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Unlocking Seamless Collaboration: TraceLink Product Information Manager Enhances U.S. DSCSA Compliance with Drop Shipment Notices



As part of our ongoing commitment to support pharmaceutical and healthcare organizations working to meet **U.S. Drug Supply Chain Security Act (DSCSA)** requirements, TraceLink has added drop shipment notice capabilities to its robust Product Information Management (PIM) solution. These shipment notices are designed to help organizations comply with DSCSA drop shipment requirements for the secure, electronic, and interoperable exchange of compliance data. With these new capabilities, TraceLink continues to pave the way for the uninterrupted flow of medicines during the 12-month stabilization period recently set forth by the FDA.

Understanding drop ship capabilities

A drop shipment is a type of shipment where the pharmaceutical manufacturer receives an order from a wholesaler but ships the product directly to the wholesaler's customer, typically a pharmacy. Drop shipments are a critical activity as they provide pharmacies with products in high demand so that they can be quickly dispensed or administered to a patient. Under DSCSA, the pharmaceutical manufacturer has a legal responsibility to provide T2 information for that product

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to pharmacies. However, with drop shipments, the shipment is made on behalf of the wholesaler, and the manufacturer may not have any information about the pharmacy other than a name and address. The proven TraceLink network approach, combined with the new drop shipment capabilities within the PIM solution, ensures that the T2 information is available to all stakeholders who require it. Specifically, the PIM drop shipment capabilities address the following two use cases:

1. Delivering T2 information to pharmacies

DSCSA requires that T2 information be exchanged in a secure, interoperable, and electronic format. The industry has aligned on GS1's EPCIS standard. Because the pharmaceutical manufacturer may not have any knowledge of the pharmacy, they are unable to determine where and how to send the T2 information. The **TraceLink PIM solution** now allows the pharmaceutical manufacturer to provide the T2 information through a secure, network-wide application that is accessible by the pharmacy. When the pharmacy receives the shipment, it can retrieve the T2 information from PIM. The T2 can be downloaded and loaded into the pharmacy's DSCSA solution. If the pharmacy is a TraceLink customer, future versions of PIM will route the T2 directly to the pharmacy's TraceLink solution.

2. Delivering T2 to the wholesaler

Drop shipments must also accommodate the wholesaler's requirement to receive the T2 information for the drop shipment. This is important as the wholesaler must maintain this information in their DSCSA solution and refer to it in the event the product is returned by the pharmacy, is part of a suspect product investigation, or is included in a recall. The new TraceLink PIM shipment capabilities enable the T2 to be delivered to the purchasing wholesaler as well as the pharmacy that received the medicine.

The key features of the drop shipment notice capability are:

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- **Filter and View Serialized Deliveries:** Filter and view shipments and receipts.
- **Filter and View T2 Documents:** Filter to view or download specific T2 documents for internal audits or audits by the FDA.
- **Access Shipment Notices for Deliveries from Pharmaceutical Manufacturers:** Mark outbound shipments as drop shipments. Send the shipment notices for these deliveries so that pharmacies can access them without linking to the sender's existing network, which allows all members of the supply chain to be in compliance with the DSCSA even if they do not have a direct business relationship with one another.
- **Send Shipment Notices for Deliveries to Pharmacies:** Automatically make shipment notices available for deliveries that are sold to pharmacies not linked to their existing network.

Future enhancements

TraceLink is committed to continuous improvement. Future capabilities will include support for pharmacies to view shipment and T2 data associated with 340B shipments. Additionally, we are working on a feature that allows shipment and T2 information to be sent directly to a TraceLink dispenser's U.S. Product Track application, making serialized data readily available in the dispenser's Serialized Operations Manager application.

Why this matters for the U.S. market

These enhancements are specifically tailored to meet the requirements of the U.S. market, where DSCSA compliance is crucial. By providing these shipment notice capabilities, TraceLink aims to simplify compliance processes, improve transparency, and enhance collaboration among all stakeholders in the pharmaceutical supply chain.

As regulatory requirements evolve, TraceLink remains dedicated to helping pharmaceutical companies stay ahead of the curve. Our PIM solution's new drop

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shipment capabilities are a testament to our commitment to simplify compliance requirements for our customers so that they can spend more time focusing on patients.

For more information on these exciting updates and how they can benefit your organization, please **reach out to our team** or **visit this page to learn more about Product Information Manager**. Together, we can continue to build a safer, more compliant pharmaceutical supply chain.

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

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