DSCSA 2023 Compliance for Retail Pharmacies

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

DSCSA 2023 Compliance Challenge

In November 2023, the U.S. Drug Supply Chain Security Act (DSCSA) will introduce significantly expanded traceability requirements for retail pharmacies. To comply with the DSCSA 2023 mandate, retail pharmacies must be able to:
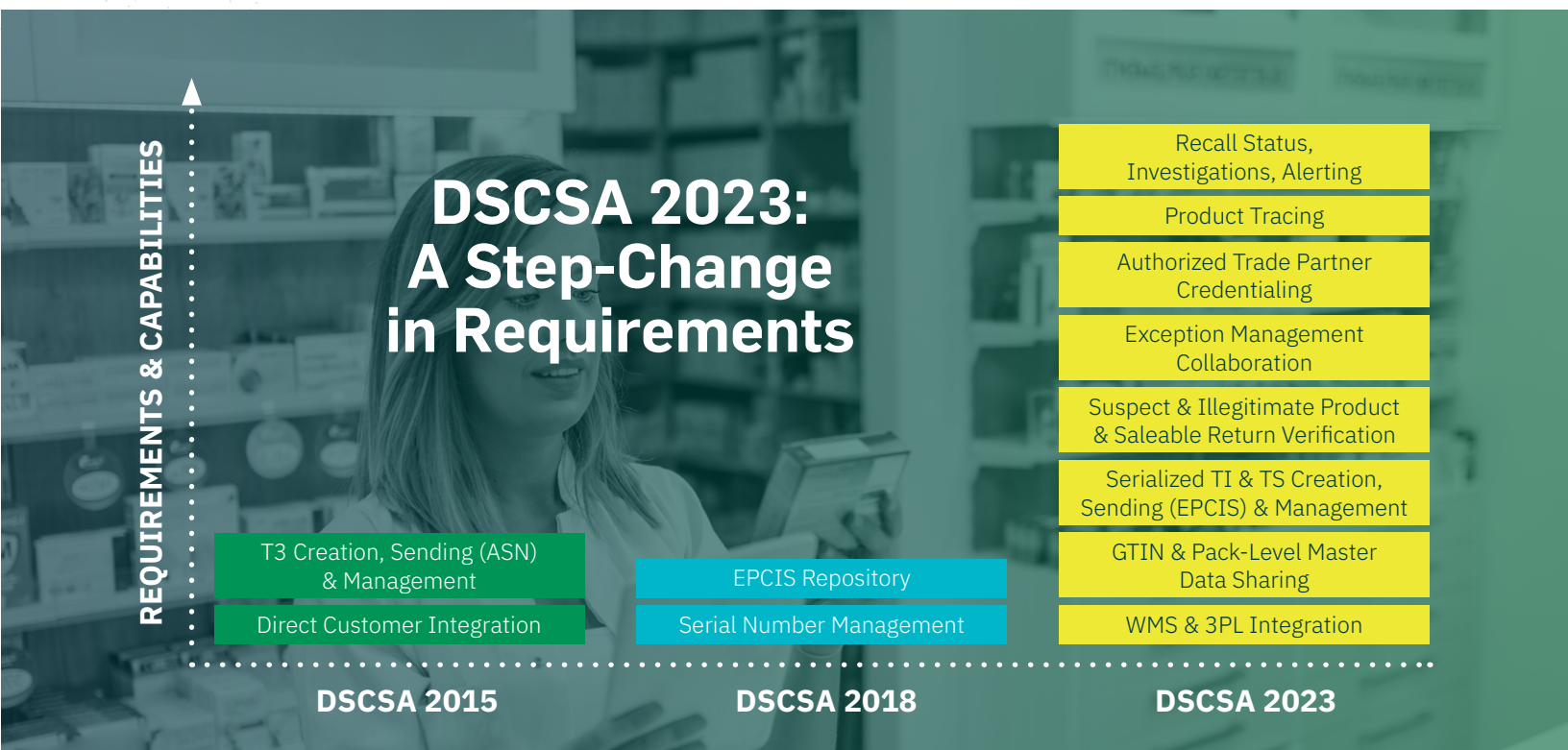
- Implement a new set of capabilities to ensure that each unit of medicine has the legally required DSCSA compliance information.

- Ensure that EPCIS transactions containing DSCSA and item-level traceability information, which contain orders of magnitude more data than the current DSCSA ASN, can be processed without delaying receiving operations.

- Rapidly develop, test, and deploy new capabilities in response to constantly evolving DSCSA regulatory and business requirements without disrupting operations or existing supplier integrations.

- Integrate with new suppliers to exchange EPCIS data.

- Support real-time suspect product verifications and verify product identifiers directly with the pharmaceutical manufacturer.

A Comprehensive Solution from TraceLink

At its core, DSCSA 2023 compliance is a network challenge with complex and evolving data exchange requirements across suppliers with varying integration capabilities. Homegrown and DIY solutions place a large burden on internal compliance and IT teams to monitor and respond to these evolving requirements.

This approach is neither scalable nor cost-effective and creates risk of medicine deliveries being quarantined during the receiving process.

TraceLink DSCSA 2023 Compliance for Retail Pharmacies runs on the TraceLink Opus network with pre-built links to leading wholesale distributors and pharmaceutical manufacturers. The result is fast and secure data exchange in compliance with the DSCSA 2023 mandate with a single integration.

DSCSA 2023: A Step-Change in Requirements

REQUIREMENTS & CAPABILITIES

DSCSA 2015
- T3 Creation, Sending (ASN) & Management
- Direct Customer Integration

DSCSA 2018
- EPCIS Repository
- Serial Number Management

DSCSA 2023
- Recall Status, Investigations, Alerting
- Product Tracing
- Authorized Trade Partner Credentialing
- Exception Management Collaboration
- Suspect & Illegitimate Product & Saleable Return Verification
- Serialized TI & TS Creation, Sending (EPCIS) & Management
- GTIN & Pack-Level Master Data Sharing
- WMS & 3PL Integration

Key Capabilities

DSCSA 2023 Compliance for Retail Pharmacies provides a comprehensive suite of solutions to enable retail pharmacies to 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 and product verifications with wholesale distributors and manufacturers.

- **Product Track:** Enables retail pharmacies to receive serialized Transaction Information (TI) and Transaction Statements (TS) electronically at scale.

- **Product Manager - Master Data Sharing:** Enables retail pharmacies to retrieve GTIN and pack-level attributes from wholesale distributors and manufacturers through a single network integration.

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- **Product Information Manager - Verification:** Facilitates both direct and indirect trade partner requests for product identifier verification.

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

- **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 Retail Pharmacies provides a comprehensive suite of solutions to enable retail pharmacies to navigate complex DSCSA challenges. Capabilities include:

- **Integrate Once, Interoperate with Everyone™:** Single integration to 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.

- **Scalability:** The introduction of item-level traceability in DSCSA 2023 substantially increases the transactions that need to be processed at operational scale. The TraceLink native cloud architecture scales to ensure that information can be retrieved and processed in real time without disrupting daily processes.

- **Continuous Compliance:** As DSCSA 2023 requirements continue to evolve, new capabilities will require that organizations 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 and achieve continuous compliance.

REAL-WORLD
USE CASE

COMPANY PROFILE:
Retail Pharmacy Chain

REVENUE:
$194 billion/year

BUSINESS CHALLENGES:
- Meeting DSCSA compliance requirements is viewed as a multi-year endeavor.
- Manage high transaction volume with upstream partner network.
- Multiple business unit structure resulted in multiple backend systems and management complexity.
- A lack of enterprise-wide visibility into multiple siloed business units.

SOLUTION:
- TraceLink DSCSA 2023 for Retail Pharmacies

RESULTS:
- Ready for DSCSA 2023 compliance requirements ahead of deadline.
- Reduced compliance costs by fully integrating suppliers for electronic DSCSA data exchange.
- Collaborating on unique network value through TraceLink.
- Access to future TraceLink network benefits including Product Availability Intelligence and Digital Recalls.

- **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 of suppliers will lead to frequent exceptions and receiving delays. 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. Additionally, the TraceLink network uses data from the distribution of medicines and machine learning algorithms to analyze drug distribution patterns and predict drug shortages or identify where a recalled product is located.

About The TraceLink Network

TraceLink DSCSA 2023 Compliance for Retail Pharmacies 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

48+
retail pharmacy chains customers representing **12,000+** nationwide pharmacy locations

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 Retail Pharmacies.