The Global Language of Business

Healthcare

GS1 US: Platform for Interoperability Framework

Tracy Nasarenko, Sr Director, Industry Engagement, Healthcare

November 18, 2022

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Speakers

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Agenda

- Overview of the GS1 Standards, specifically the EPCIS standard, a critical component to successfully exchange data under the DSCSA.
- DSCSA Stakeholder Playbook for getting started with DSCSA.
- Q&A:
  - Lessons learned from the onboarding of Manufacturers; what was expected versus unexpected; what can be shared and leveraged with other trading partners as they prepare for DSCSA; what gaps still exist?
  - What challenges are Wholesalers experiencing as they have a unique perspective of being in the middle of the supply chain.
  - What communication is needed between Wholesalers/Distributors, Dispensers, and Solution Providers?

Together, we're making it possible to follow prescription drugs and medical devices from the manufacturer to the patient, improving efficiency, safety, and patient care.

GS1 Standards: Identify, Capture, and Share

GS1 Standards for identifying, capturing, and sharing information—*about products, business locations, and more*—make it possible for companies to speak the same language, connect with each other, and move their business forward.

GS1 Standards: Identify, Capture, and Share

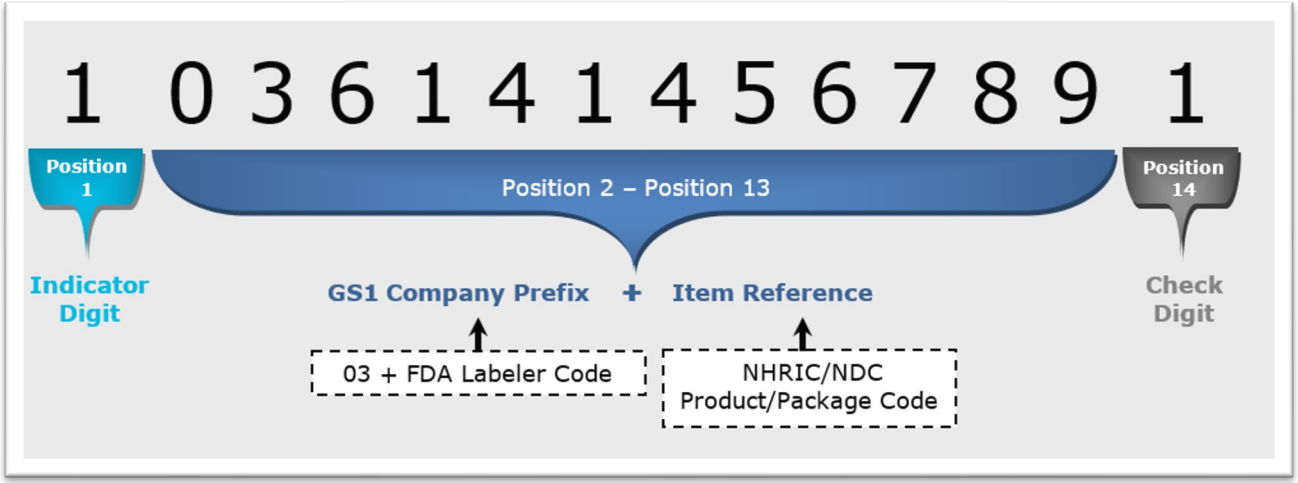
Standards used to support item-level traceability in an interoperable manner

Product Identification:
Global Trade Item Number (GTIN)

The "WHAT"

A number that uniquely identifies trade items. GTINs are used to identify products in the industry.

Pharma Manufacturers use the NDC to create a GTIN-12 in a 14-digit format



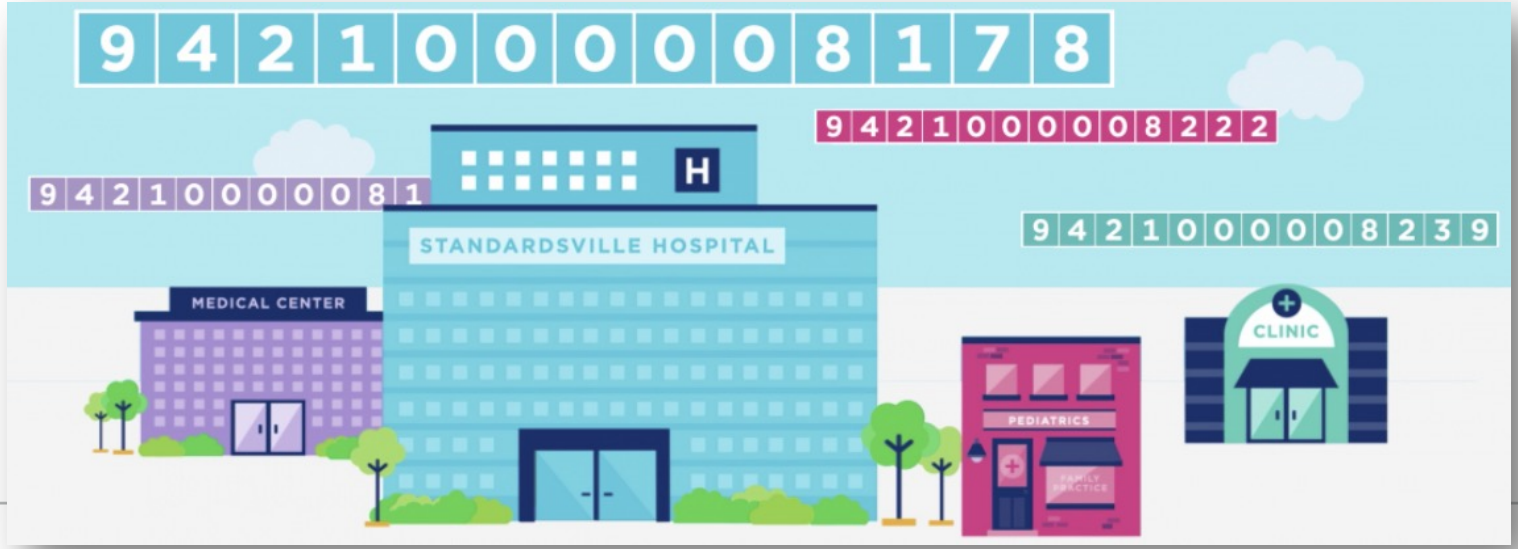
The National Drug Code* is a unique 10-digit, 3-segment numeric identifier; Labeler, Product code, and Package code

*Source: https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory

Location Identification:
Global Location Number (GLN)

The "WHO & WHERE"

A number that provides businesses the ability to know who is involved in transactions and where things are located throughout the supply chain. By uniquely identifying parties and locations, GLN helps with tracking products, optimizing processes, and providing greater visibility to transactions taking place around the world.



Why are GLNs necessary?

It is used to identify locations, legal entities, and functions in electronic business transactions in:

- Electronic Product Code Information Service (EPCIS) – In FDA's DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs, Revised Draft Guidance, it recommends that trading partners use GS1's Electronic Product Code Information Services (EPCIS) standard to provide and maintain the electronic data associated with transaction information and transaction statements.
- Verification Router Service (VRS) solutions – verification router service refers to using a third-party routing system to send product information back and forth between Trading Partners.

GS1 US Data Hub

GS1 US Data Hub® combines three powerful online tools to easily identify, create, manage, use, and verify data through one convenient, data-sharable platform.

Powered by GS1 Standards, GS1 US Data Hub helps users improve key business processes like creating, using, and sharing quality data.

Learn more: www.gs1us.org/datahub

GS1 US Data Hub | Product

Taking the guesswork out of creating barcodes and managing and sharing product information

GS1 US Data Hub | Location

Driving reliable location identification and information to improve business efficiencies

GS1 US Data Hub | Company

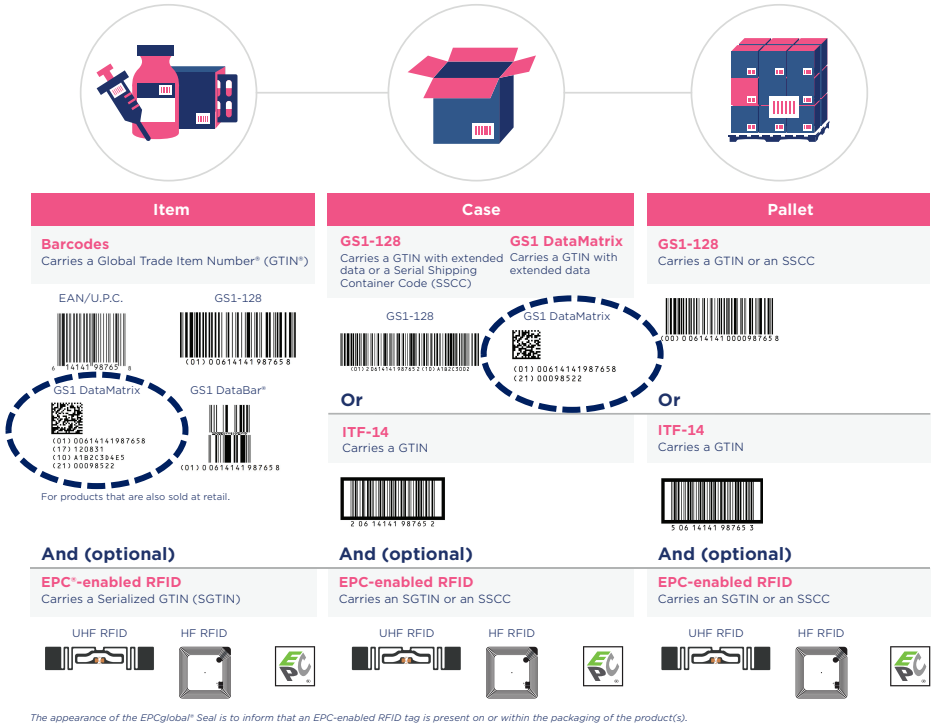
Accessing validated U.P.C. and company information for better business processes

Capture: GS1 Data Carriers

GS1 Data Carriers are capable of holding varying amounts of data to accommodate different needs for different products.

GS1 DataMatrix with GTIN

GTIN (01) 00314141999995
EXP 2021-12-31
Batch/Lot (10) 987654321GFEDCBA
Serial (21) 10000000234

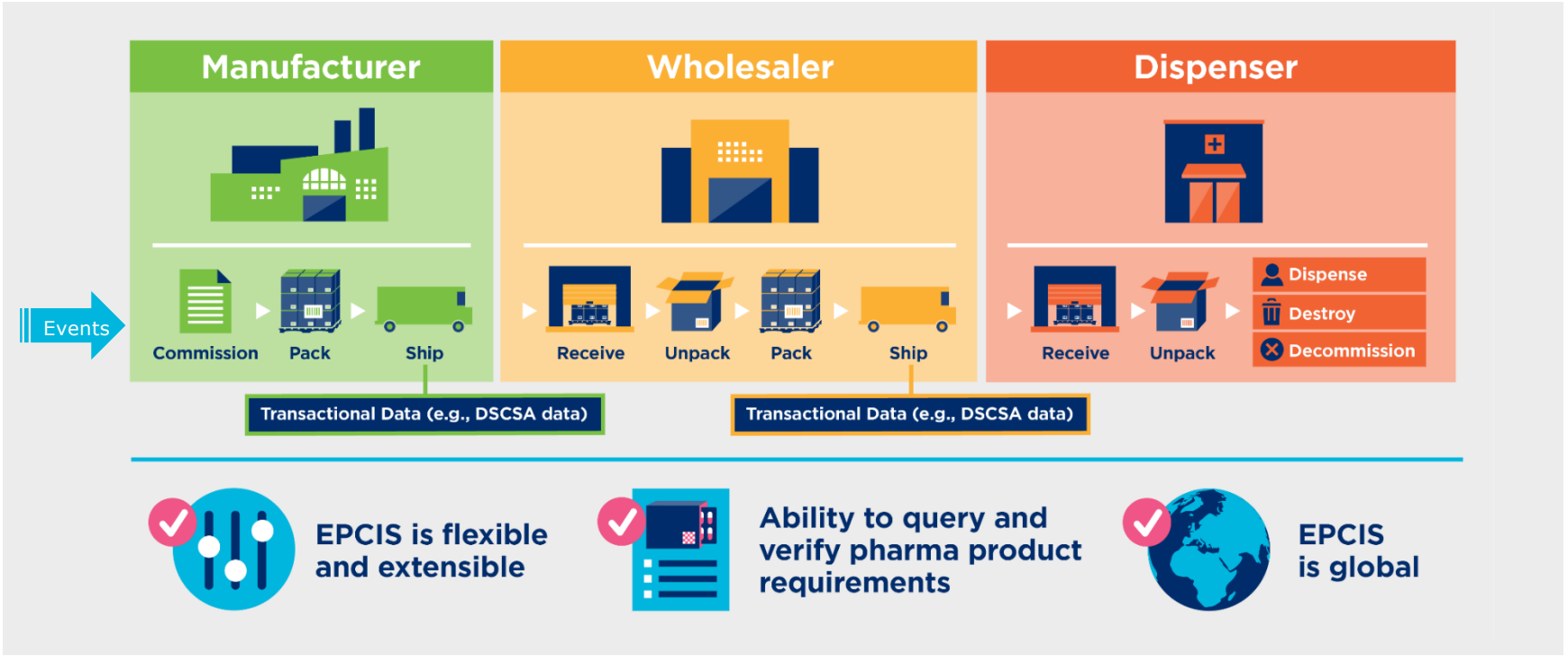


What is EPCIS?

Electronic Product Code Information Services (EPCIS) is a global GS1 Standard for creating and sharing visibility event data to enable users to gain a shared view of physical or digital objects

EPCIS that we know today very much is a **common language** that connects the events and speaks across a multitude of applications and supply chain events

EPCIS Events captured and shared by…

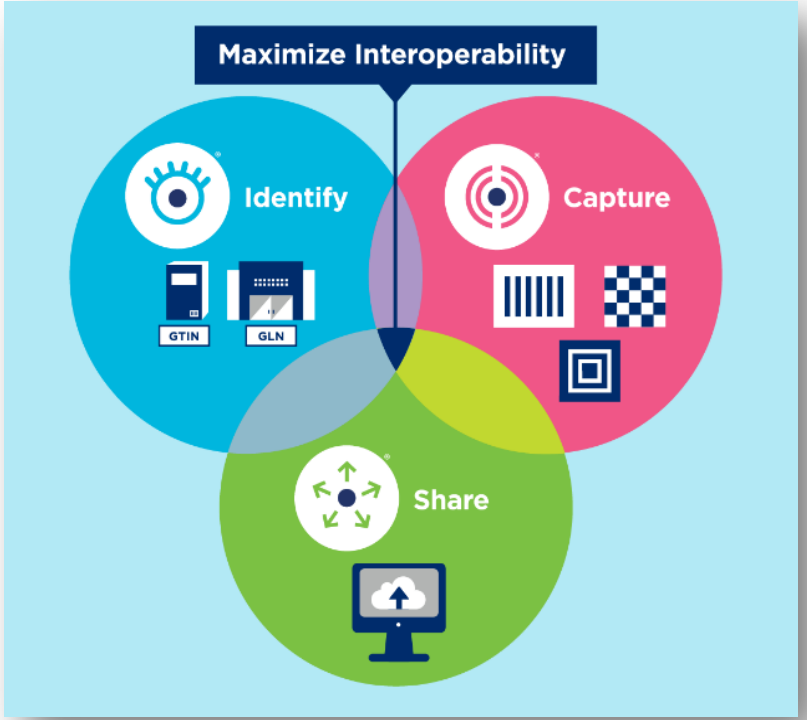


EPCIS Data Sharing

EPCIS is not a single giant database. Each party **keeps its own data and shares it only** with whom it chooses.

How do you get data from across the supply chain?

1. Capture your own EPCIS data
2. Find other parties who also have data
3. Exchange data point-to-point using EPCIS



Resources for Industry

The Rx Secure Supply Chain Workgroup

- Broad cross-section of the industry:
  - Manufacturers, Wholesale Distributors, Healthcare Providers, Dispensers, Solution Providers, and Associations
- Subject matter experts across the pharma industry
- Developing guidelines, tools, and resources for supporting the pharma industry trading partners preparing for DSCSA
- Weekly to bi-weekly conference calls

Drug Supply Chain Security Act. (DSCSA) Disclaimer:
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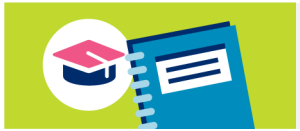
GS1 US Education & Training

GS1 US University offers diverse education and training opportunities to help individuals and companies understand how to use GS1 Standards to improve their business processes.



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Online training courses provide on-demand access to a library of educational modules, videos, and full-length certificate course materials.

Learn more: www.gs1us.org/university

GS1 US® certificate courses

DSCSA Suppliers Online Certificate Course

- Prepare for DSCSA Requirements

DSCSA Dispensers Online Certificate Course

- Prepare for serialization and for receiving products and cases

GS1 Foundations Online Certificate Course

- Barcode training at your own pace and convenience

GS1 Standards for Product Data Excellence Online Certificate Course

- Meet consumer demands for accurate product information

Speakers

Elizabeth Waldorf

Director of Global
Traceability and Standards

TraceLink

Scott Mooney

Vice President Distribution
Operations, Traceability

McKesson

DSCSA Stakeholder Playbook for getting started with DSCSA

- **What is Drug Supply Chain Security Act (DSCSA)**

- **DSCSA Stakeholder Playbook for getting started with DSCSA**
  - With one year left for November 2023, the need to focus on executing key preparation activities to meet DSCSA compliance
  - What is needed to get started with DSCSA from each stakeholder's perspective?

About Drug Supply Chain Security Act (DSCSA)

- Provides the industry a mandate to build an **electronic, interoperable system to identify and trace** certain prescription drugs as they are distributed in the United States
- Requires pharmaceutical trading partners to **maintain and share chain-of-ownership data** in a serialized, event-based approach to enable item-level traceability back to the product origin
- Will enhance the U.S. FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.
- Stakeholders include:
  - Manufacturers, Contract Manufacturers, Repackagers
  - Wholesale Distributors
  - Dispensers (Retail Pharmacy, Hospital Pharmacy, etc.)
  - Third-Party logistics providers
  - Solution Providers
  - U.S. FDA
  - State Boards of Pharmacy

For information about the act, see the 2013 Drug Supply Chain Security Act

About DSCSA

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  - Wholesale Distributors
  - Dispensers (Retail Pharmacy, Hospital Pharmacy, etc.)
  - Third-Party logistics providers
  - Solution Providers
  - U.S. FDA
  - State boards of Pharmacy

Drug Supply Chain Security Act

From the Manufacturer/Repackager perspective

Product Marking Requirements

- Understand the technical requirements for marking your serialized finished drug product with GS1 Data matrix (reference DSCSA Sec 581 (14) for use of "standardized graphic that includes, in both human and human-readable form and on a machine-readable data carrier that conforms to the standards developed by widely recognized international standards)
  - GS1 Company Prefix
  - Technical requirements
  - Artwork team and packaging vendors

GTIN Assignment & Product Listing

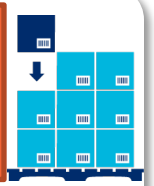
- Assign, assemble, and share the list of your Global Trade Identification Number (GTINs) for your packages which are the smallest individual saleable units of your product for distribution and intended sale to the dispenser and higher levels of homogeneous packaging (i.e., bundles, cases)

GLN Setup & Assignment

- Set up-up your Global Location Numbers (GLNs) for your corporate and site locations for exchanging serialized Transaction Information (TI)/Transaction Statement (TS) via EPCIS
  - GLN Supplier Quick Start Guide

From the Manufacturer/Repackager perspective

Product Identifier Capture During Packing & Shipping



- Capture GS1 product identifiers when packing and shipping to prepare for your serialized exchange
  - Events captured by CMOs and 3PLs
  - Implementation Guide
  - Aggregation
  - Solution Provider role
  - SOPs

Capturing TI & TS using EPCIS

- For transfer of ownership transactions of your serialized products, understand the technical requirements for exchanging serialized Transaction Information (TI) and Transaction Statement (TS) via EPCIS
  - EPCIS Events
  - Solution Providers

Trading Partner Master Data & Serialized Data Exchange Setup

- Set up your Trading Partner master data for EPCIS serialized exchanges
  - Collect and record
  - Initiate onboarding

From the Manufacturer/Repackager perspective

Operational Process Development

- Implement ongoing operational processes for capturing serialized shipments and exchanging serialized transaction information with your trading partners
  - SOPs

Maintenance Process Development

- Establish maintenance process to support operations, product, and business growth
  - New products
  - New locations
  - New FDA labeler codes
  - New trading partners

Product Verification Preparation

- Prepare to verify product identifiers (PI) for your serialized products
  - Necessary identifiers
  - Business scenarios
  - Technical requirements
  - VRS Solution
  - Authorized Trading Partner (ATP) credential

From the Manufacturer/Repackager perspective

- Implement an operational process to support verification responses
  - Update SOPs

Detail Content
- Appendix A

Document Reference
- Appendix B

Glossary
- Appendix C

From the Wholesaler/Distributor perspective

Product Identification Requirements

- Understand the technical requirements for marking your serialized shipping containers with a GS1 SSCC (reference GS1 Discussion paper on aggregation in the pharmaceutical supply chain) for use of a "standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards
  - GS1 Company Prefix
  - Technical requirements
  - Artwork team and packaging vendors

GTIN Setup for Product Listing

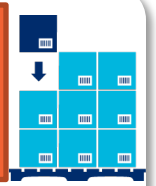
- Collect and publish the list of the Global Trade Identification Number (GTINs) for the packages you will be transacting which are the smallest individual saleable units of your product for distribution and intended sale to the dispenser and higher levels of homogeneous packaging (i.e., bundles, cases)

GLN Setup & Assignment

- Set up and share your Global Location Numbers (GLNs) for your corporate and site locations for exchanging serialized Transaction Information (TI)/Transaction Statement (TS) via EPCIS
  - GLN Supplier Quick Start Guide

From the Wholesaler/Distributor perspective

Product Identifier Capture During Packing & Shipping



- Capture GS1 product identifiers when packing and shipping to prepare for your serialized exchange
  - Events captured by CMOs and 3PLs
  - Implementation Guide
  - Solution Provider role
  - SOPs

Technical Requirements for TI/TS Exchange

- For transfer of ownership transactions of your serialized products, understand the technical requirements for exchanging serialized Transaction Information (TI) and Transaction Statement (TS) via EPCIS
  - EPCIS Events
  - Solution Providers

Trading Partner Master Data & Serialized Data Exchange Setup

- Set up your Trading Partner master data for EPCIS serialized exchanges
  - Collect and record
  - Initiate onboarding

From the Wholesaler/Distributor perspective

Operational Process Development

- Implement ongoing operational processes for capturing serialized shipments and exchanging serialized transaction information with your trading partners
  - SOPs

Maintenance Process Development

- Establish maintenance process to support product and business growth and operations
  - New products
  - New locations
  - New trading partners

Product Verification Preparation

- Prepare to verify product identifiers (PI) for your serialized products
  - Necessary identifiers
  - Business scenarios
  - Technical requirements
  - VRS Solution
  - Authorized Trading Partner (ATP) credential

From the Wholesaler/Distributor perspective

- Implement an operational process to support verification responses
  - Update SOPs

Detail Content
- Appendix A

Document Reference
- Appendix B

Glossary
- Appendix C

From the Dispenser perspective

GLN Setup & Assignment

- Look up if an existing Global Location Numbers (GLNs) has already been created or set up your GLN for your corporate and site locations for exchanging serialized Transaction Information (TI)/Transaction Statement (TS) via EPCIS
  - Share GLNs with your Trading Partners
  - GLN Supplier Quick Start Guide

Product Identifier Capture During Receiving

- Capture GS1 product identifiers when receiving shipments to prepare for your serialized exchange
  - Events captured by CMOs and 3PLs
  - Implementation Guide
  - Solution Provider role
  - SOPs

***Note: Transfers between related entities under common ownership are not governed under DSCSA (Title II, Section 581 (24)(B)(i))**

Trading Partner Master Data & Serialized Data Exchange Setup

- Set up your Trading Partner master data for EPCIS serialized exchanges
  - Collect and record
  - Initiate onboarding

From the Dispenser perspective

Operational Process Development

- Implement ongoing operational processes for capturing serialized receiving and exchanging serialized transaction information for saleable returns
  - SOPs

Maintenance Process Development

- Establish maintenance process to support product and business growth and operations
  - New products
  - New locations
  - New trading partners

Product Verification Preparation

- Prepare to verify product identifiers (PI) for your serialized products
  - Necessary identifiers
  - Business scenarios
  - Technical requirements
  - VRS Solution
  - Authorized Trading Partner (ATP) credential

From the Dispenser perspective

Verification Operational Process Development

- Implement an operational process to support verification responses
  - Update SOPs

Note: Special shipment scenarios being defined, and detail scenario choreography will be provided in GS1 US DSCSA IG R1.3 [Scenarios such as Drop Ship, Consignment, 340B, Pharmacy sales]

Detail Content
- Appendix A

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Speakers

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TraceLink

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Vice President Distribution Operations, Traceability

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Michael Mazur

Director of Trade Operations

Pfizer Inc.

Q&A:

- Lessons learned from the onboarding of Manufacturers; what was expected versus unexpected; what can be shared and leveraged with other trading partners as they prepare for DSCSA; what gaps still exist?

- What challenges are Wholesalers experiencing as they have a unique perspective of being in the middle of the supply chain.

- What communication is needed between Wholesalers/Distributors, Dispensers, and Solution Providers?

Q&A:

Contact at tnasarenko@gs1us.org

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Thank You!

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Appendix A

Detail Content

From the Manufacturer/Repackager perspective

1. Product Marking Requirements

Understand the technical requirements for marking your serialized finished drug product with GS1 Data matrix (reference DSCSA Sec 581 (14) for use of "standardized graphic that includes, in both human and human-readable form and on a machine-readable data carrier that conforms to the standards developed by widely recognized international standards)

- Obtain and license GS1 Company Prefix corresponding to your FDA labeler code (https://my.gs1us.org/product/1024/gs1-company-prefix)
- Understand technical requirements for encoding your product with GS1 Identifiers
  - DSCSA Pharma FAQs
  - GS1 US DSCSA Implementation Guideline R1.2 (Part I Chapter 5 and Chapter 6)
- Engage your artwork team and packaging line vendors to implement packaging changes for encoding your products with GS1 identifiers
  - Recommend proactively, before product distribution, assessing the barcode quality by engaging in a barcode assessment to ensure scannability and correct population of data fields; 2020 Update: Barcode Readability for DSCSA 2023 Interoperability

From the Manufacturer/Repackager perspective

- Consider building aggregation, capturing, and maintaining parent-child relationships between different packaging levels of product (Each->Case->Pallet), in your packaging to optimize serialized shipment.
- Implement a software system that is capable of provisioning, commissioning and storing serial numbers as well as receiving, reporting, and sending DSCSA data to trading partners in EPCIS format according to the GS1 Implementation Guideline

2. GTIN Assignment and Product Listing

Assign, assemble, and share the list of your Global Trade Identification Number (GTINs) for your packages which are the smallest individual saleable units of your product for distribution and intended sale to the dispenser and higher levels of homogeneous packaging (i.e., bundles, cases)

3. GLN Setup and Assignment

Set up-up your Global Location Numbers (GLNs) for your corporate and site locations for exchanging serialized Transaction Information (TI)/Transaction Statement (TS) via EPCIS

- GLN Supplier Quick Start Guide

From the Manufacturer/Repackager perspective

4. Product Identifier Capture during packing and shipping

Capture GS1 product identifiers when packing and shipping to prepare for your serialized exchange

- Consider how these events will be captured at your CMOS or 3PLs. Work with your 3rd party agents (CMOs, CPOs, and 3PLs) to arrange for getting the foundational serialized information you need from them to enable you to assemble the serialized TI/TS data you will subsequently need.
  - GS1 US Implementation Guideline for Pharmaceutical Chain of Custody
- When this occurs at your Manufacturer warehouse, reference the GS1 US DSCSA Implementation Guideline R1.2
- Aggregation will be necessary to avoid scanning every single unit (child) when shipping a higher-level homogenous unit (parent) as in the situation of a case, bundle, or pallet
- Engage solution providers for warehouse and serialization management
- Update SOPs to integrate serialization data quality checks in your packaging and distribution processes to ensure physical product and data alignment
  - During packaging, check commissioned serial numbers with your batch quantity
  - At time of shipment, check delivery quantities against serial number quantities in EPCIS data files

From the Manufacturer/Repackager perspective

5. Capturing Transaction Information (TI) and Transaction Statement (TS) using EPCIS

For transfer of ownership transactions of your serialized products, understand the technical requirements for exchanging serialized Transaction Information (TI) and Transaction Statement (TS) via EPCIS

- Construct EPCIS events to capture and share your Transaction Information (TI) and Transaction Statement (TS) using EPCIS using GS1 US DSCSA Implementation Guideline R1.2
- Engage serialized solution providers for implementing your EPCIS serialized exchanges with your trading partners

6. Trading Partner Master Data and Serialized Data Exchange Setup

Set up your Trading Partner master data for EPCIS serialized exchanges

- Collect and record your trading partner's corporate and site location GLNs in your partner master data
  - Utilize GS1 US DataHub or GS1 GEPIR to search and retrieve your trading partner GLN and GCP. Alternatively, reach out to your trading partner to collect their corporate and site GLNs
    - Can use https://www.gs1.org/services/epc-encoderdecoder to derive sGLN

From the Manufacturer/Repackager perspective

- Provide a complete list of GTINs down to the lowest saleable unit which would be included in an EPCIS file
- Initiate serialized exchange onboarding with each of your trading partners
  - Identify and establish your communication protocol
  - Specify the EPCIS endpoints for the trading partner seller and trading partner buyer
  - Exchange contact information of your trading partner and their serialization solution provider
  - Exchange serialized EPCIS test file
    - Learn about the GS1 US Pharmaceutical Conformance Test Program and obtain GS1 US Rx EPCIS Trustmarks from GS1 US to optimize the data quality of your EPCIS serialized exchanges

7. Operational Process Development

Implement ongoing operational processes for capturing serialized shipments and exchanging serialized transaction information with your trading partners

- Update SOPs to consider the process for monitoring data exchanges (including map in/map out file failures)

From the Manufacturer/Repackager perspective

- Develop systems and processes to manage and resolve data misalignment/clerical error exceptions (data no product and product/no data scenarios) in a timely fashion
- Consider developing a single email POC for DSCSA related inquiries (e.g. DSCSA@XYZ.com)

8. Maintenance Process Development

Establish maintenance process to support operations, product, and business growth

- For additional products launched and acquired, assign, and share the GTINs for package/smallest individual saleable units and higher levels of homogeneous packaging (i.e., bundles, cases) with your trading partners
- For additional locations, assign and share GLNs with your trading partners
- For new FDA labeler codes, obtain a license for the GS1 company prefix for the new FDA labeler code before assigning and sharing GTINs under the new GS1 company prefix.
- For new trading partners, collect and record your trading partner's corporate and site location GLNs in your partner master data

From the Manufacturer/Repackager perspective

9. Product Verification Preparation

Prepare to verify product identifiers (PI) for your serialized products

- Necessary for PI verification are GTIN (with the embedded NDC), Serial Number, Lot/Batch Number, and Expiration Date
- Understand PI verification business scenarios and technical requirements for responding to verification requests from your direct and indirect trading partners
  - Review GS1 US Implementation Guideline Applying Lightweight Messaging Standard for Verification of Product Identifiers
  - Engage a Verification Router Service (VRS) solution provider for help in implementing technical requirements for responding to the verification request
- Work with your VRS solution provider to set up master data and configure your verification response business rules according to your respective manufacturing policies
  - Ensure your GTIN and Connectivity Information is recorded and maintained in a Lookup Directory.
    - HDA VRS Lookup Directory Specification for Connectivity Upload and Lookup Directory Synchronization

From the Manufacturer/Repackager perspective

- Configure your verification responses based on US pharmaceutical business scenarios
  - GS1 US Implementation Guideline Applying Lightweight Messaging Standard for Verification of Product Identifiers (Section 8.3 Examples of verification responses based on U.S. supply chain business scenarios)
- Obtain your Identity and Authorized Trading Partner (ATP) credential.
  - Initiate the process of acquiring verifiable credentials and digital wallet support by joining OCI's Early Adopter Program Initiative and signing up directly with the respective service provider(s) listed.
  - Engage your VRS solution provider to present your ATP credentials with your verification responses

10. Verification Operational Process Development

Implement an operational process to support verification responses

- Update your SOPs to monitor and manage verification response exceptions
- Consider developing a single email POC for DSCSA related inquiries (e.g. DSCSA@XYZ.com)

From the Wholesaler/Distributor perspective

1. Product Identification Requirements

Understand the technical requirements for marking your serialized shipping containers with a GS1 SSCC (reference GS1 Discussion paper on aggregation in the pharmaceutical supply chain) for use of a "standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards

- Obtain and license GS1 Company Prefix (https://my.gs1us.org/product/1024/gs1-company-prefix)
- Understand technical requirements for creating SSCCs and GLNs from GS1 identifiers
  - DSCSA Pharma FAQs
  - GS1 US DSCSA Implementation Guideline R1.2 (Part I Chapter 5 and Chapter 6)
- Engage your packaging line vendors to implement label changes for SSCC with GS1 Company Prefix
  - Consider building aggregation in your packaging to optimize serialized shipment

From the Wholesaler/Distributor perspective

2. GTIN Setup for Product Listing

Collect and publish the list of the Global Trade Identification Number (GTINs) for the packages you will be transacting which are the smallest individual saleable units of your product for distribution and intended sale to the dispenser and higher levels of homogeneous packaging (i.e., bundles, cases)

3. GLN Setup and Assignment

Set up and share your Global Location Numbers (GLNs) for your corporate and site locations for exchanging serialized Transaction Information (TI)/Transaction Statement (TS) via EPCIS

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From the Wholesaler/Distributor perspective

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- When this occurs at your distributor warehouse, reference the GS1 US DSCSA Implementation Guideline R1.2
- Engage solution providers for warehouse and serialization management
- Update SOPs to integrate serialization data quality checks in your distribution processes to ensure physical product and data alignment
  - At the time of shipment, check product identifiers against the EPCIS data files received from your supplier and the product's current status

From the Wholesaler/Distributor perspective

5. Technical Requirements for TI/TS Exchange

For transfer of ownership transactions of your serialized products, understand the technical requirements for exchanging serialized Transaction Information (TI) and Transaction Statement (TS) via EPCIS

- Construct EPCIS events to capture and share your Transaction Information (TI) and Transaction Statement (TS) using EPCIS using GS1 US DSCSA Implementation Guideline R1.2
- Engage serialized solution providers for implementing your EPCIS serialized exchanges with your trading partners

6. Trading Partner Master Data and Data Exchange Setup

Set up your Trading Partner master data for EPCIS serialized exchanges

- Collect and record your trading partner's corporate and site location GLNs in your partner master data
  - Utilize GS1 US DataHub or GS1 GEPIR to search and retrieve your trading partner GLN and GCP. Alternatively, reach out to your trading partner to collect their corporate and site GLNs
    - Can use https://www.gs1.org/services/epc-encoderdecoder to derive sGLN

From the Wholesaler/Distributor perspective

- Initiate serialized exchange onboarding with each of your trading partners
  - Identify and establish your communication protocol
  - Specify the EPCIS endpoints for the trading partner seller and trading partner buyer
  - Exchange contact information of your trading partner and their serialization solution provider
  - Exchange serialized EPCIS test file
    - Learn about the GS1 US Pharmaceutical Conformance Test Program and obtain GS1 US Rx EPCIS Trustmarks from GS1 US to optimize the data quality of your EPCIS serialized exchanges

7. Operational Process Development

Implement ongoing operational processes for capturing serialized shipments and exchanging serialized transaction information with your trading partners

- Update SOPs to consider the process for monitoring data exchanges, managing and resolving exceptions

From the Wholesaler/Distributor perspective

8. Maintenance Process Development

Establish maintenance process to support product and business growth and operations

- For additional products launched and acquired, collect, and record the GTINs for package/smallest individual saleable units and higher levels of homogeneous packaging (i.e., bundles, cases) with your trading partners
- For additional locations, assign and share GLNs with your trading partners
- For new trading partners, collect and record your trading partner's corporate and site location GLNs in your partner master data

9. Product Verification Preparation

Prepare to verify product identifiers (PI) for your serialized products

- Necessary for PI verification are GTIN (with the embedded NDC), Serial Number, Lot/Batch Number, and Expiration Date
- Understand PI verification business scenarios and responses from the product's manufacturer
  - Review GS1 US Implementation Guideline Applying Lightweight Messaging Standard for Verification of Product Identifiers (Section 8.3)

From the Wholesaler/Distributor perspective

- Engage a Verification Router Service (VRS) solution provider for help in implementing technical requirements for responding to the verification request
- Work with your VRS solution provider to receive responses and establish SOPs for consideration of the response when evaluating the status of the product.
- Obtain your Identity and Authorized Trading Partner (ATP) credential.
  - Initiate the process of acquiring verifiable credentials and digital wallet support by joining OCI's Early Adopter Program Initiative and signing up directly with the respective service provider(s) listed.
  - Engage your VRS solution provider to present your ATP credentials with your verification responses

10. Verification Operational Process Development

Implement an operational process to support verification responses

- Update your SOPs to monitor and manage verification response exceptions

From the Dispenser perspective

1. GLN Setup and Assignment

Look up if an existing Global Location Numbers (GLNs) has already been created or set-up your GLN for your corporate and site locations for exchanging serialized Transaction Information (TI)/Transaction Statement (TS) via EPCIS

- Share GLNs with your Trading Partners
- GLN Dispenser Quick Start Guide

2. Product Identifier Capture during receiving

Capture GS1 product identifiers when receiving shipments to prepare for your serialized exchange

- Consider how these events will be captured at your 3PLs. Work with your 3rd party agents (3PLs) to arrange for getting the foundational serialized information you need from them to enable you to assemble the serialized TI/TS data you'll subsequently need
  - GS1 US Implementation Guideline for Pharmaceutical Chain of Custody
- When this occurs at your own dispensing location, reference the GS1 US DSCSA Implementation Guideline R1.2

From the Dispenser perspective

- Engage solution providers for dispensing serialization management
- Update SOPs to integrate serialization data quality checks in your receiving processes to ensure physical product and data alignment
  - At time of receipt, check product identifiers against the EPCIS data files received from your supplier and the product's current status
    - **Note:** *Risk under Enhanced Drug Distribution Systems Draft Guidance*

***Note: Transfers between related entities under common ownership are not governed under DSCSA (Title II, Section 581 (24)(B)(i))**

3. Trading Partner Master Data and Data Exchange Setup

Set up your Trading Partner master data for EPCIS serialized exchanges

- Collect and record your trading partner's corporate and site location GLNs in your partner master data
  - Utilize GS1 US DataHub or GS1 GEPIR to search and retrieve your trading partner GLN and GCP. Alternatively, reach out to your trading partner to collect their corporate and site GLNs
    - Can use https://www.gs1.org/services/epc-encoderdecoder to derive sGLN

From the Dispenser perspective

- Initiate serialized exchange onboarding with each of your trading partners
  - Identify and establish your communication protocol
  - Specify the EPCIS endpoints for the trading partner seller and trading partner buyer
  - Exchange contact information of your trading partner and their serialization solution provider
  - Exchange serialized EPCIS test file
    - Learn about the GS1 US Pharmaceutical Conformance Test Program and obtain GS1 US Rx EPCIS Trustmarks from GS1 US to optimize the data quality of your EPCIS serialized exchanges

4. Operational Process Development

Implement ongoing operational processes for capturing serialized receiving and exchanging serialized transaction information for saleable returns

- Update SOPs to consider the process for monitoring data exchanges, managing and resolving exceptions

From the Dispenser perspective

5. Maintenance Process Development

Establish maintenance process to support product and business growth and operations

- For additional products launched and acquired, collect, and record the GTINs for package/smallest individual saleable units and higher levels of homogeneous packaging (i.e., bundles, cases) with your trading partners
- For additional locations, assign and share GLNs with your trading partners
- For new trading partners, collect and record your trading partner's corporate and site location GLNs in your partner master data

6. Product Verification Preparation

Prepare to verify product identifiers (PI) for your serialized products. PI verification are not for saleable returns but for verification of suspect or illegitimate, exception or status check

- Necessary for PI verification are GTIN (with the embedded NDC), Serial Number, Lot/Batch Number, and Expiration Date

From the Dispenser perspective

- Understand PI verification business scenarios and responses from the product's manufacturer
  - GS1 US Implementation Guideline Applying Lightweight Messaging Standard for Verification of Product Identifiers (Section 8.3 for Verification Responses)
  - Engage a Verification Router Service (VRS) solution provider for help in implementing technical requirements for responding to verification request
- Work with your VRS solution provider to receive responses and establish SOPs for consideration of the response when evaluating the status of the product
- Obtain your Identity and Authorized Trading Partner (ATP) credential
  - Initiate the process of acquiring verifiable credentials and digital wallet support by joining OCI's Early Adopter Program Initiative and signing up directly with the respective service provider(s) listed.
  - Engage your VRS solution provider to present your ATP credentials with your verification responses

7. Verification Operational Process Development

Implement an operational process to support verification responses

- Update your SOPs to monitor and manage verification response exceptions

Appendix B

Document Reference

Document Reference

Overall:

- Drug Supply Chain Security Act (DSCSA)
- Partnership for DSCSA Governance (PDG) Blueprint
- Healthcare Distribution Alliance (HDA) Barcode Guideline

Document/Link	Manufacturers	Wholesalers	Dispensers
DSCSA Sec 581 (14)	Yes	No	No
https://my.gs1us.org/product/1024/gs1-company-prefix	Yes	Yes	No
DSCSA Pharma FAQs	Yes	Yes	No
GS1 US DSCSA Implementation Guideline R1.2	Yes	Yes	No
GLN Supplier Quick Start Guide	Yes	Yes	No
GLN Dispenser Quick Start Guide	No	No	Yes
GS1 US Implementation Guideline for Pharmaceutical Chain of Custody	Yes	Yes	Yes

Document Reference

Document/Link	Manufacturers	Wholesalers	Dispensers
GS1 US DataHub	Yes	Yes	Yes
GS1 GEPIR	Yes	Yes	Yes
https://www.gs1.org/services/epc-encoderdecoder	Yes	Yes	Yes
GS1 US Pharmaceutical Conformance Test Program	Yes	Yes	Yes
GS1 US Implementation Guideline Applying Lightweight Messaging Standard for Verification of Product Identifiers	Yes	Yes	Yes
HDA VRS Lookup Directory Specification for Connectivity Upload and Lookup Directory Synchronization	Yes	No	No
OCI's Early Adopter Program Initiative	Yes	Yes	Yes
GS1 Discussion paper on aggregation in the pharmaceutical supply chain	No	Yes	No

Appendix C

Glossary

Glossary

Term	Acronym	Definition
Drug Supply Chain Security Act	DSCSA	The Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. [Source: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa]
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).
National Drug Code	NDC	The National Drug Code is a 10-digit identification number 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.
Serialized GTIN	SGTIN	An SGTIN is the combination of a GTIN and a unique serial number of up to 20 alphanumeric characters.
Standardized Numerical Identification	SNI	SNI is the FDA's term for the unique identification mandated by the DSCSA.
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).

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Term	Acronym	Definition
Serial Shipping Container Code	SSCC	The Serial Shipping Container Code (SSCC) is the globally unique GS1 identification number used to identify individual logistic units. A “logistic unit” is defined as an item of any composition established for transport and/or storage which needs to be tracked individually and managed through the supply chain.
Global Location Number	GLN	The Global Location Number (GLN) is the globally unique GS1 Identification Number used to identify parties and locations.
Serialized Global Location Number	SGLN	The term SGLN refers to an EPC URI syntax for GLNs that is used in EPCIS. The SGLN syntax is capable of representing a plain GLN (without extension) or a GLN plus extension.
GS1 Company Prefix	GCP	A GS1 Company Prefix is a unique string of 6–11 digits issued to your company by your local GS1 Member Organization.
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.
GS1-128		GS1-128 is a linear barcode used to encode data for logistics units such as cases and pallets.
EPC	EPC®	The Electronic Product Code™ (EPC) is syntax for unique identifiers assigned to physical objects, unit loads, locations, or other identifiable entity playing a role in business operations.
Electronic Product Code Information Services	EPCIS	The EPC Information Services (EPCIS) standard defines a data model and a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain.

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Term	Acronym	Definition
Manufacturer		A manufacturer is defined in section 581(10) of the FD&C Act to mean: [W]ith respect to a product -- (A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product; (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B). [Source: https://www.fda.gov/files/drugs/published/Identifying-Trading-Partners-Under-the-Drug-Supply-Chain-Security-Act-Guidance-for-Industry.pdf]
Repackager		DSCSA defines repackager in section 581(16) of the FD&C Act as "a person who owns or operates an establishment that repacks and relabels a product or package for – (A) further sale; or (B) distribution without a further transaction." [Source: https://www.fda.gov/files/drugs/published/Identifying-Trading-Partners-Under-the-Drug-Supply-Chain-Security-Act-Guidance-for-Industry.pdf]
Wholesaler		DSCSA defines wholesale distributor in section 581(29) of the FD&C Act to mean "a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4) of the FD&C Act, as amended by [DSCSA])." [Source: https://www.fda.gov/files/drugs/published/Identifying-Trading-Partners-Under-the-Drug-Supply-Chain-Security-Act-Guidance-for-Industry.pdf]

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Term	Acronym	Definition
Contract Manufacturing Organization	CMO	For the purposes of the DSCSA, a CMO is an entity that performs manufacturing operations for the NDA/ANDA/BLA holder or a co-licensed partner of the NDA/ANDA/BLA holder, to fulfill a contractual obligation with such manufacturer, but is not responsible for the introduction of the product into interstate commerce. [Source: http://pdsaonline.org/wp-content/uploads/2015/06/PDSA-Letter_DSCSA-QA_May-2014.pdf]
Third Party Logistics	3PL	DSCSA defines a 3PL in section 581(22) of the FD&C Act to mean: [A]n entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product. [Source: https://www.fda.gov/files/drugs/published/Identifying-Trading-Partners-Under-the-Drug-Supply-Chain-Security-Act-Guidance-for-Industry.pdf]
Dispenser		The term dispenser, as defined in section 581(3) of the FD&C Act: (A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and (B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5). [Source: https://www.fda.gov/files/drugs/published/Identifying-Trading-Partners-Under-the-Drug-Supply-Chain-Security-Act-Guidance-for-Industry.pdf]