RESOURCES



PDG, HDA, and GS1 Hold Critical Workshop on DSCSA 2023 Compliance Exceptions Management

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TraceLink joined this past week with industry leaders from the Partnership for DSCSA Governance (PDG), the Healthcare Distribution Alliance (HDA), and GS1 at a key DSCSA 2023 exceptions workshop in Washington D.C. The DSCSA Exceptions Handling Workshop, held Feb. 6-7, was an interactive program where participants could analyze and propose operational processes and network data management approaches to resolve data exceptions related to the exchange and use of serialized DSCSA transaction information. This workshop comes on the heels of the recent TraceLink DSCSA webinar on Troubleshooting and Managing Exceptions Under DSCSA (watch on-demand).

As the end-to-end U.S. pharmaceutical supply chain quickly ramps up to meet the final November 27 deadlines of the Drug Supply Chain Security Act (DSCSA), new requirements for the exchange of serialized Transaction Information (unit-level serialized product identifiers and their B2B commercial transactional data) are mandated for pharmaceuticals sold between trading partners. Organizations such as HDA looked early at the potential for a significant increase in the risk of DSCSA compliance exceptions as serialized product and data flows across the supply chain (see HDA Exceptions Handling Guidelines).

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The DSCSA Workshop focused on three specific areas of the exceptions handling challenge, that of the need to (1) identify, (2) understand, and (3) resolve compliance exceptions. Some key questions and takeaways from the discussions on these three topics included:

Identify

- How can the FDA Enhanced Drug Distribution Security (EDDS) Guidance on reconciliation help inform identification of DSCSA exceptions?
- What are the underlying business processes where identification of exceptions may occur? How would those business processes be impacted? What data do those processes have or need in this area?
- How aware are pharmacy dispensers (healthcare providers, retail pharmacies, etc.) of the potential exceptions under DSCSA that may occur for products they receive and manage? How active will dispensers be in identification of potential exceptions given pharmacy receiving practices under DSCSA?
- Should the holder (possessor of the product) perform a Product Identifier verification of a product (using the VRS network) when they identify an exception?

Understand

- How will exception process analysis be related to, and distinctly separated from, related processes under suspect and illegitimate product processes identified under DSCSA?
- What can supply chain members learn from current exception processes followed under controlled product receiving methods?
- Why quantity receiving checking can play an important role in understanding a potential exception issue.
- What are the expectations on overall volume, human resource needs, and time requirements of potential exceptions to be managed (based on previous DSCSA experience, learnings from the implementation of the EU Falsified Medicines Act, and other serialized product track and trace regulations)?

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- What rules should be considered, and who makes the decision, on product disposition if there are discrepancies between the physical product received and the compliance data received?
- What solutions, standards, and procedures are needed specifically to resolve “Product but No Data” and “Data but No Product” scenarios where there may be in existence today partial standards or process support?
- What documentation, data archival needs, etc. are needed on how an issue was resolved given CFR Part 11 or other quality/audit requirements?

Why is the industry taking such a detailed look at DSCSA compliance exceptions? Because companies already face these issues. Specific examples of exceptions that occur include:

- A shipment arrives at the dock of a distributor and the first pallet label on the truck is scanned. No EPCIS file has been sent for that shipment.
- In addition to the 48 cases on a pallet, two additional cases of product have been shrink-wrapped on top of the pallet. The EPCIS file for that pallet only contains data for 48 cases and not 50.
- The US DEA (Drug Enforcement Agency) was conducting an operation at a port. They have opened a case of 48 bottles and removed two for sampling. The EPCIS file received contains data for 48 eaches. Which two have been removed?
- Due to low quality inkjet printers and ink used at a CMO, the 2D barcode and the Human Readable Information (HRI) has faded/smudged and is not readable by scanners.

Without a network based solution to manage compliance exceptions, shipments and receipts may be delayed causing potential drug shortages, inventory awaiting investigation may pile up slowing distribution operations, and pressure to make decisions without proper data increases compliance risk.

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With over a decade in supporting the serialization of product and the exchange of serialized product data between trading partners and with government agencies around the world to meet track and trace regulations, the challenge of compliance exception management is no surprise to TraceLink. TraceLink has processed almost 1 billion Transaction Histories between trading partners on our **TraceLink Network** since DSCSA went into effect in 2015, and today manages the commissioning of over 1 billion serialized product identifiers every month. Working with the over 290,000 entities on the TraceLink Network, this has given us both a deep understanding of the potential compliance exceptions faced by each segment of the supply chain, and broad insights as to the kinds of information needed by partners to identify, understand, and resolve issues before they impact product supply.

To help companies master DSCSA compliance exceptions, we augmented our core Compliance for DSCSA solutions with TraceLink Serialized Product Intelligence, and our new **Supply Chain Work Management** for Compliance Exceptions solution. SCWM for Compliance Exceptions enables **pharmaceutical manufacturers**, **wholesale distributors**, and other parties to rapidly identify, onboard, and engage supply chain partners in a multienterprise process to intake, triage, and resolve both internal and external issues associated with compliance exceptions. The solution provides a single, centralized location for cross-functional and cross-company users to collaboratively resolve compliance exceptions and capture insights into the current and historical status of exceptions, speeding resolution.

To learn more about TraceLink’s comprehensive approach to DSCSA compliance exception management, we would love to talk about your unique supply network.

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