RESOURCES



Wholesale Distributors: Pharma Manufacturers May Be Labeled ‘High-Risk' Suppliers if Not Ready for DSCSA Now

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We are nearing the end of a long ten-year journey, and manufacturers must act now to get over the finish line or they risk losing business. But more importantly, we want to avoid any disruptions to patients getting their medicines.

- Dan Walles, General Manager, Track & Trace/Compliance

Most major wholesale distributors are requiring pharmaceutical manufacturers to send serialized **U.S. Drug Supply Chain Security Act (DSCSA)** transactions in the industry-standard EPCIS digital format—or at least begin sending test transactions—three months ahead of the November 27, 2023* compliance deadline. Here is what we've learned:

- Most wholesale distributors are requiring DSCSA EPCIS transactions now so they will have DSCSA-compliant inventory by the compliance deadline.
- Manufacturers that are not DSCSA-ready today may be considered "high-risk"

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suppliers.

- Some wholesale distributors are preparing bids for alternative suppliers based on manufacturers' lack of DSCSA readiness.
- The Healthcare Distribution Alliance (HDA) recommends that manufacturers ramp up to start sending DSCSA EPCIS transactions.

"Wholesale distributors are requiring that manufacturers send the DSCSA EPCIS transactions earlier so that their inventory will have the proper compliance information," said Dan Walles, a DSCSA compliance expert and General Manager of Track-and-Trace/Compliance at TraceLink. "Without that information, the wholesale distributor cannot sell that product."

The good news for TraceLink customers is that TraceLink Product Track makes DSCSA compliance quick and easy. But manufacturers need to act fast. Download our quick-start guide, "**U.S. DSCSA 2023 Readiness: Rapid Path to Upgrading for EPCIS**," to learn more about Product Track, **and then click this link to contact TraceLink and book a meeting today**.

Manufacturers' DSCSA requirements for EPCIS data exchange



Under the final phase of DSCSA, pharmaceutical manufacturers must implement capabilities to:

- Provide serialized Transaction Information (TI) and Transaction Statements (TS) to each customer who purchases a drug product, and ensure that TI and

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TS are exchanged in a secure, interoperable, and electronic manner in accordance with the **GS1 EPCIS standard**.

- Make sure that the TI includes the product serial number at the package level for each package included in the shipment.
- Ensure that the EPCIS data sent matches the information applied to the physical item's 2D DataMatrix barcode for every unit in a customer shipment.

"Manufacturers still have a lot to do, and if they have not started testing the exchange of EPCIS data at scale, they run the risk of missing the compliance date," Walles explained. "Under the current law, this would mean they would not be able to ship, nor would wholesale distributors be able to receive the manufacturers' products.

Every major wholesale distributor will also require manufacturers to send aggregation data with DSCSA-compliant shipments, Walles added.

Get Started Today!

Download our quick-start guide today and you will learn how to easily transition to EPCIS file exchange from the current advanced shipment notices you are sending now. You will also learn how to work with the TraceLink team to rapidly implement or upgrade Product Track in a manner that minimizes disruptions and ensures a smooth go-live. Most importantly, you will see how TraceLink helps manufacturers avoid the risks of noncompliance with DSCSA.

If you are not a current TraceLink customer, we can still help. Download our guide, "**Connect Your Serialization System to the TraceLink Network for Rapid DSCSA Compliance**," to learn how to use the TraceLink network with other serialization systems to meet your customers' DSCSA requirements.

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Contact the TraceLink team to get started now

*The U.S. Food and Drug Administration (FDA) released a “Guidance for Industry” document related to the Enhanced Drug Distribution Security provisions of the DSCSA regulation. The FDA has announced a 12-month stabilization period until November 27, 2024, but the law remains in effect. The "FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements."

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Fill out the form to contact us now.

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

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