

# Healthcare

# Implementation Guideline: Applying GS1 System of Standards to Pharmaceutical Chain of Custody

Business processes for unregulated transactions between manufacturing/wholesaler trading partners

Release 1.2, March 12 2024





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#### **About GS1**

GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely-used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

#### **About GS1 US**

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely-used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration that optimizes their supply chains, drives cost performance and revenue growth while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

#### **About GS1 Healthcare**

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

#### About GS1 Healthcare US

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



# **Document Summary**

Document Item	Current Value
Document Title	Implementation Guideline: Applying GS1 Standards for Pharmaceutical Chain of Custody
Date Last Modified	March 12, 2024
Document Description	This implementation guideline was developed to provide direction for the communication of chain of custody events between supply chain partners using EPCIS.

# **Log of Changes**

Release Number – Date	Changes
Release 1.0 - March 2021	Release/publication
Release 1.1 – April 2021	Add section 9.5 <i>Transformation event for repackaging</i> to the document.
Release 1.2 – March 2024	Update content to be in line with Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability Implementation Guideline Release 1.3, December 2022



# Part I: Foundational Concepts



## 1 Preface

#### 1.1 Introduction

The purpose of this document is to establish the requirements and define specifications for capturing custody changes using Electronic Product Code Information Services (EPCIS) serialized data exchange for the U.S. market. Contract Manufacturers (CMOs), Contract Packagers (CPOs), Third Party Logistic (3PLs) and Reverse Logistics Providers (RLPs) are supply chain partners who perform services on behalf of manufacturers, repackagers and wholesalers. To facilitate operational serialized data exchanges between manufacturers, repackagers, wholesalers and their 3<sup>rd</sup> party supply chain service agents, the GS1 Healthcare US<sup>®</sup> Rx Secure Supply Chain workgroup developed this implementation guideline to provide direction for the communication of chain of custody events between supply chain partners using EPCIS. Since chain of custody event information feeds the serialized traceability required by the Drug Supply Chain Security Act (DSCSA), the Chain of Custody EPCIS event data exchanges are designed to help enable and ease the formation of subsequent DSCSA events by helping to ensure that critical field data generated in the chain of custody events are populated and transmitted. EPCIS is a GS1 Standard that helps enable 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.

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. Therefore, members of the U.S. pharmaceutical industry including over fifty organizations from across the U.S. worked together to determine how the standards can best be applied to support these applications. Leading manufacturers, wholesalers, retail pharmacies, healthcare providers, government agencies, industry associations, and third-party logistics providers, all worked together to analyze business processes and business requirements, consider the various options, and decide how the standards could best be applied. This Implementation Guideline details all of the decision points, defining each event and data element needed to support track and trace, and showing industry members how to apply the standards to their own business processes.

A Contract Manufacturing Organization (CMO), sometimes called a Contract Development and Manufacturing Organization (CDMO), is a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing. This allows major pharmaceutical companies to outsource those aspects of the business, which can help with scalability or can allow the major company to focus on drug discovery and drug marketing instead.

Services offered by CMOs include, but are not limited to: pre-formulation, formulation development, stability studies, method development, pre-clinical and Phase I clinical trial materials, late-stage clinical trial materials, formal stability, scale-up, registration batches and commercial production. CMOs are contract manufacturers, but they can also be more than that because of the development aspect. Overall it is required that CMO complies with good manufacturing practice from their client and official organization such as Food and Drug Administration.<sup>2</sup>

**Pharmaceutical Contract Packaging Organization (CPO)** is a contracted packager and performs the packaging processes for pharmaceutical preparations. It involves all of the operations from production through drug distribution channels to the end consumer.

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<sup>&</sup>lt;sup>1</sup> Contract Pharma. Contract Pharma. Retrieved on 2013-09-18.

<sup>&</sup>lt;sup>2</sup> "CMOs – Speeding Biopharmaceutical Development". BioProcess International. 2015-08-24. Retrieved 2018-09-18



Pharmaceutical packaging is highly regulated but with some variation in the details, depending on the country of origin or the region. Several common factors can include: assurance of patient safety, assurance of the efficacy of the drug through the intended shelf life, uniformity of the drug through different production lots, thorough documentation of all materials and processes, control of possible migration of packaging components into the drug, control of degradation of the drug by oxygen, moisture, heat, etc., prevention of microbial contamination, sterility, etc. Communication of proper use and cautionary labels are also regulated. Packaging is an integral part of pharmaceutical product.

Services offered by CPOs include, but are not limited to serializing drug products, aggregating serialized items into serialized parent containers, etc.

**Third-party Logistics (3PL)** in logistics and supply chain management is an organization's use of third-party businesses to outsource elements of its distribution, warehousing, and fulfillment services.

DSCSA defines 3PLs broadly to include any entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product. (Reference Identifying Trading Partners Under the Drug Supply Chain Security Act guidance document)

DSCSA defines a 3PL in section 581(22) of the FD&C Act to mean: [A]n entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product.

The key distinction between wholesale distributors and 3PLs is that, unlike a wholesale distributor, a 3PL does not take ownership of the product, and does not direct the sale or disposition of the product.

Third-party logistics providers typically specialize in integrated operations of warehousing and transportation services that can be scaled and customized to customers' needs, based on market conditions, to meet the demands and delivery service requirements for their products. Services often extend beyond logistics to include value-added services related to the production or procurement of goods, such as services that integrate parts of the supply chain. 3PL targets particular functions within supply management, such as warehousing, transportation, or material provision.<sup>3</sup>

**Reverse Logistics Provider** (**RLP**) is utilized is for all operations related to the return of products or materials. It is "the process of moving goods from their typical final destination for the purpose of capturing value, or proper disposal. Normally, logistics deal with events that bring the product towards the customer. In the case of reverse logistics, the resource goes at least one step back in the supply chain. For instance, goods move from the customer to the distributor or to the manufacturer.<sup>4</sup>

A returns processor or reverse logistics provider is defined in section 581(18) of the FD&C Act 430 as:

[A] person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

FDA considers returns processors and reverse logistics providers to be 3PLs because they are entities that provide other logistics services on behalf of other trading partners in a facility the returns processor or reverse logistics provider owns, rents, or leases, and they do not take ownership of nor direct the sale or disposition of the product. As indicated in the definition, such entities may execute the dispositioning of product, whether it is as a return, recall, or for disposal, but they are not responsible for directing whether the product is to be sold or dispositioned. This activity may include activity that has been referred to as "reverse distribution." However, if an entity takes ownership of the returned or dispositioned product or is responsible for directing the sale or disposition of the product, such entity

<sup>&</sup>lt;sup>3</sup> "Outsourcing Transport and Warehousing: Pricing, Honesty and Contentious Issues" Published in Australian Freight Logistics Magazine. Retrieved 2014-3-25.

<sup>&</sup>lt;sup>4</sup> Rengel, P. & Seydl, C. (May 2002). Completing the Supply Chain Model at seydl.at. Retrieved on 2019-07-28.



does not meet the definition of a returns processor or reverse logistics provider, but rather is engaged in wholesale distribution, subject to all the requirements for WDDs under DSCSA.<sup>5</sup>

#### 1.2 Document Information

This implementation guideline was prepared by GS1 US® and the Rx Secure Supply Chain Workgroup to assist the U.S. pharmaceutical industry in implementing GS1 System of Standards to support traceability. It is based on the GS1 General Specifications, the EPC Tag Data Standard (Version 1.13), 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, repackagers, wholesalers, and their supply chain trading partners along with pharmaceutical industry solution 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.

## 1.3 Participants

This guideline was developed through the commitment and dedication of the Rx Secure Supply Chain Workgroup, in preparation for applying GS1 System of Standards in support of the Chain of Custody best practices in the pharmaceutical industry supply chain.

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 $<sup>^{5}</sup>$  Identifying Trading Partners Under the Drug Supply Chain Security Act Guidance for Industry – August 2017 Procedural

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## 1.4 Purpose

This document specifies how EPCIS can be leveraged as a standard for contracted 3<sup>rd</sup> party agents such as CMOs, CPOs, 3PLs and RLPs to capture the operational product activities involved in the chain of custody of serialized pharmaceutical product transactions with their contracting DSCSA supply chain stakeholders: (e.g., Manufacturers, Repackagers, and Wholesalers.) It lists the specific minimum set of EPCIS event attributes, their respective usage requirements, and business rules applicable for CMOs, CPOs, 3PLs and RLPs for each supply chain event involved in the Chain of Custody business information exchange.

By so doing, this document serves as an implementation guideline for managing the serialized chain of custody information exchanges and providing guidance to industry members about how to apply the GS1 System of Standards to their own business processes to support product serialization, and item-level traceability.

## 1.5 Scope

This guideline defines the EPCIS events (XML data format) to support business process for the contracted supply chain partners of the pharmaceutical manufacturers, repackagers and wholesalers, as they manage the business transaction and chain of custody of their serialized products at the item-level. **It does not provide any guidance or advice regarding regulatory compliance.** Federal requirements for traceability in the pharmaceutical supply chain are specified in the DSCSA and subsequent FDA Guidance(s). The specifications for applying GS1 System for DSCSA and Traceability are detailed in the <u>GS1 US DSCSA Implementation Guideline, R1.2</u> and <u>GS1 US DSCSA Implementation Guideline, R1.3</u>.

This guideline reflects current U.S. industry best practices for managing the chain of custody for commercial serialized item traceability, prior to being placed into DSCSA commerce, or returns back from the pharmacy dispensers and healthcare providers.

This implementation guideline was prepared by GS1 US and the Rx Secure Supply Chain Workgroup to assist the U.S. pharmaceutical industry in implementing the GS1 System of Standards to support serialized item-level for products prior to being put into commercial commerce. This guideline does address considerations or factors, that might impact or inform the adoption of optimal traceability processes or procedures for the agents of the pharmaceutical manufacturers and wholesalers.

#### 1.6 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) 2.0
- EPCIS 1.2 Standard
- Core Business Vocabulary (CBV) 1.2 Standard
- <u>GTIN Management Standard</u> (formerly known as the GTIN Allocation Rules)
- Healthcare GTIN Allocation Rules

#### 1.7 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

#### 1.8 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.
- There are multiple reasons why a barcode may not scan and 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 <u>Procedure for Responding to Troublesome Barcodes</u> 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.

## 1.9 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:

- Content updated supporting serialized item traceability
  - Replaced the additional trade item identification value associated with GTIN with FDA NDC instead of CMS NDC
  - Enabled quick identification of drop shipments
  - Applied collective industry corrections and enhancements from evolved learnings
- Streamlined and corrected values in EPCIS Header attributes (such as setting Authority to GS1 instead of sGLN)
- Added Implementation Guideline Version, guidelineVersion, attribute in the EPCIS Header to specify the version of implementation guideline distinctly from the EPCIS standard version
- Promoted defining new GLNs not GLN extensions for internal physical locations for trading partner event exchanges
- Included guidance on reflecting individual licensed GLNs in EPCIS party and location fields



## 2 Overview of the GS1 System of Standards Used

This Section provides a brief definition of each GS1 Standard used in this guideline. (Refer to the <u>Appendices</u> of this document for more information about GS1 Standards that support serialized itemlevel traceability.)

## 2.1 Global Location Number (GLN)

The Global Location Number (GLN) is the globally unique GS1 Identification key for parties and locations and supply chain partners. The GLN can be used to identify a function (like a hospital pharmacy department or accounting department), a physical location (like a warehouse or hospital wing or even a nursing station), or a legal entity (like a health system corporation), or a digital location (like an EDI gateway). The attributes defined for each GLN (e.g., name, address, location type) help users to ensure that each GLN is specific to one unique party or location throughout the world.

## 2.2 Global Trade Item Number (GTIN)

The Global Trade Item Number® (GTIN®) is the globally unique GS1 Identification key 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.).

## 2.3 Serial Shipping Container Code (SSCC)

The Serial Shipping Container Code (SSCC) is the globally unique GS1 Identification key 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.

#### 2.4 GS1 Data Carriers

GS1 Data Carriers provide *machine-readable representations* of GS1 Identification keys that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports multiple data carriers: six barcode symbologies (i.e., GS1 barcodes) and RFID tags [i.e., GS1 Electronic Product Code (EPC®)-enabled radio frequency identification tags (EPC/RFID Tags)].

## 2.5 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 key. 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 AIs commonly used in healthcare include AI (10) for Lot/Batch Number, AI (17) for Expiration Date, and AI (21) for Serial Number.



## 2.6 Electronic Product Code Information Services (EPCIS)

The Electronic Product Code 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.)

## 2.7 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).

## 2.8 GS1 US Data Hub | Company

GS1 US Data Hub® | Company allows you to validate the relationship between products and companies by providing verified company information for over 5 million GS1 Company Prefix and identifier licensees.

## 2.9 GS1 US Data Hub | Product

GS1 US Data Hub® | Product provides access to an ever-expanding, GS1 US-validated GS1 Company Prefix database driving reliable product identification and barcodes to grow your business. Use it to search, view, and verify manufacturer and brand owner data, match company data from your list of Global Trade Item Numbers (GTINs) or Global Location Numbers (GLNs) with List Match, export the full list of GS1 US-validated GS1 Company Prefix data, and improve the quality of the data in your business applications.

## 2.10 GS1 US Data Hub | Location

GS1 US Data Hub® | Location provides trading partners with a single source of information for locations and how they are related. You may identify locations like companies and warehouses, or locations within locations, like shipping or receiving departments, improve the speed and accuracy of your supply chain activities, and ensure the right item is shipped to the right place in the supply chain at the right time. The GLN is the globally recognized identification key used in the GS1 System to uniquely identify parties (legal entities and functions) and locations (physical and digital) 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, wholesale distributors, hospitals, dispensers, as well as retail and mail-order pharmacies in order to improve the accuracy of their supply chain activities.

Important: It is recommended that trading partners to share their GLNs within the GS1 US Data Hub | Location to all subscribers to help enable visibility and searchability in support of trading partners within their supply chain.

## 2.11 GS1 US Data Hub | Location - Create/Manage

GS1 US Data Hub® | Location—Create/Manage enables traceability and efficiency by providing a single source of accurate information on locations and how they're related.



Important: It is recommended that trading partners share their GLNs within the GS1 US Data Hub | Location to all subscribers to enable visibility and searchability in support of trading partners within their supply chain.

## 2.12 GS1 US Data Hub | Location - View/Use

GS1 US Data Hub® | Location—View/Use provides validated location information from over 730,000 GLNs (Global Location Numbers). GS1 US 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.

## 2.13 Global Data Synchronization Network (GDSN)

The Global Data Synchronization Network  $^{\text{TM}}$  (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.



## 3 Background Concepts

## 3.1 Relationship between NDC – GTIN – SGTIN

The FDA National Drug Code (NDC) is a <u>U.S. regulatory identifier</u> used to identify pharmaceutical products for regulatory purposes. The GTIN is a <u>supply chain identifier</u> used to identify *products* for supply chain purposes. The SGTIN is a <u>supply chain identifier</u> 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.

NDC 1234567890

GTIN 00312345678906

SGTIN 00312345678906 101

Figure 3-1 Relationship of the NDC, GTIN and SGTIN

## 3.2 US FDA NDC Labeler Code & GS1 Company Prefix

The US FDA NDC is an 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 concatenated GS1 Company Prefix, manufacturers should first contact GS1 US to obtain a license to a GS1 Company Prefix that embeds their Labeler Code assigned to the company.

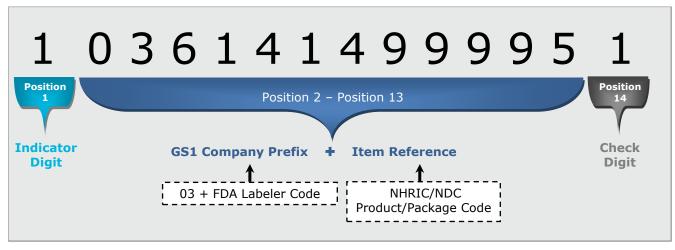


Pharmaceutical companies may have more than one GS1 Company Prefix (e.g., one GS1 Company Prefix that integrates their NDC *Labeler Code*, and other GS1 Company Prefixes that do not). Those companies will need to use the GS1 Company Prefix that integrates their *Labeler Code* when assigning GTINs that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

## 3.3 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 3-2 Segments of a GTIN-14 that embeds an NDC (based on the hypothetical GTIN "10361414999951")



## 3.4 "GTIN-12" vs. "GTIN-14" vs. "GTIN-12 in 14-digit format"

GTINs can be <u>assigned</u> as 8 digits, 12 digits, 13 digits, <u>or</u> 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 <u>encoded</u> 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 361414999951
GTIN-12 in 14-digit format 00361414999951

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.



## 3.5 Assigning vs. Storing vs. Encoding GTINs

As discussed above, GTINs can be <u>assigned</u> as 8 digits, 12 digits, 13 digits, <u>or</u> 14 digits in length. Regardless of how they are assigned, it is important to understand that GTINs are always stored in databases and <u>encoded</u> 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 3-3 Key to Assigning, Storing and Encoding GTINs

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

## 3.6 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 361414 99995 1

GTIN-12 in 14-digit format 00 361414 99995 1

- 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.

#### 3.7 Case Identification

Cases can be identified using GTIN + serial number <u>or</u> 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.

## 3.8 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.

#### 3.9 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 is provided below:

#### **SGTIN:**

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

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

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.

#### 3.10 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 key belong to the GS1 Company Prefix). Because GS1 Company Prefixes are issued in varying lengths, you will need to obtain the length of each GS1 Company Prefix you expect to encounter in your EPCIS events. Optimally, the GS1 Company Prefix(es) and pertinent identification keys (e.g., GTINs, GLNs) of trading partners will be exchanged prior to the start of exchanging EPCIS events. The on boarding process for trading partners is a good moment for this to occur. In some situations, EPCIS event data may be received without previously



exchanging GS1 Company Prefixes. To aid software in those situations, GS1 has published the GS1 Company Prefix (GCP) Length Table (https://www.gs1.org/standards/bc-epc-interop) which is comprised of a list starting digits of GCPs and the length of GCPs associated with each set of starting digits. This table is updated regularly with data from many GS1 Member Organizations.

#### 3.11 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 (unopened) 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.

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

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



## 4 Identify

GS1 Identification keys globally and uniquely identify supply chain objects (e.g., products, assets, logistic units, etc.), as well as parties (legal entities and functions) and locations (physical and digital). The table below lists the GS1 identification standards used in this guideline to support serialized item-level traceability.

**Table 4-1** GS1 Identifiers<sup>6</sup>

Supply Chain Object or Location	Serialized Item-Level						
Physical location	GLN						
Specific physical locations within physical locations (if shared with trading partners)	GLN + extension						
Parties (Legal entities, functions)	GLN						
Item	GTIN + serial number						
Kit	GTIN + serial number						
Homogeneous Case	GTIN + serial number, or SSCC						
Mixed / Partial Case	SSCC						
Pallet	SSCC						
Tote	SSCC						
Companies & warehouses	GLN						

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

In the GS1 System, products, cases, and kits<sup>7</sup> are identified with the Global Trade Item Number (GTIN). GTIN is a globally unique, standards-based, identification key 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 <u>Master Data</u> 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 https://www.gs1us.org/tools/gs1-us-data-hub for more information.

#### 4.1.1 Assigning GTINs from a GS1 Company Prefix

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

<sup>&</sup>lt;sup>6</sup> There may be other layers of packaging that are not specified here.

<sup>&</sup>lt;sup>7</sup> Consult the FDA UDI (Unique Device Identification) Rule for Kits that include a medical device.



#### 4.1.2 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 <u>check digit calculator</u> 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 4-2 Populating the 12 digits of a GTIN-12 with a US FDA NDC embedded

GTIN-12	3 1 2 3 4 5 6 7 8 9 0 6										6	
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12
		_	_								above	•
												•
Position 1	GS1 Pr											
Position 1 Position 2 through 11		abeler (	Code a	as assiç		/ FDA j	<u>olus</u> NI	DC <i>Pro</i>				created b
	NDC <i>La</i> the ma	abeler ( anufact ugh the	<i>Code a</i> urer e lengt	h of th	gned by	ler Cod	le and	the <i>Pr</i>	duct/P	Package	e Code	created b



#### 4.1.3 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 9.



**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 <u>check digit calculator</u> 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 4-3 Populating the 14 digits of a GTIN-14 with a US FDA 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
<u>Digit/Position</u>	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			Indi	cator D	igit (r	numeri	c valu	e fror	n 1 t	o 9)					
Position 2 and 3			GS1 Prefix "03"												
Positions 4 through 13	3		NDC <i>Labeler Code</i> as assigned by FDA <u>plus</u> NDC <i>Product/Package Code</i> created by the manufacturer												
			(Although the length of the <i>Labeler Code</i> and the <i>Product/Package Code</i> vary, they will always be a combined total of 10 digits.)												
Position 14			Che	ck Digi	t										

<sup>\*</sup> This indicator digit position could be populated with a numeric value of 1 to 8 for fixed measure trade items, and 9 for variable measure items.



#### 4.1.4 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 <u>text</u> field (not numeric). This is especially important for manufacturers who currently have many GTIN-12s in their systems due to the Barcode Rule.

#### 4.1.5 Data Format for EPCIS

Within the EPCIS, GTIN is stored with a serial number in EPC URI format.

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

This is discussed in detailed in the *serial number section* below.

## 4.2 Batch / Lot Numbers

#### 4.2.1 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.

#### 4.2.2 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 <u>text field</u> so that leading zeros are not inadvertently stripped off.

#### 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 (01) 00 31234 567890 6 (10) D4E5F6 Interpretation (HRI) Text



#### 4.3 Serial Numbers

#### 4.3.1 Assigning Serial Numbers

The combination of a GTIN <u>plus</u> 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 <u>plus</u> a serial number would identify a *specific* 100-count bottle of XYZ tablets. All bottles of XYZ tablets would have the same GTIN, but each bottle would be assigned a unique serial number.

The GS1 General Specifications define a serial number for use with a GTIN as an alphanumeric string whose length is variable between one and 20 characters (the specific characters allowed are defined in the GS1 General Specifications). 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-encoded RAIN RFID, 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.
- 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.
- Applications should not add or remove leading zeros to serial numbers.
- 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).
- 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.

#### 4.3.2 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 <u>stored</u> 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.

#### 4.3.3 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

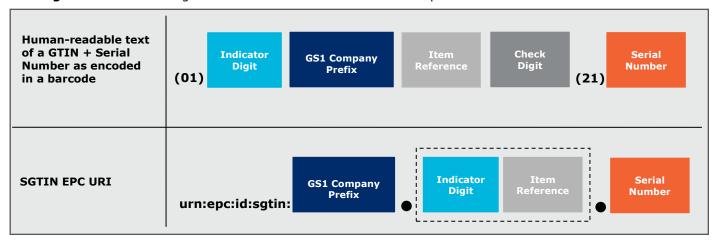
#### **Grammar:**

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 4-1 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 (01) 2 030001 123498 7 (21)123456789012 Interpretation (HRI) Text

Corresponding SGTIN-EPC URI urn:epc:id:sqtin: 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 (01) 00 31234 567890 6 (21)123456789012

Interpretation (HRI) Text

Corresponding SGTIN-EPC URI **urn:epc:id:sgtin:** 031234.0567890.123456789012



**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.

#### 4.3.4 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 4-5** Data Formats for GTIN + Serial Number Fields

Field	Data Format					
GTIN	<ul><li>14 digits</li><li>text field (not numeric)</li></ul>					
Serial Number	<ul><li>1-20 characters</li><li>text field (not numeric)</li></ul>					
Serialized GTIN EPC URI	<ul> <li>33-52 characters:</li> <li>17 characters for "urn:epc:id:sgtin:"</li> <li>13 characters for the GTIN (without the Check Digit)</li> <li>1-20 characters for the serial number</li> <li>2 periods (".")</li> <li>text field (not numeric)</li> </ul>					

## 4.4 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 key 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.

## 4.5 Assigning SSCCs from a GS1 Company Prefix

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 <u>check digit calculator</u> 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 18 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.



Position 18

Figure 4-6 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	ļļ	5	6	0	4
Digit/Position																			
How to Populate Each Digit (color-coded to coordinate with the SSCC shown above)																			
Position 1					Ex	Extension Digit (numeric value from 0 to 9)													
Positions 2 through 17						GS1 Company Prefix as assigned by GS1 US <u>plus</u> Serial Reference number as assigned by the owner of the logistics unit													

#### 4.6 Data Format for Databases

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

Check Digit

#### 4.7 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:**

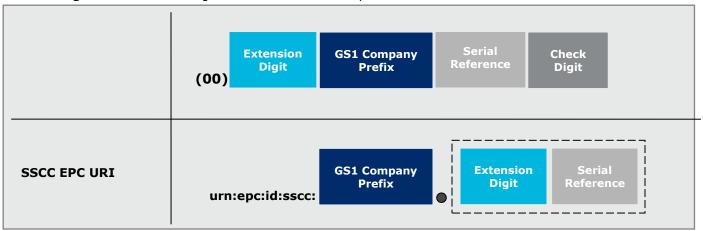
SSCC-URI ::= "urn:epc:id:sscc:" SSCCURIBody

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 4-7 How the segments of an SSCC are represented in the SSCC EPC URI format



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

## 4.8 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 <u>and</u> 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 4-8 Data Formats for SSCC Fields

Field	Data Format
SSCC	<ul><li>18 digits</li><li>text field (not numeric, to avoid dropping leading zeros)</li></ul>
SSCC URI	<ul> <li>34 characters:</li> <li>16 characters for "urn:epc:id:sscc:"</li> <li>17 characters for the SSCC (without the Check Digit)</li> <li>1 period (".")</li> <li>text field (not numeric)</li> </ul>

## 4.9 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 key for legal entities, functions, and physical locations, and digital 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 Data Hub | Location) and shared among supply chain partners.

## 4.10 Assigning GLNs from a GS1 Company Prefix

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 <u>check digit calculator</u> 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.

**Example of a GLN** 0 GLN 0 6 6 **Digit/Position** 1 2 3 4 5 6 8 9 10 11 13 How to Populate Each Digit (color-coded to coordinate with the GLN shown above) GS1 Company Prefix as assigned by GS1 US plus Location Reference Positions 1 through 12 number as assigned by the owner of the GS1 Company Prefix Position 13 Check Digit

Figure 4-9 Populating the 13 digits of a GLN

#### 4.11 Individual Licensed GLNs

Some organizations only need to identify their company or a few locations and nothing else. For those who do not need to create other GS1 Identification Keys, like GTINs or SSCCs, they have the option to license individual GLNs that are not part of a GS1 Company Prefix. This option works well for those with limited identification needs to get started identifying their parties and locations. These individually licensed GLNs, also known as individually assigned GLNs in the EPC Tag Data Standard, are issued as full, thirteen-digit numbers and are to be used in their entity. As defined in Similar content as in EPC Tag Data Standard R1.3, an individually licensed GLN is encoded in EPC format by specifying the entire individually assigned GLN stripped of its check digit into the *CompanyPrefix* component of the EPC as shown in the syntax below.

#### **General syntax:**



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

#### **Example:**

Given an example of individually assigned GLN value of 1234567890128, the corresponding EPC URN without GLN extension is as follows:

urn:epc:id:sqln:123456789012..0

Individual Licensed GLN's structure is also used for GLN managed programs.

Two existing examples of these managed programs are:

- o The Group Purchasing Organization (GPO) managed program for Healthcare Providers
- The Wholesale Distributor managed program for independent Dispensers and their sub-group of Practitioners acting as dispensers

With both programs, the GLN is issued a thirteen-digit number and is to be used in its entirety. The GLN is not derived from a GCP. For systems requiring a GCP structure, use the first 12-digits as the GCP.

Therefore, the GS1 US Data Hub® | Location is used to facilitate correct location identification. GEPIR is not an applicable tool for managed GLN programs as the GLN will not be tied to the legal entity of the location's organization.

These programs and individual licensed GLNs are for parties that only need to receive.

For the Wholesale Distributor managed program, one GLN is assigned per entity as the ship to and sold to are the same and not differentiated.



**Note**: For the Wholesale Distributor managed program:

- Expanding beyond one GLN per entity will be the responsibility of the party, not the program.
- o Please reference the <u>GS1 US Pharmaceutical Supplier GLN Quick Start Guide</u> and <u>GS1 US Pharmaceutical Dispenser/Healthcare Provider GLN Quick Start Guide f</u>or additional GLN requirements beyond the minimum supported by the Wholesale Distributor managed program

#### Illustrative Example of GLNs without an extension component

Given an example of a GLN assigned from a GS1 Company Prefix without extension component, the corresponding EPC URN without GLN extension is as follows:

urn:epc:id:sgln:0614141.12345.0

No GLN extension component present; value = 0

For GLNs that are not assigned from a GS1 Company Prefix, but rather an individually licensed GLN, the only thing that changes when creating an SGLN is where the dot goes

urn:epc:id:sgln:123456789012..0

No GLN extension component present; value = 0



**Note**: The difference between the two options below in yellow.

urn:epc:id:sgln: **0614141**.12345.0 urn:epc:id:sgln: **123456789012**..0

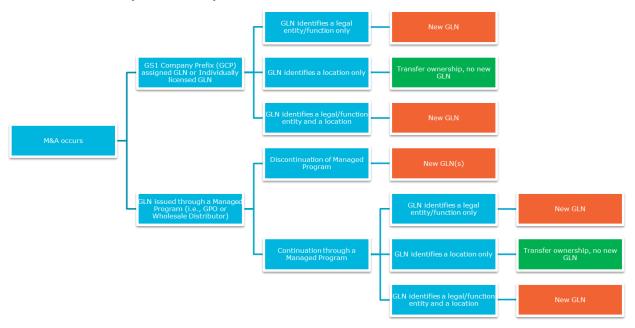
# 4.12 Mergers and Acquisitions (M&A) Impact on GLNs

Global Location Numbers serve a critical role in the identification of legal entities, functions, and physical locations. As each merger and acquisition (M&A) is unique and different, the impact on GLN(s) needs to be evaluated based on the end state of the M&A, who is the definitive owner of the GLN. In



M&A situations, GLNs should be treated as regulatory information as they are the identifiers of the seller and buyer in transactions governed by DSCSA.

#### Below illustrates potential impacts on GLNs when an M&A occurs



**Note:** For the transfer of ownership options, these would be dependent on the GS1 Company Prefix (GCP) or Individually licensed GLN officially moving to the organization.

For additional clarity please reference the GS1 GLN Management Rules specifically regarding:

- Guiding principles
- Party/location split
- Merger

How to notify GS1 US of a change in your company's ownership due to a merger, acquisition, or divestiture, please refer to <a href="https://www.gs1us.org/who-we-are/membership/mergers-acquisitions">https://www.gs1us.org/who-we-are/membership/mergers-acquisitions</a>.

Follow these steps to submit your Prefix Transfer Request:

- Step 1: Complete the <u>Company Prefix Transfer Request Form</u>.
- **Step 2:** Download and have a duly authorized officer of the selling company complete and sign the *Prefix Release Letter*.
- **Step 3:** Submit your completed Company Prefix Transfer Request Form and Company Prefix Release Letter via email to <u>dmaintenance@gs1us.org</u>. Alternatively, if you are an existing GS1 US customer, you may submit a request online via the <u>myGS1 US Customer Support Portal</u>

#### **4.13** Data Format for Databases

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



#### 4.14 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).

The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS. The SGLN syntax is capable of representing a plain GLN (without extension) or a GLN plus extension. Therefore, the same SGLN syntax can be used for any location identifier based on the GLN.

Unlike in the acronym SGTIN, the "S" in "SGLN" does *not* stand for "serialized," as the GLN all by itself refers to a specific location and so in that sense is already serialized. The "S" does not stand for anything.<sup>8</sup>

#### **General syntax:**

urn:epc:id:sqln:CompanyPrefix.LocationReference.Extension

#### **Example:**

urn:epc:id:sqln:0614141.12345.0

#### **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 GS1 Application Identifier (254) GLN extension component according to the GS1 General Specifications. A SGLN EPC appearing within EPCIS events supporting DSCSA requirements shall have a single digit zero ("0") in the GLN Extension portion of the URI syntax.

The figure below depicts how the element string of a GLN corresponds to the element string of an SGLN EPC URI:

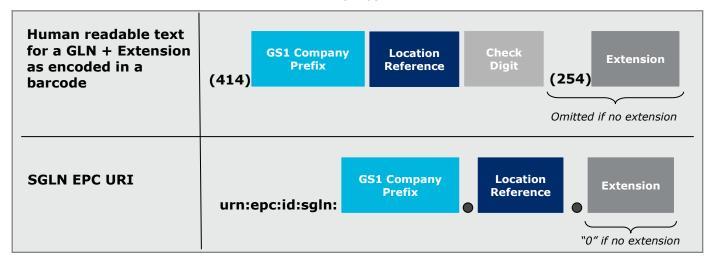
- The GS1 Company Prefix is the same as the GS1 Company Prefix digits within the GLN.
- The Location Reference is the same as it appears in the GLN key.
- The Check Digit is not used in the EPC URI format.
- The Extension is the same as the GLN extension component assigned by the managing entity to an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

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<sup>&</sup>lt;sup>8</sup> Frequently Asked Questions (FAQs) by the Pharmaceutical Industry in Preparing for the U.S. DSCSA R1.0.1 September 22, 2022



Figure 4-10 How the segments of a GLN (with or without extension) are represented in the SGLN EPC URI format



### 4.15 Caution on Assignment of GLN extension component

The Rx Secure Supply Chain Workgroup does not view the GLN extension component as suitable for EPCIS events to support DSCSA requirements for serialized item-level information. The U.S. pharmaceutical industry is an open value network comprised of a continually shifting landscape of trading partners. The GLN extension component is an optional means of identifying internal physical locations which reside within another physical location. This internal identification can be exchanged with trading partners by mutual agreement but is not suitable for open value networks. Consequently, an SGLN EPC appearing within EPCIS events supporting DSCSA requirements shall have a single digit zero ("0") in the GLN Extension portion of the URI syntax. For more information on the format of the SGLN EPC, consult section 4.14 of this guideline. Further, U.S. pharmaceutical industry companies wishing to identify internal physical locations that will be shared with trading partners within EPCIS events shall assign new GLNs not GLN extensions to those internal physical locations.

#### 4.16 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 4-11 Data Formats for GLN Fields

Table 1 11 Data Formats for GEN Fields		
Field	Data Format	
GLN	<ul><li>13 digits</li><li>text field (not numeric)</li></ul>	
GLN extension component	<ul><li>1-20 characters</li><li>text field (not numeric)</li></ul>	



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)

#### 4.17 Additional Party Identifier: DEA Number

A DEA number (DEA Registration Number) is an identifier assigned to a health care provider (such as a physician, physician assistant, nurse practitioner, optometrist, dentist, or veterinarian) by the United States Drug Enforcement Administration allowing them to write prescriptions for controlled substances.

The DEA Number may be used in addition to the GLN but does not replace the GLN. In those cases, the following URI form may be used.

#### **DEA Number in URI Form:**

http://epcis.gslus.org/hc/dea/loc/DEANumber

#### **Example:**

http://epcis.gslus.org/hc/dea/loc/12345678

#### **Examples of DEA used in various EPCIS event attributes:**

> </sourceList> <destinationList>

<destination



# 5 Capture

GS1 Data Carriers provide *machine-readable representations* of GS1 Identification keys that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports multiple data carriers: six barcode symbologies (i.e., GS1 barcodes) and RFID tags [i.e., GS1 Electronic Product Code (EPC®)-enabled radio frequency identification tags (EPC/RFID Tags)].

The table below lists the GS1 data carriers used in this guideline to support serial-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 5-1 GS1 Data Carriers Used in this Guideline

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

# **5.1 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.

#### 5.2 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 readable interpretation (HRI) text , 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 more than 180 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 (715)	NDC National Drug Code		

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 5-2 Encoding Principles

Principle Principle	T i	/ Illustration
	GTIN	AI (01)
	Serial Number	AI (21)
Each barcode data element has a two- to four-digit AI that defines data type and field size.	Batch/Lot Number	AI (10)
Solution data sypt and note of the	Expiration Date	AI (17)
	SSCC	AI (00)
	GTIN	0100361414123410
	Serial Number	21BLC0485
When encoding, each data element is preceded by its corresponding AI.	Batch/Lot Number	100192837
	Expiration Date	17241120
	SSCC	00003345678912345604



Note: Do not expect Application Identifiers (AIs) to be encoded in a defined order or sequence.

Human Readable Interpretation (HRI) is the printed representation of the data encoded in a barcode (e.g., GS1 DataMatrix or GS1-128 barcode). HRI text always appears immediately adjacent to the barcode (typically underneath linear barcodes and to the side of GS1 DataMatrix barcodes) and is subject to formatting rules specified in the GS1 General Specifications.



(01)00361414123410

(17)241120
(10)0192837

(21)BLC0485

Due to regulatory requirements, as in the example of the U.S. FDA's requirements for the NDC and expiration date in human readable form, the data content between the HRI and human readable form is equivalent in meaning but can be represented differently. As an example, in the human readable form, the NDC is listed as itself in a 3-segment hyphenated format per the U.S. FDA while in the human readable interpretation would show the NDC embedded in the GTIN with no hyphens.

Examples of the difference between the two:

Examples of the affective between the two		
	Human Readable Interpretation (HRI)	U.S. FDA Human Readable Form
National Drug Code (NDC)	(01) 003 <b>6141412341</b> 0	NDC 61414-1234-1
	*NDC is embedded in the GTIN	
<b>Expiration Date</b>	(17) 241120	EXP 20 Nov 2024



GTIN (01) 00361414123410 NDC (715) 61414 1234 1 EXP (17) NOV 20 2024 Lot (10) 0192837 SN (21) BLC0485



**Recommendation**: Owner of the product should ensure the quality of the barcode.



#### 5.2.1 Trade Items: Items, Cases & Kits

As a way of gaining uniformity throughout the supply chain, this guideline includes two best practice barcode options for items, cases, and kits: GS1 DataMatrix and GS1-128. DSCSA requirements, which commenced in 2017, include the marking of pharmaceutical products with a product identifier, serial number, batch/lot number, and expiration date.

**Table 5-3** Barcodes for Items, Cases & Kits

Barcodes for Items, 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 (on Rx Packages – e.g., Lowest Saleable Unit or homogeneous case) GS1-128 (on homogenous cases)	

#### 5.2.2 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., 2023 = 23).
- 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: 17230331



See <u>Rules for Expressing Expiration Date</u> for more information

#### **5.2.2.1** Examples

Figure 5-4 GTIN with Serial Number Encoded in a GS1 DataMatrix



Figure 5-5 GTIN with Serial Number Encoded in a GS1-128



#### 5.2.3 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 required 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 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 serial-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 <u>recommendations</u> outlined for all products that will be marked with both a UPC-A and a GS1 DataMatrix.



Figure 5-1 GTIN-12 in a UPC-A and GS1 DataMatrix





GTIN-12 encoded in a UPC-A

GTIN-12 encoded in a GS1 DataMatrix

### **5.2.4** Rules for Expressing Expiration Date

The following rules specify how the expiration date is expressed in a barcode, in human readable form, 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 form on the package SHOULD include an expiration date that includes a year, month, and non-zero day, but the human readable form MAY, if necessary, only include a year and month.
- 4. The expiration dates as expressed in EPCIS, all barcodes, and human readable form, 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 form 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.

**Important**: How the day of the month is expressed for regulated healthcare products will change starting 1 January 2025. As of that date the day of the month SHALL NOT be expressed as two zeros. A valid day of the month (e.g., last day of July = 31) SHALL be included.

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: <cbwmda:itemExpirationDate>2023-12-31</cbwmda:itemExpirationDate>

Barcode: (17)231231 HR: 2023-12-31

**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: <cbwmda:itemExpirationDate>2023-12-31</cbwmda:itemExpirationDate>

Barcode: (17)231231 HR: 2023-12

**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>2023-12-31/cbvmda:itemExpirationDate>

Barcode: (17)231200 HR: 2023-12

Example 4: NOT CONFORMING -- they do not match

EPCIS: <cbwmda:itemExpirationDate>2023-12-15</cbwmda:itemExpirationDate>

Barcode: (17)231231 HR: 2023-02

**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 2023-12-31 which is different than what EPCIS and barcode say

EPCIS: <cbvmda:itemExpirationDate>2023-12-15</cbvmda:itemExpirationDate>

Barcode: (17)231215 HR: 2023-12

**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 2023-12-31 which is different than what EPCIS says.

EPCIS: <cbwmda:itemExpirationDate>2023-12-15</cbwmda:itemExpirationDate>

Barcode: (17)231200 HR: 2023-12

**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 2023-02-28 which is different than what EPCIS and the barcode say.

EPCIS: <cbvmda:itemExpirationDate>2023-02-15</cbvmda:itemExpirationDate>

Barcode: (17)230215 HR: 2023-02

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

EPCIS: <cbwmda:itemExpirationDate>2024-02-28</cbwmda:itemExpirationDate>

Barcode: (17)240228 HR: 2024-02

#### **5.2.5 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 5-7** Barcodes for Pallets, Cases & Totes

Barcodes for Pallets, Cases & 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 5-2 SSCC Encoded in a GS1-128



Figure 5-8 SSCC Encoded in a GS1 DataMatrix



#### 5.3 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.

### **5.4** 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?). Optimally, the GS1 Company Prefix(es) and pertinent identification keys (e.g., GTINs, GLNs) of trading partners will be exchanged prior to the start of exchanging EPCIS events. The on boarding process for trading partners is a good moment for this to occur. In some situations, EPCIS event data may be received without previously exchanging GS1 Company Prefixes. To aid software in those situations, GS1 has published the GS1 Company Prefix (GCP) Length Table (<a href="https://www.gs1.org/standards/bc-epc-interop">https://www.gs1.org/standards/bc-epc-interop</a>



) which is comprised of a list starting digits of GCPs and the length of GCPs associated with each set of starting digits. This table is updated periodically with data from many GS1 Member Organizations.

(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.)

#### 5.5 GTIN + Serial Number

#### 5.5.1 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:sqtin:CompanyPrefix.ItemRefAndIndicator.SerialNumber

#### **Example:**

urn:epc:id:sqtin:0614141.112345.400806

#### **Grammar:**

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

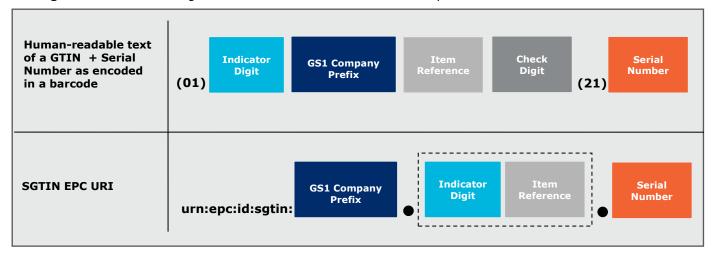
SGTINURIBody ::= 2\*(PaddedNumericComponent ".") GS3A3Component

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 5-11 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 (01) 2 030001 123498 7 (21)123456789012 Interpretation (HRI) Text

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.

#### 5.5.2 **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 5-12 Data Formats for GTIN + Serial Number Fields

Field	Data Format	
GTIN	<ul><li>14 digits</li><li>text field (not numeric)</li></ul>	
Serial Number	<ul><li>1-20 characters</li><li>text field (not numeric)</li></ul>	
Serialized GTIN EPC URI	<ul> <li>33-52 characters:</li> <li>17 characters for "urn:epc:id:sgtin:"</li> <li>13 characters for the GTIN (without the Check Digit)</li> <li>1-20 characters for the serial number</li> <li>2 periods (".")</li> <li>text field (not numeric)</li> </ul>	

# 5.6 Serialized Shipping Container Code - SSCC

#### 5.6.1 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

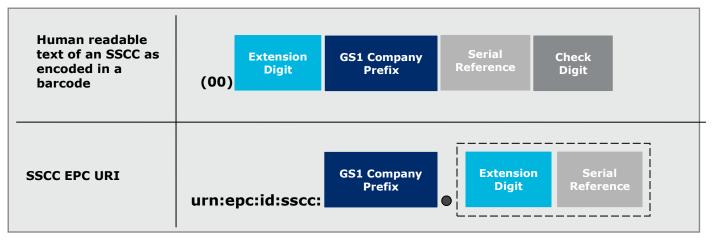
SSCCURIBody ::= PaddedNumericComponent "." PaddedNumericComponent

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 5-13 How the segments of an SSCC are represented in the SSCC EPC URI format



#### **5.6.2 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 <u>and</u> 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 5-14 Data Formats for SSCC Fields

Field	Data Format	
sscc	<ul><li>18 digits</li><li>text field (not numeric, to avoid dropping leading zeros)</li></ul>	
SSCC URI	<ul> <li>34 characters:</li> <li>16 characters for "urn:epc:id:sscc:"</li> <li>17 characters for the SSCC (without the Check Digit)</li> <li>1 period (".")</li> <li>text field (not numeric)</li> </ul>	



# **6** Share Concepts

#### 6.1 Master Data

When users assign a GS1 Identification key, 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 key 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 key for 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.

From there, GS1 Identification keys 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 key.

GS1 Identification key 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 Data Hub | 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 Data Hub | 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.

#### 6.2 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 <u>interface</u> 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 serial-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 6-1 FPCIS Data Flements

Table 6-1 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.
	EPC List	the item's unique identifier, expressed as an EPC Pure Identity URI. Depending on	GTIN, SSCC, GRAI, etc.GTIN + Serial number formatted as the SGTIN EPC
What	Parent ID	the event type, this will either be a list of	URI syntax (See 5.4.3), SSCC
	Child EPCs	EPCs, or the combination of a Parent ID and a list of child EPCs	formatted as the SSCC EPC URI syntax (See 5.8), etc.
	Event Time	the moment in time at which the event occurred	March 15, 2023 at 10:07am UTC
When	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
	Read Point	the location at which the event took place expressed as an EPC Pure Identity URI	GLN or GLNformatted as the SGLN EPC URI syntax with "0" in the extension portion (See 5.14)
Where	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 GLNformatted as the SGLN EPC URI syntax with "0" in the extension portion (See 5.14)
	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 <i>what</i> dimension that is presumed to hold until a subsequent event occurs	Saleable, Recalled, etc.
Why	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	GLNGLN formatted as the SGLN EPC URI syntax with "0" in the extension portion (See 5.14)
	Destination	transferred-to entity expressed as an EPC Pure Identity URI	GLNGLN formatted as the SGLN EPC URI syntax with "0" in the extension portion (See 5.14)

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 serialized item-level traceability.

The remainder of this document specifies how the EPCIS standard is applied to support serialized itemlevel traceability for the US pharmaceutical industry.



# **7** 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 serialized item-level traceability, recall, etc. This section presents information and concepts related to the application of EPCIS for managing events in the chain of custody of products in the pharmaceutical supply chain.

#### 7.1 Master Data in EPCIS Events

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 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, 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 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.

#### 7.2 Data Rules for this Guideline

#### 7.2.1 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 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 event time relationships for pairs of events pertaining to the same physical objects shown in Figure 7-1 below SHALL BE strictly less than the preceding event time and have non-identical times.
  - □ Event times of adjacent events of the same type SHALL have non-identical event times and SHALL appear in a logical chronological sequence. Adjacent events of the same type refer to an EPC ID undergoing successive events with the same bizStep (e.g., packing of item 123 into case 481, followed by packing of case 481 onto pallet 789 cannot share the same Event Time.)

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).



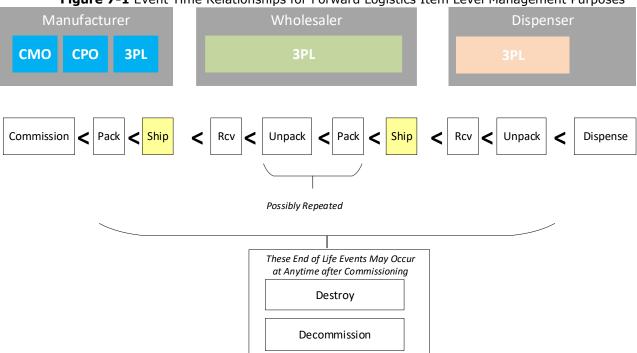


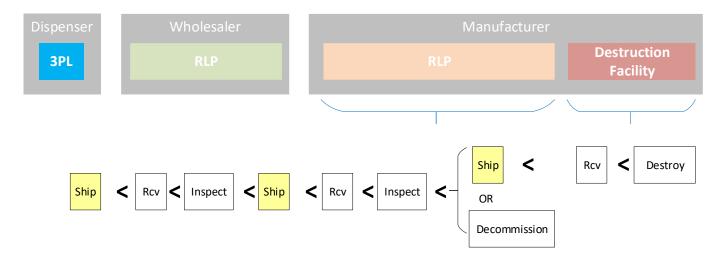
Figure 7-1 Event Time Relationships for Forward Logistics Item Level Management Purposes

The " < " symbol shows the relationships of Event Times for any single EPC. The " < " indicates that the first Event Time must be strictly less than the second Event Time.

It is permissible for the Event Time to be different from the actual moment in time provided that the rules in section 7.2 of this Implementation Guideline are followed. The event time relationships for pairs of events pertaining to the same physical objects, as diagramed in Figure 7-1, **SHALL** be strictly less than the preceding event time and **SHALL have non-identical** Event Times. Adjacent process steps (including but not limited to Commissioning, Packing and Shipping) **SHALL have non-identical** Event Times and **SHALL appear** in a chronological sequence. The Event Time of a given process step, pertaining to one uniquely serialized object, **SHALL be later** than the Event Time of the preceding adjacent step for that same uniquely serialized object This also applies to The Event Times of adjacent events of the same type, pertaining to different objects (e.g., packing of item 123 into case 481, followed by packing of case 481 onto pallet 789), **SHALL be** the real time when the event was created and recorded.



Figure 7-2 Event Time Relationships for Reverse Logistics Item Level Management Purposes



The " < " symbol shows the relationships of Event Times for any single EPC. The " < " indicates that the first Event Time must be strictly less than the second Event Time.

#### **Best Practice:**

For chain of custody 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.

#### 7.2.2 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 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 section 3.8.)
- The Read Point for an event should be a site-level GLN (without extension) expressed as an EPC URI. Such a URI begins with urn:epc:id:sqln: and ends with .0.
- For Pharmaceutical Chain of Custody event sharing between Manufacturers, Distributors, Dispensers and corresponding third party supply chain partners (CMO, CPO, 3PLs and RLPs), site-level GLN (without extension) for readPoint and bizLocation sufficiently meets the industry stakeholder requirements. Therefore, it is recommended that readPoint and bizLocation be defined in EPCIS events as a site-level GLN (without extension) expressed as an EPC URI.
- 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.

#### 7.2.3 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, urn:epcglobal:cbv:btt:desadv denoting despatch advice of delivery 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 <u>Table 6-1 EPCIS Data Elements</u> for the definition of *Source* and *Destination*.)

#### 7.2.4 The Standard Business Document Header

To support message routing and processing, the EPCIS standard leverages the Standard Business Document Header (SBDH) as an optional component for EPCIS data exchanges. The SBDH contains fields identifying the sender and receiver as well as declarations about the nature of the data contained in the message. It was originally developed for transactional data such as EDI interchanges or GS1 XML.

This guidance directs implementers to use the EPCIS Header for conveying necessary Master Data for traceability in Chain of Custody transactions. When the EPCIS Header is utilized, the SBDH shall appear with the following elements and corresponding values:



Element	Value
HeaderVersion	1.0
Sender/Identifier (with Authority = GS1)	[SGLN EPC URI, with zero ("0") in the extension portion, of the logical party who created the EPCIS event data]
Receiver/Identifier (with Authority = GS1)	[SGLN EPC URI, with zero ("0") in the extension portion, of the logical party who is receiving the EPCIS event data]
DocumentIdentification/Standard	EPCglobal
DocumentIdentification/TypeVersion	1.0
DocumentIdentification/InstanceIdentifier	[A String containing an identifier distinctly identifying this instance of the document exchanged between sender and receiver]
DocumentIdentification/Type	Events
DocumentIdentification/ CreationDateAndTime	[Date and Time when the document was created in xs:dateTime format]

The following XML snippet is an example of a conforming SBDH appearing within the EPCIS data for traceability in Chain of Custody transactions:

```
<EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
             <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
                    <sbdh:Sender>
                           <sbdh:Identifier</pre>
                           Authority="GS1">urn:epc:id:sqln:0353579.00001.0</sbdh:Identifi
                    </sbdh:Sender>
                    <sbdh:Receiver>
                           <sbdh:Identifier</pre>
                           Authority="GS1">urn:epc:id:sgln:5012345.00000.0</sbdh:Identifi
                           er>
                    </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>2023-06-02T15:14:27.574-
                           04:00</sbdh:CreationDateAndTime>
                    </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
```

#### 7.2.5 EPCIS Expiration Date

See <u>Marking Products with Both UPC-A and GS1 DataMatrix</u> <u>Marking</u> 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 required 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 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 serial-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 5-1 GTIN-12 in a UPC-A and GS1 DataMatrix





GTIN-12 encoded in a UPC-A

GTIN-12 encoded in a GS1 DataMatrix

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.

#### 7.2.6 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 or its related Aggregation event.
- The GTIN in the *Receiving* or its related *Aggregation* 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.

#### 7.3 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.gslus.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:





**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).

Specific extensions can be used amongst trading partners determined by their business needs even if not aiding a technical or regulatory requirement.

Here are some examples of extended vocabulary for bizStep, disposition, and business transaction type:

- These are business vocabulary extensions with business requirements emerging and can later be candidates for inclusion in global standard vocabulary extensions.
- Because GS1 US extensions are documented in GS1 US implementation guidelines, the industry expectations on their meaning and uses are known and set.
- Extensions created by businesses for internal tracking and processing will need to be documented
  and communicated with their trading partners to ensure expectations are set, rendering the scope
  of these extensions to be limited and therefore not mandated for sector or industry.
- Here are some examples of extended vocabulary for bizStep, disposition, and business transaction type:
  - o <a href="http://epcis.example.com/bizstep/sampling">http://epcis.example.com/bizstep/sampling</a>
    - The example bizStep represents an extension that was promoted to core business vocabulary in CBV 2.0
  - <u>http://epcis.example.com/disp/newdisposition</u>
  - o <a href="http://epcis.example.com/btt/importpermit">http://epcis.example.com/btt/importpermit</a>
  - o http://epcis.example.com/btt/notafiscal
- Listed below are examples of how an extension would be expressed:
  - o <bizStep><u>http://epcis.example.com/bizstep/sampling</u></bizStep>
  - o <disposition><u>http://epcis.example.com/disp/newdisposition</u></disposition>

#### 7.4 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.

#### 7.5 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 serialized item traceability purposes. For clarity, the EPCIS event details tables throughout this section include "Usage" with the following notations to indicate what is required for serialized item traceability purposes:



Omitted

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.

The field is always omitted in the context of this specific event.



# Part II. Application of EPCIS for Serialized Item-Level Traceability



# 8 Application of EPCIS for Serialized Item-Level Traceability

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. In this part, we specify the minimum set of EPCIS events to support serialized item-level traceability. 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).
- Both events supporting forward logistics movement of serialized product from the originating manufacturer to downstream trading partners in the supply chain are described in this implementation guideline as well as events supporting reverse logistics movement of serialized products returned by trading partners to their supplier or designated reverse logistic provider agents.
- Shipping events enable CMOs, CPOs, 3PLs and RLPs to inform the party (such as manufacturers, wholesalers, dispensers) who contracted them about serialized product shipment. More importantly, chain of custody event information feeds the serialized traceability required by DSCSA. The Shipping events generated by the 3PL, acting on behalf of manufacturer, repackager or distributor, record customer shipments and foundationally provides the details required for change-of-ownership transaction. 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 may be collected into a single EPCIS Document. 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 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 item-level traceability.
   These events are used for other business applications.

# 8.1 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.



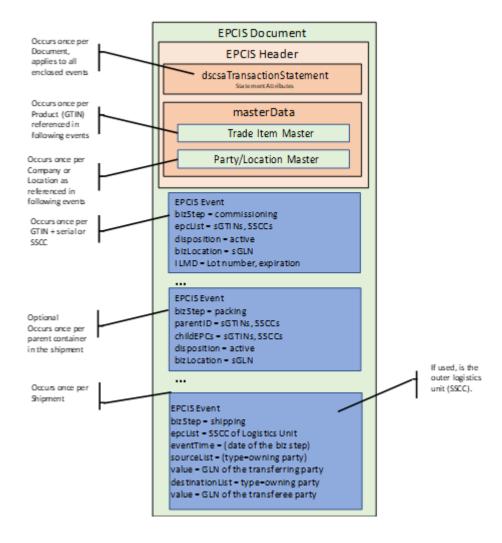


Figure 8-1 EPCIS Document Structure

# 8.2 Forward Logistic Events Captured and Shared by the Party at the Beginning of the Supply Chain

(e.g., manufacturer, repackager and their 3<sup>rd</sup> party agents: CMO, CPO and 3PL)

- Commissioning Events (Section 9.1), Transformation (Section 9.5) declaring that specified serial numbers have been introduced into the supply chain and providing information about the corresponding products.
- **Packing Events (Section** 9.2) 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 9.3) 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.



■ End-of-life Events including Destroying (Section 9.8), and Decommissioning (Section 9.11) indicate that specific products have been removed from the supply chain. These events could operationally occur anytime during the lifecycle of a serialized product.

# **8.3** Forward Logistic Events Captured and Shared by Intermediate Parties (e.g., wholesaler and their 3<sup>rd</sup> party agents: 3PL)

- Receiving Events (Section 9.4) 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 9.5), Commissioning Events (Section 9.1), and Packing Events (Section 9.2) 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 9.3) 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).
- **End-of-life Events including Destroying (Section** 9.10), and Decommissioning (Section 9.9) indicate that specific products have been removed from the supply chain. These events could operationally occur anytime during the lifecycle of a serialized product.

# 8.4 Reverse Logistic Events Captured and Shared by Parties involved in Product Return Processing and Product End of Life Management

(e.g., manufacturer, repackager, wholesaler, dispenser and their 3rd party agents: 3PL, RLP and Destruction Facility).

- Shipping Events (Section 9.3) indicating that objects have been shipped to an upstream trading partner and providing serialized item-level traceability information governing the shipment. While the Shipping events for forward logistics typically only reference the outermost (i.e., top-level) products in the packaging hierarchy, the lowest saleable units are typically reference in the EPC list for reverse logistics shipping events. Receiving Events (Section 9.4), Inspecting Events (Section 9.6) as needed indicating that objects have been received from the trading partner returning the product, with the disposition of the returned object inspected providing traceability information governing the receipt.
- End-of-life Events including Destroying (Section 9.10), and Decommissioning (Section 9.11) indicate that specific products have been removed from the supply chain. After processing returned products, they are typically decommissioned or sent to a destruction facility for destruction.

#### 8.5 Events Captured and Shared by a Party for Exception Processing

• **Void Shipping Events (Section** <u>9.12</u>) 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** 9.13) used to indicate that a prior EPCIS event is in error and should be disregarded in its entirety.

The remainder of Part II defines individual EPCIS events for different steps in the pharmaceutical supply chain process for serialized item traceability of chain of custody business events. Communication of these events facilitate the management of chain of custody events between supply chain stakeholders and their respective third-party supply chain agents who execute various supply chain activities on their behalf.



# 9 EPCIS Events for Serialized Item-Level Traceability

#### 9.1 Guideline Version in EPCIS Header

The previous release of this guideline addressed changes to EPCIS data resulting from a new version of the core EPCIS standard. This release of the guideline specifies changes to EPCIS data without migrating to a new version of the Standard.

The schema version in the root of the EPCIS file indicates which version of the EPCIS core standard is followed in the file. EPCIS files following this release (R1.2) of the guideline, will need to add a new element to the EPCIS Header of the file to reflect that fact.

What follows is an example of the new element and where it should be placed within EPCIS data:

</EPCISMasterData>

</extension>

<gslushc:guidelineVersion>GS1 US COC R1.2/gslushc:guidelineVersion>

</EPCISHeader>

#### 9.2 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.

# 9.2.1 Populating a Commissioning Event

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

Element	CoC Usage			Туре	Value	Reason
	CMO/CPO	3PL	RLP			
eventTime	Required	Required	Required	Timestamp	Date and time of event (see Section $7.2.1$ ).	EPCIS standard definition
eventTime ZoneOffset	Required	Required	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Optional	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	Required	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 <i>event-level</i> , they should be the same for all EPCs in the event.



action	Required	Required	Required	String	ADD	EPCIS standard definition
bizStep	Required	Required	Required	URI	urn:epcglobal:cbv:bizstep: commissioning	CBV standard definition
disposition	Required	Required	Required	URI	urn:epcglobal:cbv:disp: active	CBV standard definition: the disposition value "active" is always used with the bizStep "commissioning."
readPoint	Optional	Optional	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 7.2.2).	To minimize the maintenance burden of maintaining 3 <sup>rd</sup> party agent GLN master data and protecting stakeholder privacy, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.
bizLocation	Required	Required	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 7.2.2).	To minimize the maintenance burden of maintaining 3 <sup>rd</sup> party agent GLN master data and protecting stakeholder privacy, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.
bizTransact ionList	Optional	Optional	Optional	List of biz transaction s	Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.	Omitted in <i>Commissioning</i> events as there are no relevant business transactions to share.

#### 9.2.2 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	CoC Usage			Туре	Value
	CMO/CPO	3PL	RLP		
lotNumber	Conditional (see rules in the next sections)	Conditional (see rules in the next sections)	N/A	String	The lot or batch number for all of the EPCs in the epcList of the ObjectEvent.
itemExpirationDate	Conditional (see note below)	Conditional (see note below)	N/A	Date	The expiration date for all of the EPCs in the epcList of the ObjectEvent, formatted as an xsd:date. (See Section <u>5.2.4</u> for rules for expressing expiration date.)



### 9.2.3 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. Since the master data attribute values are associated with the National Drug Code (NDC), GTINs for the lowest sellable unit and higher levels of packaging for the same NDC will therefore have the same master data attribute values defined. Additionally, 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		CoC Usage		Туре	Value
	CMO/CPO	3PL	RLP		
additionalTradeItem Identification	Optional	Optional	N/A	String	The additional trade item identification associated with this GTIN.  * For DSCSA the US_FDA_NDC is a unique 3-segment number, including dashes.
additionalTradeItem IdentificationTypeC ode	Optional	Optional	N/A	String	The additional trade item identification type.  *For DSCSA, this is always the value FDA_NDC_10.
regulatedProductNa me	Optional	Optional	N/A	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.
manufacturerOfTrad eItemPartyName	Optional	Optional	N/A	String	Party name information for the manufacturer of the trade item. For DSCSA, this should be the name of the NDA holder.
dosageFormType	Optional	Optional	N/A	String	Standard forms of drugs (AEROSOL, CAPSULE, GEL, PILL, TABLET) as defined by the FDA. The FDA currently defines 143 dosage forms.
strengthDescription	Optional	Optional	N/A	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.
netContentDescripti on	Optional	Optional	N/A	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.

## 9.2.4 Commissioning Object Event Rules

• ObjectEvents for commissioning <u>item serial numbers</u> SHALL 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 <u>homogeneous containers</u> (e.g., cases and pallets of the same object) SHALL 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 <u>non-homogeneous containers</u> (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).
- <u>All</u> 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.)

### 9.2.5 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.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Commissioning Event Example. -->
<!-- CMO commissions 2 pallets, each with 2 cases of GTIN A ->4 cases
      each case has 4 LSUs -> 4 LSUs x 4 cases = 16 LSUs
     CMO sends EPCIS document to brand Manufacturer.
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcqlobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-01T08:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:039999.999999.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-01T08:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
```



```
<attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Epcistra</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Pharma LLC</attribute>
                           <attribute id="urn:epcqlobal: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>
                       <!-- master data for case -->
                       <VocabularyElement id="urn:epc:idpat:sqtin:030001.1012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:030001.1111111.0">
                           <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>
                       <!-- CMO -->
                       <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 CMO</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">Albany</attribute>
                           <attribute id="urn:epcqlobal: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>
   <gslushc:guidelineVersion>GS1 US CoC R1.2</gslushc:guidelineVersion>
</EPCISHeader>
<EPCISBody>
   <EventList>
      <!-- E1: Commissioning events (16 LSUs: 4 LSUs per case = 4x4 cases) -->
      <ObjectEvent>
          <eventTime>2023-10-01T07:04:16Z</eventTime>
          <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
          <epcList>
             <epc>urn:epc:id:sgtin:030001.0012345.11</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.12</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.13</epc>
             <epc>urn:epc:id:sqtin:030001.0012345.14</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.15</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.16</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.17</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.18</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.19</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.20</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.21</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.22</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.23</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.24</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.25</epc>
             <epc>urn:epc:id:sgtin:030001.0012345.26</epc>
          </epcList>
          <action>ADD</action>
          <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
          <disposition>urn:epcglobal:cbv:disp:active</disposition>
          <readPoint>
             <id>urn:epc:id:sqln:039999.999999.0</id>
          </readPoint>
          <bizLocation>
             <id>urn:epc:id:sqln:039999.999999.0</id>
          </bizLocation>
          <extension>
             <ilmd>
                 <cbvmda:lotNumber>A123</cbvmda:lotNumber>
                 <cbvmda:itemExpirationDate>2025-01-31</cbvmda:itemExpirationDate>
             </ilmd>
          </extension>
      </ObjectEvent>
      <!-- E2: Commissioning events (4 case SNs 110, 111, 121, 131) -->
          <eventTime>2023-10-01T07:10:16Z</eventTime>
          <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
          <epcList>
             <epc>urn:epc:id:sgtin:030001.1012345.110</epc>
             <epc>urn:epc:id:sgtin:030001.1012345.111</epc>
             <epc>urn:epc:id:sqtin:030001.1012345.121</epc>
             <epc>urn:epc:id:sgtin:030001.1012345.131</epc>
          </epcList>
          <action>ADD</action>
          <bizStep>urn:epcqlobal:cbv:bizstep:commissioning</bizStep>
          <disposition>urn:epcglobal:cbv:disp:active</disposition>
          <readPoint>
             <id>urn:epc:id:sqln:039999.999999.0</id>
          </readPoint>
          <br/>bizLocation>
```



```
<id>urn:epc:id:sgln:039999.999999.0</id>
             </bizLocation>
             <extension>
                 <ilmd>
                    <cbvmda:lotNumber>A123</cbvmda:lotNumber>
                    <cbvmda:itemExpirationDate>2025-01-31/cbvmda:itemExpirationDate>
                 </ilmd>
             </extension>
          </ObjectEvent>
          <!-- E3: Commissioning events (2 pallets of GTIN A) -->
          <ObjectEvent>
             <eventTime>2023-10-01T07:15:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                 <epc>urn:epc:id:sscc:030001.41234567890</epc>
                 <epc>urn:epc:id:sscc:030001.41234567895</epc>
             </epcList>
             <action>ADD</action>
             <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
             <disposition>urn:epcglobal:cbv:disp:active</disposition>
             <readPoint>
                 <id>urn:epc:id:sqln:039999.999999.0</id>
             </readPoint>
             <br/>
<br/>
dizLocation>
                 <id>urn:epc:id:sgln:039999.999999.0</id>
             </bizLocation>
          </ObjectEvent>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

### 9.2.6 Grouping Together Commissioning Object Events

- High volume throughput of commissioning serialized products can result in hundreds of thousands of commissioned item serial numbers that can potentially generate extra-large EPCIS document file size. Capturing one event per commissioned EPC should be avoided to prevent the operational issues of processing massive EPCIS document files. Instead of capturing the commissioning event for each commissioned EPC as single events, the commissioning events for the same GTIN and batch SHOULD BE judiciously grouped together in a single commissioning event. The list of EPCs of the same packaging level (i.e., each, case, pallet) will be combined together in a single commissioning event. Given the example of a production batch for a specific GTIN yielding commissioned objects representing eaches, cases and pallets, there would be 3 commissioning events for the same GTIN and batch: a commissioning event grouping eaches, a second commissioning event grouping cases, and a commissioning event grouping pallets.
- When combining the commissioning of EPCs for the same GTIN, batch and packaging level into a single EPCIS commissioning object event, a single eventTime SHOULD BE defined to represent the commissioning event of these judiciously grouped EPCs.

### 9.3 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.

#### 9.3.1 Populating a Packing Event

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



Element		CoC Usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
eventTime	Required	Required	Required	Timestamp	Date and time of event (see Section <u>7.2.1</u> ).	EPCIS standard definition
eventTimeZ oneOffset	Required	Required	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Optional	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
parentID	Required	Required	Required	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition
childEPCs	Required	Required	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	Required	Required	String	ADD	EPCIS standard definition
bizStep	Required	Required	Required	URI	urn:epcglobal:cbv:bizste p:packing	CBV standard definition
disposition	Required	Required	Required	URI	urn:epcglobal:cbv:disp: in_progress	CBV standard definition
readPoint	Optional	Optional	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 7.2.2).	To minimize the maintenance burden of maintaining 3 <sup>rd</sup> party agent GLN master data and protecting stakeholder privacy, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.
bizLocation	Required	Required	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 7.2.2).	To minimize the maintenance burden of maintaining 3 <sup>rd</sup> party agent GLN master data and protecting stakeholder privacy, the GLN (SGLN) values, may be provided as the (corporate) entity GLN value, in place of their contracted parties' location GLN.
bizTransacti onList	Omitted	Omitted	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 <i>Packing</i> event as there are no relevant business transactions to share.



### 9.3.2 XML Example of a Packing Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Packing Event Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcqlobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-26T17:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:030001.1111111.0</sbdh:Identifier>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-26T17:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- master data for case -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:030001.1111111.0">
                           <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>
                       <!-- CMO -->
                       <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 CMO</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">Albany</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>
      <gslushc:guidelineVersion>GS1 US CoC R1.2</gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <AggregationEvent>
             <eventTime>2023-10-26T17:10:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sqtin:030001.1012345.2222223333</parentID>
             <childEPCs>
                 <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.10000001003</epc>
             </childEPCs>
             <action>ADD</action>
             <bizStep>urn:epcglobal:cbv:bizstep:packing</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
             <readPoint>
                <id>urn:epc:id:sqln:039999.999999.0</id>
             </readPoint>
             <bizLocation>
                <id>urn:epc:id:sqln:039999.999999.0</id>
             </bizLocation>
          </AggregationEvent>
```



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

# 9.4 Shipping

Shipping is the process of initiating the transfer an object from one trading partner to another. A data carrier (i.e., a linear or 2-dimensional barcode) may have been read during this process. Only the outermost containers in the packaging hierarchy are included.

## 9.4.1 Populating a Shipping Event

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

Element		CoC Usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
eventTime	Required	Required	Required	Timestamp	Date and time of event (see Section <u>7.2.1</u> ).	EPCIS standard definition. For purposes of DSCSA, this is considered the shipping date (when bizStep = shipping).
eventTime ZoneOffset	Required	Required	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Optional	Optional	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	Required	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	Required	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	Required	Required	URI	urn:epcglobal:cbv:bizstep:ship ping	CBV standard definition
disposition	Required	Required	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	Optional	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 7.2.1).	EPCIS standard definition
bizLocation	Omitted	Omitted	Omitted	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 7.2.2).	For a Shipping event, this is unknown until a Receiving event occurs. Thus, bizLocation is always omitted in Shipping events. (Note:



Element		CoC Usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
						source and destination elements in this event provide "Ship from/to" and "Transfer from/to" information.)
bizTransact ionList	Required (either PO, DESADV)	Required (either PO, DESADV)	Optional	List of biz transactions	Business transactions governing this <i>Shipping</i> event, which may include a purchase order, delivery number or an invoice (see Section 7.2.3 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 <i>Shipping Transaction Detail</i> events (Section 9.3.5) 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, Delivery Number, Invoice, or other ID's.
sourceList	Required (source types: owning_p arty and location)	Required (source types: owning_ party and location)	Required (source type: location)	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 and another source of type urn:epcglobal:cbv:sdt:location.  • The source value with source type of urn:epcglobal:cbv:sdt: owning_party is the EPC Pure Identity URI for the GLN of the transferring party.  • The source value with source type of urn:epcglobal:cbv:sdt: location is the EPC Pure Identity URI for the source type of urn:epcglobal:cbv:sdt: location 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.
destination List	Required (destinati	Required (destinati	Required (destinati	List of destinations	Each destination in the destinationList is a pair of	Optional in the EPCIS standard, but required



Element		CoC Usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
	on types: owning_p arty and location)	on types: owning_ party and location)	on type: location)		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 and another destination of type urn:epcglobal:cbv:sdt:location.  • The destination value with destination type of urn:epcglobal:cbv:sdt: owning_party is the EPC Pure Identity URI for the GLN of the transfer-to party.  • The destination value with destination type of urn:epcglobal:cbv:sdt: location is the EPC Pure Identity URI for the GLN of the transfer-to party.  • The destination value with destination type of urn:epcglobal:cbv:sdt: location 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.	in this guideline to provide party information for DSCSA.

## 9.4.2 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 7.3 for general notes about extensions.)

Element	CoC Usage			Туре	Value
	CMO/CPO	3PL	RLP		
dropShipment	N/A	Conditional	N/A	Boolean	Flag indicating that the products are being shipped directly by the seller to the buyer's customer while the transfer of ownership transaction is between the seller and the buyer. For example, a manufacturer sells the product to the wholesaler and the manufacturer is drop shipping the product to the dispenser who is the wholesaler's customer.  Default value is false  It is recommended to capture and send EPCIS events related to drop shipments in a separate EPCIS document. An example of this is when the seller ships the product directly to the buyer's customer [shipped from Manufacturer to Dispenser but sold to Wholesaler]. Therefore, serialized products that are not drop shipped will be captured in a separate EPCIS document than serialized products that are drop shipped.



#### 9.4.3 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. When choosing to include master data, the following defines the set of attributes and their required versus optional usage requirements.

### 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.)

Element		CoC Usage		Туре	Value
	CMO/CPO	3PL	RLP		
name	Required	Required	Required	String	The name of the location or party expressed in text
streetAddress One	Required	Required	Required	String	The first line of the street address.
streetAddress Two	Optional	Optional	Optional	String	The second line of the street address.
streetAddress Three	Optional	Optional	Optional	String	The third line of the street address.
city	Required	Required	Required	String	The city.
state	Conditional	Conditional	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	Conditional	Conditional	String	The ZIP or other postal code.
countryCode	Required	Required	Required	String	The country using the standard two- letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

### 9.4.4 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. This example also illustrates the population of Standard Business Document Header (SBDH) attributes and shows how to populate the EPCIS Header with the GS1 US HC extensions and guidelineVersion.



```
<sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:08429315.1234.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-11-01T08:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                    <VocabularyElementList>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:030001.1111111.0">
                           <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>
                       <!-- 3PL for Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:08429315.1234.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 MFG 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">998 Taylor
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
486</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40129-
3336</attribute>
                           <attribute id="urn:epcqlobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                       <!-- Wholesaler -->
                       <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>
                       <!-- Wholesaler's DC-->
```



```
<VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
       </extension>
       <gslushc:guidelineVersion>GS1 US CoC R1.2/gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
       <EventList>
          <ObjectEvent>
             <eventTime>2023-11-01T07:45:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                 <epc>urn:epc:id:sscc:08429315.398765432</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:08429315.1234.0</id>
             </readPoint>
             <!-- 2 business documents: PO from buying wholesaler, Delivery Document created by
3PL -->
             <br/>
<br/>
dizTransactionList>
                 <br/>bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:039999999991:XYZPO567</bizTransaction>
                 <bizTransaction</pre>
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0842931512340:ABCDEL234</bizTransactio
n>
             </br></bizTransactionList>
             <extension>
                 <!-- Source Owning Party is Manufacturer, Source Location is 3PL -->
                 <sourceList>
                    <source
type="urn:epcglobal:cbv:sdt:owning party">urn:epc:id:sgln:030001.111111.0</source>
                    <source
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:08429315.1234.0</source>
                 </sourceList>
                 <!-- Destination Owning Party is Wholesaler Corp Office, Destination Location
is Wholesaler Distribution Center -->
                 <destinationList>
                    <destination
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:039999.999999.0</destination>
                    <destination
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:039999.345678.0</destination>
                 </destinationList>
             </extension>
              <qslushc:dropShipment>false</qslushc:dropShipment>
          </ObjectEvent>
```



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

### 9.4.5 Shipping Business Transaction Detail Event

As specified in Section 9.3.1, 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 <code>epcList</code> of a <code>Shipping</code> 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 <code>Shipping</code> event will list the pallet identifier in the <code>epcList</code>, and list both purchase orders in the <code>bizTransactionList</code>. The <code>Shipping</code> 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 <code>epcList</code> 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	(	CoC Usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
eventTime	N/A	Required	N/A	Timestamp	Date and time of event (see Section <u>7.2.1</u> ). This should precede the date and time of the corresponding <i>Shipping</i> event.	EPCIS standard definition For purposes of DSCSA, the shipping business transaction detail event time precedes the shipping date (when bizStep = shipping).
eventTimeZon eOffset	N/A	Required	N/A	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	N/A	Optional	N/A	Timestamp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	N/A	Required	N/A	List of URI	<ul> <li>EPC Pure Identity         URI for each object         associated with the         business         transactions listed         in this event.</li> <li>If the EPC of a         container is         indicated, all of its         contents are         associated with the         business         transaction.</li> </ul>	EPCIS standard definition



Element	(	CoC Usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
action	N/A	Required	N/A	String	ADD	EPCIS standard definition
bizStep	N/A	Required	N/A	URI	urn:epcglobal:cbv:bizstep:s hipping	CBV standard definition
disposition	N/A	Required	N/A	URI	urn:epcglobal:cbv:disp: in_transit	CBV standard definition. The <b>disposition</b> value "in_transit" is always paired with the <b>bizStep</b> "shipping" for forward logistics.
readPoint	N/A	Optional	N/A	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 7.2.2).  This should match the readPoint of the corresponding Shipping event.	EPCIS standard definition
bizLocation	N/A	Omitted	N/A	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 7.2.3).	For a Shipping event, this is unknown until a Receiving event occurs. Thus, bizLocation is always omitted in Shipping events.
bizTransaction List	N/A	Required (PO)	N/A	List of biz transactions	Business transactions governing this Shipping Business Transaction Detail event, which may include a purchase order, delivery number or an invoice (see Section 7.2.3 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

### 9.4.6 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.



```
<sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:08429315.1234.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-27T17:30:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for case -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#requlatedProductName">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>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sqln:030001.1111111.0">
                           <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>
                       <!-- 3PL for Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sqln:08429315.1234.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 MFG 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">998 Taylor
Ave</attribute>
                           <attribute id="urn:epcqlobal:cbv:mda#streetAddressTwo">Suite
486</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
```



```
<attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40129-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                        <!-- Wholesaler -->
                        <VocabularyElement id="urn:epc:id:sqln: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:epcqlobal:cbv:mda#city">New York</attribute>
                           <attribute id="urn:epcqlobal: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>
       <gslushc:guidelineVersion>GS1 US CoC R1.2</gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <TransactionEvent>
              <eventTime>2023-10-27T17:10:16Z</eventTime>
              <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <br/>
<br/>
dizTransactionList>
                 <br/>
<br/>
dizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:039999999991:XYZPO567</bizTransaction>
                 <br/>
<br/>bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0842931512340:ABCDEL234</bizTransactio
n>
             </br></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:08429315.1234.0</id>
              </readPoint>
          </TransactionEvent>
       </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

### 9.4.7 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"?>
<!-- Example Shipment with Multiple POs illustrating how to capture with Object and Transaction
Events -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-11-01T10:13:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:08429315.1234.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-11-01T10:13:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                    <VocabularyElementList>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:030001.1111111.0">
                           <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>
                       <!-- 3PL for Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:08429315.1234.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 MFG 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">998 Taylor
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
486</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
```



```
<attribute id="urn:epcglobal:cbv:mda#postalCode">40129-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                       <!-- Wholesaler -->
                       <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>
                       <!-- Wholesaler's DC-->
                       <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gslushc:guidelineVersion>GS1 US CoC R1.2</gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <!-- Using a Transaction Event, record the shipping contents specifically associated
with PO# 1234 -->
          <TransactionEvent>
             <!-- The transaction event's eventTime shouldshould precede the date and time of
the corresponding Shipping event. -->
             <eventTime>2023-11-01T10:08:12Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <bizTransactionList>
                 <!-- Associate PO# 1234 to the EPCs in the business transaction -->
                 <bizTransaction</pre>
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:039999999991:1234</bizTransaction>
             </br></bizTransactionList>
                 <epc>urn:epc:id:sscc:08429315.398765432</epc>
                 <epc>urn:epc:id:sqtin: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:08429315.1234.0</id>
             </readPoint>
          </TransactionEvent>
          <!-- The transaction event's eventTime shouldshould precede the date and time of the
corresponding Shipping event. -->
          <TransactionEvent>
             <eventTime>2023-11-01T10:09:12Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <bizTransactionList>
                 <!-- Associate PO# 4567 to the EPCs in the business transaction -->
                 <br/>
<br/>
dizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:039999999991:4567</bizTransaction>
             </br></bizTransactionList>
             <epcList>
                 <epc>urn:epc:id:sqtin: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:08429315.398765435</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:08429315.1234.0</id>
             </readPoint>
          </TransactionEvent>
          <!-- Shipping event for 3 SSCCs.
                  Shipment is covered by 2 Purchase Orders (POs) #1234 and #4567. -->
          <ObjectEvent>
             <eventTime>2023-11-01T10:11:12Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <epcList>
                 <epc>urn:epc:id:sscc:08429315.398765432</epc>
                 <epc>urn:epc:id:sscc:08429315.398765435</epc>
                 <epc>urn:epc:id:sscc:08429315.398765434</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:08429315.1234.0</id>
             </readPoint>
             <br/>
<br/>
dizTransactionList>
                 <!-- Both PO# 1234 and PO#4567 are associated with this shipment -->
                 <br/>bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:03999999991:1234</bizTransaction>
                 <br/>bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:039999999991:4567</bizTransaction>
                 <bizTransaction</pre>
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0842931512340:DEL123
                 </br></bizTransaction>
              </bizTransactionList>
             <extension>
                 <sourceList>
                    <source
type="urn:epcglobal:cbv:sdt:owning party">urn:epc:id:sgln:030001.111111.0</source>
                    <source
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:08429315.1234.0</source>
                 </sourceList>
                 <destinationList>
```



## 9.5 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 serial-level management should be an EPCIS *Transformation* Event populated as follows:

Element	(	CoC Usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
eventTime	Required	Requir ed	N/A	Timestamp	Date and time of event. (See Section 7.2.1)	EPCIS standard definition
eventTimeZ oneOffset	Required	Requir ed	N/A	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Option al	N/A	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
inputEPCLis t	Required	Requir ed	N/A	List of URI	List of repackaging input EPC(s) in EPC Pure Identity URI format	List of input EPCs to the repackaging process; the products that are consumed to create the repackaged product
outputEPCL ist	Required	Requir ed	N/A	List of URI	List of repackaging output EPC(s) in EPC Pure Identity URI format	List of SGTINs that are the <i>outputs</i> of the repackaging process; the repackaged products that are produced.
bizStep	Required	Requir ed	N/A	URI	urn:epcglobal:cbv:bizstep:commissioni ng	CBV standard definition
disposition	Required	Requir ed	N/A	URI	urn:epcglobal:cbv:disp:active	CBV standard definition. The <b>disposition</b> value "active" is always paired with the <b>bizStep</b> "commissioning" for forward logistics.
readPoint	Optional	Option al	N/A	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section <u>7.2.2</u> )	EPCIS standard definition



bizLocation	Required	Requir ed	N/A	URI	The location where the objects are presumed to be following the event.	EPCIS standard definition
Element	Usage	Usage	N/A	Туре	Value	Reason
bizTransact ionList	Optional	Option al	N/A	List of biz transaction s	Business transactions governing this <i>Transformation</i> event, which may include a purchase order or an invoice (See Section <u>8.2.3</u> for details) (Each transaction is represented as a pair of URIs: one URI for the type and one URI for the value.)	Optional
Instance leve	el master da	ta (ilmd)	elements			
lotNumber	Required	Requir ed	N/A	String	The lot or batch number for all of the EPCs in the outputEPCList of the repackaged product.	
itemExpiratio nDate	Required	Requir ed	N/A	Date	The expiration date for all of the EPCs in of the of the repackaged product, forma (See Section <u>5.2.3</u> .)	•

### 9.5.1 Transformation Event Example XML

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Transformation Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-02T10:13:16Z">
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier</pre>
Authority="GS1">urn:epc:id:sgln:0534245.13572.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:0374132.45902.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-02T10:13:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                        <!-- master data for lowest saleable unit GTIN A -->
                        <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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">250
pills</attribute>
                       </VocabularyElement>
                       <!-- master data for repackaged lowest saleable unit GTIN B -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:0374132.057913.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">74132-579-13</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#regulatedProductName">Celentia</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#manufacturerOfTradeItemPartyName">GS1 Repackager</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>
                       <!-- Repackager -->
                       <VocabularyElement id="urn:epc:id:sgln:0374132.45902.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1
Repackager</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">114 Delta
Street</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
1000</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Austin</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">TX</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#postalCode">78653</attribute>
                           <attribute id="urn:epcqlobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                       <!-- CPO for Repackager -->
                       <VocabularyElement id="urn:epc:id:sgln:0534245.13572.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 CPO</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">123 Barton
Springs Rd</attribute>
                          <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
2403</attribute>
                          <attribute id="urn:epcglobal:cbv:mda#city">Austin</attribute>
                          <attribute id="urn:epcglobal:cbv:mda#state">TX</attribute>
                          <attribute id="urn:epcglobal:cbv:mda#postalCode">78704-
0004</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
```



```
</VocabularyList>
      </EPCISMasterData>
   </extension>
   <gslushc:guidelineVersion>GS1 US CoC R1.2/gslushc:guidelineVersion>
</EPCISHeader>
<EPCISBody>
   <EventList>
      <!-- E1: Transformation Event from GTIN A to GTIN B -->
      <extension>
          <TransformationEvent>
             <eventTime>2023-10-02T07:04:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <inputEPCList>
                <epc>urn:epc:id:sqtin:030001.0012345.11</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.12</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.13</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.14</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.15</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.16</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.17</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.18</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.19</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.20</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.21</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.22</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.23</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.24</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.25</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.26</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.27</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.28</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.29</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.30</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.31</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.32</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.33</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.34</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.35</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.36</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.37</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.38</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.39</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.40</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.41</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.42</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.43</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.44</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.45</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.46</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.47</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.48</epc>
                <epc>urn:epc:id:sqtin:030001.0012345.49</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.50</epc>
             </inputEPCList>
             <outputEPCList>
                <epc>urn:epc:id:sgtin:0374132.057913.1001</epc>
                <epc>urn:epc:id:sgtin:0374132.057913.1002</epc>
                <epc>urn:epc:id:sgtin:0374132.057913.1003</epc>
                <epc>urn:epc:id:sgtin:0374132.057913.1004</epc>
                <epc>urn:epc:id:sqtin:0374132.057913.1005</epc>
                <epc>urn:epc:id:sgtin:0374132.057913.1006</epc>
```



```
<epc>urn:epc:id:sgtin:0374132.057913.1007</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1008</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1009</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1010</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1011</pc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1012</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1013</epc>
                    <epc>urn:epc:id:sqtin:0374132.057913.1014</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1015</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1016</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1017</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1018</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1019</epc>
                    <epc>urn:epc:id:sgtin:0374132.057913.1020</epc>
                 </outputEPCList>
                 <bizStep>urn:epcglobal:cbv:bizstep:commissioning</bizStep>
                 <disposition>urn:epcglobal:cbv:disp:active</disposition>
                 <readPoint>
                    <id>urn:epc:id:sgln:0534245.13572.0</id>
                </readPoint>
                <bizLocation>
                    <id>urn:epc:id:sgln:0534245.13572.0</id>
                 </bizLocation>
                    <cbvmda:lotNumber>R123</cbvmda:lotNumber>
                    <cbvmda:itemExpirationDate>2024-04-30/cbvmda:itemExpirationDate>
                </ilmd>
             </TransformationEvent>
          </extension>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

## 9.6 Receiving

Receiving is the process of completing the transfer of an object from one trading partner to another.

Receiving is primarily recorded in the following way:

- 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 are inferred to have been received.
  - The Receiving event should be an EPCIS Object Event populated as specified below.

#### 9.6.1 Populating a Receiving Event with an Object Event

Element	Usage	Туре	Value	Reason
eventTime	Required	Timestamp	Date & time of event. (See Section 7.2.1)	EPCIS standard definition
eventTime ZoneOffset	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.  An Object Event is used when the EPC is physically scanned.	See the discussion above regarding receiving options.



Element	Usage	Туре	Value	Reason
			<ul> <li>Could be only the outermost container</li> <li>Could be all or some contents of the innermost containers with unpacking</li> </ul>	
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 7.2.2)	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 7.2.2)	EPCIS standard definition
bizTransact ionList	Optional	List of biz transactions	Business transactions governing this <i>Receiving</i> event, which may include a purchase order, delivery number, or an invoice. (See Section <u>7.2.3</u> 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, Delivery Number, 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 and another source of type urn:epcglobal:cbv:sdt:location.  • The source value with source type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transferring party.  • The source value with source type of urn:epcglobal:cbv:sdt:location 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.	EPCIS standard definition
destination List	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 and another destination of type urn:epcglobal:cbv:sdt:location.  • The destination value with destination type of urn:epcglobal:cbv:sdt:owning_party is the EPC Pure Identity URI for the GLN of the transfer-to party.	EPCIS standard definition



Element	Usage	Туре	Value	Reason
			The destination value with destination type of urn:epcglobal:cbv:sdt:location 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.	

#### **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.

### 9.6.2 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.

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].

## 9.6.3 Capturing Receiving of Objects Scanned and XML Example

**Example Business Scenario:** A pallet containing 2 homogeneous cases of 4 bundles of inner packs containing 5 saleable eaches arrive at the wholesaler warehouse. At the receiving dock, the wholesaler scans pallet barcode and infers receipt of the contents. They capture the physical scanning of the pallet at the receiving dock using an Object Event.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Receiving Event Example -->
<!-- Example use case: A pallet containing 10 homogeneous cases of 4 bundles of inner
packs containing 5 saleable eaches arrive at the 3PL warehouse. At the receiving dock,</pre>
```



```
They capture the physical scanning of the pallet at the receiving dock using an Object
Event.
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
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="2023-11-
01T08:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier
Authority="GS1">urn:epc:id:sgln:07539426.5678.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier</pre>
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-11-01T08:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
       <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                    <VocabularyElementList>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:030001.1111111.0">
                           <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>
                       <!-- Manufacturer owned DC-->
                       <VocabularyElement id="urn:epc:id:sqln:030001.111121.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 Pharma
DC</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">7244 S
Century Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
101</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
```

the 3PL for the Wholesaler scans the pallet barcode and infers receipt of the contents.



```
<attribute
id="urn:epcglobal:cbv:mda#postalCode">40041</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                        <!-- Wholesaler -->
                        <VocabularyElement id="urn:epc:id:sqln: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>
                        <!-- 3PL for Wholesaler -->
                        <VocabularyElement id="urn:epc:id:sgln:07539426.5678.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1
WHLS 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1051
Keystone Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
785</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40131-
3336</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gslushc:guidelineVersion>GS1 US CoC R1.2/gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
       <EventList>
          <ObjectEvent>
             <eventTime>2023-11-01T07:45:16Z</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:07539426.5678.0</id>
             </readPoint>
             <br/>bizLocation>
                 <id>urn:epc:id:sqln:07539426.5678.0</id>
             </br></bizLocation>
```

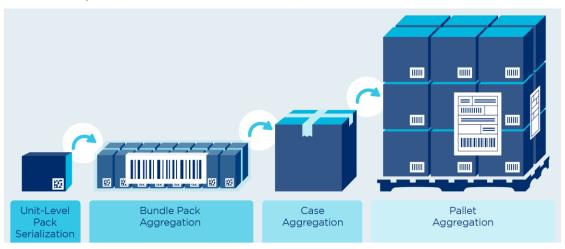


```
<!-- 2 business documents: PO from buying wholesaler, Delivery Document
created by Manufacturer -->
             <bizTransactionList>
                 <br/>
<br/>bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:039999999991:XYZPO567</bizTransacti
on>
                 <br/>bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0300011111215:ABCDEL234</bizTran
saction>
             </br></bizTransactionList>
             <extension>
                 <!-- Source Owning Party is Manufacturer, Source Location is
Manufacturer owned DC -->
                 <sourceList>
                    <source
type="urn:epcglobal:cbv:sdt:owning party">urn:epc:id:sgln:030001.111111.0</source>
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:030001.111121.0</source>
                 </sourceList>
                 <!-- Destination Owning Party is Wholesaler Corp Office, Destination
Location is 3PL for Wholesaler -->
                 <destinationList>
                    <destination
type="urn:epcglobal:cbv:sdt:owning party">urn:epc:id:sgln:039999.999999.0</destination>
                    <destination
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:07539426.5678.0</destination>
                 </destinationList>
             </extension>
          </ObjectEvent>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

### In the scenario, the packaging levels are:

- Parent = the pallet
- Child of Pallet = 2 homogeneous cases
- Child of Cases = 4 bundles of inner packs
- Child of Inner Packs = 5 eaches in each inner pack

**Note:** Aggregation is used in this example business scenario to associate a collection of trade items to a higher packaging level. It creates the parent-child relationship by associating the aggregated unit, which is the parent, with its innermost contents, the children.





### 9.6.4 Capturing Receiving under Inference

Without unpacking, companies may choose to capture the items inferred as part of the Receiving process. This can be accomplished by adding an *Aggregation* Event to the Receiving process for each inferred item to be recorded. While the Object Receiving event acknowledges which outermost containers were scanned. this Aggregation Receiving event is similar to the Object *Receiving* Event shown above with a few modifications.

## 9.6.4.1 Populating an Aggregation Event in Support of Receiving under Inference

An EPCIS Aggregation Event is populated as follows:

Element	Usage	Туре	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section <u>7.2.1</u> )	EPCIS standard definition
eventTimeZ oneOffset	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
Element	Usage	Туре	Value	Reason
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	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 7.2.2)	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 7.2.2)	EPCIS standard definition

## 9.6.4.2 Aggregation Event Extension

In addition to the EPCIS standard fields listed above, the following extension field should also be included in the EPCIS Aggregation event. (See Section 7.2.5 for general notes about extensions)

Element	Usage	Туре	Value
completeness_inferred	Required	Boolean	True if inference is being made at receiving, contents of the outermost container are not being scanned.
			False, if inference is not being made at receiving.



### 9.6.4.3 XML Examples of Business Scenarios for Receiving Under Inference

**Example Business Scenario 1:** Without unpacking, record **inferred** receiving into inventory of 2 homogeneous cases contained in a pallet that was physically scanned at the wholesaler warehouse's receiving dock. Capture receipt of 2 homogeneous cases **inferred** to be contained in the pallet using an **Aggregation Event**.

**Note:** The Aggregation Event used in capturing the inferred receipt of products that have not been unpacked utilizes *action=OBSERVE*, *bizStep=Receiving* and includes new GS1US Extension element of *completeness\_inferred=true*.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Aggregation Event Example for receiving inferred contents of pallet using only EPCIS and
CBV 1.2 constructs and use of GS1 US extension element, completeness inferred, to indicate the
inferred integrity of that aggregation (without unpacking the aggregated children from the
parent) on the basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
<!-- Example use case: A pallet containing 2 homogeneous cases of 4 bundles of inner packs
containing 5 saleable eaches arrive at the 3PL warehouse. At the receiving dock, the 3PL for
the Wholesaler scans the pallet barcode and infers receipt of the contents.
Without unpacking, record inferred receiving into inventory of 2 homogeneous cases contained in
a pallet that was physically scanned at the 3PL warehouse's receiving dock. Capture receipt of
2 homogeneous cases inferred to be contained in the pallet using an Aggregation Event.
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-11-01T08:46:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:07539426.5678.0/sbdh:Identifier>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>11002200010</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-11-01T08:46:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for case -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Wholesaler -->
                       <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>
                       <!-- 3PL for Wholesaler -->
                       <VocabularyElement id="urn:epc:id:sgln:07539426.5678.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 WHLS 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1051 Keystone
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
785</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40131-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gslushc:quidelineVersion>GS1 US CoC R1.2</qslushc:quidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <!-- Without unpacking, record inferred receiving into inventory of 2 homogeneous
cases contained in a pallet that was physically scanned
                   at the 3PL warehouse's receiving dock. Capture receipt of 2homogeneous cases
inferred to be contained in the pallet using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:46:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sscc:030001.01234567890</parentID>
             <childEPCs>
                <epc>urn:epc:id:sgtin:030001.1012345.110</epc>
                 <epc>urn:epc:id:sgtin:030001.1012345.111</epc>
             </childEPCs>
```



```
<!-- Populate with action=OBSERVE since the Aggregation Event is used to reflect
the children being received without unpacking the contents -->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
             <readPoint>
                 <id>urn:epc:id:sqln:07539426.5678.0</id>
             </readPoint>
             <br/>bizLocation>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to indicate
the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the basis
of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
-->
             <gslushc:completeness inferred>true</gslushc:completeness inferred>
          </AggregationEvent>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

**Example Business Scenario 2:** Without unpacking, record **inferred** receiving into inventory the 8 bundles of inner packs containing 5 saleable units contained in each homogeneous case that has been inferred to be contained in the pallet that was physically scanned at the wholesaler warehouse's receiving dock. For each homogeneous case, capture receipt of 4 bundles **inferred** to be contained in the homogeneous case using an **Aggregation Event**.

**Note:** The Aggregation Event used in capturing the inferred receipt of products that have not been unpacked utilizes *action=OBSERVE*, *bizStep=Receiving* and includes new GS1US Extension element of *completeness\_inferred=true*.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Aggregation Event Example for receiving inferred contents of homogenous cases using only
EPCIS and CBV 1.2 constructs and use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation (without unpacking the aggregated children
from the parent) on the basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
-->
<!-- Example use case: A pallet containing 2 homogeneous cases of 4 bundles of inner packs
containing 5 saleable eaches arrive at the 3PL warehouse. At the receiving dock, the 3PL for
the Wholesaler scans the pallet barcode and infers receipt of the contents.
Without unpacking, record inferred receiving into inventory of 4 bundles contained in each of
the 2 homogeneous cases in a pallet that was physically scanned at the 3PL warehouse's
receiving dock. Capture receipt of 8 bundles inferred to be contained in the 2 homogeneous
cases using an Aggregation Event.
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-11-01T08:49:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:07539426.5678.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
```



```
<sbdh:Identifier Authority="GS1">urn:epc:id:sqln:039999.999999.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>11002200010</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-11-01T08:49:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for case -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</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>
                       <!-- master data for bundle -->
                       <VocabularyElement id="urn:epc:id:sgtin:030001.3012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Wholesaler -->
                       <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>
                       <!-- 3PL for Wholesaler -->
                       <VocabularyElement id="urn:epc:id:sgln:07539426.5678.0">
                           <attribute id="urn:epcqlobal:cbv:mda#name">GS1 WHLS 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1051 Keystone
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
785</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40131-
3336</attribute>
                           <attribute id="urn:epcqlobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gslushc:guidelineVersion>GS1 US CoC R1.2/gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <!-- Without unpacking, record inferred receiving into inventory of 8 bundles
contained in 2 homogeneous cases. -->
          <!-- E1: Capture receipt 4 bundles inferred to be contained in first homogeneous case
using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:47:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.1012345.110</parentID>
             <childEPCs>
                <epc>urn:epc:id:sgtin:030001.3012345.300</epc>
                 <epc>urn:epc:id:sgtin:030001.3012345.301</epc>
                 <epc>urn:epc:id:sgtin:030001.3012345.302</epc>
                 <epc>urn:epc:id:sgtin:030001.3012345.303</epc>
             </childEPCs>
             <!-- Populate with action=OBSERVE since the Aggregation Event is used to reflect
the children being received without unpacking the contents -->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
             <readPoint>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </readPoint>
             <bizLocation>
                <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to indicate
the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the basis
of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
-->
             <gslushc:completeness inferred>true</gslushc:completeness inferred>
          </AggregationEvent>
          <!-- E2: Capture receipt 4 bundles inferred to be contained in second homogeneous
case using an Aggregation Event. -->
```



```
<AggregationEvent>
             <eventTime>2023-11-01T07:48:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.1012345.111</parentID>
             <childEPCs>
                <epc>urn:epc:id:sgtin:030001.3012345.304</epc>
                <epc>urn:epc:id:sqtin:030001.3012345.305</epc>
                <epc>urn:epc:id:sgtin:030001.3012345.306</epc>
                 <epc>urn:epc:id:sgtin:030001.3012345.307</epc>
             </childEPCs>
             <!-- Populate with action=OBSERVE since the Aggregation Event is used to reflect
the children being received without unpacking the contents -->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcqlobal:cbv:disp:in progress</disposition>
                <id>urn:epc:id:sgln:07539426.5678.0</id>
             </readPoint>
             <bizLocation>
                <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to indicate
the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the basis
of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream supplier.
-->
             <gslushc:completeness inferred>true</gslushc:completeness inferred>
         </AggregationEvent>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

**Example Business Scenario 3:** Without unpacking, record **inferred** receiving into inventory the 40 saleable units contained in each inner pack bundle that has been inferred to be contained in the homogeneous case of the pallet that was physically scanned at the wholesaler warehouse's receiving dock. Capture receipt of 40 saleable units **inferred** to be contained in the 8 inner pack bundles (each containing 5 saleable units) using an **Aggregation Event**.

**Note:** The Aggregation Event used in capturing the inferred receipt of products that have not been unpacked utilizes *action=OBSERVE*, *bizStep=Receiving* and includes new GS1US Extension element of *completeness\_inferred=true*.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Aggregation Event Example for receiving inferred contents of bundles using only EPCIS
and CBV 1.2 constructs and use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation (without unpacking the aggregated
children from the parent) on the basis of aggregation information
 (e.g., earlier EPCIS packing event data) provided by an upstream supplier. -->
<!-- A pallet containing 2 homogeneous cases of 4 bundles of inner packs containing 5
saleable eaches arrive at the 3PL warehouse. At the receiving dock, the 3PL for Wholesaler
scans the pallet barcode and infers receipt of the contents.
Without unpacking, record inferred receiving into inventory of 4 bundles contained in each
of the 2 homogeneous cases in a pallet that was physically scanned at the 3PL warehouse's
receiving dock. Capture receipt of 40 eaches inferred to be contained in the 8 homogeneous
cases using an Aggregation Event.
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcqlobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-11-01T08:58:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier</pre>
Authority="GS1">urn:epc:id:sqln:07539426.5678.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier</pre>
Authority="GS1">urn:epc:id:sgln:039999.999999.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>11002200010</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-11-01T08:58:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- master data for bundle -->
                       <VocabularyElement id="urn:epc:id:sgtin:030001.3012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Wholesaler -->
                       <VocabularyElement id="urn:epc:id:sgln:039999.999999.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
LLC</attribute>
                           <attribute id="urn:epcqlobal: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>
                       <!-- 3PL for Wholesaler -->
                       <VocabularyElement id="urn:epc:id:sgln:07539426.5678.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1
WHLS 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">1051
Keystone Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
785</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40131-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gslushc:guidelineVersion>GS1 US CoC R1.2</gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <!-- Without unpacking, record inferred receiving into inventory of 40 Lowest
Saleable Unit (LSUs) contained in 8 bundles. -->
          <!-- E1: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be contained in
first bundle using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:47:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sqtin:030001.3012345.300/parentID>
             <childEPCs>
                 <epc>urn:epc:id:sgtin:030001.0012345.11</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.12</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.13</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.14</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.15</epc>
             </childEPCs>
             <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents-->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
             <readPoint>
```



```
<id>urn:epc:id:sgln:07539426.5678.0</id>
             </readPoint>
             <br/>bizLocation>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->
             <gslushc:completeness inferred>true</gslushc:completeness inferred>
          </AggregationEvent>
          <!-- E2: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be contained in
2nd bundle using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:48:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.3012345.301</parentID>
             <childEPCs>
                 <epc>urn:epc:id:sgtin:030001.0012345.16</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.17</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.18</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.19</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.20</epc>
             </childEPCs>
             <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcqlobal:cbv:disp:in progress</disposition>
             <readPoint>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </readPoint>
             <br/>
<br/>
dizLocation>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->
             <gs1ushc:completeness inferred>true</gs1ushc:completeness inferred>
          </AggregationEvent>
          <!-- E3: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be contained in
3rd bundle using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:49:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.3012345.302</parentID>
             <childEPCs>
                 <epc>urn:epc:id:sgtin:030001.0012345.21</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.22</epc>
                 <epc>urn:epc:id:sqtin:030001.0012345.23</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.24</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.25</epc>
             </childEPCs>
             <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
             <action>OBSERVE</action>
```



```
<bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
             <readPoint>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </readPoint>
             <br/>
<br/>
dizLocation>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->
             <qs1ushc:completeness inferred>true</qs1ushc:completeness inferred>
          </AggregationEvent>
          <!-- E4: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be contained in
4th bundle using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:50:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.3012345.303</parentID>
             <childEPCs>
                 <epc>urn:epc:id:sgtin:030001.0012345.26</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.27</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.28</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.29</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.30</epc>
             </childEPCs>
             <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
             <readPoint>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </readPoint>
             <br/>bizLocation>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->
             <gslushc:completeness inferred>true</gslushc:completeness inferred>
          </AggregationEvent>
          <!-- E5: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be contained in
5th bundle using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:51:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.3012345.304</parentID>
             <childEPCs>
                 <epc>urn:epc:id:sgtin:030001.0012345.31</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.32</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.33</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.34</epc>
                 <epc>urn:epc:id:sqtin:030001.0012345.35</epc>
             </childEPCs>
```



```
<!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
             <readPoint>
                <id>urn:epc:id:sqln:07539426.5678.0</id>
             </readPoint>
             <br/>bizLocation>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->
             <gslushc:completeness inferred>true</gslushc:completeness inferred>
          </AggregationEvent>
          <!-- E6: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be contained in
6th bundle using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:52:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.3012345.305</parentID>
             <childEPCs>
                <epc>urn:epc:id:sgtin:030001.0012345.36</epc>
                <epc>urn:epc:id:sgtin:030001.0012345.37</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.38</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.39</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.40</epc>
             </childEPCs>
             <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </readPoint>
             <br/>
<br/>
dizLocation>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->
             <gslushc:completeness inferred>true</gslushc:completeness inferred>
          </AggregationEvent>
          <!-- E7: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be contained in
7th bundle using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:53:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.3012345.306</parentID>
             <childEPCs>
                <epc>urn:epc:id:sgtin:030001.0012345.41</epc>
                 <epc>urn:epc:id:sqtin:030001.0012345.42</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.43</epc>
```



```
<epc>urn:epc:id:sgtin:030001.0012345.44</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.45</epc>
             </childEPCs>
             <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </readPoint>
             <br/>
<br/>
dizLocation>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->
             <gslushc:completeness inferred>true</gslushc:completeness inferred>
          </AggregationEvent>
          <!-- E8: Capture receipt 5 Lowest Saleable Unit (LSU)s inferred to be contained in
8th bundle using an Aggregation Event. -->
          <AggregationEvent>
             <eventTime>2023-11-01T07:54:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.3012345.307</parentID>
             <childEPCs>
                 <epc>urn:epc:id:sgtin:030001.0012345.46</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.47</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.48</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.49</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.50</epc>
             </childEPCs>
             <!-- Populate with action=OBSERVE since the Aggregation Event is used to
reflect the children being received without unpacking the contents -->
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:receiving</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
             <readPoint>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </readPoint>
             <br/>bizLocation>
                 <id>urn:epc:id:sgln:07539426.5678.0</id>
             </bizLocation>
             <!-- Note the use of GS1 US extension element, completeness inferred, to
indicate the inferred integrity of that aggregation
                     (without unpacking the aggregated children from the parent) on the
basis of aggregation information
                     (e.g., earlier EPCIS packing event data) provided by an upstream
supplier. -->
             <gslushc:completeness inferred>true</gslushc:completeness inferred>
          </AggregationEvent>
      </EventList>
   </EPCISBody>
   </epcis:EPCISDocument>
```

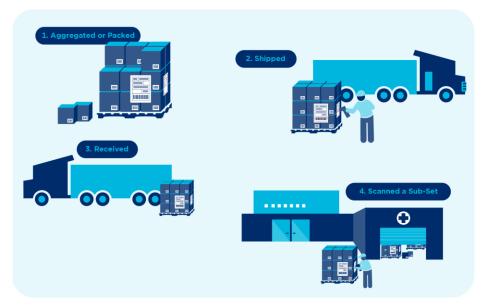
**Note:** If the pallet as used in the example above is unpacked and therefore all contents are scanned, then only an <u>Object Event</u> would be used to receive in EPCIS to represent what was done physically.



#### 9.6.5 Confirming Packaging Hierarchy during Receiving

During receiving, companies may choose to scan a subset of contained inner items, in addition to the outermost containers, in order to confirm the aggregation. If no unpacking occurs and the scanned inner items are placed back as before to the outer parent item, this will not require an event as the original receiving event would still represent these items.

**Caution:** If you break a sealed homogeneous case to scan a sub-set, you, therefore, unpack the case and are no longer able to transact the case sGTIN.



# 9.7 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.

#### 9.7.1 Populating an Unpacking Event

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

Element	CoC Usage		Туре	Value	Reason	
	CMO/CPO	3PL	RLP			
eventTime	Required	Required	N/A	Timestamp	Date and time of event. (See Section 7.2.1)	EPCIS standard definition
eventTimeZoneOffset	Required	Required	N/A	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Optional	N/A	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
parentID	Required	Required	N/A	URI	EPC of the outer container in EPC Pure Identity URI format.	EPCIS standard definition
childEPCs	Required	Required	N/A	List of URI	EPC(s) of the item(s) unpacked from the parent in EPC Pure Identity URI format.*	EPCIS standard definition.  * Although the EPCIS standard permits childEPCs to be



						omitted to indicate that all children are disaggregated from the parent, this usage is <u>not</u> permitted for this guideline.)
action	Required	Required	N/A	String	DELETE	EPCIS standard definition
bizStep	Required	Required	N/A	URI	urn:epcglobal:cbv:bizste p:unpacking	CBV standard definition
disposition	Required	Required	N/A	URI	urn:epcglobal:cbv:disp: in_progress	CBV standard definition
readPoint	Optional	Optional	N/A	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 7.2.2)	EPCIS standard definition
bizLocation	Required	Required	N/A	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 7.2.3)	EPCIS standard definition
bizTransactionList	Omitted	Omitted	N/A	List of biz transactions	Business transactions governing this event.	Omitted in the Unpacking event as there are no relevant business transactions to share

#### 9.7.2 XML Example of an Unpacking Event

<VocabularyList>

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Unpacking Event Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-29T17:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:08429315.1234.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-29T17:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
```



```
<Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- master data for case -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:030001.1111111.0">
                           <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>
                       <!-- 3PL for Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:08429315.1234.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 MFG 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">998 Taylor
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
486</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
```



```
<attribute id="urn:epcglobal:cbv:mda#postalCode">40129-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                </Vocabulary>
             </VocabularvList>
          </EPCISMasterData>
      </extension>
      <gslushc:guidelineVersion>GS1 US CoC R1.2</gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <AggregationEvent>
             <eventTime>2023-10-29T17:10:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <parentID>urn:epc:id:sgtin:030001.1012345.2222223333</parentID>
             <childEPCs>
                 <epc>urn:epc:id:sgtin:030001.0012345.10000001001</epc>
                 <epc>urn:epc:id:sgtin:030001.0012345.10000001002</epc>
             </childEPCs>
             <action>DELETE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:unpacking</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
                 <id>urn:epc:id:sgln:08429315.1234.0</id>
             </readPoint>
             <br/>
<br/>
dizLocation>
                <id>urn:epc:id:sgln:08429315.1234.0</id>
             </bizLocation>
          </AggregationEvent>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

#### 9.8 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. Although not required by DSCSA, this event can aid in recall notification.

#### 9.8.1 Populating a Dispensing Event

The dispensing event is populated as follows:

Element	Usage	Туре	Value	Reason
eventTime	Required	Timestamp	Date and time of event. (See Section <u>7.2.1</u> )	EPCIS standard definition
eventTime ZoneOffset	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



Element	Usage	Туре	Value	Reason
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:dispensin g	CBV standard definition
disposition	Required	URI	For full dispensing, use urn:epcglobal:cbv:disp:dispensed. For partial dispensing, use 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 7.2.2)	EPCIS standard definition
bizLocation	Condition al	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 7.2.2)	EPCIS standard definition  For full dispensing, this is unknown and therefore omitted.  For partial dispensing, the object is presumed to remain at the same place where the event took place until all portions have been dispensed.
bizTransact ionList	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 <b>could</b> 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).

## 9.8.2 XML Example of a Full Dispensing Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Dispensing Event: Full Dispensing Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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"
\verb|xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"| creationDate="2023-10-30T17:4\overline{5}:16Z"> | creationDate=
           <EPCISHeader>
                      <sbdh:StandardBusinessDocumentHeader>
                                 <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
                                 <sbdh:Sender>
                                            <sbdh:Identifier</pre>
Authority="GS1">urn:epc:id:sgln:0455136.24681.0</sbdh:Identifier>
                                 </sbdh:Sender>
                                 <sbdh:Receiver>
                                           <sbdh:Identifier</pre>
Authority="GS1">urn:epc:id:sgln:084436921.567.0</sbdh:Identifier>
                                 </sbdh:Receiver>
                                 <sbdh:DocumentIdentification>
                                            <sbdh:Standard>EPCglobal</sbdh:Standard>
                                            <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
                                            <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
                                            <sbdh:Type>Events</sbdh:Type>
```



```
<sbdh:CreationDateAndTime>2023-10-30T17:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Dispenser Pharmacy -->
                       <VocabularyElement id="urn:epc:id:sgln:084436921.567.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 DISP
PHRM</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">671 Grand
Ave S</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
201</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Memphis</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">TN</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#postalCode">38103</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                       <!-- Contract Pharmacy -->
                       <VocabularyElement id="urn:epc:id:sgln:0455136.24681.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 CONTRACT
PHARMACY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">142 Hill
St</attribute>
                          <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                           <attribute id="urn:epcqlobal:cbv:mda#city">Memphis</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">TN</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#postalCode">38108</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
```



```
</extension>
      <gslushc:guidelineVersion>GS1 US CoC R1.2</gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <ObjectEvent>
             <eventTime>2023-10-30T17:10:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                 <epc>urn:epc:id:sgtin:030001.0012345.1000000001</epc>
             </epcList>
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:dispensing</bizStep>
             <disposition>urn:epcqlobal:cbv:disp:dispensed</disposition>
             <readPoint>
                 <id>urn:epc:id:sgln:0455136.24681.0</id>
             </readPoint>
          </ObjectEvent>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

# 9.8.3 XML Example of a Partial Dispensing Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Dispensing Event: Partial Dispensing Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-30T17:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:0455136.24681.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:084436921.567.0/sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-30T17:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Pharmacy Corporate -->
                       <VocabularyElement id="urn:epc:id:sgln:084436921.567.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 DISP PHRM</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">671 Grand Ave
S</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Room
201</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Memphis</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">TN</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">38103</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                       <!-- Contract Pharmacy -->
                       <VocabularyElement id="urn:epc:id:sgln:0455136.24681.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 CONTRACT
PHARMACY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">142 Hill
St</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Memphis</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">TN</attribute>
                           <attribute id="urn:epcqlobal:cbv:mda#postalCode">38108</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gslushc:quidelineVersion>GS1 US CoC R1.2</qslushc:quidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <ObjectEvent>
             <eventTime>2023-10-30T17:10:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <epcList>
                <epc>urn:epc:id:sgtin:030001.0012345.1000000001</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:sqln:0455136.24681.0</id>
             </readPoint>
             <br/>bizLocation>
```



# 9.9 Inspecting

An Inspecting event should be an EPCIS Object Event to capture the physical activity of inspecting a product to assess its disposition. For example, an Inspecting event is captured when damaged product is discovered by a supply chain partner. is the process of reviewing a product to assess the condition of the serialized product. Inspecting can be operationally performed at any stage of the serialized product life cycle.

# 9.9.1 Populating an Inspecting Event

The inspecting event is populated as follows:

Element		CoC Usage		Туре	Value	Reason
	CMO/CP O	3PL	RLP			
eventTime	Required	Required	Required	Timestamp	Date and time of event. (See Section 7.2.1)	EPCIS standard definition
eventTimeZoneO ffset	Required	Required	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Optional	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	Required	Required	List of URI	EPC(s) of the inspected item(s) in EPC Pure Identity URI format	EPCIS standard definition
action	Required	Required	Required	String	OBSERVE	EPCIS standard definition.
bizStep	Required	Required	Required	URI	urn:epcglobal:cbv:bizstep: inspecting	CBV standard definition
disposition	Required	Required	Required	URI	urn:epcglobal:cbv:disp:ins pected	CBV standard definition
readPoint	Optional	Optional	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 7.2.2)	EPCIS standard definition



bizLocation	Required	Required	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event. (See Section 7.2.3)	EPCIS standard definition
bizTransactionLi st	Optional	Optional	Optional	List of biz transactions	Business transactions governing this Inspecting event.  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. May specify quality certificate or test result document.

#### 9.9.2 XML Example of an Inspecting Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Inspecting Event Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-30T17:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:08429315.1234.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-30T17:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:030001.1111111.0">
                           <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>
                       <!-- 3PL for Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:08429315.1234.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 MFG 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">998 Taylor
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
486</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40129-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gslushc:quidelineVersion>GS1 US CoC R1.2</qslushc:quidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <ObjectEvent>
             <eventTime>2023-10-30T17:10:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <epcList>
                <epc>urn:epc:id:sgtin:030001.0012345.1000000001</epc>
             </epcList>
             <action>OBSERVE</action>
             <bizStep>urn:epcglobal:cbv:bizstep:inspecting</bizStep>
             <disposition>urn:epcglobal:cbv:disp:damaged</disposition>
             <readPoint>
                 <id>urn:epc:id:sgln:08429315.1234.0</id>
             </readPoint>
```



# 9.10 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.

## 9.10.1 Populating a Destroying Event

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

Element		CoC Usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
eventTime	Required	Required	Required	Timestamp	Date and time of event. (See Section 7.2.1)	EPCIS standard definition
eventTimeZoneO ffset	Required	Required	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Optional	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	Required	Required	List of URI	EPC(s) of the destroyed item(s) in EPC Pure Identity URI format	EPCIS standard definition
action	Required	Required	Required	String	DELETE	EPCIS standard definition. (Action DELETE in an Object Event indicates that the EPCs no longer exist.)
bizStep	Required	Required	Required	URI	urn:epcglobal:cbv:bizstep: destroying	CBV standard definition
disposition	Required	Required	Required	URI	urn:epcglobal:cbv:disp: destroyed	CBV standard definition
readPoint	Optional	Optional	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 7.2.2)	EPCIS standard definition



bizLocation	Omitted	Omitted	Omitted	URI		The bizLocation is the location where the object is presumed to be following the event. For a <i>Destroying</i> event, the object no longer exists following the event. Therefore, bizLocation is always omitted for a <i>Destroying</i> event.
bizTransactionLi st	Omitted	Omitted	Omitted	List of biz transactions	Business transactions governing this event.	Omitted in the Destroying event as there are no relevant business transactions to share.

#### 9.10.2 XML Example of a Destroying Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Destroying Event Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-30T17:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:02851648.2315.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-30T17:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US_FDA_NDC</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>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:030001.1111111.0">
                           <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>
                       <!-- Destruction Facility for Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:02851648.2315.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 Destruction
Facility</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">998 Taylor
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
486</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40129-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gslushc:guidelineVersion>GS1 US CoC R1.2/gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <ObjectEvent>
             <eventTime>2023-10-30T17:10:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                <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:02851648.2315.0</id>
```



# 9.11 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).

# 9.11.1 Populating a Decommissioning Event

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

Element		CoC usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
eventTime	Required	Required	Required	Timestamp	Date and time of event. (See Section 7.2.1)	EPCIS standard definition
eventTimeZoneOff set	Required	Required	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition
recordTime	Optional	Optional	Optional	Timestamp	Date and time the event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	Required	Required	List of URI	EPC(s) of the decommissioned item(s) (in EPC Pure Identity URI format)	EPCIS standard definition
action	Required	Required	Required	String	DELETE	EPCIS standard definition. Action DELETE in an Object Event indicates that the EPCs no longer exist
bizStep	Required	Required	Required	URI	urn:epcglobal:cbv:bizs tep:decommissioning	CBV standard definition
disposition	Required	Required	Required	URI	urn:epcglobal:cbv:disp :inactive	CBV standard definition
readPoint	Optional	Optional	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place. (See Section 7.2.2)	EPCIS standard definition



bizLocation	Omitted	Omitted	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	Omitted	Omitted	List of biz transactions	Business transactions governing this event	Omitted in the Decommissioning event as there are no relevant business transactions to share

#### 9.11.2 XML Example of a Decommissioning Event

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Decommissioning Event Example -->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-30T17:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:08429315.1234.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-30T17:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:030001.1111111.0">
                           <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>
                       <!-- 3PL for Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:08429315.1234.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 MFG 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">998 Taylor
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
486</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40129-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gslushc:quidelineVersion>GS1 US CoC R1.2</qslushc:quidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <ObjectEvent>
             <eventTime>2023-10-30T17:10:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <epcList>
                <epc>urn:epc:id:sgtin:030001.0012345.1000000001</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:08429315.1234.0</id>
             </readPoint>
```



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

# 9.12 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.

*Void Shipping* is one of many mechanisms within EPCIS to manage issues in previously recorded events. *Void Shipping* is not a widely adopted practice and is not a part of the interoperable system to meet DSCSA requirements.

This section shows technically how a *Void Shipping* event can be captured to foundationally enable companies to internally capture such *Void Shipping* scenarios as part of their serialized exception management. In anticipation of exceptions stemming from serialized EPCIS trading partner exchanges, industry stakeholders will be developing technical approaches to solving data misalignment exceptions in an upcoming updated Applying GS1 Standards for DSCSA and Traceability Addendum: Diagrams and XML Examples for Serialized Exceptions Processing, R1.3. This will outline acceptable scenario-based corrections on specific applications of EPCIS/CBV constructs that will be sent by the seller and received and processed by the buyer. The adoption of this function may increase at some future point as serialized exception resolution process matures.

Due to the complexity and variety of business use cases involving cancellation or voiding, it is required for trading partners to engage in communication to identify, investigate and resolve issues. Therefore, at this time, exception communication and resolution processes are not fully automated.

**Note:** Data already sent to a downstream trading partner must require additional business processes and communication between trading partners to determine the best resolution.

#### 9.12.1 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 should be an EPCIS Object Event populated as follows:

Element	CoC Usage		Туре	Value	Reason	
	CMO/CPO	3PL	RLP			
eventTime	Required	Required	Required	Timesta mp	Date and time of event (see Section 7.2.1)	EPCIS standard definition
						This is considered the event time when the shipment was voided.
eventTimeZoneOf fset	Required	Required	Required	String	Time zone offset in effect at the time and place where the event occurred.	EPCIS standard definition



Element		CoC Usage		Туре	Value	Reason
	CMO/CPO	3PL	RLP			
recordTime	Optional	Optional	Optional	Timesta mp	Date/ time event was recorded in an EPCIS repository.	EPCIS standard definition
epcList	Required	Required	Required	List of URI	If voiding the entire shipment, the epcList is identical to the epcList of the original <i>Shipping</i> 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 <i>Shipping</i> event.	EPCIS standard definition
action	Required	Required	Required	String	OBSERVE	EPCIS standard definition
bizStep	Required	Required	Required	URI	urn:epcglobal:cbv:bizstep:void_sh ipping	CBV standard definition
disposition	Required	Required	Required	URI	urn:epcglobal:cbv:disp: in_progress	CBV standard definition. The <b>disposition</b> value "in_progress" is always paired with the <b>bizStep</b> "void_shipping" .
readPoint	Optional	Optional	Optional	URI	EPC Pure Identity URI for the GLN of the location at which the event took place (see Section 7.2.2).	EPCIS standard definition
bizLocation	Required	Required	Required	URI	EPC Pure Identity URI for the GLN of the location where the objects are presumed to be following the event (see Section 7.2.3).	EPCIS standard definition
bizTransaction List	Required (either PO, DESADV)	Required (either PO, DESADV)	Optional	List of biz transacti ons	Business transactions governing this <i>Void Shipping</i> event, which may include a purchase order or an invoice (see Section 7.2.3 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 <i>Shipping</i> event, so that the <i>Void Shipping</i> 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, Delivery Number, or other ID's.



Element	CoC Usage			Туре	Value	Reason
	CMO/CPO	3PL	RLP			
sourceList	Required (source types: owning_p arty and location)	Required (source types: owning_ party and location)	Required (source type: location)	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_par ty whose value is the EPC Pure Identity URI for the GLN of the transferring party.  If the ship-from GLN is different	EPCIS standard definition
					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 <i>Shipping</i> event, so that the <i>Void Shipping</i> event will be included if events are queried by source.	
destinationList	Required (destinati on types: owning_p arty and location)	Required (destinati on types: owning_ party and location)	Required (destina tion type: location)	List of destinati ons	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_par ty 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



#### 9.12.2 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. When choosing to include master data, the following defines the set of attributes and their required versus optional usage requirements.

#### 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.)

Element	CoC Usage			Туре	Value
	CMO/CPO	3PL	RLP		
name	Required	Required	Required	String	The name of the location or party expressed in text.
streetAddressOne	Required	Required	Required	String	The first line of the street address.
streetAddressTwo	Optional	Optional	Optional	String	The second line of the street address.
streetAddressThree	Optional	Optional	Optional	String	The third line of the street address.
city	Required	Required	Required	String	The city.
state	Conditional	Conditional	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	Conditional	Conditional	String	The ZIP or other postal code.
countryCode	Required	Required	Required	String	The country using the standard two- letter abbreviation specified in ISO 3166-1alpha-2:1997 country code [17].

# 9.12.3 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.



```
<sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-07T08:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularvList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:Location">
                    <VocabularyElementList>
                       <!-- Manufacturer -->
                       <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>
                       <!-- 3PL for Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:08429315.1234.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 MFG 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">998 Taylor
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
486</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40129-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                       <!-- Wholesaler -->
                       <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>
                       <!-- Wholesaler's DC-->
                       <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
```



```
<attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                        </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
       </extension>
       <qs1ushc:quidelineVersion>GS1 US CoC R1.2</qs1ushc:quidelineVersion>
   </EPCISHeader>
   <EPCISBody>
       <EventList>
          <ObjectEvent>
             <eventTime>2023-10-07T07:45:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <epcList>
                 <epc>urn:epc:id:sscc:08429315.212345678</epc>
             </epcList>
             <action>OBSERVE</action>
             <bizStep>urn:epcqlobal:cbv:bizstep:void shipping</bizStep>
             <disposition>urn:epcglobal:cbv:disp:in progress</disposition>
             <readPoint>
                 <id>urn:epc:id:sgln:08429315.1234.0</id>
             </readPoint>
             <br/>bizLocation>
                 <id>urn:epc:id:sgln:08429315.1234.0</id>
             </bizLocation>
             <!-- 2 business documents: PO from buying wholesaler, Delivery Document created by
Manufacturer's 3PL -->
             <br/>
<br/>
dizTransactionList>
                 <br/>bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:039999999991:XYZPO567</bizTransaction>
                 <bizTransaction</pre>
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0842931512340:ABCDEL234</bizTransactio
n>
             </br></bizTransactionList>
             <extension>
                 <!-- Source Owning Party is Manufacturer, Source Location is Manufacturer's 3PL
                 <sourceList>
                    <source
type="urn:epcglobal:cbv:sdt:owning_party">urn:epc:id:sgln:030001.111111.0</source>
                    <source
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:08429315.1234.0</source>
                 </sourceList>
                 <!-- Destination Owning Party is Wholesaler Corp Office, Destination Location
is Wholesaler Distribution Center -->
                 <destinationList>
                    <destination
type="urn:epcglobal:cbv:sdt:owning party">urn:epc:id:sgln:039999.999999.0</destination>
                    <destination
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:039999.345678.0</destination>
                 </destinationList>
             </extension>
          </ObjectEvent>
```



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

#### 9.12.4 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.

```
<?xml version="1.0" encoding="UTF-8"?>
<!-- Void Shipping Event - Example of Partial Shipment Cancellation -->
<!-- Manufacturer partially cancels shipment to the Wholesaler
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-07T08:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:08429315.1234.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:030001.111111.0</sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220002</sbdh:InstanceIdentifier>
             <sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-07T08:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      <extension>
          <EPCISMasterData>
             <VocabularyList>
                 <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sqtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Manufacturer -->
                       <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>
                       <!-- 3PL for Manufacturer -->
                       <VocabularyElement id="urn:epc:id:sgln:08429315.1234.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 MFG 3PL</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">998 Taylor
Ave</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
486</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40129-
3336</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                       <!-- Wholesaler -->
                       <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:epcqlobal: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>
                       <!-- Wholesaler's DC-->
                       <VocabularyElement id="urn:epc:id:sgln:039999.345678.0">
                           <attribute id="urn:epcglobal:cbv:mda#name">GS1 Drug Distro
Warehouse</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressOne">136 Main
St</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#streetAddressTwo">Suite
100</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#city">Louisville</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#state">KY</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#postalCode">40218</attribute>
                           <attribute id="urn:epcglobal:cbv:mda#countryCode">US</attribute>
                       </VocabularyElement>
                    </VocabularyElementList>
                 </Vocabulary>
             </VocabularyList>
          </EPCISMasterData>
      </extension>
      <gs1ushc:guidelineVersion>GS1 US CoC R1.2</gs1ushc:guidelineVersion>
```



```
</EPCISHeader>
   <EPCISBody>
       <EventList>
          <ObjectEvent>
             <eventTime>2023-10-07T07:45:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
                 <epc>urn:epc:id:sqtin: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:sqln:08429315.1234.0</id>
              </readPoint>
              <br/>
<br/>
dizLocation>
                 <id>urn:epc:id:sgln:08429315.1234.0</id>
             </bizLocation>
             <!-- 2 business documents: PO from buying wholesaler, Delivery Document created by
Manufacturer's 3PL -->
             <bizTransactionList>
                 <br/>bizTransaction
type="urn:epcglobal:cbv:btt:po">urn:epcglobal:cbv:bt:039999999991:XYZPO567</bizTransaction>
                 <br/>
<br/>bizTransaction
type="urn:epcglobal:cbv:btt:desadv">urn:epcglobal:cbv:bt:0842931512340:ABCDEL234</bizTransactio
n>
             </br></bizTransactionList>
             <extension>
                 <!-- Source Owning Party is Manufacturer, Source Location is Manufacturer owned
DC: -->
                 <sourceList>
                    <source
type="urn:epcglobal:cbv:sdt:owning party">urn:epc:id:sgln:030001.111111.0</source>
                    <source
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:08429315.1234.0</source>
                 </sourceList>
                 <!-- Destination Owning Party is Wholesaler Corp Office, Destination Location
is Wholesaler Distribution Center -->
                 <destinationList>
                    <destination
type="urn:epcglobal:cbv:sdt:owning party">urn:epc:id:sgln:039999.999999.0</destination>
                    <destination
type="urn:epcglobal:cbv:sdt:location">urn:epc:id:sgln:039999.345678.0</destination>
                 </destinationList>
              </extension>
          </ObjectEvent>
       </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

#### 9.13 EPCIS Error Declaration Mechanism

Error Declaration is not a widely adopted practice and is not currently a part of the interoperable system to meet DSCSA requirements.

This section shows technically how an Error Declaration can be used and potential situations for its use. In anticipation of exceptions stemming from serialized EPCIS trading partner exchanges, industry stakeholders will be developing technical approaches to solving data misalignment exceptions in an upcoming updated Applying GS1 Standards for DSCSA and Traceability Addendum: Diagrams and XML



Examples for Serialized Exceptions Processing, R1.3. This will outline acceptable scenario-based corrections on specific applications of EPCIS/CBV constructs that will be sent by the seller and received and processed by the buyer. The adoption of this function may increase at some future point as serialized exception resolution process matures.

Due to the complexity and variety of business use cases involving serialized exception management, it is required for trading partners to engage in communication to identify, investigate and resolve issues. Therefore, at this time, exception communication and resolution processes are not fully automated.

**Note**: Data already sent to a downstream trading partner must require additional business processes and communication between trading partners to determine the best resolution.

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.

# 9.13.1 XML Example of EPCIS Declaration Event

```
</epcis:EPCISDocument>
<?xml version="1.0" encoding="UTF-8"?>
<!-- Error Declaration Event Example -->
<!-- This example first shows an Error Declaration event for a Commissioning event which
references a corrective event..
      The Error Declaration event is followed by an example of the corrected Commissioning
event capturing the updated lot number and expiration date.
-->
<epcis:EPCISDocument xmlns:cbvmda="urn:epcglobal:cbv:mda"</pre>
xmlns:sbdh="http://www.unece.org/cefact/namespaces/StandardBusinessDocumentHeader"
xmlns:gslushc="http://epcis.gslus.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="2023-10-30T18:45:16Z">
   <EPCISHeader>
      <sbdh:StandardBusinessDocumentHeader>
          <sbdh:HeaderVersion>1.0</sbdh:HeaderVersion>
          <sbdh:Sender>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sgln:030001.111111.0</sbdh:Identifier>
          </sbdh:Sender>
          <sbdh:Receiver>
             <sbdh:Identifier Authority="GS1">urn:epc:id:sqln:039999.999999.0/sbdh:Identifier>
          </sbdh:Receiver>
          <sbdh:DocumentIdentification>
             <sbdh:Standard>EPCglobal</sbdh:Standard>
             <sbdh:TypeVersion>1.0</sbdh:TypeVersion>
             <sbdh:InstanceIdentifier>1100220001</sbdh:InstanceIdentifier>
```



```
<sbdh:Type>Events</sbdh:Type>
             <sbdh:CreationDateAndTime>2023-10-30T18:45:16Z</sbdh:CreationDateAndTime>
          </sbdh:DocumentIdentification>
      </sbdh:StandardBusinessDocumentHeader>
      on>
          <EPCISMasterData>
             <VocabularvList>
                <Vocabulary type="urn:epcglobal:epcis:vtype:EPCClass">
                    <VocabularyElementList>
                       <!-- master data for lowest saleable unit -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.0012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- master data for case -->
                       <VocabularyElement id="urn:epc:idpat:sgtin:030001.1012345.*">
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentification">0001-0123-45</attribute>
                           <attribute
id="urn:epcglobal:cbv:mda#additionalTradeItemIdentificationTypeCode">US FDA NDC</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>
                       <!-- Manufacturer -->
                       <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>
                       <!-- Wholesaler -->
                       <VocabularyElement id="urn:epc:id:sqln: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:epcqlobal: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>
      <gslushc:guidelineVersion>GS1 US CoC R1.2/gslushc:guidelineVersion>
   </EPCISHeader>
   <EPCISBody>
      <EventList>
          <!-- Error Declaration event for an invalid Commissioning event.
               This also shows the error declaration event referencing a corrective event -->
             <eventTime>2023-10-25T17:10:16Z</eventTime>
             <eventTimeZoneOffset>-05:00</eventTimeZoneOffset>
             <baseExtension>
                 <errorDeclaration>
                    <declarationTime>2023-10-30T10:12:13Z</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>2025-11-15</cbvmda:itemExpirationDate>
                </ilmd>
             </extension>
          </ObjectEvent>
          <!-- Corrective Commissioning event updating the lot number and expiration date -->
          <ObjectEvent>
             <eventTime>2023-10-29T17:10:16Z</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>urn:epc:id:sqtin:030001.0012345.10000000002</epc>
                <epc>urn:epc:id:sqtin: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:sqln:030001.111111.0</id>
             </readPoint>
             <br/>bizLocation>
                 <id>urn:epc:id:sgln:030001.111111.0</id>
             </bizLocation>
             <extension>
                <ilmd>
                    <cbvmda:lotNumber>B456</cbvmda:lotNumber>
                    <cbvmda:itemExpirationDate>2026-11-15/cbvmda:itemExpirationDate>
             </extension>
          </ObjectEvent>
      </EventList>
   </EPCISBody>
</epcis:EPCISDocument>
```

# 9.14 Chain of Custody Forward and Reverse Distribution Supply Chain Choreographies

To properly represent the specific activities and responsibilities of the agents and supply chain partners of the pharmaceutical manufacturers and wholesalers we have developed choreographies with business steps and electronic exchange of data with XML examples. These choreographies only include Rx products to be serialized in accordance with DSCSA. There are a total of thirteen unique forward distribution scenarios which should encompass the majority of business cases to be executed by a Contract Manufacturer, Contract Packager, and 3rd Party Logistics Provider on behalf of the manufacturer, repackager, wholesaler and dispenser. Additionally, there are four unique reverse logistics scenarios which should encompass the majority of business cases of executed by Reverse Logistics Providers and Destruction Facilities on behalf of the manufacturer, repackager, wholesaler and dispenser.

These supply chain choreographies are detailed in the Healthcare Addendum: Diagrams and XML Examples for Chain of Custody of Supply Chain Choreographies document.



# A Appendix: GS1 Standards

From an information management point of view, supply chain applications like 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 A-1 below summarizes some of the GS1 Standards that support item-level traceability.

Table A-1 Overview of GS1 Standards to Support Traceability

GS1 Standards Supporting 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)		
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	<b>Transactional Data:</b> AS2	Event Data:  EPCIS Capture  EPCIS Query  Discovery Services	



# **B** Appendix: Acronyms

**AI** Application Identifier

**CBV** Core Business Vocabulary

**XML** eXtensible Markup Language

**GDSN** Global Data Synchronization Network

URI Uniform Resource Identifier
URN Uniform Resource Name



# C Appendix: Glossary

## **Glossary for Extended Definitions**

#### Repackager

FDA regards Repackaging as the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug.<sup>9</sup>

Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.<sup>10</sup>

Repackager term `repackager' means a person who owns or operates an establishment that repacks and relabels a product or package for-- further sale; or distribution without a further transaction. 11

Repackaging is performed by a range of entities, including pharmacies and other facilities that specialize in repackaging drug products. FDA is aware that repackaging is done for a variety of reasons including: to meet the needs of specific groups of patients (e.g., pediatric patients or patients receiving drugs for ophthalmic use) who require smaller doses of approved sterile drug products that may not be available commercially; to reduce medication errors associated with drawing up a dose from a vial at the point of patient care; to reduce the availability of drug products that could be abused when controlled substances are left over in a vial after a dose is drawn out; to provide a particular sized container to fit into a particular device to administer the drug (such as a particular pain medication pump); for convenience for the practitioner administering an injection to a patient; to reduce waste and conserve drug supplies; and in some cases to reduce cost. Some repackagers repackage both sterile and non-sterile drug products. Examples of repackaging include tablets and capsules that are repackaged from large containers into smaller containers or blister packs, and creams and lotions are sometimes purchased in bulk and repackaged into smaller tubes or containers.

Term	Acronym	Definition
Government Definitions:		
U.S. Food and Drug Administration	U.S. FDA	The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
Drug Supply Chain Security Act	DSCSA	The Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States <sup>12</sup> .
National Drug Code	NDC	The National Drug Code is a 10-digit identification number established by the U.S. Food and Drug Administration (U.S. FDA) to identify drugs in accordance with Section 510 of the Federal Food, Drug and Cosmetic Act (Act), 21 U.S.C. §360.

<sup>&</sup>lt;sup>9</sup> For example, if tablets are removed from a blister pack and placed into a different container, that would be repackaging. However, if the blister packs containing tablets are placed into a different container for later use (without opening the individual blister packs), that would not be repackaging.

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<sup>&</sup>lt;sup>10</sup> This guidance does not apply to the compounding of drug products. Compounding is addressed in other guidance documents. See, for example, the guidances Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act and For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.

<sup>&</sup>lt;sup>11</sup> Drug Supply Chain Security Act SEC. 581. DEFINITIONS ``(16) Repackager

 $<sup>^{12} \</sup> Source: \ https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsallowers and the supply-chain and the supply-chain are supply-chain are$ 



Standardized Numerical Identification	SNI	SNI is the U.S. FDA's term for the unique identification mandated by the DSCSA.
Drug Enforcement Administration	DEA	The DEA was established in 1973 as the federal organization in charge of enforcing the controlled substances laws of the United States. [Source:
Trading Partner		https://www.dea.gov/who-we-are]
Definitions:		
		The Public Health Services 340B drug discount Program (the "340B Program") was passed by Congress in 1992 and requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations, 'Covered Entities', at significantly reduced prices. These medications need only to be provided to the Covered Entities "own patients". A 340B Contract Pharmacy is a contracted agent of the 340B Covered Entity where the covered entity is eligible for participation in the 340B program. The 340B Contract Pharmacy is not a direct participant in the 340B program and acts only as an agent and dispenses 340B priced medications to patients who are part of the covered entity. While the 340B program accommodates many dispensing arrangements for program participants, retail pharmacies became eligible to serve Covered Entities as contract pharmacies in 1996. The ability for retail pharmacies to be involved in the 340B program was expanded further in 2010
		when Covered Entities were granted the ability to establish agreements with
340B Program		multiple pharmacies to meet their 340B dispensing requirements <sup>13</sup> .
		For purposes of the DSCSA, FDA interprets the term co-licensed partner of a manufacturer, referenced in section 581(10)(B) of the FD&C Act, to mean one of two or more entities that have entered into a written agreement for the right to engage in the marketing of a prescription drug. While the term co-licensed partner is not defined in the FD&C Act, the Agency believes this
Consignment	CLP	interpretation is in alignment with industry practice and existing state laws <sup>14</sup> .  When the product is shipped to and possessed by the consignee, but the consignee does not take ownership of that product until the consignee uses the product. Consignment product is typically considered the property of the consigning supplier (typically the manufacturer, repackager, or wholesaler)
Consignment		until the product is used by the consignee (typically the dispenser) <sup>15</sup> .
Contract Manufacturing Organization	СМО	For the purposes of the DSCSA, a CMO is an entity that performs manufacturing operations for the NDA/ANDA/BLA holder or a co-licensed partner of the NDA/ANDA/BLA holder, to fulfill a contractual obligation with such manufacturer, but is not responsible for the introduction of the product into interstate commerce <sup>16</sup> .
		Providers specializing in packaging, labeling, and potentially distribution on
Contract Packaging		the behalf of manufacturers, repackagers, and wholesalers without transfer of
Organizations	CPO	ownership, just physical possession to perform services.
Direct Purchase		When product(s) are purchased directly from the manufacturer, exclusive distributor of the manufacturer, or a repackager who purchased directly unless noted as being indirectly sourced <sup>17</sup> .
Dispenser	D	The term dispenser, as defined in section 581(3) of the FD&C Act:  (A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of

<sup>&</sup>lt;sup>13</sup> Source: GS1 US Addendum: Diagrams and XML Examples for Chain of Custody of Supply Chain Choreographies

<sup>&</sup>lt;sup>14</sup> Source: U.S. FDA, "Identifying Trading Partners Under the Drug Supply Chain Security Act, Guidance for Industry, July 2022

<sup>&</sup>lt;sup>15</sup> Source: Partnership for DSCSA Governance (PDG) Foundational Blueprint for 2023 Interoperability, Chapter 3: DSCSA TI/TS Exchange Functional Design, Version 1.0, February 2, 2023

<sup>&</sup>lt;sup>16</sup> Source: http://pdsaonline.org/wp-content/uploads/2015/06/PDSA-Letter\_DSCSA-QA\_May-2014.pdf

 $<sup>^{17}</sup>$  Source: GS1 US Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability R1.3



	1	
		such entities under common ownership and control that do not act as a
		wholesale distributor; and (B) does not include a person who dispenses only
		products to be used in animals in accordance with section 512(a)(5).
		When products are being shipped directly by the seller to the buyer's
		customer while the transfer of ownership transaction is between the seller
		and the buyer. For example, a manufacturer sells the product to the
<b>.</b>		wholesaler and the manufacturer is drop shipping the product to the
Drop Shipment		dispenser who is the wholesaler's customer <sup>18</sup> .
		The term `exclusive distributor' means the wholesale distributor that directly
		purchased the product from the manufacturer and is the sole distributor of
Evaluaiva Distributor		that manufacturer's product to a subsequent repackager, wholesale
Exclusive Distributor		distributor, or dispenser <sup>19</sup> .
		When product(s) are not purchased directly from the manufacturer, exclusive
Indirect nurchase		distributor of the manufacturer, or a repackager who purchased directly
Indirect purchase		unless noted as being indirectly sourced.
		A manufacturer is defined in section 581(10) of the FD&C Act to mean: [W]ith respect to a product (A) a person that holds an application approved
		under section 505 or a license issued under section 351 of the Public Health
		Service Act for such product, or if such product is not the subject of an
		approved application or license, the person who manufactured the product;
		(B) a co-licensed partner of the person described in subparagraph (A) that
		obtains the product directly from a person described in this subparagraph or
		subparagraph (A) or (C); or (C) an affiliate of a person described in
		subparagraph (A) or (B) that receives the product directly from a person
Manufacturer	MFG	described in this subparagraph or subparagraph (A) or (B).
Primary Wholesale	1110	Wholesale distributor that purchased product directly from the manufacturer.
Distributor		Wholesale distributor that parenased product directly from the manufacturer.
		DSCSA defines repackager in section 581(16) of the FD&C Act as "a person
		who owns or operates an establishment that repacks and relabels a product
		or package for – (A) further sale; or (B) distribution without a further
Repackager	R	transaction."
		Contracted by Manufacturers to collect returned products from Dispensers
		and Wholesalers. RLPs are agents of both Wholesalers and Manufacturers.
		Only non-sellable returns are expected to be returned to RLPs. RLP services
Reverse Logistics		include processing returned products for credit; sending products to
Providers	RLP	destruction facilities for destruction; and performing recordkeeping <sup>20</sup> .
		DSCSA defines a 3PL in section 581(22) of the FD&C Act to mean:
		[A]n entity that provides or coordinates warehousing, or other logistics
		services of a product in interstate commerce on behalf of a manufacturer,
		wholesale distributor, or dispenser of a product, but does not take ownership
		of the product, nor has responsibility to direct the sale or disposition of the
Third Party Logistics	3PL	product.
		An entity that engages in the manufacture of a prescription drug for which it:
		holds the NDA or ANDA; contracts with a contract manufacturing organization
		for the physical manufacture of the drug product; is not involved in the
		physical manufacture of the drug product; and at no time takes physical
Virtual Manufacturer	VM	possession of, or stores, the drug product for wholesale distribution <sup>21</sup> .
		DSCSA defines wholesale distributor in section 581(29) of the FD&C Act to
Wholesaler/Wholesale	l	mean "a person (other than a manufacturer, a manufacturer's co-licensed
Distributor	W	partner, a third-party logistics provider, or repackager) engaged in wholesale

<sup>&</sup>lt;sup>18</sup> Source: GS1 US Applying GS1 System of Standards for DSCSA and Serialized Interoperable Traceability R1.3

<sup>&</sup>lt;sup>19</sup> Source: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act

<sup>&</sup>lt;sup>20</sup> Source: GS1 US, Addendum: Diagrams and XML Examples for Chain of Custody of Supply Chain Choreographies

<sup>&</sup>lt;sup>21</sup> Source: https://www.ncbold.com/license/30814



		distribution (as defined in section 503(e)(4) of the FD&C Act, as amended by [DSCSA])."
GS1 Standards:		
GS1 Company Prefix	GCP	A GS1 Company Prefix is a unique string of 6–11 digits issued to your company by your local GS1 Member Organization.
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).
Serialized GTIN	SGTIN	An SGTIN is the combination of a GTIN and a unique serial number of up to 20 alphanumeric characters.
Global Location Number	GLN	The Global Location Number (GLN) is the globally unique GS1 Identification Number used to identify parties and locations.
S Global Location Number	SGLN	The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS. The SGLN syntax is capable of representing a plain GLN (without extension) or a GLN plus extension.
Serial Shipping Container Code	SSCC	The Serial Shipping Container Code (SSCC) is the globally unique GS1 identification number used to identify individual logistic units. A "logistic unit" is defined as an item of any composition established for transport and/or storage which needs to be tracked individually and managed through the supply chain.
Electronic Product Code	EPC®	The Electronic Product Code™ (EPC) is syntax for unique identifiers assigned to physical objects, unit loads, locations, or other identifiable entity playing a role in business operations.
Electronic Product Code Information Services	EPCIS	The EPC Information Services (EPCIS) standard defines a data model and 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.
Data Carriers and Barcode Related:		
GS1 DataMatrix		GS1 DataMatrix is a two-dimensional (2D) barcode which may be printed as a square or rectangular symbol made up of individual squares.
Radio-Frequency Identification	RAIN RFID	The RAIN RFID alliance is a global alliance promoting the universal adoption of passive UHF RFID (called RAIN RFID). GS1 refers to "RAIN RFID" tags in this document whenever making reference to passive UHF RFID tags. NOTE: Within the UHF RFID technology space, GS1 only endorses RAIN RFID implementations that are encoded per GS1's EPC standards(which are a subset of all RAIN RFID implementations).
Universal Product Code	U.P.C.	A U.P.C. is a type of barcode. Specifically, a UPC-A is a barcode that can hold a GTIN-12, and12 and is familiar from its use on consumer products in North America.
Human Readable Interpretation	HRI	Human Readable Interpretation (HRI) is the printed representation of the data encoded in a barcode (e.g., GS1 DataMatrix or GS1-128 barcode).
Human Readable Form		Human-readable refers to product identifiers on their packaging that can be read absent of requiring a machine.



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