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Proven Mobility Solution Delivers a Faster, Better Way to Manage Serialized Warehouse Operations



New and evolving product serialization and track-and-trace mandates around the globe—including the U.S. Drug Supply Chain Security Act (DSCSA) and the European Union Falsified Medicines Directive (EU FMD)—are creating complex new challenges and requirements for pharmaceutical manufacturers, wholesale distributors, and dispensers. These include:

- **Product Aggregation Changes:** Failing to maintain an accurate record of aggregation and configuration changes as products are handed off through multiple distribution operations—including picking, packing, shipping, and returns—leads to compliance exceptions and significant supply chain disruptions. Additionally, products often come off a line unaggregated and therefore require manual aggregation.
- **Post-Batch Rework:** Configuration updates are often required due to damage, changes in aggregated containers, QA sampling errors, or errors in processing.
- **Product Verification:** Under certain regional mandates, trading partners are required to verify products with manufacturers as part of dispensing and saleable returns processes and illegitimate or suspect product investigations—and the pharma industry demands subsecond response times

for product verification requests.

- **WMS and ERP Limitations:** Current warehouse management systems (WMSs) and enterprise resource planning (ERP) systems lack the “serialization awareness” needed to fully support product aggregation management, product verification, and post-batch rework.

To avoid supply chain delays and disruptions and achieve operational excellence in this global regulatory environment, manufacturers and wholesale distributors require a mobile scanning solution that streamlines the management of serialized warehouse operations, track and trace, and verification while capturing key changes during post-batch and distribution operations.

TraceLink Smart Inventory Tracker

TraceLink Smart Inventory Tracker is a mobile solution that delivers powerful capabilities for managing serialization, track and trace, and event data capture in warehousing and distribution processes. Smart Inventory Tracker runs on commercially available mobile devices, including cell phones and scanners, and is natively connected to the highly scalable TraceLink network and plug-and-play cloud platform.

Smart Inventory Tracker delivers a faster, better, and future-proof mobile solution that enables manufacturers and wholesale distributors to maintain an accurate digital record of track-and-trace activities and ensure regulatory compliance at the edges of the supply chain.

Additionally, Smart Inventory Tracker eliminates the need to make invasive ERP or WMS changes to support serialization and track-and-trace compliance, and the solution helps to ensure customer satisfaction by reducing stockouts and delayed shipments that result from compliance exceptions.

Let’s take a look at how TraceLink Smart Inventory Tracker helps manufacturers,

wholesale distributors, and pharmacies ensure continuous compliance with regional track-and-trace while improving pharma supply chain operations.

Impacted Pharma Supply Chain Stakeholders	Business Challenges	How Smart Inventory Tracker Helps	Business Benefits
Manufacturers	Product aggregation changes often occur after products leave the manufacturing line.	Mobile solution enables you to rapidly reconfigure aggregations without bringing products back to the line.	No changes to Warehouse Management Systems (WMSs) or Enterprise Resource Planning (ERP) systems are required.
Manufacturers	Quality Assurance (QA) team members need an easy way to remove products from a batch and execute the QA process.	Mobile solution enables you to perform QA and reconfigure aggregations without bringing product back to the line.	Seamlessly perform QA functions without disrupting WMS or ERP workflows.
Manufacturers	Compliance exceptions, including those resulting from missing labels, incorrect data, wrong location, etc., often disrupt supply chain operations.	Smart Inventory Tracker includes exception management functionality, including the capability to rapidly identify a product's intended delivery location.	Ensure product supply and continuous regulatory compliance without disrupting operations.
Manufacturers Wholesale Distributors	Traditional WMSs cannot process and manage serialized product data.	Smart Inventory Tracker enables your WMS to work side by side with TraceLink.	No changes to WMS or ERP are required.
Manufacturers Wholesale Distributors Health System and Retail Pharmacies	Wholesale distributors and pharmacies need to rapidly verify products with the manufacturer as part of suspect product investigations or saleable returns processes.	Smart Inventory Tracker enables rapid verification requests from the manufacturer. The TraceLink Product Verification solution delivers automated verification to Smart Inventory Tracker with subsecond response times.	Ensure continuous compliance, uninterrupted product supply, and fewer disruptions.

Health System and Retail Pharmacies	Receiving processes are often disrupted due to regulatory requirements to confirm compliance data.	A simple scan with Smart Inventory Tracker confirms reconciliation and compliance data availability.	Ensure seamless, immediate, and continuous compliance.
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About TraceLink

Smart Inventory Tracker is built and hosted on TraceLink OPUS, the world's largest supply chain network digitalization platform. TraceLink OPUS enables manufacturers to seamlessly exchange serialized data and traceability information with direct and indirect trade partners across the supply chain. Key network metrics include:

- 2M+ serial numbers scanned by Smart Inventory Tracker monthly
- 60K+ serialized containers associated to shipments with Smart Inventory Tracker monthly
- 50K+ serialized containers reconciled to receipts with Smart Inventory Tracker monthly
- 1000+ mobile devices licensed for Smart Inventory Tracker globally
- 290K+ authenticated and onboarded TraceLink OPUS network members
- 7,300+ live CMO connections across more than 1300 customers
- 930+ distribution and logistics customers and partners
- 919M+ regulatory documents processed and exchanged
- 41.1+ billion serial numbers commissioned to date
- 14,937+ live serialization connections
- \$4.7+ billion in customer savings by avoiding point-to-point integrations

TraceLink Smart Inventory Tracker provides an essential productivity solution for pharmaceutical manufacturers, wholesale distributors, and pharmacies that physically handle their products and need to stay compliant with regional traceability mandates around the globe.

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Contact TraceLink to learn more about DSCSA compliance!

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