2022 Traceability Webinar Series

HDA Healthcare Distribution Alliance
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"DSCSA 101 and Timeline" & "EPCIS Onboarding Checklist"

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Speakers

Scott Mooney Scott A. Mooney, Vice President, Distribution Operations, McKesson Corporation

Tracy Nasarenko, Sr. Director, Community Engagement, GS1 US

Jillanne Schulte Wall, Senior Director, Health and Regulatory Policy, American Society of Health-System Pharmacists (ASHP)

Overview of DSCSA Milestones

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2015

Lot-level traceability

Manufacturers and wholesale distributors must provide lot TI, TH and TS.

2017

Product identifiers by manufacturers

Manufacturers must affix product identifiers to each package and homogenous case.

2018

Product identifiers by repackagers

Repackagers must affix product identifiers to each package and homogenous case.

2019

Verification by distributors

Wholesale distributors must only accept serialized product. They must also verify product identifiers with the manufacturer before redistributing returns. However, FDA has announced, by way of a "compliance policy" that it will not enforce this saleable returns verification requirement until November 27, 2023. The compliance policy is limited to the requirements that wholesale distributors verify saleable returned products prior to further distribution and have verification systems in place to comply with the requirements of section 582(c)(4)(D) of the FD&C Act; it does not extend to the other requirements in section 582 of the FD&C Act.

2020

Verification by dispensers

FDA has announced in this compliance policy that it will not enforce until November 27, 2023, two dispenser verification requirements that went into effect on November 27, 2020. Without this enforcement discretion, beginning November 27, 2020, dispensers would have been required to verify the product identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3. Dispensers would also have had to verify product in this manner (3 packages/10 percent) in response to a notification of illegitimate product from FDA or a trading partner. Dispensers now do not have to verify suspect and illegitimate product in this manner until November 27, 2023. Other requirements, however, are still in effect. Dispensers must still only transact product encoded with a product identifier (unless the product is grandfathered or subject to an applicable waiver, exemption or exception) and must comply with other suspect and illegitimate verification requirements, including quarantining such products, conducting investigations, and dispositioning illegitimate products.

2023

Unit-level traceability

Manufacturers, distributors and dispensers must provide and receive TI (including product identifier) and TS in a secure, electronic and interoperable manner.

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 Electronic Product Code Information Services (EPCIS)
  - Share GLNs with your Trading Partners
  - GLN Dispenser Quick Start Guide

Product Identifier Capture During Receiving

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

***Note: Transforms 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 Electronic Product Code Information Services (EPCIS) serialized exchanges
  - Collect and record
  - Initiate onboarding

EPCIS Checklist: Onboarding Checklist for Data Exchange Across the Supply Chain[1]

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Dispenser

- ✓ If setting up direct EPCIS connection(s) to receive data from your manufacturer and wholesale distributor trading partners:

- ✓ If you're accessing data in distributor portal(s):
  - Provide your GLNs and sGLNs to upstream trading partners, both wholesale distributors and any manufacturers that you have direct relationships with.
  - Ensure you have master data from upstream trading partners for data you'll receive.
  - Receive, test, and report inaccuracy/challenges with EPCIS (TI/TS)
  - Determine the need to consult or hire service providers to assist and confirm compliance with DSCSA (SOPs, VRS, etc.)
    - *Pending transition to EPCIS v1.3

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

Document Reference

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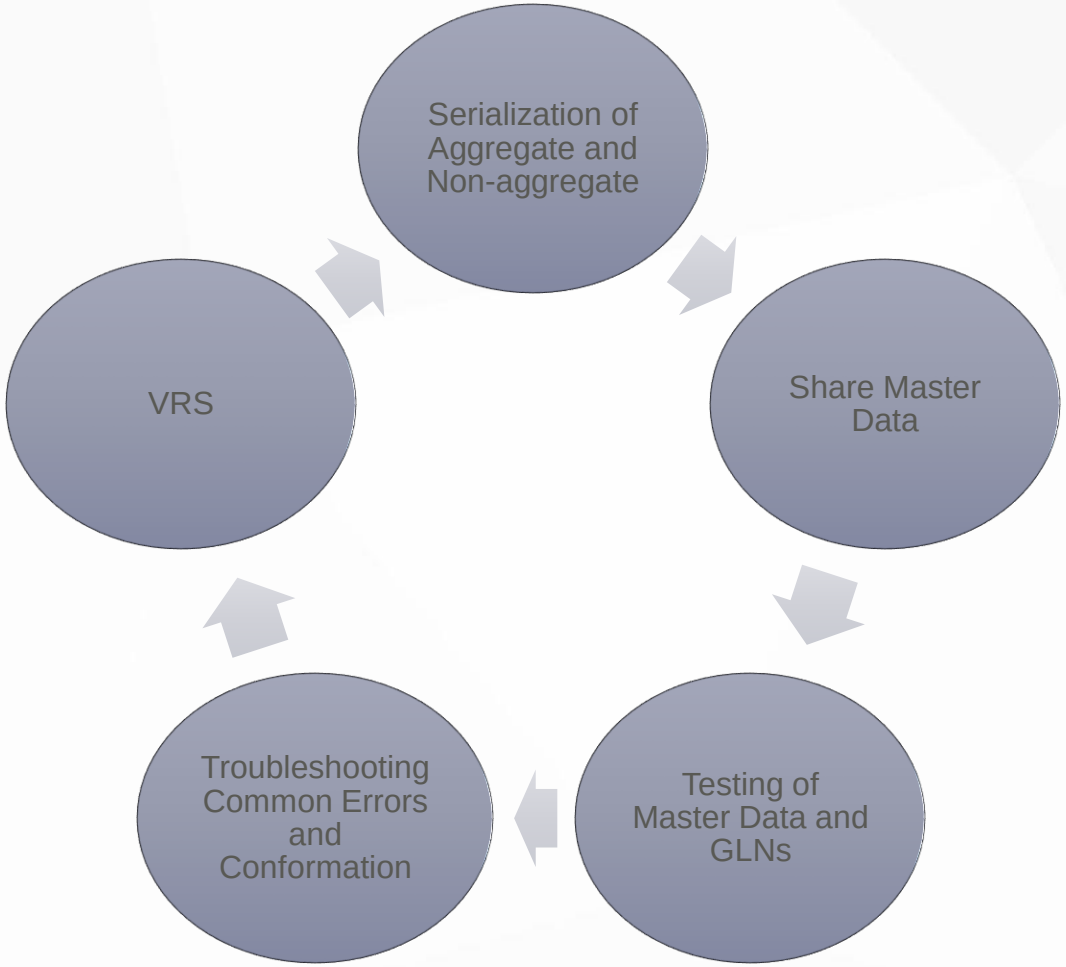
Onboarding for Data Exchange Across the Supply Chain



APPENDIX A

Detail Content

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

- DSCSA Pharma FAQs
- 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

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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 Returned 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 References:

- Drug Supply Chain Security Act (DSCSA)
- Partnership for DSCSA Governance (PDG) Blueprint
  - This document sets forth the PDG-defined compliance requirements and business requirements for 2023 interoperability. This is an evolving resource that will be continually developed to provide additional clarity to the industry with detailed functional specifications.
- Healthcare Distribution Alliance (HDA) Barcode Guideline
  - This comprehensive guideline, developed by the distribution-sector experts of HDA's Bar Code Task Force, provides specifications for barcoding and labeling healthcare products.

Document/Link	Manufacturers	Wholesalers	Dispensers
DSCSA Sec 581 (14)	Yes	No	No
https://uatgs1us.hsdyn.com/product/1024/gs1-company-prefix	Yes	Yes	No
DSCSA Pharma FAQs	Yes	Yes	Yes
GS1 US DSCSA Implementation Guideline R1.2	Yes	Yes	Yes
GLN Supplier Quick Start Guide	Yes	Yes	No

Continued to the next slide

Document Reference

Document/Link	Manufacturers	Wholesalers	Dispensers
GLN Dispenser Quick Start Guide	No	No	Yes
GS1 US Implementation Guideline for Pharmaceutical Chain of Custody	Yes	Yes	Yes
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 Returned 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]