

No Time to Delay Your Project: FDA Guides Industry to Use the Next 12 Months to Stabilize DSCSA Systems and Processes

By Shabbir Dahod, President and CEO, TraceLink

The FDA recently announced a 12-month enforcement discretion and system stabilization period for the final phase of the **U.S. Drug Supply Chain Security Act (DSCSA)**, but the law will still take effect on Nov. 27, 2023. And whether you're a pharmaceutical manufacturer, wholesale distributor, or dispenser, organizations that delay their DSCSA projects risk failing to be ready for a complex regulation. Critically, they will also miss out on the strategic competitive advantage that other industry stakeholders are acquiring right now by using DSCSA to digitalize end-to-end supply chain operations and access industry-wide supply chain intelligence.



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In guidance shared with the pharma industry in late August, the FDA stated that the enforcement discretion period is not a delay in the law and strongly urged supply chain stakeholders to avoid slowing or delaying DSCSA compliance projects. Instead, the 12-month stabilization period, which ends on Nov. 26, 2024, should be used to stabilize and mature DSCSA systems and processes with supply chain partners. But that's not the only reason to make sure that DSCSA compliance projects remain a top digitalization priority.

Ranging from advanced drug shortage predictions to item-level inventory management to the digitalization of the product recall process, many organizations are leveraging the information-sharing requirements of DSCSA to create business value right now. Organizations ought to be leading the end-to-end digitalization race, instead of standing on the sidelines.

Why the FDA announced a DSCSA stabilization period

Enacted by Congress in 2013 and designed to be rolled out in phases over a 10-year period, DSCSA seeks to prevent counterfeit, adulterated, and illegally diverted prescription medicines from entering the US supply chain and harming patients. The final and most complex phase of DSCSA requires pharma trading partners to implement a secure, electronic, and 100% interoperable digital system for tracking and tracing pharmaceutical products across the supply chain at the package level.

But as the November 2023 deadline inched closer, it became clear that many pharma supply chain stakeholders were not prepared to achieve full compliance. As a result, **the FDA announced the stabilization period** to ensure that products continue to move smoothly through the supply chain, and to give trading partners the extra time needed to finalize the implementation of DSCSA-compliant processes and systems.

DSCSA is complex, but a network approach makes it simple

As many industry stakeholders have learned, the toughest challenge associated

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with the final phase of DSCSA is the 100% secure and interoperable exchange of data required among all trading partners. To facilitate this exchange, electronic integration with all partners—including both direct and indirect trading partners—across the end-to-end pharmaceutical supply chain is a requirement. Many organizations attempted to exchange this data through point-to-point integrations and other methods. However, they quickly learned that the process of building, operating, and maintaining expensive connections with partners was simply too expensive, complex, and difficult to manage, and have abandoned this approach as a result.

In searching for alternatives, these organizations have learned that a cloud-based, digital network platform solves the point-to-point integration problem by enabling every trading partner to connect to a single interoperable network once, and then use that one connection repeatedly to onboard, manage, and exchange information with all direct and indirect trading partners across the supply chain.

Improving healthcare with digital network technology

Since 2009, TraceLink has been a pioneer in developing multiparty supply chain technologies within the healthcare and life sciences industry. The founding members of the TraceLink team initially began their supply chain digitalization journey in 2003 and understood the challenges with the point-to-point integration model. By pioneering a new digital connectivity model, the Business-to-Network (B2N) Integrate-OnceTM approach, TraceLink now enables every trading partner leveraging its shared platform to connect to the network only a single time, and then use that one connection to interoperate as needed with all direct and indirect trading partners across the supply chain.

With more than 290,000 authenticated and onboarded members now connected, the TraceLink digital network platform is the largest in the industry, enabling suppliers, contract manufacturers, brand owners, wholesale distributors, and dispensers to seamlessly exchange serialization data and traceability information

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with direct and indirect trading partners.

DSCSA compliance: A foundation for greater business value

Once an organization is connected to the network, the stage is set to leverage the information-sharing capabilities and the anonymized collective intelligence of the entire pharmaceutical industry to achieve business benefits that transcend regulatory compliance alone. With a digital network platform approach, your organization can:

- **Predict drug shortages up to 90 days in advance** with a high degree of accuracy.
- Digitalize, streamline, and speed up product recall processes.
- Leverage item-level data and product verification to improve inventory management.
- Confirm the legitimacy of products received with sub-second response times.
- Rapidly resolve compliance errors with partners to keep products moving through the supply chain.
- Manage complex shared tasks, issues, and change orders with partners in one interface.
- Digitalize and improve the exchange of multi-enterprise supply chain business information, such as purchase orders, invoices, and logistics information, and inventory data.

In short, DSCSA is complex. But a digital network platform approach can make compliance simple; it can also enhance the way pharmaceutical supply chain stakeholders do business with one another, while also improving patient outcomes.

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