RESOURCES

How to Prepare for Electronic, Interoperable Product Tracing Requirement of DSCSA 2023





Under the U.S. Drug Supply Chain Security Act (DSCSA), manufacturers and wholesale distributors have until November 27, 2023 to establish a system for product tracing at the package level. This means that all parties in the pharmaceutical supply chain will need to adhere to the requirements outlined section 582, which states:

- The Transaction Information (TI) and the Transaction Statements (TS) as required under this section shall be exchanged in a secure, interoperable, electronic manner.
- The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

The FDA recognizes there are a variety of technological approaches available to

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help organizations comply with enhanced drug distribution security requirements of DSCSA 2023, however, the Agency recommends that trading partners use a digital approach and follow the EPCIS standard.

The recent webinar in our DSCSA series, "**Preparing for Electronic, Interoperable Product Tracing**," explored the requirements of product tracing as well as a unique approach for meeting these requirements.

Here are the key takeaways:

- **The FDA has defined broad requirements for interoperable product tracing.** The November 27 transition to enhanced product tracing introduces serial numbers and expiration dates as new data elements that must be captured as part of the required Transaction Information, while the Transaction History will no longer be required. The ability to promptly respond to requests issued by a regulatory official or authorized trading partner for TI and TS is also a necessity.
- **The final guidance for elements like trace request details is still evolving.** There are ongoing conversations happening around areas like which methods of communication will the industry support (API calls, emails, portals), what format should TI details be transmitted in (JSON, CSV, XML, PDF), and what exactly "promptly" means (24 hours or 1 business day). The Partnership for DSCSA Governance (PDG) published new guidance for interoperability as of February 2.
- **Authorized trading partners and credentialing is critical to product tracing.** Authorized trading partners—manufacturers, wholesale distributors, repackagers, and dispensers—are key stakeholders in the pharmaceutical supply chain. Being able to verify their identity through credentialing is important to ensuring the success of product tracing efforts.
- **Operating on a network is the most effective way to meet the product tracing requirement.** Supply chain partners interact with each other multiple times a day. Being able to digitalize these interactions on a

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platform that virtually connects your supply chain makes it easy to assemble serialized transaction information objects on the fly, as necessitated by product tracing requirements. Operating on the TraceLink network allows for seamless integration with your trading partners as well as easy onboarding, as more than 290,000 companies are already on the platform.

Start Preparing for DSCSA 2023 Today

TraceLink has a global services team that can quickly execute a DSCSA readiness assessment and recommend the necessary steps to achieve compliance by November 27, 2023. Contact your TraceLink Account Executive or Services Project Manager to get this project started now or email us at DSCSA [at] tracelink.com.

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

You can also **watch the on-demand recording** to learn more about DSCSA product tracing requirements, the latest news on evolving guidance, and the value of using a network for product tracing.

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