



PREPARING FOR **DSCSA** Drug Supply Chain Security Act

March 2024

What Do I Need to Know About GLNs?

Dear McKesson Customer,

As the DSCSA Nov. 27, 2024, effective date approaches, we want to share the latest details on timing and actions underway to help you continue to prepare for it.

This FAQ is specifically created to answer questions about GLNs and what actions McKesson is taking to support you.

If you have additional questions regarding GLNs or how DSCSA will impact your business, please contact your McKesson Sales team member or Customer Support.

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DSCSA Overview & FAQ

GENERAL DSCSA INFORMATION

Q1 What is DSCSA?

The Drug Supply Chain Security Act, signed into law on November 27, 2013, outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. These requirements will enhance the FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. Implementation of these requirements will also improve the detection and removal of potentially dangerous drugs from the drug supply chain to protect U.S. consumers.

Q2 What is McKesson's official response to the August 25, 2023, FDA Announcement?

On Friday, August 25, 2023, the U.S. Food and Drug Administration (FDA) announced through a compliance policy that it would not take action to enforce the Enhanced Drug Distribution Security requirements of the Drug Supply Chain Security Act (DSCSA), section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act until November 27, 2024. The FDA is providing a one-year "Stabilization Period" from the statutory deadline of November 27, 2023. This Stabilization Period will allow all key players within the supply chain (manufacturers, distributors, dispensers and trading partners) to mature processes and refine operations that are required to comply with these specific package-level tracing requirements. The FDA will continue to enforce the other DSCSA requirements during this Stabilization Period.

The FDA expects all parties to continue progressing toward stabilization and maturing the implemented systems during this Stabilization Period. McKesson will continue to roll out enhanced DSCSA capabilities including:

- Sending enhanced DSCSA Transaction Information using customer portals and EPCIS (Electronic Product Code Information Services) data files
- Providing additional educational tools to help prepare dispensers for the full DSCSA implementation

During this Stabilization Period, McKesson will continue to provide the lot-level DSCSA Transaction Information, Transaction History and Transaction Statements using the existing portals and DSCSA enabled EDI files.

McKesson will continue to monitor the FDA's policy and requirements for DSCSA serialization implementation and will adapt its processes as needed.

Given the FDA announcement of the Stabilization Period, the following is an overview of McKesson's key dates.

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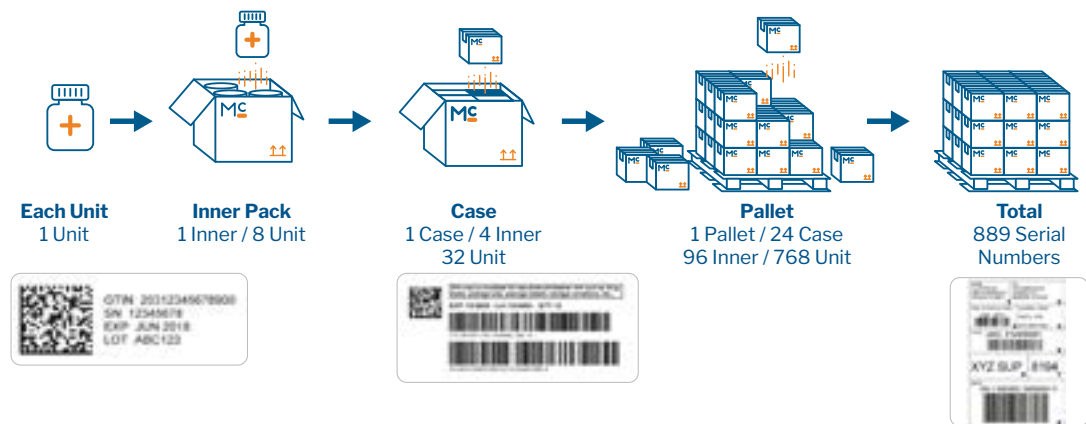
McKesson Key Action Dates for DSCSA Enforcement

Stakeholder		Current Status	Target & Timing
Supplier	Manufacturer, Re-packager	Provide accurate and complete aggregated serialized data.	APRIL 01 2024
Distributor	Wholesale Distributor	Capture accurate and complete aggregated serialized data for shipments.	JUNE 30 2024
Customer	Dispenser, Provider	Provide Sold-To and Ship-to GLNs.	JULY 01 2024

Q3 What traceability changes will be implemented during the Stabilization Period?

During the Stabilization Period, all DSCSA Transaction Information for in-scope products will continue to be shared in a lot-based format and, as it is made available, in a serial-based format. On November 27, 2024, in addition to the previous requirements for DSCSA Transaction Information, **serialized product identifier information for in-scope products must be added** to the DSCSA Transaction Information.

- A new serial number is provisioned by the manufacturer at each salable product unit (e.g., pallet, case, box, each) of packaging to be uniquely identified.
- Each serial number must be tracked through all transactional events across the supply chain (events can include packing, shipping, receiving, returns, etc.)



Beginning on November 27, 2024, the current Lot-based Transaction History will be sunset and electronic-based approaches will be used among all trading partners to meet the enhanced requirements.

McKesson will use the FDA recommended Electronic Product Code Information Services (EPCIS) standard to provide and maintain the data associated with Transaction Information and Transaction Statements.

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Q4 **How will in-scope products/ items and trading partners be identified in the new interoperable electronic exchange?**

GS1 (Global Standard 1) standard identifiers will be used for product and party/location identification in the interoperable electronic exchange.

Products will be identified by a Global Trade Identification Number (GTIN).

Trading partners will be identified by the Global Location Number (GLN).

Q5 **Will NDC numbers continue to be on bottles or will GTINs replace NDC numbers?**

In-scope DSCSA product will continue to have NDC numbers. The GTIN includes the NDC.

Q6 **Which drugs fall under the DSCSA requirements for product tracing, product identifier, authorized trading partner, and verification?**

DSCSA requirements do not apply to nonprescription drugs (over-the-counter drugs) or animal drugs (drugs subject to section 512 of the FD&C Act). Drugs that fall under the DSCSA requirements are defined by the FD&C Act.

Product tracing, product identifier, authorized trading partner, and verification requirements in Section 582 of the Act apply to product as defined by Section 581(13) of this Act. Product means “a prescription drug in finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution).”

The section 582 requirements do not apply to:

- Blood or blood components intended for transfusion
- Radioactive drugs or biologic products
- Imaging drugs
- Certain intravenous (IV) products
- Medical gases
- Certain homeopathic drugs
- Lawfully compounded drugs

There are also exclusions, refer to the [definition of transaction noted in section 581\(24\)](#) of the FD&C Act. This list of applicable DSCSA drugs is dynamic and is subject to change.

This information is available on the item product page of all McKesson ordering portals.

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Q7 ***If a manufacturer is granted an exception to the DSCSA requirements and does not need to provide serialized data, how will we distinguish between an FDA-granted exception and a case of missing data?***

To distinguish between an FDA-granted exception and a case of missing data, customers should cross reference the indicator in your ordering portal against data provided in your Transaction History to determine if the product is subject to DSCSA.

ALL ABOUT GLN'S

Q8 ***What is a GLN?***

A GLN, or Global Location Number, is a unique identifier that lets businesses know who is involved in transactions and where things are located throughout the supply chain.

Establishing and submitting your GLN number(s) is imperative to continue to conduct business with McKesson. We are requesting all customers to have one or more GLNs on file with McKesson by June 30, 2024, to allow the parties in the supply chain to mature and test their systems and processes prior to November 27, 2024.

Q9 ***What does a GLN look like?***

A GLN is a 13-digit number consisting of a company prefix, a location reference, and a check digit.

Q10 ***How do I obtain my GLN number?***

Global Location Numbers (GLNs) are typically created by the customer who has purchased a license to create GLNs from GS1 or under GS1's Managed GLN program based on submissions by wholesalers or group purchasing organizations.

Each customer should obtain a GLN for:

- Sold To - represents the party acquiring ownership of the DSCSA in-scope product shipped.
- Ship To - represents the physical location where the DSCSA in-scope products are being delivered.

These numbers may be the same for some customers if their Sold-To and Ship-To addresses are identical.

If you have not created a GLN or need assistance retrieving a Global Location Number, please visit gs1us.org to get a GLN. Please be advised that a registration fee is involved.

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Following are more details about the GLN retrieval process for each segment.

Community Pharmacy and Practitioners

To aid in the adoption of GLNs for DSCSA purposes, McKesson and other distributors have purchased a group license from GS1 for the identification of independent and small customers with nine or fewer locations (excluding government facilities). Based on data submitted by McKesson and other distributors, GS1 is creating GLNs and posting those GLNs to the GS1 Data Hub tool for these independent and small customers. McKesson and other distributors will have visibility to those GLNs. The goal is to eliminate the work necessary for independent and small customers to speed up identification. Customers who meet these criteria do not need to take any action now with respect to GLN.

Customers who have more than nine locations must create their own GLNs. Please visit gs1us.org.

Health Systems and Clinics

Many health systems, through their group purchasing organizations, have GLNs in the GS1 Data Hub which we will use to identify such customers.

We are completing a review of the GS1 Data Hub to determine customers that do not have a GLN. A plan to gather that information is forthcoming.

Large Retail and National Accounts

Most Large Retail and National Accounts can generate GLNs using their Global Company Prefix (GCP) from GS1. If all your locations do not have individual GLNs, please contact GS1 for assistance in generating the necessary GLNs.

We are currently collecting GLN information from all Strategic Account customers. We are reviewing that information to identify customers that do not have a GLN.

Specialty Provider Customers & The US Oncology Network

McKesson is conducting a review to determine which practices still require GLNs and, where possible, will assign GLNs to those practices. At this time, there is no action required of our practices. If Specialty Provider customers and practices in The US Oncology Network need to sign up for their own GLN, their account manager or RSVP/RVP will contact them directly.

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Q11 How can I find my GLN number on the GS1.org site?

GS1 has a search function to help locate the GLN: Search by Party Name | GEPIR (gs1.org) The search is available by company or GLN.

Q12 For health system covered entities, do contract pharmacies count as locations?

If the health system covered entity owns the contract pharmacy, then the contract pharmacy is a location within the health system. If, on the other hand, the contract pharmacy is separate, it will need to have its own Ship To GLN. In that situation, the Sold To GLN will be the health system covered entity.

Q13 Where can I find my GLN?

You can find your GLN in a few ways:

1. Visit the my.GS1US.org website to search for your GLN.
2. Contact your McKesson Customer Support Team.
3. McKesson has begun printing **Sold-To** and **Ship-To** GLN's on invoices for many pharmacy customers. If we do not have a GLN on file for you, these fields will populate with a series of zeroes. **Here is a sample invoice:**

The image shows a sample McKesson invoice. At the top left is the McKesson logo. The word 'Invoice' is centered at the top. On the right side, there is a box containing 'Billing No.: 123456789', 'Billing Date: 123456789', and 'PDR: 123456789'. Below this, there is a table with four columns: 'Customer' (123456), 'Route' (000), 'Stop' (000), and 'Page' (1 of 2). The main body of the invoice contains 'MCKESSON CORPORATION' and '1234 Pharmacy Drive, United States, US 12345' on the left. 'Phone: 123456789' and 'DEA: 123456789' are in the middle. 'BILL TO:' and 'SHIP TO:' sections follow, both pointing to '1234 Pharmacy Drive, United States, US 12345'. 'DEA: 123456789' and 'PNCY: 123456' are also present. Below this, 'Sold To GLN' and 'Ship To GLN' are highlighted in yellow. At the bottom, there is a table header with columns: 'NDC/UPC', 'ITEM', 'DEL. DOC', 'QTY', 'LN', 'ITEM DESCRIPTION', 'AMP OR R', 'UNIT', 'EXTENDED', 'R', 'RETAIL', 'X', 'PRICE', 'D', 'AMOUNT', 'M'.

Q14 How do I request a GLN?

Before requesting a GLN, please be sure to confirm that you do not already have a GLN by searching the my.GS1US.org website or by contacting your McKesson Customer Support team to see if we have the GLN(s) assigned to your account loaded in our system.

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If you are unable to locate your GLN:

McKesson can assist independent and small businesses with nine or fewer locations (with the exception of government facilities) in getting their GLN(s) as a GS1 US GLN issuing partner. This is at no cost to you.

Customers with more than nine locations will need to visit the my.GS1US.org website to create a GLN(s).

Q15 How can I identify if a distributor created a GLN?

GLNs created by GS1 based on information provided by distributors or GPOs begin with either 1100 or 1200. Additionally, some GS1 issued Single Location GLNs also begin with 1100 or 1200.

Q16 Is my GLN the same for all locations?

If you have more than one Ship To location or if your Sold To location is separate from your Ship To location, you will need a GLN for each distinct location. If your Sold To and Ship To location are the same, you only need one GLN.

Q17 What if the GLN I have in my records is different from what McKesson has on file or if there are multiple GLNs assigned to my location?

A particular location only needs a single GLN to identify itself. The same GLN should be used for all suppliers servicing that location. If the GLN(s) you have are different from the ones McKesson has on file, please contact your McKesson Customer Support team.

Q18 What if McKesson assigned a GLN to my business and I don't want to use that GLN?

If for any reason you desire to secure your GLN at your own expense or maintain it with GS1 yourself, we can deactivate the McKesson assigned GLN. Before attempting to secure your own GLNs from GS1, to avoid receiving an error that a GLN already exists, your McKesson assigned GLN will need to be deactivated. Please contact your McKesson Customer Support Team via email:

- For our Community Pharmacy & Health Mart, Health Systems, Large Retail and National Accounts Government customers, email DSCSA-PharmaCustomerSupport@McKesson.com
- For MPB specific questions, email DSCSA-MPBCustomerSupport@McKesson.com
- For Specialty Provider and the US Oncology Network related questions, email DSCSA-ProviderSolutions@mckesson.com

Q19 If the address of my location changes, do I need a new GLN?

Yes, any change to the physical address of the location requires the allocation of a new GLN. For more information on the rules regarding GLNs, visit the [GS1 GLN allocation rules](#) document. Contact your McKesson Customer Support Team with any changes to your GLN and address.

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Q20 *If the ownership or name of a pharmacy or facility changes, does the GLN transfer with this information change?*

For most ownership, location and name changes, a new GLN will need to be procured. For more information on the rules regarding GLNs, visit the [GS1 GLN allocation rules](#) document.

Q21 *Does my GLN stay the same no matter what distributor I use?*

Yes, GLNs are universal. All suppliers and distributors, that have elected to use GLNs as customer identifiers, will use the same GLN for common customers.

Q22 *How long does it take for me to get a new GLN number assigned?*

McKesson has a direct connection with the GS1 US Data Hub system to check for previously assigned GLNs and, where appropriate, to assign GLNs when one is needed. The process takes just a couple of minutes when we receive a request to assign or correct a GLN.

Q23 *If I have multiple locations under one GLN indicating common ownership, can I transfer DSCSA in-scope product between locations?*

Yes, you may transfer DSCSA in-scope product between locations that share the same Sold To GLN, which indicates common ownership and control. Should a product be returned following such a transfer, McKesson will complete an association test to verify that the returned product matches our historical DSCSA record with the correct Sold To GLN and product serial number.

Q24 *Will McKesson still be able to assist in requesting GLNs for customers with Nine or less locations under the GS1 Managed GLN program?*

Yes, McKesson will still be able to assist in requesting GLNs for customers with nine or less locations under the GS1 Managed GLN program, with the exception of all government facilities. GS1 will create GLN(s) for the customer based on information provided by McKesson and McKesson will load the GS1 created GLN to the customer account.

Q25 *If a Federally Qualified Healthcare Center (FQHC) has more than nine contract pharmacies, are they responsible for obtaining GLNs for those contract pharmacies?*

The covered entity only needs to have a GLN as the Sold To location. The contract pharmacies have their own Ship To GLNs.

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Q26 *How does a GLN for a contract pharmacy need to be provided since a hospital and pharmacy is involved?*

Entities under common ownership frequently use the same Sold To GLN. For a 340B replenishment account, McKesson loads the covered entity GLN as the Sold To GLN and the contract pharmacy GLN the Ship To GLN.

Q27 *I have five 340B contract pharmacies where McKesson distributes DSCSA in-scope products. The 340B covered entity is a separate company, the purchaser of the products and a customer of McKesson. Will I be able to comply with DSCSA regulations by not being the purchaser of the drugs?*

For 340B replenishment programs, the purchaser is the covered entity, which generally bears the responsibility for the DSCSA Drug Traceability requirements. The covered entity may enter into an agreement with the contract pharmacy(ies) to share the responsibility for DSCSA compliance.

Q28 *Do I input my GLN in the ordering system and how does the GLN transmit through the ordering process?*

The ordering process for a customer will remain exactly as it is today. You do not need to enter your GLN. Ordering is done by account number.

Q29 *What is an sGLN?*

An sGLN has a slightly different format from the 13-digit GLN for use in EPCIS files. It has all the similar identifiers as found in the GS1-issued GLN: Sold To, Sold By, Ship To and Ship From. It is different in format because EPCIS is based on the JSON computer language which requires this formatting. The GLN and sGLN both point to the same GS1-issued GLN, but [sGLN] has decimals in the middle of it and [the GLN] is a straight 13-digit string of integers.

Q30 *There are GLNs in GS1 that were established by McKesson. If I would like to make a change, but I'm not the "owner" of the GLN, how do I make changes?*

There is an option in GS1 Data Hub to request a change of "ownership" of the GLN. When you request a change of ownership in the GS1 Data Hub, the GS1 Data Hub automatically sends this request to the entity that owns that GLN.

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Q31 *Is McKesson using Bill To GLNs?*

McKesson is not using Bill To GLNs for DSCSA. The Pharma Distribution team uses Sold To and Ship To GLNs in our reporting. Sold To is used to represent the customer's legal entity (corporation, LLC, etc.). The Ship To is the physical location receiving the product. The Sold To and Ship To can be the same if the billing and shipping addresses are the same.

NEXT STEPS AND WHAT TO EXPECT

Q32 *What changes do I need to make prior to the DSCSA serialization enforcement date of November 27, 2024?*

Please use the FDA link to find a full list of actions that should be taken at <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>

In summary, McKesson recommends the following:

- Prior to November 27, 2024, you should make changes, including but not limited to the following:
- All customers (dispensers, health systems, pharmacies, etc.) should be prepared to respond directly to regulators if asked about tracing information for DSCSA in-scope products they purchased.
- All trading partners, including dispensers, are expected to be able to search the repositories where their serial DSCSA transaction information and transaction statements are stored and retrieve the requested information upon request.
 - Beginning in the Summer of 2024, DSCSA transaction data where available will be accessible through McKesson portals or your in-house or third-party system where you requested this information to be transferred.
- All trading partners must confirm that the serial number of the saleable DSCSA in-scope product they intend to return was purchased from McKesson before initiating the return.
- DSCSA in-scope product returns where McKesson is unable to verify or associate the serial number of the product cannot be accepted as a saleable return under the DSCSA.

Your pharmacy should have procedures to identify and investigate suspect and illegitimate product according to the requirements in DSCSA. The DSCSA transaction data may assist you in conducting these investigations. Additional information for dispensers from NACDS, NCPA, HDA and NABP about dispenser requirements is available at www.dscsa.pharmacy.

IMPORTANT NOTE: For some of these processes, McKesson will provide a more detailed process communication to enable testing of our systems and processes prior to November 27, 2024.

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Q33 **Where can I find more information on the requirements of a pharmacy, and related best practices, to comply with DSCSA?**

We recommend that you refer to the [FDA.gov](https://www.fda.gov) website for more information. The American Society of Health-System Pharmacists (ASHP) and National Community Pharmacists Association (NCPA) may also have relevant resources.

Q34 **Will a pharmacy be able to sell to doctor's offices or clinics as of Nov. 27, 2024?**

Please refer to the FDA guidance found here: <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>

Q35 **Do I need to purchase scanners to receive DSCSA in-scope product as of November 27, 2024?**

No, scanners are not required to receive DSCSA in-scope product. McKesson does not supply or sell scanners.

Need more information or have further questions?

As McKesson continues to prepare for DSCSA serialization implementation, we will update these FAQs. Our internal project team overseeing this effort is working diligently to refine processes, mature systems, and facilitate the build of interoperable data flows to be prepared for the November 27, 2024, enforcement date.

IMPORTANT NOTE: For some of these processes, McKesson will provide a more detailed communication outlining our expectations of our customers to enable interoperable testing of our respective systems and processes prior to November 27, 2024.

McKesson online ordering platforms will be updated as information is available. For questions regarding DSCSA you can also contact us via email.

- For our Community Pharmacy & Health Mart, Health Systems, Large Retail and National Accounts Government customers, email DSCSA-PharmaCustomerSupport@McKesson.com
- For MPB specific questions, email DSCSA-MPBCustomerSupport@McKesson.com
- For Specialty Provider and the US Oncology Network related questions, email DSCSA-ProviderSolutions@mckesson.com

What do I do if I do not receive a response on an inquiry?

Please allow 24 hours for a reply to any inquiry sent to one of the DSCSA mailboxes. If you do not receive a follow-up, please contact Customer Support directly via your toll-free number.

DSCSA Acronym List and Definitions

ACRONYM	TERM	DEFINITION
ATTP	Advanced Track and Trace Pharmaceuticals	A global repository called ATTP will store serialization data from McKesson and will allow searching, downloading and printing upon request. Customers may use the portal link to manage DSCSA transaction data during the six years of record retention period.
DSCSA	Drug Supply Chain Security Act	Among other things, establishes requirements for electronic product tracing and verification of prescription pharmaceuticals at the package level in the US drug supply chain from manufacturer to dispensers.
DSR	Digital Serialized Repository	A system with data from manufacturers.
EPCIS	Electronic Product Code Information Services	EPCIS is the standard for creating, capturing and storing information to trace and track DSCSA in-scope products through the supply chain.
GCP	Global Company Prefix	A licensed number of four to twelve digits issued by GS1 member organization to a user company to entitle that user company to create any of the GS1 identification keys (GTIN, GLN, SSCC, etc.)
GLN	Global Location Number	A GLN, or Global Location Number, is a unique identifier that lets businesses know who is involved in transactions and where things are located throughout the supply chain.
GPO	Group Purchasing Organization	A GPO is an entity that helps healthcare providers and practices realize efficiencies and savings by aggregating purchasing volumes to negotiate discounts with manufacturers, distributors and other vendors.
GS1	Global Standards 1	GS1 standard identifiers provide a common language and help to create seamless work processes that allow businesses to identify, capture, and globally share information.
GTIN	Global Trade Identification Number	Products are identified by a Global Trade Identification Number. The GTIN can be used to identify types of products at any packaging level.
NDC #	National Drug Code #	A unique, 3-segment numeric identifier assigned to each medication listed under Section 510 of the U.S. Federal Food, Drug and Cosmetic Act. The first segment of the NDC identifies the labeler (i.e., the company that manufactures or distributes the drug).
RA	Return Authorization	Permission by McKesson to allow the customer to return a product to us. Products cannot be returned without a return authorization.
Serialization	Serialization	Serialization is the practice of generating a unique identifier for pharmaceutical products and printing the code on the label or packaging prior to distribution.
sGTIN	Serialized Global Trade Identifier Number	A serialized Global Trade Identification Number. It is a combination of a Global Trade Item Number (GTIN) plus a serial number.
sGLN	Serialized Global Location Number	The GLN and sGLN both point to the same GS1-issued GLN, but sGLN has decimals in the middle of it and the GLN is a straight 13-digit string of integers.
SSCC	Serialized Shipping Container Code	A barcode used as universal identifier for freight across the supply chain. SSCC barcodes are unique labels that identify a freight item or logistics unit (pallet, container, etc.) to provide important delivery information including contents, destination, and other handling criteria.
UAT	User Acceptance Testing	Testing conducted to determine if the requirements of a specification or design are met.