Product Track for Pharmaceutical Manufacturers

A rich and flexible data management system for the secure creation and exchange of track-and-trace data to meet requirements for compliance with the U.S. Drug Supply Chain Security Act.

The new item-level traceability requirements of the U.S. Drug Supply Chain Security Act (DSCSA)—which take effect starting on November 27, 2023—introduce significant complexity and industry-wide challenges compared to the previous lot-level traceability mandate.

- Trade partners must ensure that Transaction Information (TI) with serialized product identifiers and Transaction Statements (TS) are provided for each unit of product that they receive. The data must be exchanged in a secure, electronic, and interoperable manner.

- While the law doesn't specify an electronic format, the pharmaceutical supply chain is adopting the Electronic Product Code Information Service (EPCIS) standard to encode and communicate transaction data, replacing advanced shipment notices (ASNs) primarily used today for lot-level data exchange.

- The law will require new network connectivity tools to establish digital connections with direct suppliers and trade partners, and often with indirect trade partners under certain business conditions.

Product Track for Pharmaceutical Manufacturers

TraceLink Product Track for Pharmaceutical Manufacturers provides an extensive array of compliance data management, operational process support, and supply chain data exchange capabilities for DSCSA compliance. With Product Track, pharmaceutical manufacturers are empowered to securely create, manage, and seamlessly exchange compliance data with supply chain trading partners.

Key Capabilities

- **Support multiple distribution models:** Business rules and data management capabilities cover a broad range of TI and TS use cases, including direct purchase, secondary distribution, drop shipment, exclusive distributor, loan/borrow, repackaging, returns, co-license/affiliate, and more.

- **Exchange compliance data:** Generate and exchange EPCIS data and optional business data as needed depending on the current state and history of the product.

- **Simplify network connectivity:** Seamlessly connect and share compliance information with trading partners using the TraceLink "Integrate Once, Interoperate with Everyone™" network model and data mapping capabilities. Note: See sidebar for more information.

- **Integrate supply chain processes:** Integrate with a diverse set of business and operational use cases, including:
  - Initial transactions for new and repackaged products being introduced into the supply chain.
  - Shipments and receipts between trade partners.
  - Returns and other special supply chain transactions.
  - Exceptions, including void transactions, update product status and quantity, resend transaction, and more.

- **Support drop shipments:** Make compliance data available to drop shipment recipients.

- **Portal access for all trading partners:** TraceLink provides a secure web portal that supports trading partners without capabilities for full data integration. Become a preferred supplier by using the same portal as hundreds of other suppliers that your customers use.

- **Find information quickly:** Easily search for and retrieve compliance data based on a wide range of search parameters, including dates, product identifiers, and more.

- **DSCSA compliance data reconciliation:** Reconcile compliance data against physical inventory.

- **Exception management:** Resolve errors, such as errors related to quantities in a shipment, in DSCSA compliance documents while maintaining a full audit trail of changes.

- **Data management:** Retain and manage compliance data for the full DSCSA-mandated record retention period.

THE TRACELINK NETWORK ENABLES THE FASTEST PATH TO DSCSA COMPLIANCE

TraceLink developed its industry-leading track-and-trace solutions on a network platform because it was the most efficient design to support the full intent of the DSCSA law: to protect the U.S. drug supply chain from end to end. This forward-thinking approach has not only produced the most comprehensive solution, but it is the fastest to deploy with lowest total cost of ownership:

- **Fastest:** With more than 290,000 members, all or most of your trading partners are already fully pre-integrated into the TraceLink network.

- **Lowest TCO:** Purpose-built solutions on the network provide complete end-to-end serialization traceability, interoperable data exchange, and product verification at the lowest total cost of ownership.

- **Better:** The TraceLink network and DSCSA compliance solutions are built on a highly scalable cloud platform to process data-intensive transactions at no additional cost.

- **Future Proof:** Continuous investment in network solutions for supply network orchestration, artificial intelligence, and multienterprise integration extends value beyond serialization and compliance.

Key Benefits

Network:

- TraceLink Integrate Once, Interoperate with Everyone™ requires only a single integration to the TraceLink network to send EPCIS data. This eliminates the costs and time associated with creating and maintaining hundreds of new trade partner integrations that would be required to replace the ASN-based TI and T3 statements currently in use. Without the TraceLink network approach, these trade partner integrations can cost $10,000 to $15,000 each and can add months or years to the DSCSA 2023 upgrade project.

Scalability:

- Interoperable exchange of TI transactions in EPCIS format is a major step change from the current lot tracing mandate and requires that all pharmaceutical manufacturers, wholesale distributors, healthcare pharmacies, and retail pharmacies upgrade systems and processes. The TraceLink network and DSCSA compliance solutions are built on a highly scalable cloud platform to process data-intensive DSCSA transactions at operational scale at no additional cost.

Continuous Compliance:

- TraceLink continuously monitors evolving DSCSA and other regional compliance requirements, standards, and partner requirements to update our solutions as required. For major new compliance initiatives, TraceLink taps into its 6500-member Cloud Community to get industry input on meeting new requirements. New compliance requirements are applied across the network so that all trading partners are upgraded at once and out-of-sync transactions are eliminated. This greatly reduces the costs associated with monitoring compliance requirements and industry approaches to meet these requirements, as well as costs associated with updating integrations and solutions.

Ensure Supply:

- TraceLink solutions run on a platform with an active-active architecture, providing zero recovery time and no data loss with global 24x7 support to ensure shipments are not delayed by late, missing, or corrupt EPCIS transactions. Drug product shipments cannot be received into inventory and dispensed to patients unless the physical serialized product matches the EPCIS sent by the supplier.

Lowest Total Cost of Ownership:

- TraceLink delivers "Compliance as a Service" that includes the Product Track solution, partner integrations, and monitoring of regulations and standards to ensure continuous compliance. Unlike other solution providers, TraceLink software is purpose-built and does not require complex integrations and business logic to be developed.

Improve Patient Outcomes:

- Help to protect the drug supply chain while increasing patient safety, improving patient access to medicine, and helping to ensure positive patient outcomes.

REAL-WORLD CASE STUDY

COMPANY PROFILE: Large multinational pharmaceutical manufacturer based in Japan

BUSINESS CHALLENGES:
Needed a solution to support the U.S. DSCSA 2023 requirement for 100% interoperable, electronic exchange of serialized TI and TS data with their approximately 1,500 downstream partners and customers.

The company attempted to implement a legacy compliance solution without a digital network platform, but ultimately determined it was not viable and would not enable them to meet the November 27, 2023 DSCSA deadline on time.

The legacy solution failed because each of the pharma company's partners would have to comply with an email invitation and response verification process, a process which was not scalable.

Additionally, separate B2B connections had to be established when required by the pharma company's customers.

SOLUTION:
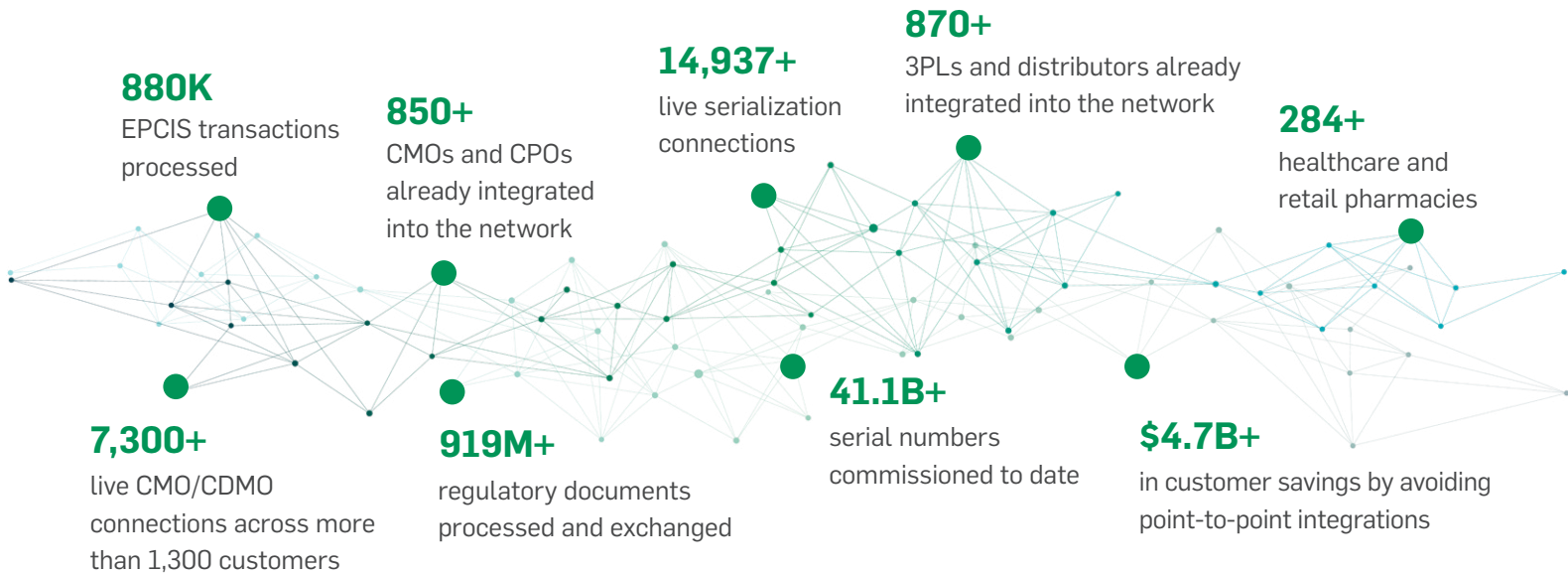- TraceLink Product Track for Pharmaceutical Manufacturers

RESULTS:
More than 93% of the pharma company's customers were already integrated into the TraceLink network, saving time and reducing the risk of noncompliance with DSCSA.

The company was able to immediately begin sharing serialization and track-and-trace compliance data with partners.

About The TraceLink Network

TraceLink is the leading provider of end-to-end product orchestration on a digital network platform. TraceLink Product Track for Pharmaceutical Manufacturers is built and hosted on TraceLink Opus, the world's largest supply chain network digitalization platform for pharma and life sciences. Opus enables interoperable exchange of serialization data and traceability information with direct and indirect trade partners across the supply chain. Key network metrics include:

880K
EPCIS transactions processed

850+
CMOs and CPOs already integrated into the network

14,937+
live serialization connections

870+
3PLs and distributors already integrated into the network

284+
healthcare and retail pharmacies

7,300+
live CMO/CDMO 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 Product Track for Pharmaceutical Manufacturers.

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