# 3 Critical Areas to Address Before the DSCSA Stabilization Period Ends



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The **DSCSA stabilization period** concludes on Nov. 27 and many companies in the life sciences and healthcare supply chain are finalizing their systems and processes for compliance and product traceability. Where does your DSCSA compliance project stand?

Whether you're just starting or looking to finish up, there are a few key areas that are easy to overlook in the final push to meet the compliance requirements. In this article, TraceLink's Center of Excellence looks at three critical action items you won't want to forget as you finalize your systems and processes for DSCSA.

## 1. Establish DSCSA SOPs

The DSCSA stabilization period may end on Nov. 27, but DSCSA itself is just beginning. Many companies have spent a lot of time working to ensure they have the technical capabilities required for compliance but much less time thinking about the processes surrounding compliance. This also includes processes that may not be necessary for compliance but could be beneficial for improving other areas of operations.

Some examples of standard operating procedures (SOPs) could include:

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- **Product identifier verification:** How will items be inspected for DSCSA-compliant product identifiers? What happens if a product doesn't have a DSCSA-compliant identifier? What is your process for responding to a verification request?
- **Product tracing:** What are the processes for shipping and receiving product and confirming the validity of the product tracking data? Are there systems in place for storing product tracing data in compliance with DSCSA or will a third-party vendor be used? Are there processes for documenting waste?
- **Special product scenarios:** How will returned and recalled product be managed? Are there agreements and processes in place with trade partners to acquire or send serialized product data for drop shipments and 340B product?
- **Suspect or illegitimate product investigation:** How will suspect product be handled when it's identified? Are there processes in place for responding to suspect or illegitimate product notifications from trade partners or federal entities?

In many instances, the solution you're leveraging for DSCSA compliance may impact the processes and procedures you put in place. The TraceLink **DSCSA Compliance solution** was designed around the reality that the various companies making up the pharmaceutical supply chain all have their own unique requirements based on their systems, processes, and other preferences. Our solution supports various approaches to managing DSCSA processes in order to enhance your flexibility.

### 2. Prepare for DSCSA compliance exceptions

Once the DSCSA stabilization period ends, there will be an influx of DSCSA-related compliance exceptions stemming from the increased volume of serialized product data being exchanged. According to the Healthcare Distribution Alliance, most compliance exceptions will fall into one of these five categories:

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

While rigorous testing may help eliminate some potential issues, the reality is that exceptions will still surface once data is being exchanged in a live distribution setting. This can significantly delay product shipping and receiving, as every exception must be resolved before the transfer of product ownership can be completed and the product can be passed further down the supply chain or dispensed to a patient.

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.

TraceLink **Process Orchestration for Empowered Teams (POET)** digitalizes and automates the exception management process. Leveraging a shared application designed for managing multienterprise supply chain processes, this solution enables trading partners to manage and resolve exceptions collaboratively in a fraction of the time. And because the entire process is handled through a single platform, trade partners can also automatically capture a digital record of the issue, all triaging steps performed, and the resolution achieved, making these records readily available to demonstrate process adherence.

### 3. Future-proof systems and processes

DSCSA has evolved tremendously since its first announcement in 2013. As the industry grows accustomed to operating in a world of serialized product, DSCSA will continue to evolve to help the industry effectively deter, detect, and remove

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illegitimate drugs from the supply chain. These changes could include anything from applying new FDA guidance to implementing new releases of core standards like EPCIS.

While these changes improve patient safety and supply chain security, they do require companies to constantly update and rethink their core DSCSA systems and processes. This is in addition to change they already manage as a part of their everyday operations, like:

- Onboarding new suppliers with varying levels of technical capabilities.
- Upgrading system infrastructure for better performance and security.
- Modifying systems and processes to accommodate mergers and acquisitions.
- Implementing product and solution enhancements from their vendors.

TraceLink is dedicated to ensuring our customers are constantly in **compliance with DSCSA**, and our network-based platform infrastructure plays a key role in that. Our network-tenant architecture enables TraceLink to deploy new functionality across the network to ensure all companies are upgraded at the same time—no mismatches from desynced update rollouts.

We also work closely with all the key standards organizations and regulatory agencies to understand how new requirements and specifications should be implemented. This enables customers to stay compliant with DSCSA without having to devote precious internal resources to compliance.

### Are you ready for Nov. 27?

The DSCSA stabilization period ends in less than 200 days, which doesn’t leave much time to finalize your DSCSA compliance project. If you’re concerned you won’t be ready in time, TraceLink can help. Our network-based approach to integration is the fastest, easiest way to connect with hundreds or even thousands of trade partners and begin exchanging serialized product data in support of the DSCSA 2023 requirements.

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TraceLink is happy to review your DSCSA project in these final months leading up to the end of the stabilization period. If you're using a competitor's solution or considering an in-house approach, fill out the form and get in touch today. If you're a TraceLink customer with any questions, contact your account executive for a deeper discussion on your implementation.

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Contact TraceLink to review your DSCSA strategy!
Fill out the form to schedule a review now.

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

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