



DSCSA 2023 Compliance for Drug Manufacturers

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) introduces significant regulatory compliance challenges and operational complexity for manufacturers:

- Manufacturers must provide serialized Transaction Information (TI) and Transaction Statements (TS) to their trading partners for each unit they sell, requiring the configuration of thousands of B2B integrations.
- ASNs exchanged via EDI will no longer be sufficient to exchange serialized product data.
- The exchange of item-level traceability data will significantly increase operational performance requirements and exceptions.
- New verification use cases for suspect and illegitimate product investigations will require an expansion of the VRS model and support for Authorized Trade Partner initiatives.
- Requirements will continue to evolve up to and after November 2023, necessitating an architecture that speeds deployment of solution upgrades with minimal disruption.

A Comprehensive Solution from TraceLink

TraceLink DSCSA 2023 Compliance for Drug Manufacturers was built specifically to meet these challenges. The solution suite enables pharmaceutical manufacturers to create and maintain serialized TI and TS and securely exchange DSCSA traceability data via EPCIS with wholesale distributors, healthcare dispensers, and retail pharmacies.

The key to enabling this seamless and secure data exchange is Opus, the digital network that powers DSCSA 2023 Compliance for Drug Manufacturers. Built to support DSCSA compliance since its inception in 2015, Opus enables manufacturers to exchange EPCIS information with more than 290K network members via a single integration.



By November 2023, drug manufacturers 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 & illegitimate product & saleable returns verification
- ✓ Warehouse management system & 3PL integration
- ✓ Product tracing



Key Capabilities

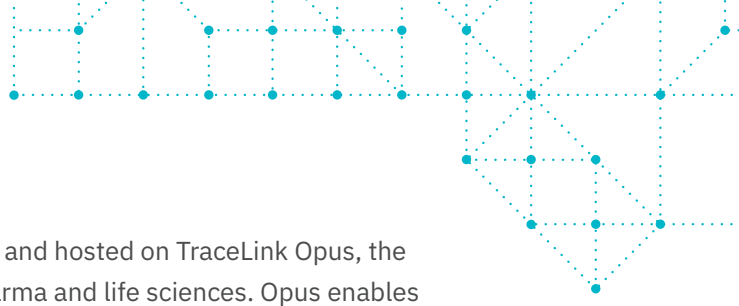
DSCSA 2023 Compliance for Drug Manufacturers provides a comprehensive suite of solutions to help manufacturers navigate complex DSCSA challenges. Capabilities include:

- **Integrate Once, Interoperate with Everyone™:** Enables a single integration to the TraceLink network for seamless exchange of EPCIS transactions with all partners.
- **Product Track:** Enables manufacturers to create and send serialized TI and TS at scale to trading partners.
- **Product Information Management Master Data Sharing:** Enables manufacturers to load GTIN and pack-level attributes for dispensers through a single network integration.
- **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 shipping and receiving, and ensures warehouse operations are synchronized with the warehouse management system.
- **Drop Shipment Network:** Enables manufacturers to provide required serialized T2 data to align with drop shipments made directly to dispensers whether the customer is on the TraceLink network or not.
- **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 Drug Manufacturers enables manufacturers to achieve DSCSA compliance quickly and securely. Benefits include:

- **Integrate Once, Interoperate with Everyone™:** Single integration on the Opus network for all customers and suppliers. TraceLink manages B2B connectivity and data translation for exchanging EPCIS transactions, GTIN, master data, and verification requests. No cost onboarding for all customers and 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 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.
- **Reduce Supply Risk:** The requirements of DSCSA 2023 create opportunities for manufacturers and wholesale distributors 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 Drug Manufacturers is built and hosted on TraceLink Opus, the world's largest supply chain network digitalization platform for pharma and life sciences. Opus enables manufacturers to seamlessly exchange serialization data and traceability information with direct and indirect trade partners across the supply chain. Key network metrics include:

290K+

authenticated and onboarded network members

2,645+

pharmaceutical manufacturer customers and partners

14,937+

live serialization connections

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 TraceLink DSCSA 2023 Compliance for Drug Manufacturers.

