DSCSA 2023 Compliance for Dispensers

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

DSCSA 2023 Compliance Challenges

In November 2023, item-level traceability under the U.S. Drug Supply Chain Security Act (DSCSA) will introduce significant regulatory compliance challenges and operational complexity for health system and retail pharmacies. Dispensers must be able to:

- Receive and ensure they match updated Transaction Information (TI) and Transaction Statements (TS), including the serialized product identifier data, to the physical products they receive from suppliers.

- Gather and produce information for each transaction going back to the manufacturer in the event of an investigation or recall as the Transaction History is sunset.

- Verify the serialized product identifier at the package level as part of suspect or illegitimate product investigations.

A Comprehensive Solution from TraceLink

TraceLink DSCSA 2023 Compliance for Dispensers was built to help healthcare and retail pharmacies achieve compliant and secure data exchange. The solution suite enables dispensers to receive, validate, and store electronic TI and TS from suppliers, which they can quickly retrieve upon request by a trade partner or regulatory authority.

The key to enabling this seamless and secure data exchange is Opus, the digital network that powers DSCSA 2023 Compliance for Dispensers. Built to support DSCSA compliance since its inception in 2015, the solution enables dispensers to receive item-level EPCIS information, verify products as part of suspect or illegitimate product investigations, and achieve compliance with the FDA's DSCSA 2023 mandate.

Capabilities Required
for Meeting DSCSA 2023

Multienterprise Network Capabililties
(direct & indirect suppliers

Wholesaler Integration

Pharmaceutical MAH Integration

Authorized Trade Partner Check

GTIN & Pack-Level Master Data

Suspect Product Verification

Recall Product Tracing

Serialization & EPCIS Repository

Pharmacy Operations Capabilities

Compliance Document Search & Retrieval

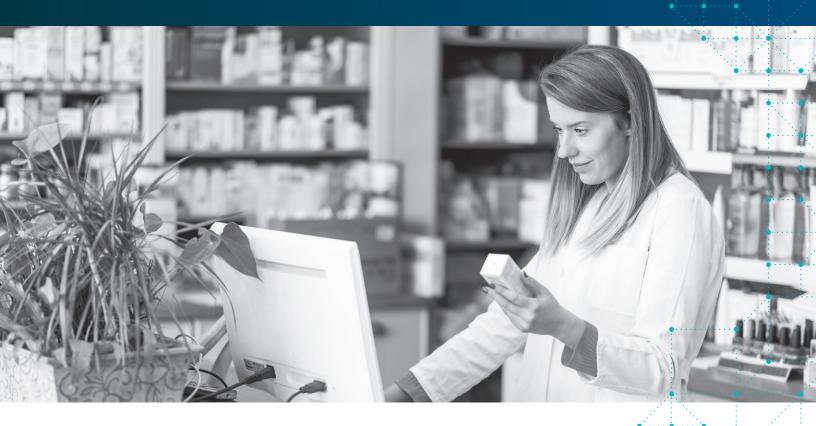Serialized Receiving

Pharmacy Management System Integration

Other 3rd Party System Integration

By November 2023, dispensers must implement the following capabilities:

✓ Serialized TI and TS creation & EPCIS data sharing

✓ Authorized trade partner credentialing

✓ Exception management collaboration

✓ GTIN and pack-level master data sharing

✓ Recall status, investigations, alerting

✓ Suspect and illegitimate product and saleable returns verification

✓ Warehouse management system and 3PL integration

✓ Product tracing

Key Capabilities

DSCSA 2023 Compliance for Dispensers provides a comprehensive suite of solutions to help manufacturers navigate complex DSCSA challenges. Capabilities include:

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

- **Product Track:** Enables dispensers to receive, validate, and store serialized TI and TS received from suppliers in the EPCIS format and retrieve it upon request.

- **Product Information Manager - Master Data Sharing:** Enables dispensers to receive GTIN and pack-level attributes from manufacturers, with master data changes updated automatically.

- **Product Information Manager - Product Verification:** Enables dispensers to verify the product identifier of a serialized medicine, providing correct verification request routing and visibility into the verification result and product status (stolen, recalled, expired, etc.).

- **Serialized Operations Manager:** Provides an operational repository for serialized inventory information and events to automate workflows and facilitate product movements, packaging change activities, and product status updates.

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

- **Drop Shipment Network:** Routes serialized T2 data to the dispenser's Product Track solution, enabling the DSCSA receiving process to be performed the same way for all shipment receipts.

- **Opus Network Platform:** Simplifies integration and data exchange and enables dispensers to manage exceptions in pharmacy operations. The Opus network also uses data flowing through its diverse supplier ecosystem to power predictive analytics that help prevent drug shortages and simplify recalls.

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Key Benefits

Informed by nearly a decade of work with companies across the U.S. pharmaceutical supply chain, TraceLink DSCSA 2023 Compliance for Dispensers simplifies compliance with regulatory, business, and supply network requirements. Business benefits include:
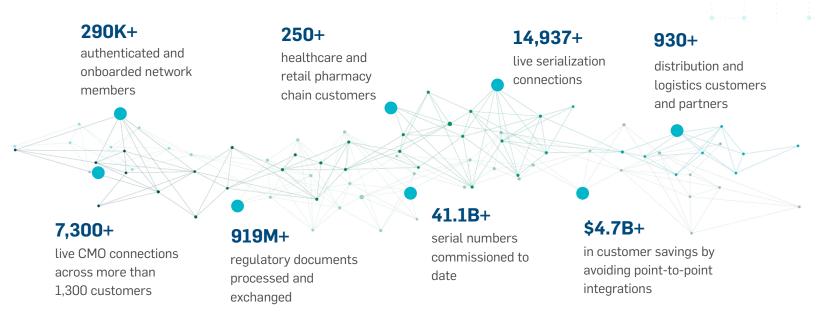
- **Integrate Once, Interoperate with Everyone™:** Single integration on the Opus network for all suppliers. TraceLink manages B2B connectivity and data translation for exchanging EPCIS transactions, GTIN, master data, and verification requests. No-cost onboarding for all suppliers.

- **Scalable Cloud Architecture:** The introduction of item-level traceability in DSCSA 2023 will substantially increase the data and transactions processed 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.

- **DSCSA 2023 Compliance Simplified:** As DSCSA 2023 mandates continue to evolve, new capabilities will be required. 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 requirements of DSCSA 2023 create opportunities for dispensers to mitigate supply disruptions such as drug shortages and recalls. By operating on the TraceLink network, intelligence regarding the distribution of medicines and their locations can be determined in real time. Machine learning algorithms analyze the drug distribution patterns to predict when a drug shortage may occur or identify where a recalled product is located. Achieving these benefits requires a network approach.

About The TraceLink Network

TraceLink DSCSA 2023 Compliance for Dispensers is built and hosted on TraceLink Opus, the digital network platform for end-to-end product orchestration. Opus, the world's largest digital network platform for pharma and life sciences, 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

250+
healthcare and retail pharmacy chain customers

14,937+
live serialization connections

930+
distribution and logistics customers and partners

7,300+
live CMO connections across more than 1,300 customers

919M+
regulatory documents 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 Dispensers.