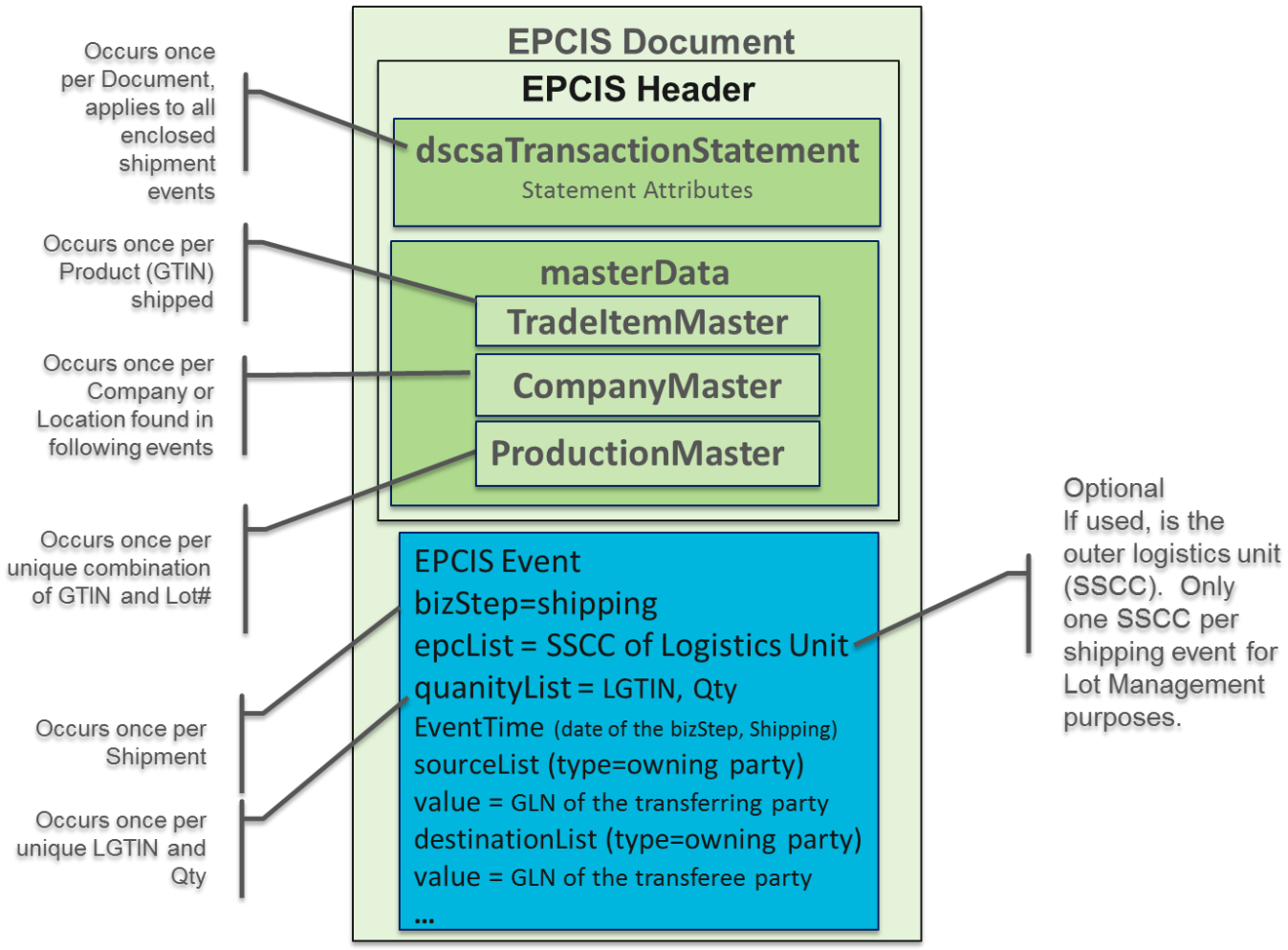
This section specifies the minimum set of EPCIS events to support lot-level management pursuant to Phase 1 of the DSCSA. Key points:

- The EPCIS *Shipping* event is used to record and exchange DSCSA lot-level information for each sale/transfer of ownership. Each trading partner records and exchanges this *Shipping* event for each sale/transfer of ownership.
  - *Shipping* events will be captured at the individual saleable unit.
  - Product identifier (GTIN) and lot number are data elements in the *Shipping* event per DSCSA Transaction Information requirements. These data elements relate to the products contained in the shipment.
- In addition to the *Shipping* event, the EPCIS *Transformation* event is also used in repackaging scenarios to record the relationship between the original product and the repackaged product.
- Phase 1 of the DSCSA does not require the product identifier (GTIN) and lot number of the products contained in the case to be marked on the case. Companies will determine for themselves how they will capture/enter that data into their Shipping events (e.g., have system prompt shipping staff to enter that data manually; create a product identifier/lot number barcode for each lot and have shipping staff scan that barcode for each case in the lot to record the data electronically; etc.).

9 Overview of Lot-Level Management

A *Shipping* event can occur once for each Transaction Information (i.e., homogeneous product shipment) or occur multiple times for each Transaction Information (i.e., mixed pallet, mixed cases or totes). All *Shipping* events covered by the same Transaction Statement are bundled together into one EPCIS Document.

Figure 9-1 EPCIS Document Structure



10 DSCSA Lot-Level Data Elements

DSCSA 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, traceability information includes both the unique identifier for a pharmaceutical product (i.e., the NDC/GTIN), as well as its dose and strength information. When using EPCIS events to provide DSCSA content, the NDC/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 DSCSA data elements is provided in the table below.

Table 10-1 DSCSA Lot-Level Data Elements

Type of Information	DSCSA Data Attribute	EPCIS Segment
Transaction Statement	affirmTransactionStatement	dscsaTransactionStatement extension
	directPurchase	*Shipping* Event Extension
	receivedADirectPurchaseStatementFromPreviousWholesaleDistributor	*Shipping* Event Extension
Transaction Information	the proprietary or established name or names of the product	GTIN-level product master data accompanying an EPCIS *Shipping* Event
	the strength and dosage form of the product	GTIN-level product master data accompanying an EPCIS *Shipping* Event
	the National Drug Code number of the product	GTIN-level product master data accompanying an EPCIS *Shipping* Event
	the container size	GTIN-level product master data accompanying an EPCIS *Shipping* Event
	the number of containers	EPCIS *Shipping* Event (epcQtyList)
	the lot number of the product	masterData Extension (production lot elements)
	the date of the transaction	▪ If the date of the shipment is less than 24 hours after the date of the transaction, then use EPCIS *Shipping* Event (eventTime). ▪ If the date of the shipment is more than 24 hours after the date of the transaction, then use *Shipping* Event Extension (transactionDate)
	expiration date	masterData Extension (production lot elements)
	the date of the shipment, if more than 24 hours after the date of the transaction	EPCIS *Shipping* Event (eventTime)
	the business name and address of the person from whom ownership is being transferred	Party master data accompanying an EPCIS *Shipping* Event
	the business name and address of the person to whom ownership is being transferred	Party master data accompanying an EPCIS *Shipping* Event
Transaction History	Transaction History is a series of Transaction Information records	*there are no data attributes unique to Transaction History*

11 EPCIS Events for Lot-Level Management

There are two types of EPCIS events utilized for DSCSA lot-level management:

- The EPCIS *Shipping* event is used to record and exchange DSCSA lot-level information for each sale/transfer of ownership. Each trading partner records and exchanges this *Shipping* event for each sale/transfer of ownership.
- The EPCIS *Transformation* event is used in repackaging scenarios to record the relationship between the original product and the repackaged product.

11.1 Shipping Event

11.1.1 Populating a Shipping Event for Lot-Level Management

A *Shipping* event for lot-level management should be an EPCIS Object Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 8.2.1). In situations where DSCSA permits redaction of the date, the value 1970-01-01T00:00:00Z may be used instead.	EPCIS standard definition For purposes of DSCSA, this is considered the shipping date (when bizStep = shipping).
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
quantityList	Required	Complex Type	quantityElement *(see elements at the bottom of this table)*	List of LGTINS for the lowest saleable unit.
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The **disposition** value "in_transit" is always paired with the **bizStep** "shipping" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 8.2.2).	EPCIS standard definition
bizLocation	Omitted	URI	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, Business Location is always omitted for a *Shipping* event. (Note that extension elements in this event provide "Ship from" and "Ship to" information.)

Element	Usage	Type	Value	Reason
bizTransactionList	Optional	List of biz transactions	Business transactions governing this *Shipping* event, which may include a purchase order or an invoice (see Section 8.2.3 for details). (Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.)	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for PO, Invoice or other ID's.
sourceList	Required	List of sources	One source of type "owning Party" whose value is GLN of the transferring party. (Each source is represented as a pair of URIs: one URI for the type and one URI for the value.)	EPCIS standard definition
destinationList	Required	List of destinations	One destination of type "owning Party" whose value is GLN of the transferee party. (Each destination is represented as a pair of URIs: one URI for the type and one URI for the value.)	EPCIS standard definition
quantityElement elements				
epcClass	Required	String	LGTIN epcClass URI containing the GTIN and the lot of the individual saleable unit	
quantity	Required	Integer	The number of instances of GTIN/lot (specified by epcClass) that are shipped.	

11.1.2 Shipping Event Extension for Lot-Level Management

In addition to the EPCIS standard fields listed above, the following extension is also included in the EPCIS *Shipping* event for lot-level management. (See Chapter 15 for general notes about extensions.)

Element	Usage	Type	Value
transactionDate	Conditional *	Timestamp	The date in which the transfer of ownership occurred. Due to operational differences, it is possible for the shipping date (event time) to be different than the transaction date. *NOTE: DSCSA requires Transaction Date for *certain* shipments. Consult with your regulatory advisor to determine what is required for your products/shipments.
directPurchase	Optional	Boolean	`True` if products were purchased "directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer." (DSCSA, Sec. 582(c)(1)(A)(ii)(AA)) When this is `True`, the shipper may redact the lot number in this event and in prior transaction information for the same product, and also redact the eventTime and quantity in prior transaction information for the same product. Omitting this element is the same as specifying `false`.

Element	Usage	Type	Value
receivedADirectPurchase StatementFromPrevious WholesaleDistributor	Optional	Boolean	`True` if the product shipped in this event was received directly from a wholesaler who provided a direct purchase statement in its transaction information (see **directPurchase**). This must be true of all products listed in the event. When this is `True`, the shipper need not provide transaction information prior to the transaction information in which the direct purchase statement was included. Omitting this element is the same as specifying `false`.

11.1.3 EPCIS Header Extensions for Shipping Events for Lot-Level Management

In addition to the EPCIS standard fields listed above, the following data are also included in the EPCIS Header associated with a group of *Shipping* events for lot-level management.

Element	Usage	Type	Value
affirmTransactionStatement	Required	Boolean	True / False ***See Note below***
legalNotice	Optional	String	Any additional text the shipper wishes to provide to affirm the transaction statement.

Note: By indicating "True" to the "affirmTransactionStatement" attribute, the transfering company afirms all applicable statements included in DSCSA Sec. 581. (27), which reads:

"(27) TRANSACTION STATEMENT. — The 'transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction —

"(A) is authorized as required under the Drug Supply Chain Security Act;

"(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

"(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

"(D) did not knowingly ship a suspect or illegitimate product;

"(E) had systems and processes in place to comply with verification requirements under section 582;

"(F) did not knowingly provide false transaction information; and

"(G) did not knowingly alter the transaction history."

11.1.4 EPCIS Header Master Data for Lot-Level Management

Master data is included in the EPCIS Header of an EPCIS document for lot-level management. The content of this extension is a `VocabularyList` element that conforms to the EPCIS Master Data Schema. Within that element, there are three types of master data:

- trade item master data,
- company master data, and
- production lot master data.

11.1.4.1 Trade Item Master Data

Trade item master data is included in the `VocabularyList` element using a `Vocabulary` element whose type is `urn:epcglobal:epcis:vtype:EPCClass`. Each vocabulary element has an ID that is the EPC Pure Identity Pattern URI corresponding to the GTIN of the trade item. The attributes are defined below. Include one set of attributes for each trade item in all shipments included in the overall document.

Element	Usage	Type	Value
additionalTradeItemIdentification	Conditional *	String	The additional trade item identification associated with this GTIN. *For DSCSA, this is always the NDC in 11-digit format. NDC is required for DSCSA, but conditional for all other applications.
additionalTradeItemIdentificationTypeCode	Conditional *	String	The additional trade item identification type. *For DSCSA, this is always the value FDA_NDC_11
regulatedProductName	Required	String	The prescribed, regulated or generic product name or denomination that describes the true nature of the product and is sufficiently precise to distinguish it from other products according to country specific regulation. For DSCSA, this should exactly match the regulatory filing for the product.
manufacturerOfTradeItemPartyName	Required	String	Party name for the manufacturer of the trade item. For DSCSA, should be the name of the NDA holder.
dosageFormType	Required	String	Standard forms of drugs (AEROSOL, CAPSULE, GEL, PILL, TABLET) as defined by the FDA. The FDA currently defines 143 dosage forms.
strengthDescription	Required	String	Free text describing strength/potency of product, including unit of measure (e.g., 60 mg, 25 ml). This should match the regulatory filing for the product.
netContentDescription	Required	String	Free text describing the number of units contained in a package of product (for example, 60 Tablets, 100 ounces). This is also known as pack size. This should match the regulatory filing for the product.

11.1.4.2 Company Master Data

Company master data is included in the `VocabularyList` element using a `Vocabulary` element whose type is `urn:epcglobal:epcis:vtype:Location`. Each vocabulary element has an ID that is the EPC Pure Identity Pattern URI corresponding to the SGLN of the party. The attributes are defined below:

Element	Usage	Type	Value
name	Required	String	The name of the location or party expressed in text.
streetAddressOne	Required	String	The first line of the street address.
streetAddressTwo	Optional	String	The second line of the street address.
streetAddressThree	Optional	String	The third line of the street address.
city	Required	String	The city.

Element	Usage	Type	Value
state	Conditional	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Conditional	String	The ZIP or other postal code.
countryCode	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

11.1.4.3 Production Lot Master Data

Production Lot master data is included in the `VocabularyList` element using a `Vocabulary` element whose type is `urn:epcglobal:epcis:vtype:EPCClass`. Each vocabulary element has an ID that is the EPC Class URI corresponding to the LGTIN of the GTIN+lot. The attributes are defined below:

Element	Usage	Type	Value
itemExpirationDate	Required	Date	The expiration date for all of the EPCs in the epcList of the ObjectEvent, formatted as an xsd:date.

11.1.5 Shipping Event Example XML

This example shows both a single *Shipping* event from the manufacturer to a wholesaler/distributor, as well as an EPCIS Header that includes product master attributes and party master data for the source and destination.

```
<epcis:EPCISDocument
  xmlns:epcis="urn:epcglobal:epcis:xsd:1"
  xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
   xmlns:cbvmda="urn:epcglobal:cbv:mda"
  xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns"
  schemaVersion="1.2" creationDate="2014-05-30T15:14:27.574-04:00">
  <EPCISHeader>
    <sbdh:StandardBusinessDocumentHeader>
      <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
      <sbdh:Sender>
        <sbdh:Identifier Authority="SGLN">urn:epc:id:sgln:030000.000000.0</sbdh:Identifier>
      </sbdh:Sender>
      <sbdh:Receiver>
        <sbdh:Identifier Authority="SGLN">urn:epc:id:sgln:0614141.00000.0</sbdh:Identifier>
      </sbdh:Receiver>
      <sbdh:DocumentIdentification>
        <sbdh:Standard>EPCglobal</sbdh:Standard>
        <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
        <sbdh:InstanceIdentifier>1234567890</sbdh:InstanceIdentifier>
        <sbdh:Type>Events</sbdh:Type>
        <sbdh:CreationDateAndTime>2014-05-30T15:14:27.574-04:00</sbdh:CreationDateAndTime>
      </sbdh:DocumentIdentification>
    </sbdh:StandardBusinessDocumentHeader>
    <extension>
      <VocabularyList>
      <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
        <VocabularyElementList>
          <VocabularyElement id="urn:epc:class:lgtin:030000.0000001.L1">
            <attribute id="urn:epcglobal:cbv:mda#itemExpirationDate">2015-10-31</attribute>
              </VocabularyElement>
          <VocabularyElement id="urn:epc:idpat:sgtin:030000.0000001.*">
```

```
        <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">00000000001</attribute>
         <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">FDA_NDC_11</attribute>
        <attribute id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
        <attribute id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma
LLC</attribute>
        <attribute id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
        <attribute id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
        <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
       </VocabularyElement>
      </VocabularyElementList>
    </Vocabulary>
    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
      <VocabularyElementList>
       <VocabularyElement id="urn:epc:id:sgln:030000.000000.0">
        <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
        <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George Ave</attribute>
             <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
             <attribute id="urn:epcglobal:cbv:mda#city">Washington</attribute>
             <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
             <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-6789</attribute>
             <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
       </VocabularyElement>
       <VocabularyElement id="urn:epc:id:sgln:0614141.00000.0">
        <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro LLC</attribute>
        <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
             <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
             <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
             <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-1502</attribute>
             <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
       </VocabularyElement>
      </VocabularyElementList>
    </Vocabulary>
     </VocabularyList>
   </extension>
    <gs1ushc:dscsaTransactionStatement>
    <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
    <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA Sec.
581(27)(A)-(G).</gs1ushc:legalNotice>
   </gs1ushc:dscsaTransactionStatement>

 </EPCISHeader>
 <EPCISBody>
  <EventList>
   <ObjectEvent>
    <eventTime>2014-04-01T10:11:12Z</eventTime>
    <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
    <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:030000.000000.0</id>
    </readPoint>
    <extension>
     <quantityList>
      <quantityElement>
       <epcClass>urn:epc:class:lgtin:030000.0000001.L1</epcClass>
       <quantity>100</quantity>
      </quantityElement>
```

```
      </quantityList>
      <sourceList>
        <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030000.000000.0</source>
      </sourceList>
      <destinationList>
        <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:0614141.00000.0</destination>
      </destinationList>
     </extension>
    </ObjectEvent>
   </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

11.2 Transformation Event for Repackaging

The EPCIS *Transformation* event is used in repackaging scenarios to record the relationship between the original product and the repackaged product. A *Transformation* event for lot-level management should be an EPCIS *Transformation* Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 8.2.1)	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
inputQuantityList	Required	Complex Type	quantityElement *(see elements at the bottom of this table)*	List of LGTINs that are the *inputs* to the repackaging process; the products that are consumed to create the repackaged product
outputQuantityList	Required	Complex Type	quantityElement *(see elements at the bottom of this table)*	List of LGTINs that are the *outputs* of the repackaging process; the repackaged products that are produced.
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:commissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:active	CBV standard definition. The **disposition** value "active" is always paired with the **bizStep** "commissioning" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 8.2.2).	EPCIS standard definition
bizLocation	Optional	URI	The location where the objects are presumed to be following the event.	EPCIS standard definition
bizTransactionList	Optional	List of biz transactions	Business transactions governing this *Transformation* event, which may include a purchase order or an invoice (see Section 8.2.3 for details). (Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.)	Optional
quantityElement elements				
epcClass	Required	String	LGTIN epcClass URI containing the GTIN and the lot	
quantity	Required	Integer	The number of instances of GTIN/lot (specified by epcClass) that are consumed as input or produced as output.	

11.2.1 Transformation Event Example XML

This example shows a shipping event from a repackager who purchased product indirectly from a wholesaler/distributor. After the product is repackaged, the product is then sold by the repackager to a dispenser. This example XML shows both a shipping event and a transformation event to record the relationship between the original product and the repackaged product.

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<!-- Lot Choreography End to End Examples: REPACKAGING - EXAMPLE 4: R/W2->D -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gs1ushc="http://epcis.gs1us.org/hc/ns" xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2" xsi:schemaLocation="urn:epcglobal:epcis:xsd:1 EPCglobal-epcis-1_2.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" creationDate="2014-06-02T15:14:27.574-
04:00">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>
            <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
            <sbdh:Sender>
                <sbdh:Identifier
Authority="SGLN">urn:epc:id:sgln:0353579.00001.0</sbdh:Identifier>
            </sbdh:Sender>
            <sbdh:Receiver>
                <sbdh:Identifier
Authority="SGLN">urn:epc:id:sgln:5012345.00000.0</sbdh:Identifier>
            </sbdh:Receiver>
            <sbdh:DocumentIdentification>
                <sbdh:Standard>EPCglobal</sbdh:Standard>
                <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                <sbdh:InstanceIdentifier>1234567890</sbdh:InstanceIdentifier>
                <sbdh:Type>Events</sbdh:Type>
                <sbdh:CreationDateAndTime>2014-06-02T15:14:27.574-04:00</sbdh:CreationDateAndTime>
            </sbdh:DocumentIdentification>
        </sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                        <VocabularyElementList>
                            <VocabularyElement id="urn:epc:idpat:sgtin:030000.0000001.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">00000000001</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">FDA_NDC_11</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500
pills</attribute>
                            </VocabularyElement>
                            <VocabularyElement id="urn:epc:idpat:sgtin:0353579.012610.*">
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">53579012610</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">FDA_NDC_11</attribute>
                                <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">REpcistra</attribute>
```

```
                        <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Repackager LLC</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
                        <attribute
id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#netContentDescription">250
pills</attribute>
                    </VocabularyElement>
                </VocabularyElementList>
            </Vocabulary>
            <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                <VocabularyElementList>
                    <VocabularyElement id="urn:epc:id:sgln:030000.000000.0">
                        <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George
Ave</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                    </VocabularyElement>
                    <VocabularyElement id="urn:epc:id:sgln:0353579.00001.0">
                        <attribute id="urn:epcglobal:cbv:mda#name">GS1 Repackager
LLC</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">201 Broadway
Ave</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Bldg
10</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#city">Cambridge</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#state">MA</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#postalCode">02138</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                    </VocabularyElement>
                    <VocabularyElement id="urn:epc:id:sgln:0614141.00000.0">
                        <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave
S</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                    </VocabularyElement>
                    <VocabularyElement id="urn:epc:id:sgln:5012345.00000.0">
                        <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pere et Fils
Pharmacy</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1313
Mockingbird Lane</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#city">Paris</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#state">TX</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#postalCode">76543</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                    </VocabularyElement>
                </VocabularyElementList>
            </Vocabulary>
        </VocabularyList>
    </EPCISMasterData>
```

```
      </extension>
      <gs1ushc:dscsaTransactionStatement>
         <gs1ushc:affirmTransactionStatement>true</gs1ushc:affirmTransactionStatement>
         <gs1ushc:legalNotice>Seller has complied with each applicable subsection of FDCA Sec.
581(27)(A)-(G). As indicated below, product was purchased directly from the manufacturer,
manufacturer's exclusive distributor or repackager who purchased directly from a
manufacturer.</gs1ushc:legalNotice>
      </gs1ushc:dscsaTransactionStatement>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
         <!-- Transaction History (TH) for M to W1 -->
         <ObjectEvent>
            <eventTime>1970-01-01T00:00:00.000Z</eventTime>
            <eventTimeZoneOffset>+00:00</eventTimeZoneOffset>
            <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:030000.000000.0</id>
            </readPoint>
            <extension>
               <quantityList>
                  <quantityElement>
                     <epcClass>urn:epc:class:lgtin:030000.0000001.L1</epcClass>
                     <quantity>100</quantity>
                  </quantityElement>
               </quantityList>
               <sourceList>
                  <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030000.000000.0</source>
               </sourceList>
               <destinationList>
                  <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:0614141.00000.0</destination>
               </destinationList>
            </extension>
         </ObjectEvent>
         <!-- Transaction History (TH) of sale for W1 to R/W2 -->
         <ObjectEvent>
            <eventTime>2014-04-01T11:00:00.000-04:00</eventTime>
            <eventTimeZoneOffset>-04:00</eventTimeZoneOffset>
            <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:0614141.00000.0</id>
            </readPoint>
            <extension>
               <quantityList>
                  <quantityElement>
                     <epcClass>urn:epc:class:lgtin:030000.0000001.L1</epcClass>
                     <quantity>100</quantity>
                  </quantityElement>
               </quantityList>
               <sourceList>
                  <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:0614141.00000.0</source>
               </sourceList>
```

```
                <destinationList>
                    <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:0353579.00001.0</destination>
                </destinationList>
            </extension>
        </ObjectEvent>
        <extension>
            <TransformationEvent>
                <eventTime>2014-06-01T11:00:00.000-04:00</eventTime>
                <eventTimeZoneOffset>-04:00</eventTimeZoneOffset>
                <inputQuantityList>
                    <quantityElement>
                        <epcClass>urn:epc:class:lgtin:030000.0000001.L1</epcClass>
                        <quantity>100</quantity>
                    </quantityElement>
                </inputQuantityList>
                <outputQuantityList>
                    <quantityElement>
                        <epcClass>urn:epc:class:lgtin:0353579.012610.L123</epcClass>
                        <quantity>200</quantity>
                    </quantityElement>
                </outputQuantityList>
                <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
                <disposition>urn:epcglobal:cbv:disp:active</disposition>
                <readPoint>
                    <id>urn:epc:id:sgln:0353579.00001.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:0353579.00001.0</id>
                </bizLocation>
            </TransformationEvent>
        </extension>
        <!-- Transaction Information (TI) -->
        <ObjectEvent>
            <eventTime>2014-06-02T11:00:00.000-04:00</eventTime>
            <eventTimeZoneOffset>-04:00</eventTimeZoneOffset>
            <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:0353579.00001.0</id>
            </readPoint>
            <extension>
                <quantityList>
                    <quantityElement>
                        <epcClass>urn:epc:class:lgtin:0353579.012610.L123</epcClass>
                        <quantity>200</quantity>
                    </quantityElement>
                </quantityList>
                <sourceList>
                    <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:0353579.00001.0</source>
                </sourceList>
                <destinationList>
                    <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:5012345.00000.0</destination>
                </destinationList>
            </extension>
```

```
    <gs1ushc:receivedADirectPurchaseStatementFromPreviousWholesaleDistributor>true</gs1ushc:rece
ivedADirectPurchaseStatementFromPreviousWholesaleDistributor>
          </ObjectEvent>
       </EventList>
    </EPCISBody>

         </epcis:EPCISDocument>
```

Part III. Application of EPCIS for Serialized Item-Level Traceability

Phase 3 of the DSCSA establishes package level requirements for the interoperable, electronic tracing of products. This will involve sharing chain-of-ownership data in a manner that allows for serialized item traceability back to the product origin (usually the manufacturer), including the electronic exchange of transaction information for each sale of certain prescription drugs and verification of product identifiers at the package level.

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 provides the data needed to support serialized item-level traceability. This Part we specify the minimum set of EPCIS events to support serialized item-level traceability pursuant to Phase 3 of the DSCSA. Key points:

- Events will be captured at the instance-level, where an instance is identified by a GTIN+serial (item or homogeneous case) or SSCC (heterogeneous case or pallet).
- DSCSA change-of-ownership transaction information is integrated into the EPCIS *Shipping* event. Each trading partner records and exchanges this *Shipping* event for each sale/transfer of ownership.
- EPCIS *Packing* and *Unpacking* events record the packaging hierarchy of item to case to pallet. To the extent that *Shipping* events reference only outer-level identifiers, accompanying *Packing* and *Unpacking* events provide the details of what is inside the outer containers.
- EPCIS *Commissioning* events provide a means for the manufacturer to affirm the validity of serial numbers (and for any party to affirm the validity of an SSCC), as well as to provide associated product master data.
- EPCIS *Receiving*, *Void Shipping*, *Dispensing*, *Decommissioning*, and *Destroying* events, as well as EPCIS error declarations, are specified to provide a standardized way to record the complete lifecycle of products for business purposes beyond DSCSA compliance.
- A suitable collection of the above events comprises the Transaction Information, and Transaction History **(DSCSA sunsets the TH requirement as November 27, 2023)** for purposes of DSCSA. Those events may be collected into a single EPCIS Document, with a **Transaction Statement** included in the EPCIS Document header, in order to create a single XML document containing all DSCSA-required information (Transaction Information, Transaction History **(TH sunset as of November 2023)**, and **Transaction Statement**) for a transaction. To avoid repetition of product master data (e.g., drug name, dosage form, etc.) and party/location master data (e.g., postal address), such attributes are also carried in the header of the EPCIS document rather than repeated within each EPCIS event.
- The specification of EPCIS events and master data in this guideline is also intended to support a possible future state where event and master data are shared on-demand through EPCIS queries rather than through point-to-point delivery of EPCIS documents.
- Supply chain parties may collect additional EPCIS events not required for lot-level management or item-level traceability. These events are used for other business applications.

12 Overview of Serialized Item-Level Traceability Concepts

For purposes of serialized item traceability, each party in the supply chain captures and shares 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 to be captured by each party for serialized item traceability is provided below. Detailed definitions of each EPCIS event are specified in subsequent subsections in this section.

12.1 Events Captured and Shared by the Party at the Beginning of the Supply Chain (e.g., manufacturer)

- **Commissioning Events (Section 14.1)** declaring that specified serial numbers have been introduced into the supply chain and providing information about the corresponding products.
- **Packing Events (Section 14.2)** providing the hierarchical relationships (e.g., item-to-case, case-to-pallet) between objects as they exist at the point of shipping. The beginning-of-supply-chain 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 14.3)** indicating that objects have been shipped to a downstream trading partner and providing serialized item-level traceability 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.

12.2 Events Captured and Shared by Intermediate Parties (e.g., distributor)

- **Receiving Events (Section 14.4)** indicating that objects have been received from an upstream trading partner and providing traceability 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 14.5), Commissioning Events (Section 14.1), and Packing Events (Section 14.2)** 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 14.3)** indicating that objects have been shipped to a downstream trading partner and providing serialized item-level traceability 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).

12.3 Events Captured and Shared by the Party at the End of the Supply Chain (e.g., Hospital, Pharmacy, etc.)

- **Receiving Events (Section 14.4)** indicating that objects have been received from an upstream trading partner and providing serialized item-level traceability 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 14.5) and Packing Events (Section 14.2)** 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 14.6), Destroying (Section 14.7), and Decommissioning (Section 14.8)** represent business processes that occur at the end of the supply chain (typically at a hospital or pharmacy) indicating that specific products have been removed from the supply chain. (NOTE: Periodically, end-of-life events could occur with earlier trading partners in the supply chain.)

12.4 Events Captured and Shared by a Party for Exception Processing

- **Void Shipping Events (Section 14.9)** indicating that objects previously indicated has having been shipped by their appearance in one or more prior *Shipping* events were, in fact, not shipped. This event is created by a shipper upon discovery that the prior *Shipping* event is in error.
- **Error Declaration Events (Section 14.10)** used to indicate that a prior EPCIS event is in error and should be disregarded in its entirety.

This remainder of Part defines individual EPCIS events for different steps in the pharmaceutical supply chain process for serialized item traceability purposes. Some of these events are required for DSCSA compliance as well as for other traceability applications; others are defined for the benefit of traceability applications but are not required for DSCSA compliance.

13 DSCSA Item-Level Data Elements

DSCSA 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, traceability information includes both the unique identifier for a pharmaceutical product (i.e., the GTIN), as well as its dose and strength information. When using EPCIS events to provide DSCSA content, the GTIN is present in the EPCIS event data itself, while the dose and strength information is obtained from the master data associated with the GTIN.

A list of the DSCSA data elements (from the DSCSA law) is provided in the table below.

Table 13-1 DSCSA Item-Level Data Elements

Type of Information	DSCSA Data Attribute	EPCIS SEGMENT
Transaction Statement	affirmTransactionStatement	dscsaTransactionStatement extension
	directPurchase	*Shipping* event Extension
Transaction Information	the proprietary or established name or names of the product	GTIN-level product master data accompanying an EPCIS *Commissioning* Event
	the strength and dosage form of the product	GTIN-level product master data accompanying an EPCIS *Commissioning* Event
	the NDC number of the product	GTIN-level product master data accompanying an EPCIS *Commissioning* Event
	the container size	GTIN-level product master data accompanying an EPCIS *Commissioning* Event
	the number of containers	Calculated from EPCIS *Shipping* Event, and associated *Aggregation* Event
	the lot number of the product	Instance-level product master data in the Instance/Lot Master Data (ILMD) section of an EPCIS *Commissioning* Event
	the date of the transaction	If the date of the shipment is less than 24 hours after the date of the transaction, then use EPCIS *Shipping* Event (eventTime). If the date of the shipment is more than 24 hours after the date of the transaction, then use *Shipping* Event Extension (transactionDate)
	the date of the shipment, if more than 24 hours after the date of the transaction	EPCIS *Shipping* Event (eventTime)
	the business name and address of the person from whom ownership is being transferred	Party master data accompanying an EPCIS *Shipping* Event
	the business name and address of the person to whom ownership is being transferred	Party master data accompanying an EPCIS *Shipping* Event
Transaction History	Transaction History is a series of Transaction Information records	*there are no data attributes unique to transaction history*

14 EPCIS Events for Serialized Item-Level Traceability

14.1 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.

14.1.1 Populating a Commissioning Event

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

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section *8.2.1*).	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the commissioned item in EPC Pure Identity URI format. ▪ If more than one EPC is included, they should all have the same value for ILMD attributes defined below, or should all require these attributes to be omitted. ▪ EPCs having different values for these attributes should be shared in different *Commissioning* events.	Because the ILMD attributes below are at the *event-level*, they should be the same for all EPCs in the event.
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:commissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:active	CBV standard definition: the disposition value "active" is always used with the bizStep "commissioning."
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 8.2.2).	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 8.2.2).	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions	Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	Omitted in *Commissioning* events as there are no relevant business transactions to share.

14.1.2 Commissioning Event Instance/Lot Master Data (ILMD) Attributes

In addition to the EPCIS standard fields shown above, the following Instance/Lot Master Data (ILMD) attributes are also included in a *Commissioning* event. All of these ILMD attributes are defined in the EPCIS Core Business Vocabulary (CBV), and are in namespace `urn:epcglobal:cbv:mda`.

Element	Usage	Type	Value
lotNumber	Conditional *(see rules in the next sections)*	String	The lot or batch number for all of the EPCs in the epcList of the ObjectEvent.
itemExpirationDate	Conditional *(see note below)*	Date	The expiration date for all of the EPCs in the epcList of the ObjectEvent, formatted as an xsd:date. (See Section 6.1.1.1.4 for rules for expressing expiration date.)

14.1.3 Commissioning Event Master Data

When an EPCIS document includes one or more *Commissioning* events, the EPCIS header should contain master data including the following attributes for each distinct GTIN referenced in any *Commissioning* event. Note that if several *Commissioning* events in the same EPCIS document reference the same GTIN, the master data attributes for that GTIN need only be included *once* in the header.

All of the following master data attributes are defined in the EPCIS Core Business Vocabulary (CBV), and are in namespace `urn:epcglobal:cbv:mda`.

Element	Usage	Type	Value
additionalTradeItemIdentification	Conditional *	String	The additional trade item identification associated with this GTIN. *Always an NDC in 11-digit format for DSCSA.
additionalTradeItemIdentificationTypeCode	Conditional *	String	The additional trade item identification type. *For DSCSA, this is always the value FDA_NDC_11.
regulatedProductName	Required	String	The prescribed, regulated or generic product name or denomination that describes the true nature of the product and is sufficiently precise to distinguish it from other products according to country specific regulation. For DSCSA, this should exactly match the regulatory filing for the product.
manufacturerOfTradeItemPartyName	Required	String	Party name information for the manufacturer of the trade item. For DSCSA, this should be the name of the NDA holder.
dosageFormType	Required	String	Standard forms of drugs (AEROSOL, CAPSULE, GEL, PILL, TABLET) as defined by the FDA. The FDA currently defines 143 dosage forms.
strengthDescription	Required	String	Free text describing the strength or potency of the product, including the unit of measure (for example, 60 mg, 25 ml). This should match the regulatory filing for the product.
netContentDescription	Required	String	Free text describing the number of units contained in a package of the product (for example, 60 Tablets, 100 ounces). This is also known as pack size. This should match the regulatory filing for the product.

14.1.4 Commissioning Object Event Rules

- `ObjectEvents` for commissioning item serial numbers SHOULD include the ILMD elements to define the lot number and expiration date, and the containing EPCIS Document SHOULD include the GTIN-level product master data.
- `ObjectEvents` for commissioning homogeneous containers (e.g., cases and pallets of the same object) MAY include the ILMD elements to define the lot number and expiration date, and the containing EPCIS Document MAY include the GTIN-level product master data.
- `ObjectEvents` for commissioning non-homogeneous containers (e.g., cases and pallets of different items, lots, etc.) SHOULD NOT include the ILMD elements to define the lot number and expiration date, and the containing EPCIS Document SHOULD NOT include GTIN-level product master data (except to the extent that the same document contains other *Commissioning* events that do indicate the inclusion of product master data for the same GTINs).
- All of the EPCs within a single *Commissioning* event SHALL either be item serial numbers and/or homogeneous containers having the same lot number and expiration date or be non-homogeneous containers. Multiple *Commissioning* events SHALL be used for EPCs that differ in lot number or expiration date, or for non-homogeneous containers vs. items and homogeneous containers. (This is because the lot number and expiration date given in a single *Commissioning* event applies to *all* of the EPCs in that event.)

14.1.5 XML Example of a Commissioning Event

This example shows both a single *Commissioning* event including the ILMD section that provides instance-level master data, as well as an EPCIS Header that includes GTIN-level product master data.

```
<epcis:EPCISDocument
     xmlns:cbvmda="urn:epcglobal:cbv:mda"
     xmlns:epcis="urn:epcglobal:epcis:xsd:1"
     schemaVersion="1.2"
     creationDate="2012-03-25T17:10:16Z">
  <EPCISHeader>
    <sbdh:StandardBusinessDocumentHeader>...</sbdh:StandardBusinessDocumentHeader>
    <extension><EPCISMasterData>
    <VocabularyList>
      <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
        <VocabularyElementList>
          <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
            <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">00001012345</attribute>
            <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">FDA_NDC_11</attribute>
       <attribute id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
       <attribute id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma
LLC</attribute>
       <attribute id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
       <attribute id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
       <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
          </VocabularyElement>
        </VocabularyElementList>
      </Vocabulary>
     </VocabularyList>
    </EPCISMasterData></extension>
  </EPCISHeader>
  <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>
        <extension>
          <ilmd>
            <cbvmda:lotNumber>A123</cbvmda:lotNumber>
            <cbvmda:itemExpirationDate>2015-03-15</cbvmda:itemExpirationDate>
          </ilmd>
        </extension>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

14.2 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.

14.2.1 Populating a Packing Event

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

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 8.2.1).	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
parentID	Required	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition
childEPCs	Required	List of URI	EPC(s) of the item(s) being packed into the parent presented in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:packing	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 8.2.2).	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 8.2.2).	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions	Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	Omitted in the *Packing* event as there are no relevant business transactions to share.

14.2.2 XML Example of a Packing Event

```
<epcis:EPCISDocument
   xmlns:epcis="urn:epcglobal:epcis:xsd:1"
   schemaVersion="1.2"
   creationDate="2012-03-26T17:10:16Z">
  <EPCISBody>
    <EventList>
      <AggregationEvent>
        <eventTime>2012-03-26T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <parentID>urn:epc:id:sgtin:030001.1012345.22222223333</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>
      </AggregationEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

14.3 Shipping

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

14.3.1 Populating a Shipping Event

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

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 8.2.1).	EPCIS standard definition. For purposes of DSCSA, this is considered the shipping date (when bizStep = shipping).
eventTimeZone Offset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	The EPC(s) of the outermost containers in the packaging hierarchy. Most likely, SSCCs of Cases or Pallets.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. **disposition** value "in_transit" is always paired with **bizStep** "shipping" for forward logistics
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 8.2.2).	EPCIS standard definition
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 8.2.2).	For a *Shipping* event, this is unknown until a *Receiving* event occurs. Thus, bizLocation is always omitted in *Shipping* events. (Note: **source** and **destination** elements in this event provide "Ship from/to" and "Transfer from/to" information.)
bizTransaction List	Optional	List of biz transactions	Business transactions governing this *Shipping* event, which may include a purchase order or an invoice (see Section 8.2.3 for details). Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. If more than one business transaction of the same type is included, then this event does not specify which objects in the epcList are associated with which business transaction. Optionally, the shipper may include one or more *Shipping Transaction Detail* events (Section 14.3.5) to associate specific objects with each business transaction.	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for PO, Invoice or other ID's.

Element	Usage	Type	Value	Reason
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party whose value is the EPC Pure Identity URI for the GLN of the transferring party. If the ship-from GLN is different from the transferring party's GLN, sourceList shall also include a second source of type urn:epcglobal:cbv:sdt:location whose value is the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list.	Optional in the EPCIS standard, but required in this guideline to provide party information for DSCSA.
destinationList	Required	List of destinations	Each destination in the destinationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type urn:epcglobal:cbv:sdt:owning_party whose value is the EPC Pure Identity URI for the GLN of transfer-to party. If ship-to GLN is different from the transfer-to party's GLN, destinationList shall also include a second destination of type urn:epcglobal:cbv:sdt:location whose value is EPC Pure Identity URI of ship-to GLN. Each GLN URI must match one of the companies in the company master data list.	Optional in the EPCIS standard, but required in this guideline to provide party information for DSCSA.

14.3.2 Shipping Event Extension

In addition to the EPCIS standard fields listed above, the following extension fields may also be included in the EPCIS *Shipping* event. (See Section 8.3 for general notes about extensions.)

Element	Usage	Type	Value
transactionDate	Conditional *	Timestamp	The date in which the transfer of ownership occurred. Due to operational differences, it is possible for the shipping date (event time) to be different than the transaction date. * NOTE: DSCSA requires Transaction Date for *certain* shipments. Consult with your regulatory advisor to determine what is required for your products/shipments.
directPurchase	Optional	Complex Type *(see elements at bottom of this table)*	Used to indicate if products were purchased directly from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that purchased directly from the manufacturer. ▪ If the directPurchaseEPCs sub-element is omitted, the directPurchase field applies to all products in the shipment, including product contained inside the packages listed explicitly in the shipping event. ▪ If directPurchaseEPCs sub-element is included, the directPurchase field applies only to those products whose identifiers are explicitly listed in the directPurchaseEPCs sub-element, including product contained inside packages listed explicitly in directPurchaseEPCs.
directPurchase elements (see note below)			
@value	Required	Boolean	True if products were purchased directly from the manufacturer, from the exclusive distributor of the manufacturer, or from a repackager that purchased directly from the manufacturer. ▪ If the directPurchaseEPCs sub-element is omitted, this applies to all products in the shipment, including product contained inside the packages listed explicitly in the shipping event. ▪ If the directPurchaseEPCs sub-element is included, this applies only to those products whose identifiers are explicitly listed in the directPurchaseEPCs, including product contained inside packages listed explicitly in the directPurchaseEPCs.
directPurchaseEPCs	Optional	List of URI	If specified, limits the applicability of the directPurchase statement to the specified products or packages, including product contained inside any specified package. Each EPC shall either be: ▪ an EPC listed in the main epcList of this *Shipping* event, **or** ▪ an EPC that is aggregated to one of the EPCs listed in the main epcList of this *Shipping* event. If omitted, the directPurchase statement applies to all products in this *Shipping* event.

Note: Since the shipping content can be a mixture of direct and indirect purchases, two variations for the direct purchase extension to *Shipping* event are supported by the *directPurchase* data construct. The following examples illustrate the two variations for the direct purchase extension to the *Shipping* event:

Variation 1: All products on the pallets named in this shipping event are direct purchased products.

```
<gs1ushc:directPurchase value="true"/>
```

Variation 2: A subset of the products contained in the *Shipping* event are directly purchased.

Below is an example of a shipping event scenario containing three pallets, wherein pallet #1 is directly purchased, two out of the four cases inside pallet #2 are directly purchased, and pallet #3 is indirectly purchased.

```
<gs1ushc:directPurchase value="true">
  <directPurchaseEPCs>
    <!-- Pallet#1 and all of its contents are directly purchased. The EPC
below is the SSCC of Pallet #1 -->
    <epc>urn:epc:id:sscc:030001.02468024680</epc>
    <!-- Pallet#2 contains 4 homogeneous cases but only case1 and case2
are directly purchased. The two EPCs below are the SGTINs of those two
cases. -->
    <epc>urn:epc:id:sgtin:030001.1123456.400</epc>
    <epc>urn:epc:id:sgtin:030001.1123456.401</epc>
  </directPurchaseEPCs >
</gs1ushc:directPurchase>
```

14.3.3 Shipping Event Master Data

When an EPCIS document includes one or more *Shipping* events, the EPCIS header should contain master data including the following attributes for each distinct party or location referenced in the source list or destination list of any *Shipping* event. Note that if several *Shipping* events in the same EPCIS document reference the same party or location, the master data attributes for that party or location need only be included *once* in the header.

party or location master data elements *(include one set of attributes for each trading partner found in any Shipping event within scope of the header. This group of attributes may be available via an EPCIS query in future versions of this guideline.)*			
name	Required	String	The name of the location or party expressed in text
streetAddressOne	Required	String	The first line of the street address.
streetAddressTwo	Optional	String	The second line of the street address.
streetAddressThree	Optional	String	The third line of the street address.
city	Required	String	The city.
state	Conditional	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Conditional	String	The ZIP or other postal code.
countryCode	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

14.3.4 XML Example of a Shipping Event

This example shows both a single *Shipping* event, as well as an EPCIS Header that includes party master data for the source and destination.

```
<epcis:EPCISDocument
     xmlns:cbvmda="urn:epcglobal:cbv:mda"
     xmlns:epcis="urn:epcglobal:epcis:xsd:1"
     schemaVersion="1.2"
     creationDate="2012-03-27T17:10:16Z">
  <EPCISHeader>
    <sbdh:StandardBusinessDocumentHeader>...</sbdh:StandardBusinessDocumentHeader>
    <extension><EPCISMasterData>
    <VocabularyList>
      <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
        <VocabularyElementList>
          <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George
Ave</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
            <attribute id="urn:epcglobal:cbv:mda#city">Washington</attribute>
            <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-6789</attribute>
            <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
          </VocabularyElement>
          <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro LLC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
            <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
            <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
            <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-1502</attribute>
            <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
          </VocabularyElement>
       </VocabularyElementList>
      </Vocabulary>
     </VocabularyList>
    </EPCISMasterData></extension>
  </EPCISHeader>
  <EPCISBody>
    <EventList>
      <ObjectEvent>
       <eventTime>2012-03-27T17:10:16Z</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>
       <extension>
```

```
        <sourceList>
          <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
        </sourceList>
        <destinationList>
          <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
        </destinationList>
      </extension>
    </ObjectEvent>
  </EventList>
 </EPCISBody>
</epcis:EPCISDocument>
```

14.3.5 Shipping Business Transaction Detail Event

As specified in Section 14.3.5, a *Shipping* event may optionally contain references to business transactions such as purchase orders or invoices. In some cases, a shipment may contain objects that belong to two or more business transactions of the same type (two or more purchase orders, two or more invoices, etc.). Separate *Shipping* events may be used so that each *Shipping* event only refers to a single business transaction of each type.

Sometimes, however, a single object listed in the `epcList` of a *Shipping* event contains objects belonging to two or more business transactions; for example, a single pallet (identified by SSCC) that contains several cartons belonging to one purchase order and several more cartons belonging to a different purchase order. In this situation, the *Shipping* event will list the pallet identifier in the `epcList`, and list both purchase orders in the `bizTransactionList`. The *Shipping* event itself, therefore, does not indicate which cartons belong to which purchase order.

In such situations, the shipper may optionally include one or more *Shipping Business Transaction Detail* events as specified in this section. Each *Shipping Business Transaction Detail* indicates a single business transaction of a given type, and in its `epcList` indicates just those objects that are associated with that business transaction. These may be objects that are contained within the objects listed in the corresponding *Shipping* event. In the example above, each *Shipping Business Transaction Detail* event would list the identifiers of the cartons (SSCCs or SGTINs) that belong to a given purchase order.

A *Shipping Business Transaction Detail* event shall be an EPCIS Transaction Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 8.2.1). This should match the date and time of the corresponding *Shipping* event.	EPCIS standard definition For purposes of DSCSA, this is considered the shipping date (when bizStep = shipping).
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	▪ EPC Pure Identity URI for each object associated with the business transactions listed in this event. ▪ If the EPC of a container is indicated, all of its contents are associated with the business transaction.	EPCIS standard definition

Element	Usage	Type	Value	Reason
action	Required	String	ADD	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_transit	CBV standard definition. The **disposition** value "in_transit" is always paired with the **bizStep** "shipping" for forward logistics.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 8.2.2). This should match the readPoint of the corresponding *Shipping* event.	EPCIS standard definition
bizLocation	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 8.2.2).	For a *Shipping* event, this is unknown until a *Receiving* event occurs. Thus, bizLocation is always omitted in *Shipping* events.
bizTransaction List	Required	List of biz transactions	Business transactions governing this *Shipping Business Transaction Detail* event, which may include a purchase order or an invoice (see Section 8.2.3 for details). Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. In a *Shipping Business Transaction Detail* event, only one business transaction of a given type shall be included.	EPCIS standard definition

14.3.5.1 XML Example of a Shipping Business Transaction Detail Event

This example shows both a single *Shipping* event, as well as an EPCIS Header that includes party master data for the source and destination.

```
<epcis:EPCISDocument
     xmlns:cbvmda="urn:epcglobal:cbv:mda"
     xmlns:epcis="urn:epcglobal:epcis:xsd:1"
     schemaVersion="1.2"
     creationDate="2012-03-27T17:10:16Z">
  <EPCISBody>
   <EventList>
     <TransactionEvent>
       <eventTime>2012-03-27T17:10:16Z</eventTime>
       <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
       <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>
```

```
      <epcList>
        <epc>urn:epc:id:sgtin:030001.1012345.22222223333</epc>
        <epc>urn:epc:id:sgtin:030001.1012345.22222224444</epc>
      </epcList>
      <action>ADD</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>
    </TransactionEvent>
  </EventList>
 </EPCISBody>
</epcis:EPCISDocument>
```

14.3.5.2 XML Example of a Shipment Covered by Multiple Purchase Orders

This example shows how to capture a shipment containing 3 pallets with SSCCs and illustrates how to associate 2 Purchase Orders (POs) to the specific shipment content.

- SSCC 003000100000001012 is the first pallet with all of its contents covered by PO# 1234.
- SSCC 003000100000001029 is the second pallet with all of its contents covered by PO# 4567.
- SSCC 003000100000001036 is the third pallet which contains 5 cases of which:
  - 2 cases (SGTINs with serials 401, 402) belong to PO# 1234 and
  - 3 cases (SGTINs with serials 501, 502, 503) belong to PO#4567.

This XML example shows one *Shipping* event and two additional *Shipping Business Transaction Detail* events to map the specific content to individual POs.

```
<?xml version="1.0" encoding="UTF-8"?>
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:epcis="urn:epcglobal:epcis:xsd:1" schemaVersion="1.2" creationDate="2016-03-
15T10:11:16Z">
    <EPCISHeader>
        <sbdh:StandardBusinessDocumentHeader>...</sbdh:StandardBusinessDocumentHeader>
        <extension>
            <EPCISMasterData>
                <VocabularyList>
                    <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                        <VocabularyElementList>
                            <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George
Ave</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#city">Washington</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-
6789</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                            </VocabularyElement>
                            <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                                <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                                <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave
S</attribute>
```

```
                        <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
378</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-
1502</attribute>
                        <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                    </VocabularyElement>
                </VocabularyElementList>
            </Vocabulary>
        </VocabularyList>
    </EPCISMasterData>
  </extension>
</EPCISHeader>
<EPCISBody>
  <EventList>
    <!-- Shipping event for 3 SSCCs 101, 102, and 103.
                    Shipment is covered by 2 Purchase Orders (POs) #1234 and #4567. -->
    <ObjectEvent>
      <eventTime>2016-03-15T10:11:12Z</eventTime>
      <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
      <epcList>
        <epc>urn:epc:id:sscc:030001.00000000101</epc>
        <epc>urn:epc:id:sscc:030001.00000000102</epc>
        <epc>urn:epc:id:sscc:030001.00000000103</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>
        <!-- Both PO# 1234 and PO#4567 are associated with this shipment -->
        <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:1234</bizTransaction>
        <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:4567</bizTransaction>
      </bizTransactionList>
      <extension>
        <sourceList>
          <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
        </sourceList>
        <destinationList>
          <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
        </destinationList>
      </extension>
    </ObjectEvent>
    <!-- Using a Transaction Event, record the shipping contents specifically associated
with PO# 1234 -->
    <TransactionEvent>
                    <!-- Use the same eventTime in the transaction event as in the
shipping event -->
      <eventTime>2016-03-15T10:11:12Z</eventTime>
      <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
      <bizTransactionList>
        <!-- Associate PO# 1234 to the EPCs in the business transaction -->
        <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:1234</bizTransaction>
```

```
            </bizTransactionList>
            <epcList>
               <epc>urn:epc:id:sscc:030001.00000000101</epc>
               <epc>urn:epc:id:sgtin:030001.1123456.401</epc>
               <epc>urn:epc:id:sgtin:030001.1123456.402</epc>
            </epcList>
            <action>ADD</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>
         </TransactionEvent>
         <!-- Use the same eventTime in the transaction event as in the shipping event -->
         <TransactionEvent>
            <eventTime>2016-03-15T10:11:12Z</eventTime>
            <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
            <bizTransactionList>
               <!-- Associate PO# 4567 to the EPCs in the business transaction -->
               <bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:0399999999991:4567</bizTransaction>
            </bizTransactionList>
            <epcList>
               <epc>urn:epc:id:sgtin:030001.1123456.501</epc>
               <epc>urn:epc:id:sgtin:030001.1123456.502</epc>
               <epc>urn:epc:id:sgtin:030001.1123456.503</epc>
               <epc>urn:epc:id:sscc:030001.00000000102</epc>
            </epcList>
            <action>ADD</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>
         </TransactionEvent>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

14.4 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.
    - If the *Receiving* event is to be recorded using this method (i.e., where only the outermost containers are included in the *Receiving* event), the *Receiving* event should be an EPCIS Object Event populated as specified below.
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 this method (i.e., where hierarchy is declared explicitly), share as many *Receiving* Events as needed to express the hierarchy. Each event should be an EPCIS Aggregation Event where instead of the epcList field there are Parent ID and ChildEPCs fields to express the hierarchy, and all other fields (including the action) are as specified below.

14.4.1 Populating a Receiving Event

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date & time of event (see Section 8.2.1).	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date & time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the received item(s) in EPC Pure Identity URI format. ▪ If an Object Event is used, only the outermost containers in the packaging hierarchy are included. ▪ If Aggregation Events 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.*
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:receiving	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition.
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 8.2.2).	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event see Section 8.2.2).	EPCIS standard definition

Element	Usage	Type	Value	Reason
bizTransactionList	Optional	List of biz transactions	Business transactions governing this *Receiving* event, which may include a purchase order or an invoice. (See Section 8.2.3 for details.) Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	Optional from an EPCIS standard perspective, but certain regulations & business agreements may require for PO, Invoice or other ID's.
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party whose value is the EPC Pure Identity URI for the GLN of the transferring party. Each GLN URI must match one of the companies in the company master data list.	EPCIS standard definition
destinationList	Required	List of destinations	Each destination in the desintationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include one destination of type urn:epcglobal:cbv:sdt:owning_party whose value is the EPC Pure Identity URI for the GLN of the transfer-to party. If the ship-to GLN is different from the transfer-to party's GLN, destinationList shall also include a second destination of type urn:epcglobal:cbv:sdt:location whose value is the EPC Pure Identity URI of the ship-to GLN. Each GLN URI must match one of the companies in the company master data list.	EPCIS standard definition

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 sourceList and destinationList in your *Receiving* event.

14.4.2 Receiving Event Master Data

When an EPCIS document includes one or more *Receiving* events, the EPCIS header should contain master data including the following attributes for each distinct party or location referenced in the source list or destination list of any *Receiving* event. Note that if several *Receiving* events in the same EPCIS document reference the same party or location, the master data attributes for that party or location need only be included *once* in the header.

party or location master data elements *(include one set of attributes for each trading partner found in any Receiving event within the scope of the header. This group of attributes may be available via an EPCIS query in future versions of this guideline.)*			
name	Required	String	The name of the location or party expressed in text
streetAddressOne	Required	String	The first line of the street address.
streetAddressTwo	Optional	String	The second line of the street address.
streetAddressThree	Optional	String	The third line of the street address.
city	Required	String	The city.
state	Conditional	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Conditional	String	The ZIP or other postal code.
countryCode	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

14.4.3 XML Example of a Receiving Event

```
<epcis:EPCISDocument
xmlns:cbvmda="urn:epcglobal:cbv:mda"
xmlns:epcis="urn:epcglobal:epcis:xsd:1"
schemaVersion="1.2"
creationDate="2012-03-28T17:10:16Z">
  <EPCISHeader>
    <sbdh:StandardBusinessDocumentHeader>...</sbdh:StandardBusinessDocumentHeader>
    <extension><EPCISMasterData>
    <VocabularyList>
      <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
        <VocabularyElementList>
          <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George
Ave</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
            <attribute id="urn:epcglobal:cbv:mda#city">Washington</attribute>
            <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-6789</attribute>
            <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
          </VocabularyElement>
          <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro LLC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
            <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
            <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
            <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-1502</attribute>
            <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
```

```
          </VocabularyElement>
        </VocabularyElementList>
      </Vocabulary>
    </VocabularyList>
  </EPCISMasterData></extension>
 </EPCISHeader>
<EPCISBody>
  <EventList>
    <ObjectEvent>
      <eventTime>2012-03-28T18:10:16Z</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>
      <extension>
        <sourceList>
          <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
        </sourceList>
        <destinationList>
          <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
        </destinationList>
      </extension>

    </ObjectEvent>
  </EventList>
 </EPCISBody>
</epcis:EPCISDocument>
```

14.5 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.

14.5.1 Populating an Unpacking Event

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

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1.)	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
parentID	Required	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition
childEPCs	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 not permitted for this guideline.)
action	Required	String	DELETE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:unpacking	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2.)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2.)	EPCIS standard definition
bizTransactionList	Omitted	List of biz transactions	Business transactions governing this event.	Omitted in the *Packing* event as there are no relevant business transactions to share

14.5.2 XML Example of an Unpacking Event

```
<epcis:EPCISDocument
   xmlns:epcis="urn:epcglobal:epcis:xsd:1"
   schemaVersion="1.2"
   creationDate="2012-03-29T17:10:16Z">
  <EPCISBody>
    <EventList>
      <AggregationEvent>
        <eventTime>2012-03-29T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <parentID>urn:epc:id:sgtin:030001.1012345.22222223333</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>urn:epcglobal:cbv: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>
      </AggregationEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

14.6 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* events, 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.

14.6.1 Populating a Dispensing Event

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

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1.)	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC of the dispensed item in EPC Pure Identity URI format.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:dispensing	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:partially_dispensed	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2.)	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 8.2.2.)	EPCIS standard definition
bizTransactionList	Optional	List of biz transactions	Business transactions governing this *Dispensing* event. Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	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).

14.6.2 XML Example of a Dispensing Event

```
<epcis:EPCISDocument
   xmlns:epcis="urn:epcglobal:epcis:xsd:1"
   schemaVersion="1.2"
   creationDate="2012-03-30T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
        <eventTime>2012-03-30T17:10:16Z</eventTime>
        <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
        <epcList>
```

```
          <epc>urn:epc:id:sgtin:030001.0012345.10000000001</epc>
        </epcList>
        <action>OBSERVE</action>
        <bizStep>urn:epcglobal:cbv:bizstep:dispensing</bizStep>
        <disposition>urn:epcglobal:cbv:disp:partially_dispensed</disposition>
        <readPoint>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </readPoint>
        <bizLocation>
          <id>urn:epc:id:sgln:039999.111111.0</id>
        </bizLocation>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

14.7 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.

14.7.1 Populating a Destroying Event

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

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section 8.2.1)	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the destroyed item(s) in EPC Pure Identity URI format	EPCIS standard definition
action	Required	String	DELETE	EPCIS standard definition. (Action DELETE in an Object Event indicates that the EPCs no longer exist.)
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:destroying	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:destroyed	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2)	EPCIS standard definition
bizLocation	Omitted	URI		The bizLocation 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, bizLocation is always omitted for a *Destroying* event.
bizTransactionList	Omitted	List of biz transactions	Business transactions governing this event.	Omitted in the *Destroying* event as there are no relevant business transactions to share.

14.7.2 XML Example of a Destroying Event

```
<epcis:EPCISDocument
   xmlns:epcis="urn:epcglobal:epcis:xsd:1"
   schemaVersion="1.2"
   creationDate="2012-03-31T17:10:16Z">
  <EPCISBody>
    <EventList>
      <ObjectEvent>
```

```
        <eventTime>2012-03-31T17:10:16Z</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>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

14.8 Decommissioning

Decommissioning is the end of life event for the EPC identifier. 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).

14.8.1 Populating a Decommissioning Event

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

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event. See Section 8.2.1.	EPCIS standard definition
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	EPC(s) of the decommissioned item(s) (in EPC Pure Identity URI format)	EPCIS standard definition
action	Required	String	DELETE	EPCIS standard definition. Action DELETE in an Object Event indicates that the EPCs no longer exist
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:decommissioning	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:inactive	CBV standard definition
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 8.2.2.)	EPCIS standard definition
bizLocation	Omitted	URI		The bizLocation 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 bizLocation is always omitted for a *Decommissioning* event.
bizTransactionList	Omitted	List of biz transactions	Business transactions governing this event	Omitted in the *Decommissioning* event as there are no relevant business transactions to share

14.8.2 XML Example of a Decommissioning Event

```
<epcis:EPCISDocument
   xmlns:epcis="urn:epcglobal:epcis:xsd:1"
   schemaVersion="1.2"
   creationDate="2012-04-01T17:10:16Z">
  <EPCISBody>
```

```
    <EventList>
      <ObjectEvent>
        <eventTime>2012-04-01T17:10:16Z</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>
      </ObjectEvent>
    </EventList>
  </EPCISBody>
</epcis:EPCISDocument>
```

14.9 Void Shipping

Void Shipping is the standard EPCIS mechanism for indicating that objects previously recorded in one or more prior *Shipping* events were, in fact, not shipped. Potential business situations wherein a *Void Shipping* event should be considered include:

- Shipment Cancellation after a prior *Shipping* event has been recorded and sent to a trading partner
- Late discovery that a shipment believed to have occurred did not actually occur
- Late discovery that some of the lowest saleable units intended to be in the shipment were not included

14.9.1 Populating a Void Shipping Event

Upon the discovery that the prior *Shipping* event is in error, the shipper creates a *Void Shipping* event. A *Void Shipping* event shall be an EPCIS Object Event populated as follows:

Element	Usage	Type	Value	Reason
eventTime	Required	Timestamp	Date and time of event (see Section 8.2.1).	EPCIS standard definition For purposes of DSCSA, this is considered the shipping date (when bizStep = shipping).
eventTimeZoneOffset	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	List of URI	If voiding the entire shipment, the epcList is identical to the epcList of the original *Shipping* event. If partially voiding a shipment (i.e., selected content that was discovered to not have been shipped), the epcList enumerates the EPCs of the objects that were erroneously included in the original *Shipping* event.	EPCIS standard definition
action	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	URI	urn:epcglobal:cbv:bizstep:void_shipping	CBV standard definition
disposition	Required	URI	urn:epcglobal:cbv:disp:in_progress	CBV standard definition. The **disposition** value "in_progress" is always paired with the **bizStep** "void_shipping".
readPoint	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 8.2.2).	EPCIS standard definition
bizLocation	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 8.2.2).	EPCIS standard definition

Element	Usage	Type	Value	Reason
bizTransaction List	Optional	List of biz transactions	Business transactions governing this *Void Shipping* event, which may include a purchase order or an invoice (see Section 8.2.3 for details). Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value. Should match the bizTransactionList of the prior *Shipping* event, so that the *Void Shipping* event will be included if events are queried by business transaction.	Optional from an EPCIS standard perspective, however, certain regulations and business agreements may require the use for PO, Invoice or other ID's.
sourceList	Required	List of sources	Each source in the sourceList is a pair of URIs: one URI for the type and one URI for the value. The sourceList shall include one source of type urn:epcglobal:cbv:sdt:owning_party whose value is the EPC Pure Identity URI for the GLN of the transferring party. If the ship-from GLN is different from the transferring party's GLN, sourceList shall also include a second source of type urn:epcglobal:cbv:sdt:location whose value is the EPC Pure Identity URI of the ship-from GLN. Each GLN URI must match one of the companies in the company master data list. Should match the sourceList of the prior *Shipping* event, so that the *Void Shipping* event will be included if events are queried by source.	EPCIS standard definition
destinationList	Required	List of destinations	Each destination in the desintationList is a pair of URIs: one URI for the type and one URI for the value. The destinationList shall include 1 destination of type urn:epcglobal:cbv:sdt:owning_party whose value is the EPC Pure Identity URI for the GLN of transfer-to party. If ship-to GLN is different from the transfer-to party's GLN, destinationList shall also include a 2nd destination of type urn:epcglobal:cbv:sdt:location whose value is EPC Pure Identity URI of ship-to GLN. Each GLN URI must match one of the companies in the company master data list. Should match the destinationList of the prior *Shipping* event, so that the *Void Shipping* event will be included if events are queried by destination.	EPCIS standard definitions

14.9.2 Void Shipping Event Master Data

When an EPCIS document includes one or more *Void Shipping* events, the EPCIS header should contain master data including the following attributes for each distinct party or location referenced in the source list or destination list of any *Void Shipping* event. Note that if several *Void Shipping* events in the same EPCIS document reference the same party or location, the master data attributes for that party or location need only be included *once* in the header.

party or location master data elements *(include one set of attributes for each trading partner found in any Void Shipping event within scope of the header. This group of attributes may be available via an EPCIS query in future versions of this guideline.)*			
name	Required	String	The name of the location or party expressed in text.
streetAddressOne	Required	String	The first line of the street address.
streetAddressTwo	Optional	String	The second line of the street address.
streetAddressThree	Optional	String	The third line of the street address.
city	Required	String	The city.
state	Conditional	String	The state, province, or region using the standard two-letter abbreviation specified in ISO 3166-2:1998 country subdivision code [16].
postalCode	Conditional	String	The ZIP or other postal code.
countryCode	Required	String	The country using the standard two-letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

14.9.3 XML Example of a Void Shipping Event (entire shipment cancellation)

This example illustrates how to declare a shipment cancellation using a *Void Shipping* event. This shows both a single *Void Shipping* event, as well as an EPCIS Header that includes party master data for the source and destination.

```
<epcis:EPCISDocument
     xmlns:cbvmda="urn:epcglobal:cbv:mda"
     xmlns:epcis="urn:epcglobal:epcis:xsd:1"
     schemaVersion="1.2"
     creationDate="2012-03-28T17:10:16Z">
  <EPCISHeader>
    <sbdh:StandardBusinessDocumentHeader>...</sbdh:StandardBusinessDocumentHeader>
    <extension><EPCISMasterData>
    <VocabularyList>
      <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
        <VocabularyElementList>
          <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George
Ave</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
            <attribute id="urn:epcglobal:cbv:mda#city">Washington</attribute>
            <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-6789</attribute>
            <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
          </VocabularyElement>
          <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro LLC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
            <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
```

```
            <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
            <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-1502</attribute>
            <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
          </VocabularyElement>
        </VocabularyElementList>
      </Vocabulary>
    </VocabularyList>
  </EPCISMasterData></extension>
 </EPCISHeader>
 <EPCISBody>
  <EventList>
    <ObjectEvent>
     <eventTime>2012-03-28T17:10:16Z</eventTime>
     <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
     <epcList>
       <epc>urn:epc:id:sscc:030001.01234567890</epc>
     </epcList>
     <action>OBSERVE</action>
     <bizStep>urn:epcglobal:cbv:bizstep:void_shipping</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>
     <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>
     <extension>
       <sourceList>
         <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
       </sourceList>
       <destinationList>
         <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
       </destinationList>
     </extension>
    </ObjectEvent>
  </EventList>
 </EPCISBody>
</epcis:EPCISDocument>
```

14.9.4 XML Example of a Void Shipping Event (partial shipment cancellation)

This example illustrates how to declare that one of the lowest saleable unit (LSU) was erroneously not included in the prior physical shipment. This shows both a single *Void Shipping* event, as well as an EPCIS Header that includes product and party master data for the source and destination.

```
<epcis:EPCISDocument
     xmlns:cbvmda="urn:epcglobal:cbv:mda"
     xmlns:epcis="urn:epcglobal:epcis:xsd:1"
     schemaVersion="1.2"
     creationDate="2012-03-29T17:10:16Z">
 <EPCISHeader>
   <sbdh:StandardBusinessDocumentHeader>...</sbdh:StandardBusinessDocumentHeader>
```

```
    <extension><EPCISMasterData>
    <VocabularyList>
      <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
        <VocabularyElementList>
          <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
            <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">00001012345</attribute>
            <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">FDA_NDC_11</attribute>
       <attribute id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
       <attribute id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma
LLC</attribute>
       <attribute id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
       <attribute id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
       <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
          </VocabularyElement>
        </VocabularyElementList>
      </Vocabulary>
      <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
        <VocabularyElementList>
          <VocabularyElement id="urn:epc:id:sgln:030001.111111.0">
            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma LLC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1295 S George
Ave</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
            <attribute id="urn:epcglobal:cbv:mda#city">Washington</attribute>
            <attribute id="urn:epcglobal:cbv:mda#state">DC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#postalCode">12345-6789</attribute>
            <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
          </VocabularyElement>
          <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
            <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro LLC</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">230 Park Ave S</attribute>
            <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room 378</attribute>
            <attribute id="urn:epcglobal:cbv:mda#city">New York</attribute>
            <attribute id="urn:epcglobal:cbv:mda#state">NY</attribute>
            <attribute id="urn:epcglobal:cbv:mda#postalCode">10003-1502</attribute>
            <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
          </VocabularyElement>
       </VocabularyElementList>
      </Vocabulary>
     </VocabularyList>
    </EPCISMasterData></extension>
  </EPCISHeader>
  <EPCISBody>
   <EventList>
     <ObjectEvent>
      <eventTime>2012-03-29T17:10:16Z</eventTime>
      <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
      <epcList>
        <epc>urn:epc:id:sgtin:030001.0012345.10000000003</epc>
      </epcList>
      <action>OBSERVE</action>
      <bizStep>urn:epcglobal:cbv:bizstep:void_shipping</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>
```

```
      <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>
      <extension>
        <sourceList>
          <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
        </sourceList>
        <destinationList>
          <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
        </destinationList>
      </extension>
    </ObjectEvent>
  </EventList>
 </EPCISBody>
</epcis:EPCISDocument>
```

14.10 EPCIS Error Declaration Mechanism

Occasionally, an EPCIS event previously generated and shared with a trading partner is later discovered to be incorrect. In such scenarios, the preferred approach is to create a new EPCIS event that reverses the earlier, incorrect event. For example:

- if a *Packing* event is discovered to be incorrect, an *Unpacking* event may be generated
- if a *Shipping* event is discovered to be incorrect, a *Void Shipping* event may be generated

There are certain types of data errors that are difficult or impossible to reverse in this way. For example:

- an end-of-life event such as *Destroying* cannot have any subsequent event
- a *Commissioning* event for a serial number that was not actually commissioned cannot be reversed with an ordinary event
- an event with an incorrect event time creates a problem with constructing a valid history no matter what new events are created

For these situations, EPCIS provides an *Error Declaration* mechanism. The *Error Declaration* mechanism allows a new event to be created whose effect is to indicate that a prior event was in error and should be disregarded completely; such an event is referred to here as an *Error Declaration* event. The *Error Declaration* event may also include a reference to one or more new events whose intent is to provide corrected information; however, this may be omitted if the corrective events have not yet been generated or if the correct outcome is to have no event at all (i.e., the prior event did not simply have incorrect data – it should not have been created in the first place).

An *Error Declaration* event is not a new business step or event type. Rather, it is an exact copy of the erroneous event, with an added section that marks it as an error declaration. This is so that any query that matches the erroneous event will also match the corresponding error declaration, so that the querying party will know the original event should be disregarded.

Note: See Section 7.4.1.2 of the EPCIS 1.2 standard for details about the *Error Declaration* mechanism.

The following example shows an EPCIS document containing (1) an *Error Declaration* for a *Commissioning* event, and (2) a corrected *Commissioning* event that has an updated lot number and expiration date.

```
<epcis:EPCISDocument
    xmlns:cbvmda="urn:epcglobal:cbv:mda"
     xmlns:epcis="urn:epcglobal:epcis:xsd:1"
     schemaVersion="1.2"
     creationDate="2012-03-25T17:10:16Z">
  <EPCISHeader>
    <sbdh:StandardBusinessDocumentHeader>...</sbdh:StandardBusinessDocumentHeader>
    <extension><EPCISMasterData>
    <VocabularyList>
      <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
        <VocabularyElementList>
          <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
            <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">00001012345</attribute>
            <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">FDA_NDC_11</attribute>
       <attribute id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
       <attribute id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma
LLC</attribute>
       <attribute id="urn:epcglobal:cbv:mda#dosageFormType">PILL</attribute>
```

```
      <attribute id="urn:epcglobal:cbv:mda#strengthDescription">100mg</attribute>
      <attribute id="urn:epcglobal:cbv:mda#netContentDescription">500 pills</attribute>
         </VocabularyElement>
       </VocabularyElementList>
     </Vocabulary>
    </VocabularyList>
   </EPCISMasterData></extension>
 </EPCISHeader>
 <EPCISBody>
   <EventList>
     <ObjectEvent>
      <eventTime>2012-03-25T17:10:16Z</eventTime>
      <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
           <baseExtension>
              <errorDeclaration>
                 <declarationTime>2012-03-30T10:12:13Z</declarationTime>
                 <reason>urn:epcglobal:cbv:er:incorrect_data</reason>
                 <correctiveEventIDs>
                    <correctiveEventID>urn:uuid:f81d4fae-7dec-11d0-a765-
00a0c91e6bf6</correctiveEventID>
                 </correctiveEventIDs>
               </errorDeclaration>
           </baseExtension>
      <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>
      <extension>
        <ilmd>
         <cbvmda:lotNumber>A123</cbvmda:lotNumber>
         <cbvmda:itemExpirationDate>2015-03-15</cbvmda:itemExpirationDate>
        </ilmd>
      </extension>
     </ObjectEvent>
      <ObjectEvent>
      <eventTime>2012-03-25T17:10:16Z</eventTime>
      <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
           <baseExtension>
              <eventID>urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6</eventID>
           </baseExtension>
      <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>
      <extension>
        <ilmd>
          <cbvmda:lotNumber>B456</cbvmda:lotNumber>
          <cbvmda:itemExpirationDate>2017-04-25</cbvmda:itemExpirationDate>
        </ilmd>
      </extension>
    </ObjectEvent>
  </EventList>
 </EPCISBody>
</epcis:EPCISDocument>
```

A Appendix: 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.

Table A-1 Converting an 11-digit NDC to a 10-digit NDC

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

B Appendix: GS1 Standards

From an information management point of view, supply chain applications like lot-level management and item-level traceability 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 lot-level management and item-level traceability.

Table B-1 Overview of GS1 Standards to Support Traceability

GS1 Standards Supporting Lot-Level Management & Item-Level Traceability			
Identification Standards	**Trade Items**	Global Trade Item Number (GTIN)	
	Locations & Trading Partners	Global Location Number (GLN)	
	Logistics Units	Serial Shipping Container Code (SSCC)	
	Individual Assets	Global Individual Asset Identifier (GIAI)	
	Returnable Assets	Global Returnable Asset Identifier (GRAI)	
AIDC Standards	**GS1 BarCodes**	GS1-128 GS1 DataMatrix RSS EAN/UPC ITF-14 Composite Component	
	GS1 EPC/RFID		
Data Standards	**Master Data:** Global Data Dictionary Item Business Messaging Standard Party Business Messaging Standard	**Transactional Data:** eCom/EDI	**Event Data:** EPCIS Schema EPCIS Core Business Vocabulary
Sharing & Communication Standards	**Master Data:** GDSN Data Hub | Location EPCIS Master Data	**Transactional Data:** AS2	**Event Data:** EPCIS Capture EPCIS Query Discovery Services

C Appendix: Acronyms

AI	Application Identifier
CBV	Core Business Vocabulary
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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