How to Automate Compliance Exception Management During the DSCSA Stabilization Period



If 2023 was the year of **implementing systems and processes for meeting the U.S. Drug Supply Chain Security Act (DSCSA) requirements**, 2024 is the year of system and process maturation. The **FDA's "stabilization period**" offers the industry time to refine their implementations, providing companies with 10 more months to further test and operationalize their DSCSA systems and processes to minimize disruption to the pharmaceutical supply chain.

A significant challenge that the industry will face as it takes a critical look at DSCSA processes is how to handle DSCSA-related compliance exceptions. This article looks at what the industry can do to improve exception management before the end of the stabilization period and how TraceLink can help automate and streamline this process.

New DSCSA requirements for product traceability result in new exceptions

In 2023, the final set of requirements for the U.S. DSCSA went into effect. Under this mandate, all entities in the pharmaceutical supply chain are now required to exchange serialized unit-level product data in a digital, interoperable, and secure manner to enhance drug traceability. While most trading partners are capable of sending and receiving lot-level transaction data with minimal problems, the shift to

© TraceLink Inc. 2009 - 2025 All Rights Reserved

electronic exchange of serialized unit-level data adds another layer of complexity.

As trading partners continue to implement and fine-tune their new DSCSA processes and systems, there will be mismatches between the data received and the product received in the shipment, **resulting in compliance exceptions**. According to the **Healthcare Distribution Alliance**, most compliance exceptions will fall into one of these five categories:

- Data issues
- Product, no data
- Data, no product
- Damaged packaging and labeling with unreadable serial numbers
- Unavailable for distribution due to compliance exceptions

Exceptions have the potential to delay product delivery. Every exception must be resolved before the trading partner can send the product downstream or sell it to customers, and every delay impacts both the company's profits and the availability of affected medications to patients.

Efficient exception management remains an elusive target

Resolving compliance-related exceptions quickly is vital to ensuring that product flows smoothly across the pharmaceutical supply chain. However, managing exceptions has proven to be a complex process. It requires close coordination between multiple companies across the supply chain as they investigate issues and then work together to get them resolved. This collaboration often takes place over the phone or email, with relevant data shared via spreadsheets—hardly an efficient or speedy process.

In addition to the inefficiency of this disjointed collaboration process, there is another challenge this approach presents: maintaining records and documentation. When exception resolution is happening across various systems and multienterprise teams, it's easy for crucial steps in the process to go

© TraceLink Inc. 2009 - 2025 All Rights Reserved

undocumented as they get lost in email conversations and ad hoc meetings. This not only impedes internal process evaluation and improvement, but also makes it difficult to demonstrate process adherence during audits.

On top of this, many companies have not devoted as much effort to developing DSCSA standard operating procedures as they have in other areas, like DSCSA strategy development and budgeting. This was shown clearly in a **benchmarking survey that TraceLink conducted in 2023**, which revealed authoring and executing SOPs like exception management is where most respondents showed the lowest level of preparedness. Only 25% of health systems and 39% of retail pharmacies said their DSCSA SOPs were “well underway.”

In short, exception management is both a process that is inherently difficult to execute, and a process that hasn’t been fully developed at many companies. This poses significant risk to the industry, especially with the end of the stabilization period coming in November and the rise of compliance exceptions that will come with it.

Automate exception management and speed successful resolution with TraceLink

A digital and automated exception management solution is the answer to the growing challenge of compliance exception management. Digitalizing and automating this complex process not only helps accelerate the speed of resolution, it reduces the amount of time your employees need to dedicate to exception management.

TraceLink Supply Chain Work Management (now POET) is specifically designed to digitalize and automate the exception management process so it can be executed in a fraction of the time. It eliminates disjointed, time-consuming exception management processes with a powerful network platform that enables you to quickly connect and start working with trade partners to resolve exceptions. By centralizing exception management in a single platform, Supply Chain Work

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Management (now POET) can also automatically capture a digital record of the issue, triaging steps performed by partners, and the resolution achieved, making these records readily available to demonstrate process adherence.

Supply Chain Work Management (now POET) 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 process. Benefits include:

- Quick exception creation following industry guidelines through a user interface or API.
- Configurable internal triage, including impact assessment and alerts.
- Preconfigured templates designed specifically for DSCSA compliance exceptions.
- Greater visibility into compliance status with rich dashboards and historical data.
- Customizable workflows that fit the requirements of any supply network.

If you'd like to learn more about effectively managing DSCSA compliance exceptions, contact your TraceLink Account Executive to get started now or email us at DSCSA [at] tracelink.com (**DSCSA[at]tracelink[dot]com**).

BlogProcess Orchestration for Empowered Teams (POET)DSCSA for Dispensers, DSCSA for Manufacturers
Contact TraceLink to get started with Supply Chain Work Management (now POET)!
Fill out the form to contact us now.

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

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Related Content



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

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.

View More

© TraceLink Inc. 2009 - 2025 All Rights Reserved



TraceLink Introduces Supply Chain Work Management for Compliance Exceptions to Accelerate Exception Resolution

New capability for Supply Chain Work Management enables seamless resolution of supply chain exceptions and ensures adherence to regulations like DSCSA.

View More

© TraceLink Inc. 2009 - 2025 All Rights Reserved