GS1 US

The Global Language of Business

Healthcare

Frequently Asked Questions (FAQs) by the Pharmaceutical Industry in Preparing for the U.S. DSCSA

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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.

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

1 Introduction

Many individuals and companies are preparing to meet the requirements of the U.S. Drug Supply Chain Security Act (DSCSA). This document provides answers to frequently asked questions (FAQ) in the industry. It has been created to aid trading partners across the supply chain in applying GS1 Standards to DSCSA requirements.

This FAQ guide was prepared by GS1 US® and the Secure Supply Chain Workgroup to assist the U.S. pharmaceutical industry in implementing GS1 Standards to support traceability. It was developed using information obtained from a wide variety of members of the U.S. pharmaceutical supply chain from manufacturers to providers. Additionally, the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* published November 7, 2016 was a significant source for the answers to these FAQ.

The questions in this document are organized into four main sections:

- Section 2: IDENTIFY - questions about GS1 identification numbers, including the identification of trade items (products), logistic units, parties, and locations.
- Section 3: CAPTURE - questions about barcodes and RFID tags.
- Section 4: SHARE - questions about GS1 data sharing standards including Electronic Product Code Information Services (EPCIS) and master data,
- Section 5: additional questions beyond the above three topics.

Important: As with all GS1 Standards and solutions, the recommendations contained in this FAQ guide are 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.

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

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2 IDENTIFY: Questions about GS1 identification numbers

The questions in this section are all about identifying things – assigning a GS1 identification number to something in the real world so that it can be unambiguously referenced in data that is captured within an organization and shared with other organizations.

The questions in this section are organized into four topics:

- Section 2.1: questions about identifying trade items (products) using the Global Trade Item Number® (GTIN®). Questions in this section also address the U.S. FDA National Drug Code (NDC).
- Section 2.2: questions about identifying logistic units using the Serial Shipping Container Code (SSCC).
- Section 2.3: questions about identifying parties and locations using the Global Location Number (GLN).

- Section 2.4: questions about the GS1 Company Prefix (GCP), which is a building block for creating all GS1 identification numbers including GTINs, SSCCs, and GLNs. If you read any of the previous three topics, you should read this one as well.

2.1 Questions about the Global Trade Item Number (GTIN)

The questions in this section are all about identifying trade items (products) using the Global Trade Item Number (GTIN). Questions in this section also address the U.S. FDA National Drug Code (NDC).

2.1.1 What is a Global Trade Item Number (GTIN)?

The Global Trade Item Number (GTIN) is the globally unique GS1 identification number used to identify "trade items" (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product, and are used to identify products as they move through the global supply chain to the hospital or consumer/patient. The GTIN is used to uniquely identify a product at each packaging level (e.g., a bottle of 30 tablets; a case of 100 bottles of tablets, etc.).

2.1.2 What is a National Drug Code (NDC)?

The National Drug Code is a 10-digit identification number[1] established by the U.S. Food and Drug Administration (FDA) to identify drugs in accordance with Section 510 of the Federal Food, Drug and Cosmetic Act (Act), 21 U.S.C. §360. The NDC is used by the manufacturer or relabeler to electronically submit registration and drug listing information to the FDA. The NDC consists of 3 segments which specify the drug product's labeler, trade product and package size. Each NDC code uniquely identifies a specific drug having a particular dosage form, strength, and package size.

2.1.3 How is the GTIN different from the NDC?

The GTIN differs from the NDC in two ways:

The GTIN is used to identify all types of trade items, including drugs, medical devices, consumer products outside of the healthcare sector, and non-consumer trade items across all sectors. The GTIN is used for trade items around the world. The NDC is only used to identify drugs, and only drugs subject to U.S. FDA regulation.

The GTIN uniquely identifies not only the individual sale unit of packaging, but also higher level groupings such as homogeneous cases, homogeneous pallets, etc. So, for example, a 30-tablet bottle of Drug XYZ will have one GTIN, and a 12-bottle case of the same drug will have a different GTIN. The NDC only identifies the drug itself, and does not distinguish between the individual sale unit and higher level groupings.

2.1.4 What is the relationship between an NDC and a GTIN?

Drug trade items that have an NDC can be given a GTIN that embeds the NDC. This is a best practice.

For an individual sale unit, the NDC is embedded in a GTIN-12 by combining the following elements in left-to-right order:

- The digit "3"
- The 10-digit NDC
- A check digit, computed from the previous 11 digits according to the GS1 *check digit calculator*

[1] Occasionally, an NDC appears in an 11-digit format, especially in the context of processing reimbursement claims. This FAQ discusses the NDC in the context of identifying pharmaceuticals for DSCSA reporting, and in particular the NDC as embedded in the GTIN, and for these purposes the 10-digit format is always used.

For example, the 10-digit NDC 0001012345 results in GTIN-12 300010123455, which can be used to identify the individual sale unit for this NDC.

In some situations, the GTIN-12 has to be expressed in 14-digit format, which is done by adding two zero digits to the left of the GTIN-12. The 14-digit format of the previous example is 00300010123455. When storing a GTIN in a database, the 14-digit format should always be used – see Question 2.1.5.

For a higher level grouping such as a homogeneous case, homogeneous pallet, etc., the NDC is embedded in a GTIN-14 by combining the following elements in left-to-right order:

- The digit between 1 and 8 (inclusive) chosen differently for each grouping. This is called the "indicator digit"
- The two digits "03"
- The 10-digit NDC
- A check digit, computed from the previous 13 digits according to the GS1 *check digit calculator*

For example, the 10-digit NDC 0001012345 results in GTIN-14 10300010123452 if indicator digit "1" is used.

The same NDC results in GTIN-14 20300010123459 if indicator digit "2" is used. The first GTIN could be used to identify a homogeneous case of this NDC, and the second to identify a homogeneous pallet or a different-sized case.

It does not matter what value of the indicator digit is used to identify a given grouping, as long as the value of the indicator digit is between 1 and 8 (inclusive) and each configuration gets a different indicator digit.

2.1.5 How many digits does a GTIN have?

It depends. A GTIN that is assigned for an individual sale unit has 12 digits and is called a GTIN-12. This allows it to be carried in a UPC-A barcode, the usual barcode that is scanned at point-of-sale in North America. A GTIN that is assigned for a higher level grouping such as a homogeneous case, homogeneous pallet, etc., has 14 digits and is called a GTIN-14. The first digit of such a GTIN is a digit between 1 and 8 (inclusive) and is called the indicator digit. These are the two lengths of GTIN that are used for U.S. pharmaceuticals, where the NDC is embedded in the GTIN. (There are also 8-digit and 13-digit GTINs that are used for individual sale units, primarily by non-U.S. manufacturers, but a GTIN that embeds an NDC code is never a GTIN-8 or GTIN-13.)

However, when a GTIN is carried in a GS1-128, GS1 DataMatrix, GS1 DataBar®, or GS1 QR barcode, it is always represented as 14 digits. A GTIN-12 is padded by adding two zero digits to the left to make 14 digits, when it is carried in these barcodes. The same is true when GTINs are stored in databases: both GTIN-12 and GTIN-14 are stored as 14 digits, with the GTIN-12 padded on the left with two zero digits. The only context in which a GTIN-12 appears as only 12 digits is in a UPC-A barcode.

For this reason, it is easiest to think of a GTIN as always having 14 digits, even though for an individual sale unit it is really 12 digits preceded by two zero "filler" digits.

The following table illustrates all four lengths of GTINs. The next-to-last column shows how each GTIN appears in 14-digit format, as is typically stored in databases and as used in GS1-128, GS1 DataMatrix, GS1 DataBar, and GS1 QR barcodes.

Table 2-1 GTIN Formats and Barcodes

GTIN type	Application	Example	Example expressed as 14 digits, as in a database or GS1-128, GS1 DataMatrix, GS1 DataBar, or GS1 QR barcode	Barcodes supported
GTIN-12	Individual sale unit, including U.S. pharmaceuticals that have an NDC	300010123455	00300010123455	UPC-A GS1-128 GS1 DataMatrix GS1 DataBar GS1 QR
GTIN-14	Higher level grouping, including U.S. pharmaceuticals that have an NDC	10300010123452	10300010123452	GS1-128 GS1 DataMatrix GS1 DataBar GS1 QR
GTIN-13	Individual sale unit, but never for U.S. pharmaceuticals that have an NDC	5012345678900	05012345678900	EAN-13 GS1-128 GS1 DataMatrix GS1 DataBar GS1 QR
GTIN-8	Individual sale units of small physical size, but never for U.S. pharmaceuticals that have an NDC	50112340	00000050112340	EAN-8 GS1-128 GS1 DataMatrix GS1 DataBar GS1 QR

2.1.6 What happens when my case quantity changes? Do I need another GTIN?

Yes. You need a new GTIN to identify a case containing a different number of trade items or to identify a pre-defined pallet configuration containing a different quantity of cases. You would follow the procedure in Question 2.1.4 but using a different indicator digit.

2.1.7 If I already have an NDC, do I need a GTIN?

Yes. The GTIN is what enables you to use your NDC in GS1 barcodes including the U.P.C. barcode and GS1 DataMatrix, as well as to use the NDC in GS1 data sharing standards including EPCIS. For each drug identified by an NDC, you will create a GTIN for the corresponding individual sale unit as described in Question 2.1.4. If you have higher-level groupings such as homogeneous cases, you will create GTINs for those as well (again, see Question 2.1.4).

2.1.8 If I am using my NDC to create a GTIN, do I need a GS1 Company Prefix?

Yes. All GTINs are built from a GS1 Company Prefix, and a GTIN that embeds an NDC is no exception. However, you will need to make sure you get a GS1 Company Prefix that embeds your NDC labeler code. This helps assure that the procedure for embedding an NDC in a GTIN as described in Question 2.1.4 will work properly.

Besides allowing you to create GTINs from your NDCs, which you can then use in GS1 barcodes and GS1 data sharing standards (see Question 2.1.4), the same GS1 Company Prefix can be used to create other GS1 standard identifiers including the SSCC and GLN. See Question 2.2.8.

2.1.9 Do I need to register my GTINs with GS1 US, or other entities like FDA?

No. GS1 US does not require you to register individual GTINs with GS1 US. You have to license a GS1 Company Prefix from GS1 US (see Questions 2.1.8 and 2.4.7) and GS1 US will maintain a record of that.

The FDA already requires that NDCs be registered with the FDA. The DSCSA does not require any additional registration of the NDC beyond that already required, nor do GTINs need to be registered with the FDA.

The DSCSA does require reporting of transaction information and transaction history when ownership of individual instances of drugs are transferred in the supply chain, and GTINs are used as part of this reporting when GS1 data sharing standards are used.

2.1.10 How do I communicate my GTINs and NDCs to my trading partners?

When you use EPCIS to share transaction information or transaction history with your downstream trading partner, the EPCIS message includes master data that includes the GTIN (and consequently, the NDC which is embedded within) and other descriptive information required by DSCSA including the drug name, manufacturer name, dosage form, strength, and net content. See section 11.1.4.1 Trade Item Master Data from the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2*.

Your trading partner may have additional requirements for sharing information about your GTINs and NDCs, so be sure to check with those partners for details.

2.1.11 What is a Serialized GTIN (SGTIN)?

An SGTIN is the combination of a GTIN and a unique serial number of up to 20 alphanumeric characters. Each instance of a given trade item receives a different serial number. For example, a particular GTIN might be assigned to identify the trade item "30-tablet bottle of drug XYZ." All 30-tablet bottles of drug XYZ will have the same GTIN, but each individual 30-tablet bottle of drug XYZ will have a different serial number, and therefore a different SGTIN. In this way, the SGTIN can be used to track and trace that one individual bottle through the supply chain.

2.1.12 What is a Standardized Numerical Identification (SNI)?

SNI is the FDA's term for the unique identification mandated by the DSCSA. The FDA provides guidance for the SNI for package-level identification of prescription drugs, in which it specifies that an SNI should include the National Drug Code (NDC) for the drug and a unique serial number of up to 20 alphanumeric characters generated by the manufacturer or repackager. An SGTIN can be used as an SNI, as explained below.

2.1.13 Are SGTIN and SNI the same thing?

Not the same, but compatible. The SNI as defined by the FDA only pertains to drugs that are identified by a National Drug Code (NDC), while an SGTIN can be used to identify any trade item. However, the *FDA SNI Guidance* Section III (F) explicitly states that the use of a serialized NDC is compatible with, and may be presented within, an SGTIN. GS1 US recommends the use of SGTIN as a best practice for meeting requirements involving the SNI.

An SGTIN can also be created for a trade item that does not have an NDC (e.g., a non-drug trade item, or a drug trade item not subject to FDA regulation such as a non-U.S. drug). In that case, the GTIN part of the SGTIN does not embed an NDC, and the SGTIN is not an SNI.

2.1.14 Where can I get a list of U.S. GTINs?

GS1 US does not publish a list of all GTINs. There is not a source currently in the U.S. for a list of GTINs. It is recommended that you contact the product manufacturer to obtain a complete list of their GTIN data.

2.1.15 Where can I get a global list of GTINs?

GS1 does not publish a comprehensive list of all GTINs. There are certain countries in the world (*not* including the U.S.) which require their GTINs to be registered with the local GS1 Member Organizations (MOs), so it may be possible to obtain a list of GTINs for those countries from those MOs.

2.1.16 What is the 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). HRI text always appears immediately adjacent to the barcode (typically underneath for linear barcodes and to the right of GS1 DataMatrix barcodes), and is subject to formatting rules specified in the *GS1 General Specifications*.

A label may also repeat other information found in the barcode, such as the expiration date or lot number, on some part of the label not near the barcode. Such printed information is not considered HRI and is not subject to GS1 formatting rules (though other regulations governing label content may apply.)

2.2 Questions about the Serial Shipping Container Code (SSCC)

The questions in this section are all about identifying logistic units using the Serial Shipping Container Code (SSCC).

2.2.1 What is a Serial Shipping Container Code?

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.

Common logistic units in the pharmaceutical industry include a pallet of cases picked to order, a mixed case of items picked to order, a homogeneous case of items that contains fewer than a full case, a plastic tote containing items picked to order. Unlike a trade item, each logistic unit contains different contents.

2.2.2 What is an SSCC used for?

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" to facilitate simple tracking of goods and reliable look up of complex load detail. The SSCC enables the logistics unit to be tracked individually, which brings benefits for order and delivery tracking and automated goods receiving. Because the SSCC provides a unique number for the delivery, it can be used as a lookup number to provide detailed information regarding the contents of the load.

The SSCC can be encoded in a barcode or Electronic Product Code (EPC®)/RFID tag to help the logistic unit to be accurately and easily identified as it travels between trading partners, anywhere in the world. When SSCC data is shared electronically via EDI or EPCIS, companies can share information about the status of logistic units in transit, and reliably link it to related transport information such as shipment details.

2.2.3 Who generates an SSCC?

The shipping party creates the SSCC. When building a shipment for the buyer, the shipping party creates an SSCC using the Shipper's GS1 Company Prefix (see Section 2.4) and places a logistics label containing the SSCC on the shipping unit (e.g., tote, pallet, etc.). Suppliers are responsible for assigning (allocating) SSCCs to their logistics units.

2.2.4 How is an SSCC generated?

An SSCC is a string of 18 digits that is globally unique. An SSCC is generated by combining the following four components in left-to-right order:

- **Extension Digit**: A single digit between 0 and 9 (inclusive). The Extension Digit is available to increase the capacity of the Serial Reference. It has no other logic or meaning. Shippers who do not need the additional capacity may simply use 0 (or any other fixed value) for the extension digit.
- **GS1 Company Prefix**: A globally unique number assigned by GS1 US to the company/organization who generates the SSCC (see Section 2.4). The GS1 Company Prefix is between 6 and 11 digits; the shorter the GS1 Company Prefix, the longer the serial reference (below) and therefore the greater number of SSCCs that may be allocated.
- **Serial Reference**: A number assigned by the holder of the GS1 Company Prefix to uniquely identify a logistic unit. This segment, together with the extension digit, is the "serial" part that is assigned one-by-one by the company to create a globally unique SSCC for each logistic unit. The number of digits in the Serial Reference varies in length depending on the length of the GS1 Company Prefix, so that the total number of digits in the SSCC is 18.
- **Check Digit**: A single digit computed from the previous 17 digits according to the GS1 *check digit calculator*.

2.2.5 How is an SSCC different than a GTIN?

SSCCs are distinctly different from GTINs. The SSCC acts as a license plate to track a shipment of logistics units through the supply chain. The GTIN uniquely identifies trade items (products and services).

2.2.6 What is an Extension Digit?

The Extension Digit is available to the creator of the SSCC to increase the capacity of the serial number. It has no defined logic and can be any digit between 0 and 9.

2.2.7 How do I differentiate SSCCs by packaging level? Do I use different extension digits?

No. The extension digit has no defined logic, and therefore does not indicate packaging level. It is not considered best practice to attempt to use the extension digit to identify packaging level or otherwise assign intelligence to the extension digit.

The only reliable way to determine the packaging level of the SSCC is to look up the SSCC in some information source. For example, the EPCIS data used to record the transaction information for DSCSA may be consulted to find out the composition of an SSCC in the transaction.

2.2.8 My company already has a GS1 Company Prefix which it uses to assign GTINs. Does my company need another GS1 Company Prefix to use SSCCs?

No. You can use the same GS1 Company Prefix that you already use for GTINs to create SSCCs. If you have more than one GS1 Company Prefix, you can use any or all of them to create SSCCs (and so you will have greater capacity than if you just had one GS1 Company Prefix).

2.2.9 What are some examples of when I should apply an SSCC?

Common logistic units in the pharmaceutical industry include a pallet of cases picked to order, a mixed case of items picked to order, a homogeneous case of items that contains fewer than a full case, a plastic tote containing items picked to order. Unlike a trade item, each logistic unit contains different contents.

2.2.10 Can I use a SSCC when shipping partial homogeneous cases? What about mixed cases?

Yes to both. SSCCs should be used to identify partial cases of homogeneous items or mixed cases of different items.

2.2.11 What is the lifecycle of a SSCC and can it be re-used?

The SSCC is assigned for the lifetime of the transport item and is a mandatory element on the GS1 Logistic Label. The life cycle of the SSCC is from the time the Supplier tenders the shipment until it is received by the buyer. SSCC's may never be re-used, because there may be historical data records that refer to the SSCC even though the shipment has been received.

2.2.12 Should the GTIN be included in the SSCC?

No. A GTIN identifies a trade item, and the SSCC identifies a logistic unit, which are two different things.

The logistic unit identified by an SSCC *contains* trade items identified by GTINs. The trade items inside the logistic unit are identified by GTINs. An Advanced Ship Notice (ASN) or EPCIS Event records the relationship between the SSCCs and the contained GTINs.

2.2.13 Can I have a GTIN and a SSCC together?

Generally not on the same package. If a package is a trade item (e.g., an individual unit of use or a homogeneous case of fixed composition) it will carry a GTIN; if a package is a logistic unit (e.g., a partial case, a mixed case, or a pallet picked to order), it will carry an SSCC. The logistic unit identified by an SSCC *contains* trade items identified by GTINs, but the SSCC and GTIN are not marked on the same package.

An exception is a homogeneous case of fixed composition that is manufactured and marked with an SGTIN, but later that case is shipped *by itself* and so is also a logistic unit for the purpose of that shipment. In that scenario, the case could be given an SSCC as well. For purposes of data reporting, the case SGTIN would be considered as packed inside the logistic unit SSCC (that is, the SSCC just has one SGTIN as its contents), even though they are the same physical package.

The following table summarizes the identifiers present for serialized DSCSA compliance.

Table 2-2 Identifiers for DSCSA Compliance

Scenario	Identifier on Lowest Saleable Unit	Identifier on case	Identifier on pallet
Full homogeneous case where there is a GTIN for that case configuration, and the case is packed onto a pallet with other cases	SGTIN (based on the item-level GTIN)	SGTIN (based on the case-level GTIN)	SSCC
Partial/incomplete homogeneous case, and the case is packed onto a pallet with other cases	SGTIN (based on the item-level GTIN)	SSCC	SSCC (different than the case-level SSCC)
Mixed case, and the case is packed onto a pallet with other cases	SGTIN (based on various item-level GTINs)	SSCC	SSCC (different than the case-level SSCC)
Full homogeneous case where there is a GTIN for that case configuration, and the case is shipped by itself as a logistic unit	SGTIN (based on the item-level GTIN)	SGTIN (based on the case-level GTIN) and SSCC	n/a
Partial/incomplete homogeneous case, and the case is shipped by itself as a logistic unit	SGTIN (based on the item-level GTIN)	SSCC	n/a
Mixed case, and the case is shipped by itself as a logistic unit	SGTIN (based on various item-level GTINs)	SSCC	n/a

2.2.14 Do I need to purchase special equipment to scan an SSCC?

No. SSCCs are carried in GS1 standard barcodes (often the GS1-128 barcode) and most barcode scanning hardware and software is capable of reading it.

2.2.15 How many SSCCs can I create?

The number of SSCCs you can create depends on how many digits are in the Serial Reference part when you create the SSCC (see Question 2.2.4), which in turn depends on the length of your GS1 Company Prefix. See the following table:

Table 2-3 SSCC Capacity of GS1 Company Prefixes

GS1 Company Prefix Digits	Serial Reference Digits	Number of SSCCs (if extension digit not used)	Number of SSCCs (if extension digit is used)
6	10	10,000,000,000	100,000,000,000
7	9	1,000,000,000	10,000,000,000
8	8	100,000,000	1,000,000,000
9	7	10,000,000	100,000,000
10	6	1,000,000	10,000,000
11	5	100,000	1,000,000

If you have more than one GS1 Company Prefix, your total capacity is the sum of the individual capacity provided by each GS1 Company Prefix.

2.2.16 Can mixed or partial cases be in the same logistics unit identified by an SSCC?

Yes, mixed or partial cases may be contained in the same logistic unit identified by an SSCC.

2.2.17 Do I need to put more than one SSCC label on a carton or pallet?

Each logistic unit should have at least one barcode containing the SSCC. It is recommended that a pallet should contain an additional barcode containing the same SSCC on the adjacent side.

2.2.18 How do I pass SSCCs to my trading partners? Where does an SSCC appear in EPCIS?

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

When sending SSCCs to trading partners using EPCIS, SSCCs are represented in EPC URI format.

Source reference: *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2*, section 5.2.3.

2.2.19 How do I use the SSCC on a logistic unit which I am receiving?

The SSCC enables the logistic unit to be tracked individually, which brings benefits for order and delivery tracking and automated goods receiving. This is especially true when you use ASN or EPCIS data to find out the expected contents of the logistic unit identified by that SSCC.

2.3 Questions about the Global Location Number (GLN)

The questions in this section are all about identifying **parties** and **locations** using the Global Location Number (GLN).

2.3.1 What is a Global Location Number (GLN)?

The Global Location Number (GLN) is the globally unique GS1 Identification Number used to identify parties and locations. The GLN can be used to identify a legal entity (like a health system corporation), a functional entity (like a hospital pharmacy or accounting department), or a physical location (like a warehouse or hospital wing or even a loading dock door, storage location, or nursing station).

2.3.2 What is a corporate GLN? Where would I use my corporate GLN?

A "corporate GLN" is the GLN that refers to your company as a legal entity. You can use it in any context where you need to identify your company as a legal entity. For example, in DSCSA transaction information, you are required to identify the seller and the buyer (as parties to the transaction), and you would use the corporate GLN of the seller and the corporate GLN of the buyer for that, respectively.

2.3.3 What other kinds of GLNs are there besides a corporate GLN? Where would I use them?

A GLN can identify a functional entity like a hospital pharmacy or accounting department. A GLN can also identify a physical location like a warehouse or hospital wing or even a loading dock door, storage location, or nursing station.

You can use these GLNs in any context where you need to identify a specific functional entity or physical location. For example, EPCIS data describes the physical location where business process steps take place, such as the warehouse where a shipment is packed, and you would use the GLN for that location.

2.3.4 Who generates a GLN?

The GLN for a legal entity is assigned by GS1 US when the legal entity first registers for a GS1 Company Prefix. For other GLNs, such as functional entities within the legal entity or physical locations, the company that owns the functional entity or that owns or occupies the physical location generates the GLN.

2.3.5 How is a GLN generated?

A GLN is a string of 13 digits that is globally unique. A GLN is generated by combining the following three components in left-to-right order:

- **GS1 Company Prefix**: A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers including GLNs. (See Section 2.4.) The GS1 Company Prefix is between 6 and 11 digits; the shorter the GS1 Company Prefix, the longer the location reference (below) and therefore the greater number of GLNs that may be allocated.
- **Location Reference**: A number assigned by the holder of the GS1 Company Prefix to uniquely identify a legal entity, functional entity, or physical location. This segment is the "serial" part that is assigned one-by-one by the company to create a globally unique GLN for each entity or location. The number of digits in the Location Reference varies in length depending on the length of the GS1 Company Prefix, so that the total number of digits in the GLN is 13.
- **Check Digit**: A single digit computed from the previous 12 digits according to the GS1 *check digit calculator*.

For a corporate GLN assigned by GS1 US when a company first registers for a GS1 Company Prefix, GS1 US generates the GLN usually using all zeros for the location reference part. When the company generates its own GLNs, it should not reuse the location reference previously used by GS1 US to create the corporate GLN.

2.3.6 What are all the ways a GLN is used in EPCIS data for DSCSA?

GLNs are used for several purposes within EPCIS data for DSCSA:

- In the **read point** of an EPCIS event, which identifies the physical location where a business process step took place. This is typically a physical location GLN, though a functional entity or legal entity GLN may be used if the reporting party does not wish to reveal more detailed location information.
- In the **business location** of an EPCIS event, which identifies the physical location where physical objects are expected to be following the business process described by the event. This is typically a physical location GLN, though a functional entity or legal entity GLN may be used if the reporting party does not wish to reveal more detailed location information.
- In the **source** and **destination** lists of an EPCIS shipping or receiving event, to identify the "sold by" and "sold to" parties to the transaction. These are typically legal entity GLNs, or possibly functional entity GLNs if the functional entity is considered to be the party to the transaction.
- In the **source** and **destination** lists of an EPCIS shipping or receiving event, to identify the "ship from" and "ship to" parties to the transaction, if these are different than the "sold by" and "sold to" parties (e.g., in the case of a drop shipment or consignment sale). These are typically legal entity GLNs, or possibly functional entity GLNs if the functional entity is considered to be the party to the transaction.
- In the **business transaction** lists of an EPCIS event, to uniquely qualify a business transaction identifier such as a purchase order number or invoice number. This is typically a legal entity GLN, or possibly a functional entity GLN if different functional entities within the same legal entity have independent systems for generating business transaction numbers. In the latter case, using different functional entity GLNs to qualify the business transaction numbers helps to assure the resulting identifier is globally unique, even if the different functional entities happen to generate the same business transaction number.
- In **master data** contained within the EPCIS header of an EPCIS document, to link party and location master data to the GLNs contained within the EPCIS events. This avoids having to repeat information such as name and address inside of every event that refers to a party or location.
- In the **standard business document header (SBDH)** in the EPCIS header of an EPCIS document, to identify the party sending the message and the receiving party. These are typically legal entity GLNs, or functional entity GLNs if senders and receivers need to be distinguished at the functional entity level.

2.3.7 If I have a DEA Registration Number, Health Industry Number (HIN), or Dun & Bradstreet number (DUNS), do I need a GLN?

Yes, it is recommended to have a GLN so that you can make full use of GS1 Standards for barcoding and data sharing.

- If you already have a GS1 Company Prefix (which you will if you are already creating GTINs or SSCCs), you can use the same GS1 Company Prefix to create GLNs. In fact, GS1 US already created a corporate GLN for you when you registered your first GS1 Company Prefix.
- If you do not have a GS1 Company Prefix (most often hospitals or pharmacies who do not create GTINs or SSCCs), you can obtain a GS1 Company Prefix from GS1 US. GS1 Company Prefixes are available in at various capacities, and the GS1 US team will assist you in determining the right capacity for your organization's GLN and other needs. Please see Question 2.4.7 for more information.

2.3.8 What if my trading partner doesn't have a GLN? Can I still exchange EPCIS messages with partners who do not have a GLN?

Yes. The preferred way to identify your trading partner is the GLN. However, if the trading partner does not have a GLN, the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* provides a way to use a DEA Registration Number or Dun & Bradstreet Number (DUNS) instead.

Note: You need to have a globally unique identifier for your downstream trading partner so that you can identify them in the "sold to" and "ship to" portions of EPCIS shipping events you create (and in the corresponding master data). Likewise, you need a globally unique identifier for your upstream trading partner so that you can identify them in the "sold by" and "ship from" portions of EPCIS receiving events you create.

2.3.9 How do I obtain a trading partner GLN?

Ask your trading partner for the GLN as part of the on-boarding process for setting up the trading partner within your system. If your trading partner sends you EPCIS data, you can also find their GLN(s) in that data.

2.3.10 Do I need to register my GLNs with GS1 US or other entities like FDA?

No. Neither GS1 US nor the FDA requires you to register your GLNs. GS1 US, of course, already has a record of the corporate GLN that GS1 US created for you when you first registered for a GS1 Company Prefix.

2.3.11 If I don't register my GLNs, how do I communicate to my trading partners my GLNs?

It is up to you to find the best way to communicate your GLNs to your trading partners as part of the onboarding process for initiating trade with your trading partner.

2.3.12 I'm a Manufacturer or Repackager. Do I need a GLN?

Yes. It is recommended that you have a GLN so that you can construct EPCIS event data to meet DSCSA requirements.

As a manufacturer or repackager, you likely already have a GS1 Company Prefix that you use to create GTINs for the products you originate, as well as to create SSCCs for logistic units that you make. You can use that GS1 Company Prefix to create a GLN, or simply use the corporate GLN that GS1 US created for you when you first registered for a GS1 Company Prefix.

2.3.13 I'm a Wholesaler, Dispenser, CMO, 3PL, or Contract Packager. Do I need a GLN?

Yes. It is recommended that you have a GLN so that you can construct EPCIS event data to meet DSCSA requirements.

As a wholesaler, CMO, 3PL, or contract packager, you likely already have a GS1 Company Prefix that you use to create SSCCs for logistic units that you make. You can use that GS1 Company Prefix to create a GLN, or simply use the corporate GLN that GS1 US created for you when you first registered for a GS1 Company Prefix.

2.3.14 I'm a pharmacy, doctor, hospital, health facility, or other dispenser. Do I need a GLN?

Yes. It is recommended that you have a GLN so that your suppliers can construct EPCIS event data to meet DSCSA requirements.

If you do not already have a GS1 Company Prefix, you can obtain a GS1 Company Prefix having minimum capacity in order to minimize the cost of obtaining the GS1 Company Prefix. See Question 2.4.7.

2.3.15 How many GLNs can I create?

The number of GLNs you can create depends on how many digits are in the Location Reference part when you create the GLN (see Question 2.3.5), which in turn depends on the length of your GS1 Company Prefix. See the following table:

Table 2-4 GLN Capacity of GS1 Company Prefixes

GS1 Company Prefix Digits	Location Reference Digits	Number of GLNs (including your corporate GLN)
6	6	1,000,000
7	5	100,000
8	4	10,000
9	3	1,000
10	2	10
11	1	1

If you have more than one GS1 Company Prefix, your total capacity is the sum of the individual capacity provided by each GS1 Company Prefix.

2.3.16 How do I determine the number of GLNs I need? What is my basic guiding principle for knowing which of my functional entities I need to set up with a GLN?

At a minimum, you will need one corporate GLN to identify your company as a legal entity. You can also use this in the read point and business location fields of EPCIS events if you do not want to report location in any greater detail.

If you have functional entities that you consider to be parties to transactions with trading partners, independently from the parent legal entity, then you should create GLNs for each of those. Also, if you have multiple functional entities that independently create business transaction numbers such as purchase order numbers or invoice numbers, you should create a GLN for each such functional entity so that you can uniquely qualify the business transaction numbers. (See also Question 2.3.6.)

If you wish to identify location information in EPCIS events to greater granularity, whether for internal use only or for sharing with trading partners, you will need to create a GLN for each physical location you want to identify. (If you have a very large number of physical locations, you may be able to use the GLN Extension; see Question 2.3.17.)

2.3.17 What is a GLN Extension and how does it work?

The GLN Extension is a string consisting of 1–20 alphanumeric characters that you add to a GLN to create a unique identifier. Typically, the GLN used for this purpose is a containing location. For example, if you have a GLN that represents a given warehouse, then you could use the combination of a GLN and GLN Extension to uniquely identify each bin in the warehouse. Each bin's identifier would consist of the warehouse's GLN plus a GLN Extension that is different for each bin.

The GLN Extension enables you to create an essentially unlimited number of location identifiers. Some companies may wish to identify a large number of physical locations (e.g., identifying individual bins in a large warehouse). While it is possible to do this with individual GLNs, the GLN capacity provided by a single GS1 Company Prefix may be insufficient (see Question 2.3.15).

Note: GLN Extensions are not needed to comply with DSCSA reporting requirements. They are only used when collecting very fine-grained location information, most often for internal use only.

2.3.18 What is an 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. 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 entity or location and so in that sense is already serialized. The "S" does not stand for anything.

2.3.19 If one physical warehouse (in-house or third party) is storing products for multiple legal entities (LE), does it need multiple GLNs (one for each LE) or can just one GLN be used to record events for multiple LEs?

If the legal entities in questions are the parties to the transaction for purposes of DSCSA, then separate GLNs need to be used so that each GLN can have different name and address information.

2.3.20 Are my products linked to a specific GLN? What is the relationship between GS1 Company Prefix, GTIN, and GLN?

No. Both the GTIN and the GLN (as well as the SSCC) are constructed from a GS1 Company Prefix. However, no relationship between a GTIN or GLN (or SSCC) is implied by the fact that they share the same GS1 Company Prefix or the fact that they use different GS1 Company Prefixes. A company that creates GTINs and GLNs (and SSCCs) can use any GS1 Company Prefix it has duly licensed to create any of those identifiers. It does not matter, for example, whether the GTIN is manufactured in the facility with the GLN – that GTIN and GLN could have the same GS1 Company Prefix or different GS1 Company Prefixes.

2.4 Questions about the GS1 Company Prefix (GCP)

2.4.1 What is a GS1 Company Prefix?

A GS1 Company Prefix is a unique string of 6–11 digits issued to your company by your local GS1 Member Organization. These digits are part of every GS1 identification number that you create (e.g., GTIN, SSCC, GLN, etc.). Because your GS1 Company Prefix is different from every other company's GS1 Company Prefix worldwide, the GS1 identification numbers you create are also globally unique.

2.4.2 Does the GS1 Company Prefix uniquely identify my company or brand?

No. The GS1 Company Prefix is not an identifier. It is a string of digits that is used as a part of GS1 identification numbers. A GS1 Company Prefix does not uniquely identify a company or brand because a given company could have more than one GS1 Company Prefix, and sometimes a company uses the same GS1 Company Prefix to identify products of several brands.

The unique identifier for a company is a corporate GLN; see Question 2.3.2.

2.4.3 Why do different GS1 Company Prefixes have different lengths?

The GS1 Company Prefix can be anywhere between 6–11 digits in length. This enables each company to choose a GS1 Company Prefix that gives them a suitable capacity for creating GS1 identification numbers. The shorter the GS1 Company Prefix, the more digits are available for the company to allocate themselves, and therefore the greater the capacity. See the tables in Questions 2.2.15 and 2.3.15 to illustrate.

When you register for a GS1 Company Prefix, you specify what capacity, and therefore what GS1 Company Prefix length, you want. The fees for larger capacity (i.e., shorter GS1 Company Prefix) are somewhat higher.

2.4.4 If the GS1 Company Prefix is of variable length, isn't there a possibility that numbers created from prefixes of different length can collide?

No, because of the way GS1 Company Prefixes are assigned to companies. For example, if GS1 US assigns 7-digit GS1 Company Prefix 0614141 to a company, it will *not* assign 8-digit prefix 06141411 to another company, because numbers created from the latter would collide with numbers assigned by the first company.

2.4.5 What is the relationship of an FDA labeler code and a GS1 Company Prefix?

The FDA National Drug Code (NDC) number is a 10-digit identifier constructed from three segments: a 4–5 digit labeler code assigned by the FDA to a drug manufacturer, a product code assigned by the manufacturer, and a package code assigned by the manufacturer.

The NDC may be embedded in a GS1 Global Trade Item Number (GTIN) for use in GS1 barcodes and data sharing standards. Question 2.1.4 explains in detail how this works. When this is done, the labeler code becomes part of the GS1 Company Prefix portion of the GTIN. Specifically, the GS1 Company Prefix consists of the digits "03" followed by the 4–5 digits of the labeler code, resulting in a 6- or 7-digit GS1 Company Prefix. Just as the labeler code is assigned to a drug manufacturer for its exclusive use in creating NDCs, the GS1 Company Prefix consisting of "03" followed by the labeler code is assigned by GS1 US to the same manufacturer for its exclusive use in creating GTINs that embed those NDCs.

This means that if you are a drug manufacturer and you need to create GTINs that embed your NDCs, you must obtain a GS1 Company Prefix corresponding to your FDA labeler code (or for each FDA labeler code, if you have more than one). You will tell GS1 US your labeler code when you apply, and the GS1 Company Prefix you get will consist of "03" followed by the digits of your labeler code.

This is in contrast to manufacturers of trade items other than drugs (or for drugs not subject to FDA regulations, such as drugs not sold in the U.S.), and for companies who don't manufacture trade items at all but need a GS1 Company Prefix to create SSCCs or GLNs. Those companies will receive a GS1 Company Prefix that does not embed a NDC labeler code. It will always be a GS1 Company Prefix that does *not* begin with "03."

2.4.6 What is a U.P.C. Company Prefix?

GS1 US uses the term "U.P.C. Company Prefix" to refer to the portion of a GS1 Company Prefix that is encoded in a UPC-A barcode symbol. The U.P.C. Company Prefix is the same as the GS1 Company Prefix with the initial "0" character removed. So if your GS1 Company Prefix is 030001, the corresponding U.P.C. Company Prefix is 30001.

If a GS1 Company Prefix begins with a digit other than "0," that GS1 Company Prefix cannot be used in UPC-A barcode symbols, and there is no corresponding U.P.C. Company Prefix. Most GS1 Company Prefixes issued by GS1 US, including all GS1 Company Prefixes that embed an NDC labeler code, do begin with "0" so that there is a corresponding U.P.C. Company Prefix and so that GTINs created from these prefixes may be used in UPC-A barcode symbols. (In other countries, consumer products are

usually marked with an EAN-13 barcode, which looks very similar to a UPC-A barcode but carries 13 digits instead of 12, so that it can accommodate GTINs created from GS1 Company Prefixes that begin with a non-zero first digit.)

When interacting with GS1 US, take care to note whether the term GS1 Company Prefix or U.P.C. Company Prefix is used, so that there is no misunderstanding about whether the first digit is included or not.

2.4.7 How do I get a GS1 Company Prefix?

Fill out the online application on the GS1 US website:

https://www.gs1us.org/upcs-barcodes-prefixes/get-started-guide/1-get-a-gs1-us-issued-company-prefix

When you fill out this application, you do something slightly different depending on whether you are a drug manufacturer or not.

- If you are a drug manufacturer and you are already assigning NDCs using your FDA labeler code, you will answer "yes" to the question "Does your company require the Food and Drug Administration (FDA) assigned NDC (national Drug Code) or NHRIC (National Health Related Items Code) labeler Code assigned as your GS1 Company Prefix?." You will be asked to provide your labeler code so that you can be issued a GS1 Company Prefix consisting of "03" followed by your labeler code.
- If you are not a drug manufacturer – that is, you are seeking a GS1 Company Prefix only to create SSCCs or GLNs, or non-drug GTINs – you will answer "no" to the question. Then you will be asked to select what capacity you want. If you select "1 – 10", you will be issued an 11-digit GS1 Company Prefix, giving you a capacity for 10 GLNs and 100,000 SSCCs (or 1,000,000 SSCCs if you use the extension digit). If you select "1 – 100,000", you will be issued a 7-digit GS1 Company Prefix, giving you a capacity for 100,000 GLNs and 1,000,000,000 SSCCs (or 10,000,000,000 SSCCs if you use the extension digit).

You will then be asked to pay the initial license fee. Within three business days, you'll get a welcome email from GS1 US. It includes all the important information you need to get started, including your prefix certificate and access to myGS1 US—your online member center. You can start creating barcodes right away with GS1 US Data Hub®| Product or you can work with a GS1 US Solution Provider to create barcodes for you.

Your initial fee provides the Company Prefix to you for one year. After that, you will pay the annual renewal fee to continue using the GS1 US-issued Company Prefix for your barcodes and product identification.

2.4.8 I have an NDC. Do I need a GS1 Company Prefix?

Yes. Even though you already have an NDC labeler code, you still need to register for a GS1 Company Prefix that embeds that labeler code so that you can use GS1 barcodes and data sharing standards. You cannot just add "03" to the NDC labeler code on your own – you have to register with GS1 US.

2.4.9 I'm a Manufacturer or Repackager. Do I need a GS1 Company Prefix?

Yes. Even though you already have an NDC labeler code, you still need to register for a GS1 Company Prefix that embeds that labeler code so that you can use GS1 barcodes and data sharing standards. You cannot just add "03" to the NDC labeler code on your own – you have to register with GS1 US.

2.4.10 I'm a Wholesaler, CMO, 3PL, or Contract Packager. Do I need a GS1 Company Prefix?

Yes. You need a GS1 Company Prefix so that you can create Serial Shipping Container Codes (SSCCs) for logistic units you create (e.g., pallets, totes picked to order, partial cases, shippers, etc.), and so that you can identify yourself as a legal entity and your locations using the Global Location Number (GLN). You will use the SSCCs in barcode that you put on your logistic units, and use both the SSCCs and GLNs in GS1 data sharing standards including EPCIS.

2.4.11 I'm a pharmacy, doctor, hospital, health facility, or other dispenser. Do I need a GS1 Company Prefix?

Yes. You need a GS1 Company Prefix so that you can identify yourself as a legal entity and identify locations using the Global Location Number (GLN). You will use the GLNs in GS1 data sharing standards including EPCIS.

2.4.12 Our company does business in multiple countries. Do I need a GS1 Company Prefix for each country?

No. Your GS1 Company Prefix can be used to create GTINs, SSCCs, GLNs, or any other GS1 identification number for use globally. You are encouraged to license your GS1 Company Prefix with the country where you are headquartered and where you will look to receive GS1 support.

However, if you are manufacturer or repackager who needs to embed NDC numbers into GTINs, then you must register with GS1 US to receive a GS1 Company Prefix that embeds your labeler code. This will allow you to create GTINs that embed the NDC (see Question 2.1.4). If you have more than one NDC labeler code, each needs to be registered to get corresponding GS1 Company Prefixes.

Only GS1 US offers GS1 Company Prefixes that embed NDC labeler codes. If you do not need your GS1 Company Prefix to embed an NDC labeler code (e.g., because you only need to create SSCCs and GLNs, or GTINs for non-U.S. drugs), then you can get your GS1 Company Prefix from GS1 in any country.

Your company can use your GS1 Company Prefix to create identifiers to be used in other countries as long as the local country regulations do not have specific restrictions.

2.4.13 I have a GS1 Company Prefix from outside the U.S. Can I use this for the U.S.?

Yes, you may use your GS1 Company Prefix in the U.S. to create SSCCs, GLNs, and GTINs, but only for non-U.S. drugs. A specific prefix for every country is not necessary, which is one of the advantages of using a globally recognized standard. Note that since GS1 member companies can manufacture products anywhere in the world, GS1 Company Prefixes do not identify the country of origin for a given product.

However, if you are a manufacturer or repackager who creates GTINs for drugs identified by a U.S. FDA National Drug Code (NDC), you need a GS1 Company Prefix issued by GS1 US that embeds your NDC labeler code so that you can create GTINs that embed your NDCs. See Questions 2.1.4 and 2.4.5.

2.4.14 If I have multiple GS1 Company Prefixes. Can I use them all to generate GS1 identifiers (e.g., GTINs, SSCC, and GLNs)?

Yes. You can use any of your GS1 Company Prefixes to generate any GS1 identification number.

However, if you are a manufacturer or repackager who creates GTINs for drugs identified by a U.S. FDA National Drug Code (NDC), you must use the specific GS1 Company Prefix that embeds your NDC labeler code so that you can create GTINs that embed the NDC. See Questions 2.1.4 and 2.4.5.

2.4.15 Do I need multiple GS1 Company Prefixes if I have multiple NDC labeler codes?

Yes. For each NDC labeler code that you use, you must register for a GS1 Company Prefix that embeds that labeler code, so that you can create GTINs that embed NDCs that use that labeler code. See Question 2.1.4.

2.4.16 If I am in multiple lines of businesses (e.g., Manufacturer, Wholesaler, 3PL, Repackager, Dispenser, etc.), do I need a GS1 Company Prefix for each line of business?

Not necessarily. A single GS1 Company Prefix may be used by multiple business units or business functions as long as they are all part of the same legal entity that licensed the GS1 Company Prefix.

However, if one of those business units or functions is a manufacturer or repackager who creates GTINs for drugs identified by a U.S. FDA National Drug Code (NDC), that business unit or function must use the specific GS1 Company Prefix that embeds its NDC labeler code so that it can create GTINs that embed the NDC. See Questions 2.1.4 and 2.4.5.

While multiple business units may share a GS1 Company Prefix, this may create extra work if one of those business units is sold off to another legal entity or spun out as a separate legal entity. In those cases, the new entity will no longer be able to use the original GS1 Company Prefix, which is still being used by the remaining business units of the original company. This may require reassignment of GLNs, updating of systems that generate SSCCs, etc. If each business unit has its own GS1 Company Prefix, the GS1 Company Prefix belonging to a given business unit can be transferred as an asset to the acquiring company or new entity, so that existing identifiers may continue to be used unchanged. For this reason, some companies having multiple business units choose to license a separate GS1 Company Prefix for each business unit even though they are not required to.

2.4.17 When a repackager creates a new package for pharmaceutical product, but still labels it with the manufacturer's original NDC, should they have their own unique GTIN?

Per the FDA in the Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs from August 31, 2016, if a repackager, relabeler, or private label distributor is subject to the establishment registration requirement at section 510 of the act, then that person is also subject to the barcode requirements and must use its own NDC numbers on its products. In other words, a manufacturer, repacker, relabeler, or private label distributor cannot and should not use an NDC number that is not assigned to it. Use of another establishment’s NDC number in the barcode would cause the product to be misbranded under section 502(a) of the Act because the drug’s label would be misleading.

3 CAPTURE: Questions about barcodes and RFID

The questions in this section are all about **capturing** data from the physical world using barcodes or RFID tags (collectively referred to as “data carriers”).

GS1 data carriers provide machine-readable representations of GS1 Identification Numbers that facilitate automatic identification and data capture. In order to accommodate a variety of environments and applications, the GS1 System supports six barcode symbologies, plus radio-frequency identification tags (RFID).

3.1 Barcodes

3.1.1 What is a 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. This representation is an ordered grid of dark and light squares bordered by a finder pattern. The finder pattern is partly used to specify the orientation and structure of the symbol. The data is encoded using a series of dark or light squares based upon a pre-determined size. The size of these squares is known as the X-dimension.

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, pharmaceutical manufacturers are marking products with a GS1 DataMatrix to satisfy DSCSA serialization/traceability requirements.

3.1.2 What is a GS1-128 barcode?

GS1-128 is a linear barcode used to encode data for logistics units such as cases and pallets. The use of this barcode supports fast and accurate data capture and inventory tracking, adding visibility to your supply chain.

GS1-128 barcodes are commonly used to label a logistic unit with a Serial Shipping Container Code (SSCC).

3.1.3 What is a QR Code and how is it different from a GS1 DataMatrix?

A QR Code is a two-dimensional matrix symbology consisting of square modules arranged in a square pattern. The symbology is characterized by a unique finder pattern located at three corners of the symbol. QR Code Version 2005 is the only version that supports GS1 identification numbers, including Function 1 Symbol Character. QR Code symbols are read by two-dimensional imaging scanners or vision systems. (Reference: *GS1 General Specifications*)

A QR (Quick Response) code is the trademark for a two-dimensional barcode first designed for the automotive industry. The QR Code is a square barcode, which is made up of black modules (square dots/pixels), arranged in a square pattern on a white background. It is text-based data, which has been encoded to be read by specific hardware (image based scanners) or software (applications or "apps") contained in smart phones.

3.1.4 What is the physical difference between a GS1 DataMatrix and a QR Code?

GS1 DataMatrix and QR Codes can be distinguished by the naked eye by looking at the finder patterns. A GS1 DataMatrix will appear to have a solid black line on two sides of the symbol. A QR Code has a distinctive square "bulls-eye" pattern in three of the four corners.

3.1.5 Why are QR codes not recommended for serialization?

QR Codes cannot be used in regulated healthcare environments.

3.1.6 Which of the barcodes do I need to be compliant with DSCSA in November 2017?

DSCSA requires pharmaceutical products to be marked with a barcode that carries its NDC (typically embedded within a GTIN), serial number, lot number, and expiration date. Prior FDA regulations require individual sale units to be marked with a linear barcode containing the NDC.

To satisfy both of 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). Higher-level groupings that do not cross point-of-sale such as homogeneous cases are marked with just the GS1 DataMatrix.

3.1.7 Can I have multiple barcodes on my products?

Yes. You may have both a linear barcode as well as the required GS1 DataMatrix on your products. It is not recommended, however, to have more than one linear barcode or more than one GS1 DataMatrix.

3.1.8 What are AIs? How are AIs manifested in the barcode and/or human readable information?

GS1 Application Identifiers (AIs) are used in barcodes that are capable of holding more than one data element, such as the GS1 DataMatrix. In such barcodes, each data element is prefixed with a GS1 Application Identifier (AI) to indicate the meaning of that data element. 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 barcodes encoded data.)

For example, the AI for GTIN is 01. Thus, when "01" appears in the encoded content of a barcode that uses AIs, it means the next 14 digits are a GTIN. The AI for Serial Number is 21. Thus, when "21" appears in the barcode it means the next characters are a Serial Number.

The combination of a single AI and the following data is called a "GS1 Element String." A series of GS1 Element Strings in a single barcode is called a "concatenated element string."

Note that the UPC-A, UPC-E, EAN-13, and EAN-8 barcodes only hold a single data element - a GTIN - and so they do not include AIs. AIs are used in barcodes that can hold multiple data elements. These barcodes include the GS1 DataMatrix, GS1-128, GS1 DataBar, and GS1 QR.

3.1.9 How are AIs used in a data carrier?

There is an AI for each GS1 Identification Number (GTIN, SSCC, etc.). 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; etc.). The following table lists the AIs that are relevant for DSCSA.

Table 3-1 GS1 Application Identifiers Applicable to DSCSA Requirements

Use Case	Typical Barcode Type	Data Element	AI	Characters following the AI
Serialized drug (trade item)	GS1 DataMatrix	GTIN	01	14 digits
		Expiration Date	17	6 digits
		Batch/Lot Number	10	1-20 alphanumeric characters (*)
		Serial Number	21	1-20 alphanumeric characters (*)
Logistic unit (mixed case, pallet, etc.)	GS1-128	SSCC	00	16 digits
Location tag in a warehouse	GS1-128 GS1 DataMatrix	GLN	414	13 digits
		GLN Extension	254	1-20 alphanumeric characters (*)

(*) As this data element is of variable length, it must be followed by an <FNC1> terminator character unless it is the last data element in the barcode. See Question 3.1.11.

3.1.10 Is there a specific order in which AIs should be encoded in the barcode?

No. AIs may be encoded in any order. However, for the most efficient encoding, it is best to have fixed-length data elements precede variable-length elements. It is also traditional to have the first data element be the GS1 identification number (e.g., GTIN, SSCC, GLN, etc.).

Systems that read barcodes must *not* rely on AIs being arranged in any particular order – they must be prepared to process the data regardless of the ordering of AIs.

3.1.11 What is a FNC1 character? How is it represented? Why is it needed? What is the guidance for including FNC1?

FNC1 stands for "Function Code 1," and it refers to a special code that can take the place of a character within the content of a barcode.

FNC1 is required by GS1 Standards for two different purposes:

- The first character in any GS1 barcode is FNC1. This identifies the remaining content as complying with GS1 Standards, and therefore enables scanners and software to understand and process the data according to GS1 Standards.
- If the data content of a GS1 element string (the data following an AI code) is of variable length, an FNC1 indicates the end of that data element. This is not required for a variable length data element that is the very last data element in the barcode.

FNC1 does not exist in computer character sets such as ASCII or Unicode. It only exists in barcodes. When a barcode scanner delivers the content of a barcode to a computer in ASCII, the ASCII control character GS (code 29 decimal) is typically used to represent FNC1.

To instruct your barcode printer or barcode printing software to include FNC1 in the right places, consult the documentation for that printer or software to find out how.

3.1.12 How do I know if my barcode is correct?

GS1 US and other companies provide fee-based barcode verification services.

Here is how verification services typically work:

- You submit samples of your barcoded item(s) in their final packaged form. If you are submitting a barcode that is located directly on an irregularly shaped unit, the item in its entirety is needed for review. Artwork samples (e.g., laser prints, bromides, mock-ups and proofs) can be tested to provide an interim report on barcode size and quiet zones. However, final samples of actual packaging are needed to provide a complete verification report.
- Your solution provider will test your barcode(s) for compliance with GS1 Standards using a formal verification process. Testing assesses size, color, print quality, quiet zones, barcode height, location/placement, and calculation of the check digit.
- Your solution provider will deliver a detailed report showing how your barcode(s) performed.

3.1.13 What happens if the AI value encoded in the data carrier is different than the human readable interpretation (HRI)?

Barcode scanners only read the barcode content, not the human readable interpretation (HRI). So if the data encoded in the barcode is not the same as the data in the HRI, different data will be used depending on whether the barcode is scanned or the data is manually keyed in by a person reading the HRI. This is obviously an undesirable situation. Quality assurance procedures should include verification that the barcode content and HRI match exactly and are both the data that is intended.

3.1.14 What happens if the AI used to record the data element is incorrect?

If the AI is wrong, the data will not be interpreted by systems processing the data. Quality assurance procedures should include verification that the barcode content and AI match.

3.1.15 What is the difference between a U.P.C. and a GTIN?

Briefly, a GTIN is a number and a U.P.C. is a barcode that contains the number.

In more detail, a Global Trade Item Number (GTIN) is a globally unique number that identifies a trade item -- a product or service that may be priced, ordered or invoiced at any point in the supply chain.

A U.P.C. is a type of barcode. Specifically, a UPC-A is a barcode that can hold a GTIN-12, and is familiar from its use on consumer products in North America. Because most consumers only know about the GTIN because of the numbers printed beneath a UPC-A barcode, in colloquial usage a "UPC number" is synonymous with a GTIN. But technically speaking, the GTIN is the number, and the UPC-A is the barcode.

The UPC-A is not the only barcode that can hold a GTIN. The GS1 DataMatrix, GS1-128, GS1 DataBar, and GS1 QR barcodes are all types of barcodes that can hold a GTIN as well as other data elements. In these barcodes, a GTIN is always prefixed by the Application Identifier (AI) "01", and the GTIN is always expressed in 14-digit format (by prefixing with additional "0" digits as needed).

There are other barcodes which, like the UPC-A, can only hold a GTIN and so do not include an AI. These include the EAN-13, which is very similar to a UPC-A but holds a GTIN-13 and so is used with GTINs created from GS1 Company Prefixes issued outside North America; the UPC-E, which is smaller than a UPC-A but limited to GTIN-12s that have "0" digits in particular positions; and the EAN-8, which is similar to a UPC-E but holds a GTIN-8.

When GTINs are shared in electronic data, they are either represented as a 14-digit string (prefixing with "0" digits as needed to make 14 digits), or as an EPC URI. The EPC URI form is used in EPCIS data.

3.1.16 When including AIs in barcodes (such as GS1-128 or GS1 DataMatrix), is there a preference as to what AIs are included (as it relates to DSCSA)? Are there any restrictions?

For an item-level package or homogeneous case, DSCSA requires a linear or 2-dimensional data matrix barcode with a product identifier affixed to, or imprinted upon, the package or homogeneous case corresponding to the standardized numerical identifier, lot number, and expiration date assigned to the product by the manufacturer or the repackager. The GS1 AIs corresponding to these DSCSA requirements are:

- **GTIN** AI (01)
- **Expiration Date** AI (17)
- **Serial Number** AI (21)
- **Batch/Lot Number** AI (10)

Note the sequence of the fixed length AIs first, followed by variable length as defined in 3.1.10

The Healthcare Distribution Alliance (HDA) also recommends the use of these four AIs (01), (21), (17), and (10).

Case Quantity AI (30) is an additional identifier which may have been included in the past. The *GS1 General Specifications* and GS1 Standards no longer permit inclusion of case quantity represented by AI (30) in the GS1 DataMatrix. However, during a transition period where the historical GS1-128 primary and secondary linear barcode symbols are still in use, case quantity using AI (30) in the secondary symbol will continue to be used.

Applications reading barcodes must be prepared to process the barcode no matter the sequence of the AIs. Applications should *not* rely on the AIs appearing in any particular sequence. Applications reading barcodes must also be prepared to process the barcode even if it contains additional AIs beyond the above four.

While barcode reading applications should work correctly even if additional AIs are present, the use of additional AIs is discouraged to avoid possible problems if downstream barcode reading applications are not implemented correctly.

4 SHARE: Questions about GS1 data sharing standards

The questions in this section are all about **sharing** data between trading partners using GS1 data sharing standards.

The questions in this section are organized into two topics:

- Section 4.1: Questions about the **EPCIS** standard for sharing visibility event data, including transaction information required by the DSCSA.
- Section 4.2: Questions about GS1 Standards for sharing **master data**, which provides descriptive information about GS1 identification numbers.

4.1 Questions about EPCIS

The questions in this section are all about the **EPCIS** standard for sharing visibility event data, including transaction information required by the DSCSA.

4.1.1 What is 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. EPCIS breaks down supply chain business processes into individual steps such as commissioning, packing, shipping, receiving, and so forth, and provides a standard language in which a party carrying out one of these steps can communicate the essential business information about that step to trading partners who need to know the *what*, *when*, *where*, and *why* of each step. Each such step is called an "event", and the term "EPCIS event" refers to the data record that describes an event using the standard EPCIS language.

4.1.2 How is EPCIS used to meet DSCSA requirements?

DSCSA requires manufacturers, distributors, and dispensers to capture and share information, using standards for interoperable exchange of information, about transactions in the supply chain in which ownership of pharmaceutical products is transferred. EPCIS provides a standard language to express this information in an interoperable manner. The DSCSA law does not specifically require the use of EPCIS, but GS1 US and its member companies have worked to create a method for applying EPCIS to meet the requirements of DSCSA, and many companies will adopt EPCIS as the preferred method for doing so.

The method to use EPCIS to meet requirements of DSCSA is specified in the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2*. This document specifies in detail how to apply EPCIS and related standards to meet the requirements of DSCSA.

4.1.3 In more detail, how are the various data requirements of DSCSA satisfied by EPCIS?

The DSCSA law speaks of three kinds of data:

- **Transaction information (TI)**: information about the transfer of ownership of one or more pharmaceutical products from one party to another, where the products are identified either at the batch/lot level or at the individual serial level.
- **Transaction history (TH)**: transaction information from prior transactions, up to and including when the products were first sold by the manufacturer.
- **Transaction statement (TS)**: an affirmation by a party that it has met the requirements of the DSCSA that the data is accurate.

The DSCSA law requires different combinations of these ingredients to be sent and received by different supply chain parties by different deadlines. The *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* specifies a standard way to utilize the EPCIS standard to express all three types of data:

- Transaction information (TI) is represented in EPCIS as one or more EPCIS events, using specific vocabulary, master data, and extensions specified in the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* so that the events contain all of the information DSCSA requires to be present in transaction information. The collection of events for a given transaction may be gathered together in an EPCIS Document for transmission as a single message.
- Transaction history (TH) is simply the same EPCIS events as in transaction information, but including events from prior transactions as well. In certain instances, DSCSA allows certain information to be omitted from the transaction history and the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* specifies how that is done.
- The transaction statement (TS) is represented in an EPCIS document using DSCSA-specific data elements in the header of an EPCIS Document, as specified in the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2*.

4.1.4 Why should I use EPCIS to meet the data requirements of DSCSA?

EPCIS is designed to support full track and trace of products for many different purposes. By using EPCIS to meet the requirements of DSCSA, you lay the foundation not only for DSCSA compliance, but also for using supply chain data for a myriad of purposes including tracking and tracing recalled product, new product introduction, anti-counterfeiting, product authentication at point of use, optimization of supply chain routes, and more. EPCIS lays the foundation for knowing where your products are at any time, any place in the supply chain, and the possible uses of this data for business benefit are limitless. In this respect, EPCIS is far superior to siloed approaches such as devising a single-purpose data model exclusively for DSCSA compliance. The EPCIS approach allows all companies to maximize the return on the investment made in gathering the data in the first place.

Many of the leading companies in the U.S. pharmaceutical market have stated their desire to standardize on EPCIS and the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* as the preferred means to meet DSCSA data requirements. Using EPCIS helps assure that you are using a best practice for DSCSA data reporting and you will have the greatest degree of interoperability with other trading partners.

4.1.5 Exactly what GS1 Standards are involved in using EPCIS for DSCSA?

EPCIS itself is a general-purpose standard intended to support traceability across a wide variety of industry sectors and business processes. Other standards are layered on top of EPCIS to create a "stack" that is tailored specifically for complying with DSCSA. The layers of the stack are:

- The **EPCIS standard** itself, which defines the fundamental structure of an "event" with data dimensions of *what*, *when*, *where*, and *why*. The EPCIS standard defines the "grammar" of the language.

- **Vocabulary standards**, which specify the data that populates the *what*, *where*, and *why* dimensions of EPCIS data. (The *when* dimension just contains common concepts of date and time, which are already governed by widely used standards.) If the EPCIS standard defines the "grammar" of the language, the vocabulary standard define the "words" you use with that grammar. Vocabulary standards for EPCIS include:
  - The *GS1 General Specifications*, which define GS1 identification numbers including the GTIN, SSCC, and GLN. You use the GTIN and SSCC to populate the *what* dimension of EPCIS events, and GLN to populate the *where* and part of the *why* dimensions.
  - The GS1 EPC Tag Data Standard, which defines the EPC URI syntax that is used to represent GS1 identification numbers within EPCIS data.
  - The GS1 Core Business Vocabulary (CBV), which provides detailed specifications of data that populate the *why* dimension of EPCIS data.
- The ***GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2***, which specifies particular combinations of EPCIS and the vocabulary standards to meet the requirements of DSCSA. If EPCIS is the "grammar" and the vocabulary standards are the "words," the guideline tells you how to write the specific "sentences" that meet DSCSA data requirements.

It is important to recognize that the EPCIS standard by itself is not enough. You *must* follow the specifications in the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* in order to create data that meets DSCSA requirements and that will be interoperable with other trading partners in the U.S. pharmaceutical supply chain.

Fortunately, the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* provides you everything you need, including the relevant parts of the EPCIS and vocabulary standards and examples showing how those parts fit together. In most cases you need only refer to the implementation guideline to find out what you need to do, and not the EPCIS standard or the vocabulary standards. There are extensive business and technical examples included in the three addenda that accompany the guideline.

4.1.6 What version of EPCIS (1.0, 1.1, or 1.2) do I need?

To meet the requirements of DSCSA and achieve interoperability with trading partners, you should use **Release 1.2** of the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability*. This in turn makes reference to EPCIS Version 1.2 and the Core Business Vocabulary (CBV) 1.2. Each of these documents has its own series of version numbers, so it is a coincidence that the latest version of all three is 1.2 (though this makes it easier to remember!).

It is important to recognize that the EPCIS standard by itself is not enough. You *must* follow the specifications in the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* in order to create data that meets DSCSA requirements and that will be interoperable with other trading partners in the U.S. pharmaceutical supply chain. Therefore, when speaking with trading partners or solution providers, you should always verify that they are using Release 1.2 of the GS1 US implementation guideline. Merely complying with Release 1.2 of EPCIS, without making use of the GS1 US implementation guideline is not sufficient.

4.1.7 My trading partner or solution provider only supports Release 1.1 of the guideline. What do I do?

Release 1.2 of the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability* has been available since November 2016. It is the only version that is capable of meeting all data requirements of DSCSA, including both lot management and serialized traceability. Earlier versions do not. For example, Release 1.1 of the GS1 US implementation guideline specifies data for serialized traceability that *almost* meets DSCSA requirements, but it lacks the transaction statement and a few other necessary ingredients.

As Release 1.2 of the GS1 US implementation guideline has only been available to the public since November 2016, not all trading partners or solution providers have fully implemented this version. If your trading partner or solution provider only supports Release 1.1, find out from them what their plan is for supporting Release 1.2.

4.1.8 Do I need EPCIS to be compliant for lot level management?

No. EPCIS is the GS1 US-recommended approach to comply with all data reporting requirements of DSCSA, including lot management. However, other approaches also exist, including the use of Advance Ship Notices (ASNs). Confirm with your trading partners which method(s) they support.

4.1.9 Do I need EPCIS to be compliant for serialized item traceability?

No. EPCIS is the GS1 US-recommended approach to comply with all data reporting requirements of DSCSA, including serialized item traceability. Many of the leading companies in the U.S. pharmaceutical market have stated their desire to standardize on EPCIS and the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* as the preferred means to meet DSCSA data requirements. Using EPCIS helps assure that you are using a best practice for DSCSA data reporting and you will have the greatest degree of interoperability with other trading partners.

4.1.10 What do I need to enable EPCIS exchange with trading partners?

The details vary from company to company, but at a high level you will need to follow these steps:

- Implement GS1 identification numbers for all relevant business processes: assign GTINs for trade items, use SSCCs to identify logistic units, and use GLNs to identify legal entities and physical locations. (See all the questions in Section 2 of this FAQ.)
- Update your business processes to capture all of the information needed for DSCSA reporting:
  - If you are a manufacturer, this means assigning unique serial numbers to your products and capturing information when you apply those serial numbers to the products ("commissioning"), as well as tracking those serial numbers during packaging and shipping operations.
  - If you are a wholesaler or 3PL, this means tracking serial numbers of products you receive and through your warehousing operations including shipping.
  - If you are a dispenser, this means tracking serial numbers of products you receive and dispense.
- Implement or procure a software system that is capable of processing DSCSA data. This includes receiving information from the systems that implement the business processes as outlined above, storing that information and making the stored information available for reporting, sending DSCSA data to trading partners in EPCIS format according to the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2*, and receiving DSCSA data from trading partners. This system will likely interface with other information systems you have, including enterprise resource planning (ERP) systems, master data management (MDM) systems, etc.
- Work with your trading partners to gather needed information (e.g., your partners' GLNs), and to verify that the trading partner is capable of processing data conforming to the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* and that the data they send you conforms as well.
- Implement a quality assurance program that regularly assesses the completeness, accuracy, and compliance to standards of DSCSA data.

4.1.11 How do I determine if I'm ready to send EPCIS messages?

Run through each of your business scenarios, and confirm that your software system produces data that is complete, accurate, and fully compliant with *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2*. Additionally, arrange a pilot test with some of your trading partners so you can test sending your EPCIS data and assure that your trading partners accurately received the information you sent and that they are able to successfully process them and vice versa.

4.1.12 How do I determine if I'm ready to receive EPCIS messages?

Ask your trading partners to run through each of business scenarios in which they would send you data, and to send you sample data. Then, confirm that the sample data they send you is complete, accurate, and fully compliant to the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2*.

4.1.13 What EPCIS events do I need/generate/consume?

EPCIS is designed to be flexible, so that the EPCIS events needed in any situation depend on the circumstances of the business scenario. For example, a pharmacy does not need to receive an EPCIS commissioning event from an manufacturer in order to meet DSCSA requirements for receiving a product from a wholesaler, but it may want to receive the EPCIS commissioning event in order to verify the authenticity of the product (above and beyond DSCSA requirements). All of the ways that companies may benefit from sharing EPCIS data is an evolving story.

However, the following outlines the *minimum* requirements for EPCIS event sharing to meet DSCSA requirements in normal forward progress through the supply chain, as specified in the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* (Sections 12.1–12.3).

- When a **manufacturer** or **repackager** ships product to a **wholesaler**, the manufacturer or repackager generates, and the wholesaler consumes, the following EPCIS events:
  - Commissioning events for all SGTINs and SSCCs involved in the shipment. The commissioning events for the SGTINs will include batch and expiration date information, and the master data accompanying the events will include product level master data.
  - Packing events that fully account for the packaging hierarchy of products in the shipment, up to and including the highest level containers.
  - Shipping event(s) that include all of the highest level containers in the shipment, along with "sold by" and "sold to" information including master data for the GLNs involved.
- When a **wholesaler** ships product to another **wholesaler**, or to a **dispenser**, the shipping wholesaler generates, and the receiving wholesaler or dispenser consumes, the following EPCIS events:
  - Commissioning events for all SGTINs and SSCCs. This may include SGTIN commissioning events previously received from the manufacturer, so that the required batch and expiration date information is present, as well as commissioning events generated by the wholesaler for SSCCs it creates.
  - Packing events that fully account for packaging hierarchy of products in the shipment, up to and including the highest level containers. This may include packing events previously received from the manufacturer for cases or other groupings that were not unpacked by the wholesaler, as well as packing events generated by the wholesaler for new groupings it created (picked to order).
  - Shipping event(s) that include all of the highest level containers in the shipment, along with "sold by" and "sold to" information including master data for the GLNs involved.

- When a **manufacturer** or **repackager** ships product directly to a **dispenser** as a drop shipment, the manufacturer or repackager generates, and the dispenser consumes, the same EPCIS events as indicated above for a manufacturer shipping to a wholesaler.
- When a **dispenser** resells product to another **dispenser**, the selling dispenser generates, and the purchasing dispenser consumes, the same EPCIS events as indicated above for a wholesaler shipping to a dispenser.

In all cases, DSCSA requires parties receiving data to be prepared to respond to government verification requests or requests for compliance documentation, and to archive data for a specified time interval.

4.1.14 Can I scan a barcode and generate EPCIS events based on what I scanned?

Yes, but an EPCIS event is not merely a barcode scan. An EPCIS event is the record of a particular step of a business process. So, in addition to the identifiers scanned from the barcode (i.e., the *what* dimension of an EPCIS event), the EPCIS event also includes the date and time (the *when* dimension), location identifiers (the *where* dimension), and data that describes the business context including the business step being carried out (the *why* dimension).

So generally speaking, an EPCIS event does not come directly out of a barcode scanner, but rather the barcode scan is an input to software that is implementing a particular step of a business process such as packing, shipping, receiving, etc. It is the job of this software to assemble all of the information needed to construct the EPCIS event, including the data coming out of the barcode scanner, and deliver it as a finished EPCIS event.

4.1.15 How can I use EPCIS to verify products (e.g., saleable returns)?

In this scenario, the task is to confirm that a particular SGTIN represents a valid product (i.e., that the GTIN is a valid GTIN and that the serial number is one that the manufacturer confirms is valid and not already known to have been returned or destroyed).

Using the EPCIS query interface, it is possible to issue an EPCIS query to the manufacturer for the EPCIS commissioning event that matches a specified SGTIN. The manufacturer and other parties can also be queried for other events that might indicate the SGTIN is no longer in circulation (e.g., a destroying event). That data can then be examined to answer the question.

In such scenarios, there is often product verification software designed to automate the various EPCIS queries and analysis of the query results. In this way, EPCIS plays the crucial behind-the-scenes data sharing role, but users experience the process as using a product verification system rather than "using EPCIS." Several companies are piloting systems of this kind.

4.1.16 Do I need to capture destruction events to be compliant? Do I need to share them with my trade partners?

No. DSCSA does not require capture or reporting of destruction events, but they may be very useful for purposes of track and trace. See Question 4.1.15 for one example of this.

4.1.17 Do I need to track my returns? Who needs to capture return transactions?

Yes. In order for receiving supply chain parties to verify saleable returned products, the receiving party shall capture the receiving event of the returned product. This will enable the receiving party to systematically search its event repository for the matching transaction information and transaction statement associated with the returned product.

4.1.18 Do I need to generate EPCIS events for drop-ships? To whom do I need to send them? From whom do I receive them from?

Yes. EPCIS events should be generated for drop ships. The seller who is shipping the products directly to the drop-ship entity will generate and send DSCSA compliance documents to the drop-ship entity.

4.1.19 What happens if some of my trading partners are not ready to receive EPCIS events?

It is advantageous to initiate DSCSA EPCIS exchanges with trading partners as soon as possible, starting with trading partners who are ready to receive EPCIS. It is not necessary for all trading partners to be ready to get started. You can generate, store and hold EPCIS events in an EPCIS repository until specific trading partners are ready to receive them.

4.1.20 When do all my trading partners have to be ready to exchange EPCIS messages?

DSCSA law specifies the deadlines for compliance for various kinds of trading partners. If EPCIS is the chosen means to meet the requirements of the law, those deadlines apply. Obviously, it is advisable for trading partners to be ready to share EPCIS data and test this with trading partners well in advance of regulatory deadlines.

4.1.21 What is EPC URI format?

EPC URI format is the way that GS1 identification numbers (SGTIN, SSCC, and GLN) appear within EPCIS data. URI stands for Uniform Resource Identifier, and is a standard syntax for representing identifiers of all types on the Internet. EPCIS uses URI syntax so that all types of identifiers have a consistent representation within EPCIS data.

See the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* for details of how to express SGTIN, SSCC, and GLN identifiers in EPC URI format.

4.1.22 How are aggregations represented in EPCIS?

An EPCIS aggregation event with a business step of "packing" records the completion of a business process step in which one or more child objects are aggregated to a parent object. The aggregation event indicates the unique identifier of the parent, and a list of the unique identifiers of the children.

The parent and children in an aggregation event might be SGTINs or SSCCs. The table below shows some common scenarios.

Table 4-1 Aggregation Event Scenarios

Business scenario	Parent identifier	Children identifiers
12 saleable units packed into a case of 12, where a case of 12 is a standard configuration for this product.	SGTIN of the case (the GTIN is the GTIN for the case-of-12 configuration)	12 SGTINs of the saleable units (the GTIN is the GTIN of the unit)
11 saleable units packed into a case – where a case of 11 is *not* a standard configuration for this product (i.e., a partial case). The case is considered a logistic unit.	SSCC of the partial case (as this is not a standard configuration, the case does not have a GTIN so an SGTIN cannot be used)	11 SGTINs of the saleable units (the GTIN is the GTIN of the unit)
20 cases packed into a standard pallet configuration of 20 cases, where a pallet of 20 cases is a standard configuration for this product that can be ordered.	SGTIN of the pallet (the GTIN is the GTIN for the pallet-of-20-cases configuration)	20 SGTINs of the cases (the GTIN is the GTIN for the case-of-12 configuration)
A variety of saleable units packed into a carton or tote, according to a particular delivery order being filled.	SSCC of the carton or tote	SGTINs of the saleable units, based on a variety of GTINs depending on what was ordered
Cases of different products packed onto a pallet, according to a particular delivery order being filled.	SSCC of the pallet	The identifiers of the cases, which could include: ▪ SGTINs for standard case configurations ▪ SSCCs for partial cases or mixed cases picked to order

The table illustrates that both SGTINs and SSCCs may appear as either parents or children, or both. (The one exception is that if the parent is an SGTIN, the children cannot be SSCCs because an SGTIN must be of fixed composition.)

For a packaging hierarchy of two or more levels, multiple EPCIS aggregation events are required to express the complete content. For example, if a pallet contains 20 cases, and each case contains 12 saleable units, then 21 aggregation events are needed: 20 aggregation events each of which expresses the content of a single case (parent = case-level SGTIN, children = 20 saleable unit GTINs), and one more aggregation event to express the content of the pallet (parent = pallet-level SGTIN or SSCC, children = 20 case-level SGTINs).

4.2 Questions about Master Data

The questions about **master data**, which provides descriptive information about GS1 identification numbers.

4.2.1 What is master data?

Master data refers to data that describes the meaning of an identifier. For example, given a GTIN identifier such as 10300010123452, master data associated with that identifier might provide information such as the name of the product, the name of the manufacturer, the product's physical dimensions, and so on.

Master data is usually static over the life of the identifier. For this reason, it is generally more efficient to separate master data from the identifier itself, so even if the identifier is repeated again and again in different transaction data, the master data doesn't need to be repeated. Instead, transaction data contains just the identifiers, and master data consulted separately to understand what the identifiers mean. This approach is taken in EPCIS as specified in the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* to reduce the total volume of data that is shared.

4.2.2 What master data do I need?

The following master data is required for DSCSA compliance:

Table 4-2 Master Data related to DSCSA

Entity to which master data is associated	DSCSA requirement	Master data element name(s)
Trade item *(i.e., master data associated with a GTIN)*	Proprietary or established name of the product	regulatedProductName
	Name of manufacturer	manufacturerOfTradeItemPartyName
	Dosage form of the product	dosageFormType
	Strength of the product	strengthDescription
	The National Drug Code number of the product	additionalTradeItemIdentification
	The container size	netContentDescription
Trade item instance *(i.e., master data associated with an SGTIN or with a GTIN+lot)*	The lot number of the product	lotNumber
	Expiration date	itemExpirationDate
Legal entity or party to transaction *(i.e., master data associated with a GLN)*	Business name	name
	Business address	streetAddressOne streetAddressTwo streetAddressThree city state postalCode countryCode

Note: See also the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* Section 10 Table 10-1 and Section 13, Table 13-1 for additional cross reference information mapping DSCSA Data elements to EPCIS data elements.

4.2.3 Why do I need to send master data?

DSCSA requires certain information to be included as part of transaction information (TI) that is sent between parties. In EPCIS, some of this data is handled as master data to avoid repeating the information when the same identifier appears in multiple transactions in the same message or in multiple parts of the same transaction. You need to send this data because it is required by DSCSA.

4.2.4 Can I send master data separately? Why not?

No. DSCSA currently requires that all transaction history, transaction information, and transaction statement data be sent in a single document, including those parts of transaction history and transaction information that are master data.

4.2.5 What options do I have for sharing master data?

The *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* specifies that master data be included in the EPCIS header of each EPCIS Document that is shared. The header should include master data for every identifier (GTIN or GLN) that is referenced by EPCIS events within that EPCIS document. However, for any given identifier the master data need only be included once within the EPCIS document, even if the identifier is referenced multiple times within the EPCIS events contained in that document.

Other methods exist for sharing master data, including the EPCIS Master Data Query and the GS1 Global Data Synchronization Network™ (GDSN®). However, because DSCSA currently requires that all data be sent in a single document, these methods may not be used; see Question 4.2.4.

4.2.6 What is the GDSN? How does publishing/subscribing to the GDSN affect the way I provide or receive master data and exchange messages via EPCIS?

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

See Questions 4.2.4 and 4.2.5 for more about the applicability of GDSN for meeting DSCSA requirements.

4.2.7 What if my master data is different than my trading partner?

The authoritative source for master data is the company that created the identifier. So for a GTIN, the authoritative source is the brand owner, and for a GLN the authoritative source is the party identified by the GLN or who operates the location identified by the GLN. In case of discrepancies between trading partners, the data from the authoritative source should be used. If another party believes that data to be in error, that party should coordinate with the authoritative source to understand the discrepancy and determine how to address it.

4.2.8 What happens if the unit of measure (UOM) differs between trading partners? (e.g., I refer to Carton (CT) and my trading partner calls my carton an EA (each))

DSCSA regulation does not attempt to standardize units of measure, and in *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* the netContentDescription master data attribute does not attempt to standardize this either. This may be addressed in future versions. Resolving these UOM discrepancies are subject to discussions between trading partners.

5 Additional Questions

5.1.1 I want to participate in a serialized pilot with my trading partner. How can I sign up?

Pilots are coordinated bi-laterally between interested trading partners, so discuss this with your trading partner.

5.1.2 How can I tell who else is participating in a serialized pilot?

You may contact your trading partners to confirm if they have participated in serialized pilots. The Healthcare Distribution Alliance (HDA) supported the industry by overseeing 9 different scenarios for pilots of salable returns between wholesale distributors and manufacturers. Approximately 30 companies participated in the HDA salable returns pilots.

5.1.3 Who can I contact for questions on how to get started with serialization?

The *GS1 US Solution Provider Finder* program provides a profile of the companies and type of services which they provide for serialization. There are many excellent companies providing a full array of services for serialization.

5.1.4 How should I assign serial numbers?

The most important thing is to assure that serial numbers are unique within a given GTIN, and never reused. This helps assure that any data containing a serialized GTIN (SGTIN) unambiguously refers to a single instance of the product, and there is no ambiguity even when looking at historical data.

It is a best practice not to attempt to embed any intelligence or meaning into the serial number. The serial number should just be a unique number. Do not attempt to embed information such as manufacturing date, manufacturing line, or similar information into the serial number. Such information can be tracked in an external database, by associating it with the unique, non-intelligent serial number.

Many companies choose to assign serial numbers randomly, rather than sequentially. Possible advantages of random serial numbers include:

- making it harder for a counterfeiter or other bad actor to guess a legitimate serial number,
- making it harder for somebody observing serial numbers in the supply chain to infer sales volumes, and
- complying with regulations that require random serial numbers.
    - The U.S. FDA currently does not require serial numbers to be random, but other countries do. Therefore, if the same software system is being used to manage serial numbers for both the U.S. and other countries, it might be desirable to randomize for the U.S. as well.

If random serial numbers are used, care should be taken to assure serial numbers are unique. It is not sufficient to just generate random serial numbers and hope that a duplicate will not occur because it is statistically unlikely; numbers need to be generated by a procedure that guarantees no duplicates will occur.

5.1.5 What is the standardized date format for DSCSA?

The DSCSA regulation itself does not specify the format of dates.

The *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* summarizes the rules to be followed so that dates conform to relevant GS1 Standards, including the GS1 Standards for dates in barcodes, the GS1 EPCIS standard, and other pharmaceutical industry best practice.

The following rules are quoted from the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2*, Section 6.1.1.1.4:

1. EPCIS data SHALL contain an expiration date that includes a year, month, and non-zero day, in YYYY-MM-DD format as required by XML standards.
2. It is STRONGLY RECOMMENDED that the barcode contain an expiration date that includes a year, month, and non-zero day, in YYMMDD format according to the *GS1 General Specifications*. While the *GS1 General Specifications* permit a day of 00, it is NOT RECOMMENDED that this be used.
3. The human readable text on the package SHOULD include an expiration date that includes a year, month, and non-zero day, but the human readable text MAY, if necessary, only include a year and month. (Human readable text in this context refers to text that is not adjacent to the barcode. The human readable indication beneath the barcode, also called HRI, always matches the content of the barcode.)

4. The expiration dates as expressed in EPCIS, all barcodes, and human readable text, SHALL be consistent with each other. "Consistent" means that all three have an identical year, month, and non-zero day; or if one or more forms do not specify a day of the month (omitted from human readable and/or 00 in the barcode) that the remaining forms, specify the last day of the month. This is in keeping with United States Pharmacopeia (USP) guidance which specifies that an expiration date on a label lacking a day, should be understood to refer to the last day of the month.

The GS1 US implementation guideline also gives examples of how these rules are applied.

5.1.6 Do we need to specify a day of the month in our expiration date?

The date in EPCIS data must include a non-zero day of the month, as required by XML standards.

It is strongly recommended that the barcode data also contain a non-zero day of the month.

Human-readable text on the label (other than the HRI beneath the barcode, which must always match the barcode data) should contain a day of the month, but may, if necessary, only include a year and month.

See Question 5.1.5 and the section of the *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2* referenced there.

6 Additional Resources

The following publications of GS1 and GS1 US may be helpful.

- *GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability Release 1.2* (November 2016).
  - This document is a comprehensive guide to applying GS1 Standards for all aspects of DSCSA compliance, including assigning identifying numbers (SGTIN, SSCC, and GLN), using GS1 barcodes, and EPCIS data sharing. This is the most important reference for any company involved in DSCSA.
- *GS1 General Specifications*
  - This is the GS1 Standard that provides normative definitions of GS1 identification numbers including GTIN, SSCC, and GLN, as well as GS1 barcode standards including GS1-128 and GS1 DataMatrix.
- *EPC Information Services Standard (EPCIS) Release 1.2* and *Core Business Vocabulary Standard (CBV) Release 1.2*
  - These GS1 Standards define the standard for sharing of detailed visibility event data throughout supply chains.

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