



# Meeting the Demands of the Drug Supply Chain Security Act and Enabling an Effective and Secure Pharmaceutical Supply Chain

In order to comply with the Drug Supply Chain Security Act (DSCSA), we first need to understand it. Then we can consider how organizations can comply and improve the effectiveness, efficiency, and security of their supply chains.

These provisions apply to manufacturers, re-packagers, wholesale distributors, dispensers, and third-party logistics providers as noted below:

- **Product identification:** Manufacturers and re-packagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.
- **Product tracing:** Manufacturers, wholesaler drug distributors, re-packagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- **Product verification:** Manufacturers, wholesaler drug distributors, re-packagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
- **Detection and response:** Manufacturers, wholesaler drug distributors, re-packagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as suspect,

meaning that it may be counterfeit, unapproved, or potentially dangerous.

- **Notification:** Manufacturers, wholesaler drug distributors, re-packagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders if an illegitimate drug is found.
- **Wholesaler licensing:** Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available through a public database.
- **Third-party logistics provider licensing:** Third-party logistics providers, those who provide storage and logistical operations related to drug distribution, to obtain a state or federal license.

These are substantial responsibilities falling upon pharmaceutical manufacturers, wholesalers, distributors, re-packagers, and logistics companies. Current, enterprise-focused technologies are not well-equipped to handle multi-party transactions and workflows, due to the difficulties in integrating systems, and collecting and reconciling the data from all the organizations involved in handling product across the end-to-end supply chain.

One Network Enterprises' Digital Supply Chain Network™ is specifically designed to be multi-party, multi-tier platform,

with robust supply chain management tools for planning and execution across the end-to-end supply chain. Its unique data model supports all various data formats and systems and translates data into a real-time single version of the truth for all trading partners on the network.

This enables the platform to provide authoritative information about orders, shipments, product quality and availability, etc., from ingredients and APIs to finished packaged drugs and devices. It provides real-time tracking of serialized product, including support for cold chain chemicals and drugs, as well as full chain of custody information with precision recall capabilities. The benefits for pharmaceutical-related organizations are significant.

### ONE Solution Supports GMP & DSCSA

The ONE solution offers an interoperable platform for trading partners to exchange information in a secure manner. Trading partners can exchange all product identification datasets such as Serial Number, Expiration Date, Lot Number, National Drug Code (NDC) and Advance Shipment Notifications (ASNs) electronically. The ONE solution supports key GMP requirements and enabling DSCSA compliance in the following ways:

- Ability to generate and manage serial numbers
- Share serial numbers and events with packaging sites and carrier systems
- Track serialized inventory operations across plant and warehouse operations
- Automatically trigger compliance activities including notifications, receipts, and exceptions so that daily operations remain compliant

ONE can generate package barcodes. It supports a host of barcode formats (configurable at implementation). For product tracing and verification, it supports GS1 EPCIS event (outbound and inbound) API for any of these parties as part of logistics tracking events including writing to a blockchain.

As part of the “detection of response” requirements, ONE auto-detects suspicious conditions, such as unknown location and re-introduction. It can then expand exception detection workflows as plug-ins to its exception framework (as needed).

The Chain of Custody solution can also store and monitor temperature logs, important for cold chain products integrated with 3PL providers and freight forwarders on the network handling their part of the supply chain.

### One Network’s Supply Chain Solution Suite

In addition, One Network provides a full suite of supply chain solutions. They are all multi-party and multi-tier, designed to connect and coordinate across trading partners, systems and networks. They are adaptable and extensible, to meet your needs now and in the future.

Because all solutions run on a single network, they work together intelligently and in real-time, so planning is always synched to execution, while supply is always synched to demand and coordinated with logistics.

Typical planning solutions run in batch process, using stale data, guesstimates for lead times, and take hours to prepare and run. When you finally have a forecast, few have faith in it.

The Digital Supply Chain Network’s unique integrated business planning engines use actual demand and supply conditions to recalculate plans for every item at every location in real-time as needed. The optimized execution engines use these highly accurate plans to automatically execute the vast majority of transactions with real-time decision-making technology (NEO), enabling users to focus only on the exceptions.

NEO Predictive Analytics and Smart Prescriptions are key elements of the NEO Platform. NEO intelligent agents continually monitor your supply chain to find and fix potential problems before they impact your customers and your business. E.g. NEO analyzes real-time demand at the shelf, adjusts the forecast, and helps synchronize supply to demand. NEO also provides smart prescriptions to guide users to resolve complex issues optimally, ensuring your supply chain keeps running smoothly, effectively, and efficiently.

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### Transform your supply chain and lead your industry with the Digital Supply Chain Network™:

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