DSCSA 2023: How to Handle the Influx of DSCSA Compliance Exceptions



The deadline for complying with the final phase of the U.S. Drug Supply Chain Security Act (DSCSA) is November 27, 2023.

With less than seven months to go, organizations across the end-to-end pharmaceutical supply chain—including manufacturers, wholesale distributors, third-party logistics providers, and dispensers—need to act with urgency and prepare now. That includes getting ready for an influx of DSCSA compliance errors, also known as exceptions, that stem from the implementation of a 100% interoperable system for exchanging EPCIS data.

Compliance exceptions can occur due to anything from a mismatch between EPCIS data and the corresponding physical product received to a missing label, and can lead to significant supply chain disruption if not promptly resolved. This requires real-time, multienterprise collaboration between supply chain trading partners.

A Spike in Exceptions Under DSCSA 2023: What to Expect

DSCSA requires trading partners to provide Transaction Information (TI) and Transaction Statement (TS) data whenever prescription drugs change hands between authorized trading partners.

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As the pharmaceutical supply chain implements the requirements mandated by DSCSA, the shift from exchanging lot-level data to unit-level serialized data presents a major obstacle. Exchanging that much data in a secure, interoperable, and fully electronic manner adds significant complexity to supply chain operations that will result in a rise in compliance exceptions, especially in the early stages. The Healthcare Distribution Alliance reports that organizations can expect a rise in **several different types of exceptions that can be grouped into six categories**:

- Data Issues
- Damaged Products
- Product, No Data
- Data, No Product
- Packaging
- Product Hold

When an exception occurs, it can result in product holds and derail supply chain operations. Exceptions must be resolved before the trading partner can sell the product downstream. Resolving the error or discrepancy requires a collaborative effort between trading partners, but this is often a complex and time-consuming process. This is largely due to the cumbersome and disjointed process for managing exceptions across the end-to-end supply chain, which is often handled over portals, phone calls, and email communication. These communication mediums are not purpose built for the task of resolving compliance exceptions and result in a lack of supply chain visibility, poor communication, and lengthy issue resolution times.

How a Network Approach Improves Exception Management

TraceLink eliminates the need for point-to-point integrations and disjointed exception management processes with a powerful network platform that connects

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all trading partners across the end-to-end supply chain, enabling real-time, workflow-driven multienterprise collaboration and rapid exception resolution. With more than 290,000 network members around the globe, including manufacturers, wholesalers, dispensers and logistics providers, the TraceLink OPUS Digital Network Platform provides customers with a 100% secure, interoperable system for exchanging serialization and track-and-trace compliance data in the GS1 EPCIS format.

The TraceLink network also serves as the foundation for real-time collaboration and exception management between supply chain partners. **TraceLink Supply Chain Work Management (now POET) for Compliance Exceptions** provides a single, centralized location to collaboratively resolve compliance exceptions and capture insights into the current and historical status of exceptions. The solution's task management capability enables users to create cross-functional and cross-company workflows to quickly intake, triage, and resolve compliance exceptions. Subject matter experts at multiple companies can be assigned tasks and deadlines to ensure exceptions are resolved in a timely manner, with all stakeholders working from the same centralized system and using the same data.

Supply Chain Work Management (now POET) for Compliance Exceptions delivers a faster, better, and future-proof way to resolve DSCSA compliance exceptions at the lowest total cost of ownership by digitalizing the end-to-end exception resolution processes. Benefits include:

- Quick exception creation following industry guidelines.
- Flexible exception creation through user interface or API.
- Rapid onboarding of partners across the end-to-end supply chain.
- Configurable internal triage, including impact assessment and alerts.
- Real-time collaboration with upstream and downstream partners to resolve errors fast.
- Preconfigured issues templates designed specifically for DSCSA compliance exceptions.

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- Greater visibility into compliance status with rich dashboards, reports, and historical data.
- Customizable workflows that can be adapted to fit the requirements of any supply network.

Watch this quick video clip from our DSCSA Webinar Series to see Amanda Bettman, General Manager of Supply Network Orchestration at TraceLink, explain how Supply Chain Work Management (now POET) for Compliance Exceptions can help organizations address the influx of DSCSA compliance exceptions.



Start Preparing for Exception Management Under DSCSA Today

Supply Chain Work Management (now POET) for Compliance Exceptions is a proven solution, shown to improve collaboration and speed up the exception resolution process. Additionally, organizations across the pharmaceutical industry are leveraging Supply Chain Work Management (now POET) for use cases outside of DSCSA, including processes related to product quality management, artwork changes, purchase order management. and much more.

If you'd like to learn more about managing DSCSA compliance exceptions with TraceLink Supply Chain Work Management (now POET) for Compliance Exceptions, our global services team can perform a complimentary DSCSA readiness assessment for you. Contact your TraceLink Account Executive to get started now or email us at DSCSA [at] tracelink.com (**DSCSA[at]tracelink[dot]com**).

DSCSA [at] tracelink.com (START YOUR READINESS ASSESSMENT)

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Build Your Track-and-Trace Compliance Foundation at FutureLink

FutureLink is a pharmaceutical industry conference designed to help manufacturers, distributors, healthcare providers, and retail pharmacies build targeted, impactful solutions to ensure compliance, gain supply chain visibility, and enable real-time process collaboration through end-to-end product orchestration. Join us on May 22-24 in Boston, Massachusetts, and walk away with your DSCSA 2023 playbook and supply chain digitalization roadmap. **Visit the event page to learn more about FutureLink today**.

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Thank you for contacting us; we'll be in touch shortly.

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DSCSA 2023 item-level traceability requirements are a step change over pharmacies' current 2015 lot-level requirements, introducing significant operational and regulatory challenges around.

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Point-to-Point Predicament: Why a Network Approach Matters for Reducing DSCSA Costs & Accelerating Digitalization

DSCSA 2023 isn’t just about sending EPCIS transactions—its item-level traceability requirement will require a tremendous shift from all members of the pharmaceutical supply chain.

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