

How Smart Inventory Tracker Makes DSCSA-Compliant Shipping and Receiving Fast and Easy: A Q&A with TraceLink's Ashley Murdock and Christine Kearns

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The final phase of the U.S. Drug Supply Chain Security Act (DSCSA) requires that physical product shipments across the pharmaceutical supply chain be accompanied by matching item-level compliance data at each transfer of ownership. The most efficient and effective way to ensure that pharmaceutical product transactions are DSCSA-compliant is to verify that you have the correct Transaction Information and Transaction Statements—also known as T2 information—using TraceLink Smart Inventory Tracker.

In this interview, TraceLink Solution Consultants Ashley Murdock and Christine Kearns discuss the key benefits of Smart Inventory Tracker for pharmaceutical manufacturers, wholesale distributors, health system dispensers, and retail pharmacies. Both Christine Kearns and Ashley Murdock are DSCSA compliance experts with extensive experience guiding manufacturers, wholesale distributors, and health system and retail pharmacies on how to navigate highly complex and evolving DSCSA requirements. They also explain why Smart Inventory Tracker is a critical tool as the U.S. pharmaceutical supply chain makes the switch from lot-

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level traceability to item-level serialization.

What is Smart Inventory Tracker?

Smart Inventory Tracker is a turnkey mobile solution that runs on handheld scanners and mobile devices and enables stakeholders across the pharmaceutical supply chain to rapidly scan serialized products to verify compliance data and record serialized events, such as shipping, receiving, returns, aggregation, disaggregation, status updates, and more. Smart Inventory Tracker works out of the box and seamlessly runs alongside existing enterprise resource planning (ERP) systems, warehouse management systems (WMSs), and inventory management systems.



Ashley Murdock

If a wholesale distributor chooses not to use Smart Inventory Tracker, what challenges might they face?

Murdock: On the receiving side, wholesale distributors have a requirement to reconcile the compliance data with the physical product. Without Smart Inventory Tracker, they would have to pull up the digital information and go through all the serial numbers one by one to match those up. They would have to record every serial number coming in somehow, probably on a piece of paper or pack slip, and then bring that to a computer where they would start to record that serialization

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data. Not only is this a cumbersome and error-prone process, using paper pack slips is no longer compliant as of November 27, 2023. On the outbound side, they would need to again record all of the serial numbers that are going out to customers, and then come back into TraceLink and enter those.

If a health system or retail pharmacy chooses not to use Smart Inventory Tracker, what challenges might they face?

Kearns: If dispensers are unable to get real-time feedback during the receiving process, they may have to hold the product in quarantine, or they may have to ship it back to the supplier. Smart Inventory Tracker gives real-time feedback based on successful or failed reconciliation so that they can either put it on the shelf or quarantine it until the exception is resolved. Smart Inventory Tracker is the least disruptive method for checking that you have compliance data for your medicine so it's available for patients.

What is the top benefit of Smart Inventory Tracker for pharma manufacturers?

Ashley Murdock: The main benefit for pharmaceutical manufacturers is the capability to automate manual processes. For example, anyone who packages serialized product and has a line management system—but doesn't have the capability to aggregate product—can aggregate product with the **Smart Inventory Tracker** application. There is also no need to implement changes to their WMS or ERP to accommodate serialized products. Smart Inventory Tracker also works for manufacturers without an ERP or WMS.

What is the top benefit of Smart Inventory Tracker for wholesale distributors?

Murdock: Similar to the manufacturing side, the systems that wholesale distributors have in place were not designed to support multiple levels of serialized aggregation. Now that aggregation is the preferred way of doing business,

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wholesale distributors need tools that support the aggregation process. Instead of making costly customizations to their WMS—which can be a heavy lift—wholesale distributors can simply use Smart Inventory Tracker to provide the aggregation-related functionality that is not supported by any of their current business systems.



Christine Kearns

What is the top benefit of Smart Inventory Tracker for health system dispensers and retail pharmacies?

Christine Kearns: Hospital and retail dispensers use systems that are geared towards the National Drug Code (NDC), and those systems typically do not have or support serialized compliance data. Where is the compliance data? The suppliers are sending it to them through the TraceLink network, and Smart Inventory Tracker provides the fastest way to get immediate feedback that compliance data matches the physical receipt. With Smart Inventory Tracker, they can scan for compliance data whether they are in the warehouse, on the receiving dock, or in the pharmacy.

The final phase of DSCSA requires wholesale distributors to send and receive product data at the individual item level. How does this impact distributors and how can Smart Inventory Tracker help?

Murdock: It actually impacts them in every area of their warehouse. Let's start with receiving: Guidance from the FDA allows for receiving product at the aggregated case or pallet level. Smart Inventory Tracker understands the parent-child relationship of the aggregated data and can manage the disaggregation or reaggregation of pallets and cases as product is moved through the warehouse. If something needs to be taken out of the commercial supply chain, for example, to

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be decommissioned or destroyed, Smart Inventory Tracker can scan and record that transaction. For outbound shipping, wholesale distributors can disaggregate or reaggregate new cases or pallets so downstream partners can better understand the product that they are receiving.

How will the switch to item-level serialization impact pharmacy operations, and how can Smart Inventory Tracker help?

Kearns: Like wholesale distributors, pharmacy dispensers need to receive and reconcile physical product against the compliance information. When the final phase of DSCSA goes into effect, the switch from lot-level to item-level serialization means that there will be a lot more data to process. While you can continue to utilize TraceLink's web user interface to check for compliance data, Smart Inventory Tracker enables you to reconcile the physical product you are receiving against the compliance information that was sent to you through TraceLink. Getting real-time feedback based on successful or failed reconciliation is invaluable, especially in a world of unit-level serialization.

What is the relationship between TraceLink Serialized Operations Manager, Product Track U.S., and Smart Inventory Tracker?

Kearns: Serialized Operations Manager is the core TraceLink serialization module. This is the repository where all of the inbound and outbound serialization data resides. Smart Inventory Tracker is the mobile user interface used to interact with Serialized Operations Manager. Product Track U.S. is our U.S. compliance module. All of our customers' U.S. compliance data messages come in through **Product Track**, including serial numbers, aggregation information, and parent-child relationships. Smart Inventory Tracker talks synchronously with Serialized Operations Manager to enable single-scan receiving with compliance data confirmation.

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