DSCSA 2023 Compliance for Wholesale Distributors

Integrate once, interoperate with all suppliers and customers to achieve item-level traceability compliance and improve operational efficiency

DSCSA 2023 Compliance Challenges

In November 2023,* item-level traceability under U.S. Drug Supply Chain Security Act (DSCSA) introduces significant regulatory compliance challenges and operational complexity for wholesale distributors:

- Wholesale distributors must exchange serialized Transaction Information (TI) and Transaction Statements (TS) with customers and suppliers for each unit they sell, requiring the configuration of hundreds to thousands of B2B integrations.

- Wholesaler distributors must have the capability to handle serialized and aggregated products and properly account for products that have been repacked, damaged, or destroyed.

- Based on regulatory requirements, ASNs exchanged via EDI will no longer be sufficient for exchanging serialized product data.

- The exchange of item-level traceability data will significantly increase operational performance requirements and exceptions, and a specific capability to manage exceptions across trading partner networks will be critical to maintaining operational efficiency.

- New product verification use cases for suspect and illegitimate product investigations will require an expansion of the VRS (Verification Router Service) model and support for Authorized Trade Partner initiatives.

- DSCSA 2023 requirements will continue to evolve up to and after November 2023,* necessitating a technology architecture that speeds deployment of solution upgrades with minimal disruption or changes to enterprise systems or business operations.

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DSCSA 2023 Compliance for Wholesale Distributors

TraceLink DSCSA 2023 Compliance for Wholesale Distributors enables wholesale distributors to receive and send serialized TI and TS and securely exchange DSCSA traceability data via EPCIS with drug manufacturers, health system dispensers, and retail pharmacies through a single digital connection to the 290,000+ member TraceLink Opus Network.

Warehouse operations are simplified with scanning of aggregate barcodes and integration with warehouse management systems to receive serialized shipments with a single scan. Wholesale distributors can also verify product identifiers to support saleable returns and suspect product investigations.

Wholesale distributors can track and manage serialized products within their operations with minimal modifications to their existing warehouse management systems. The TraceLink solution creates a "digital twin" of the physical product flow to provide the required serialization capabilities and operates over the top of the existing IT systems.

DSCSA 2023: A Step-Change in Requirements

REQUIREMENTS & CAPABILITIES →

DSCSA 2015	DSCSA 2018	DSCSA 2023
		Recall Status, Investigations, Alerting
		Product Tracing
		Authorized Trade Partner Credentialing
		Exception Management Collaboration
		Suspect & Illegitimate Product & Saleable Return Verification
		Serialized TI & TS Receiving & Sending (EPCIS)
		GTIN & Pack-Level Master Data Sharing
T3 Receiving & Sending (ASN)	EPCIS Repository	WMS & 3PL Integration
Direct Customer Integration	Serial Number Management	

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Key Capabilities

DSCSA 2023 Compliance for Wholesale Distributors provides a comprehensive suite of solutions to help wholesale distributors navigate complex DSCSA challenges. Capabilities include:

- **Integrate Once, Interoperate with Everyone™:** Enables a single integration to the TraceLink network for seamless exchange of EPCIS transactions with all partners.

- **Product Track:** Enables wholesale distributors to receive and send serialized TI and TS at scale.

- **Product Information Management - Master Data Sharing:** Enables wholesale distributors to receive new and updated GTIN and pack-level master data from MAHs through a single integration.

- **Product Information Management - Verification:** Facilitates the creation of product verification requests for salable returns and suspect product investigations, routes those requests to the correct MAH, and receives a response in less than one second.

- **Serialized Operations Manager:** Provides a repository for serialized inventory information and events to automate workflows and facilitate product status updates.

- **Smart Inventory Tracker:** Enables mobile scanning for serialized shipping and receiving, and ensures warehouse operations are synchronized with the warehouse management system.

- **Supply Chain Work Management for Compliance Exceptions:** Enables multienterprise reporting of and collaborative follow up on exceptions occurring as products and EPCIS data are exchanged between trading partners.

- **Drop Shipment Network:** Stores a copy of serialized T2 data for drop shipments to support any returns processing.

- **Opus Network Platform:** Simplifies integration, data exchange, and exception management with trading partners. The Opus network also uses the data flowing through it to power predictive analytics for preventing drug shortages and simplifying recalls.

Key Benefits

DSCSA 2023 Compliance for Wholesale Distributors enables wholesale distributors to achieve DSCSA compliance quickly and securely. Benefits include:
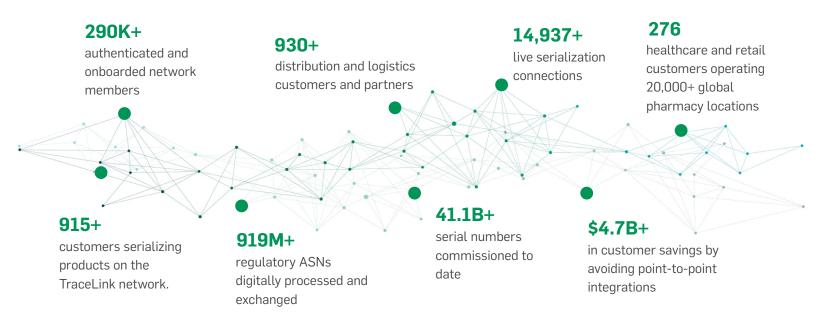
- **Integrate Once, Interoperate with Everyone™:** Single integration on the Opus network enables data exchanges with all customers and suppliers. TraceLink manages B2B connectivity and data translation for exchanging EPCIS transactions, GTIN and pack-level master data, and verification requests. There is no need to create and maintain expensive point-to-point integrations. No-cost onboarding for all customers and suppliers.

- **Scalability:** The introduction of item-level traceability in DSCSA 2023 will substantially increase the volume of data and transactions, requiring processing at operational scale. The TraceLink native cloud architecture scales to ensure that information can be retrieved and processed in real time without disrupting operational processes.

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- **Continuous Compliance:** As DSCSA 2023 requirements continue to evolve, new capabilities will be required. As a result, organizations will need to rapidly update and validate their compliance solutions without disrupting existing integrations. With the TraceLink Opus network tenant architecture, all customers are updated simultaneously, ensuring that they have the latest functionality. This approach ensures that our customers remain compliant continuously.

- **Ensure Supply:** The additional verification steps required for DSCSA 2023 compliance, multiple versions of EPCIS, custom extensions, and inclusion of non-serialized products in shipments from hundreds or even thousands of suppliers will lead to frequent exceptions. Exceptions will delay receiving and shipping products and create supply interruptions. By operating on the TraceLink network with proven DSCSA solutions that support all versions of EPCIS, custom extensions, and real-time exception follow up, supply risk, and failure to supply fines are minimized.

About The TraceLink Network

DSCSA 2023 Compliance for Wholesale Distributors is built and hosted on TraceLink Opus, the world's largest supply chain network digitalization platform for life sciences. Opus enables organizations to seamlessly exchange serialization data and compliance information with trade partners across the supply chain. Key network metrics include:

290K+
authenticated and onboarded network members

930+
distribution and logistics customers and partners

14,937+
live serialization connections

276
healthcare and retail customers operating 20,000+ global pharmacy locations

915+
customers serializing products on the TraceLink network.

919M+
regulatory ASNs digitally processed and exchanged

41.1B+
serial numbers commissioned to date

$4.7B+
in customer savings by avoiding point-to-point integrations

[Contact TraceLink to learn more about DSCSA 2023 Compliance for Wholesale Distributors.](#)

*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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