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NETWORK FOR GREATER GOOD

TraceLink Track and Trace for Pharmaceutical Manufacturers

Manage all global track-and-trace mandates with a scalable and flexible serialization solution delivered on the industry-leading supply chain network digitalization platform.

Pharmaceutical manufacturers are tasked with the monumental challenge of serializing tens of millions—even billions in some cases—of product units to meet existing and emerging global compliance mandates. To achieve this goal, manufacturers need a comprehensive solution that can easily handle all aspects of serialization—generation, labeling, aggregation, decommissioning, and destruction—and track-and-trace processes, including scanning, shipping, verification, and compliance.

Track and Trace for Pharmaceutical Manufacturers

The TraceLink Track and Trace for Pharmaceutical Manufacturers solution suite provides global serialization and traceability on a supply chain network digitalization platform that connects pharmaceutical manufacturers with all CMOs and downstream partners across the end-to-end supply chain, enabling the seamless exchange of serialization and traceability data to meet global compliance requirements.

Key Capabilities

- The TraceLink Opus "Integrate Once, Interoperate with Everyone™" capability links all trading partners together on a supply chain network digitalization platform with a single integration, enabling them to seamlessly exchange EPCIS data with customers. Manufacturers can also exchange serialization and track-and-trace data with internal and external packaging lines, and contract manufacturers.

- Generate, import, replenish, and provision serialized product identifiers for companies across one or more packaging hierarchies to meet compliance requirements—including commissioning, aggregation, and transformation—of serial numbers and related events.

- Serialization repository and operational hub for packaging, warehouse, and distribution activities supports the management of inbound/outbound product movements, commissioning, aggregation, and transformation of serial numbers and related events, pack/repack/labeling activities, status changes, and more.

- Securely publish, retrieve, and share product, company, and partner master data across supply networks to enhance supply chain performance, meet regulatory requirements, and execute operational use cases such as product identity verification.

- Quickly integrate with more than 20 regional regulatory compliance solutions (e.g., U.S. Drug Supply Chain Security Act (DSCSA), European Union Falsified Medicines Directive (FMD), etc.) that can be configured based on each country's unique regulations, specifications, processes, and workflows—reducing the time and cost of compliance and giving companies greater control and visibility across diverse markets.

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- Verify serialized product identifiers upon customer request.
- Mobile solution automates warehouse processes involving serialized product, including receiving, pick/pack/ship, internal transfers, inventory counting, and returns.
- Advanced operational analytics reporting solution enables proactive monitoring of serialized production and operational and compliance reporting events.

Key Benefits

- **Integrate Once, Interoperate with Everyone™:** The TraceLink network platform eliminates point-to-point integrations by enabling all customers and trading partners to integrate only once and then interoperate with anyone else on the network with point-and-click configuration, resulting in massive cost savings. Trading partner onboarding is provided by TraceLink at no additional cost.
- **Scalability:** The TraceLink platform architecture utilizes modern technologies on Amazon Web Services to manage 100s of millions to 100s of billions of transactions daily. A highly scalable solution eliminates operational disruptions due to data processing and timeout errors. Ensuring that data can be processed, stored, and retrieved ensures compliance, increases customer satisfaction, and minimizes the impact on patient safety.
- **Continuous Compliance:** Reduce compliance costs with automatic updates that support new and evolving global regulations and guidelines, technical standards, serialization and compliance software, and workflows.
- **Ensure Supply:** Improve on-time, in-full customer deliveries with a global serialization control tower that gives your organization a comprehensive view into product identity and serialized product operations.
- **Cost Reduction:** Reduce costs by centrally managing the allocation of serial numbers, which provides greater control to finetune serial number requests and better visibility into serialization processes, including product status updates, commissioning, and aggregation.
- **Improve Operational Efficiency:** Increase efficiency with automated workflows that link serialized product operations to existing product packaging, warehousing, distribution, and supply chain operations.
- **Improve Patient Outcomes:** Protect the drug supply chain while increasing patient safety, improving patient access to medicine, and helping to ensure positive patient outcomes with automated product identity verifications by distributors, pharmacies, and healthcare dispensers.

REAL-WORLD USE CASE

COMPANY PROFILE:
Global Biopharmaceutical

REVENUE:
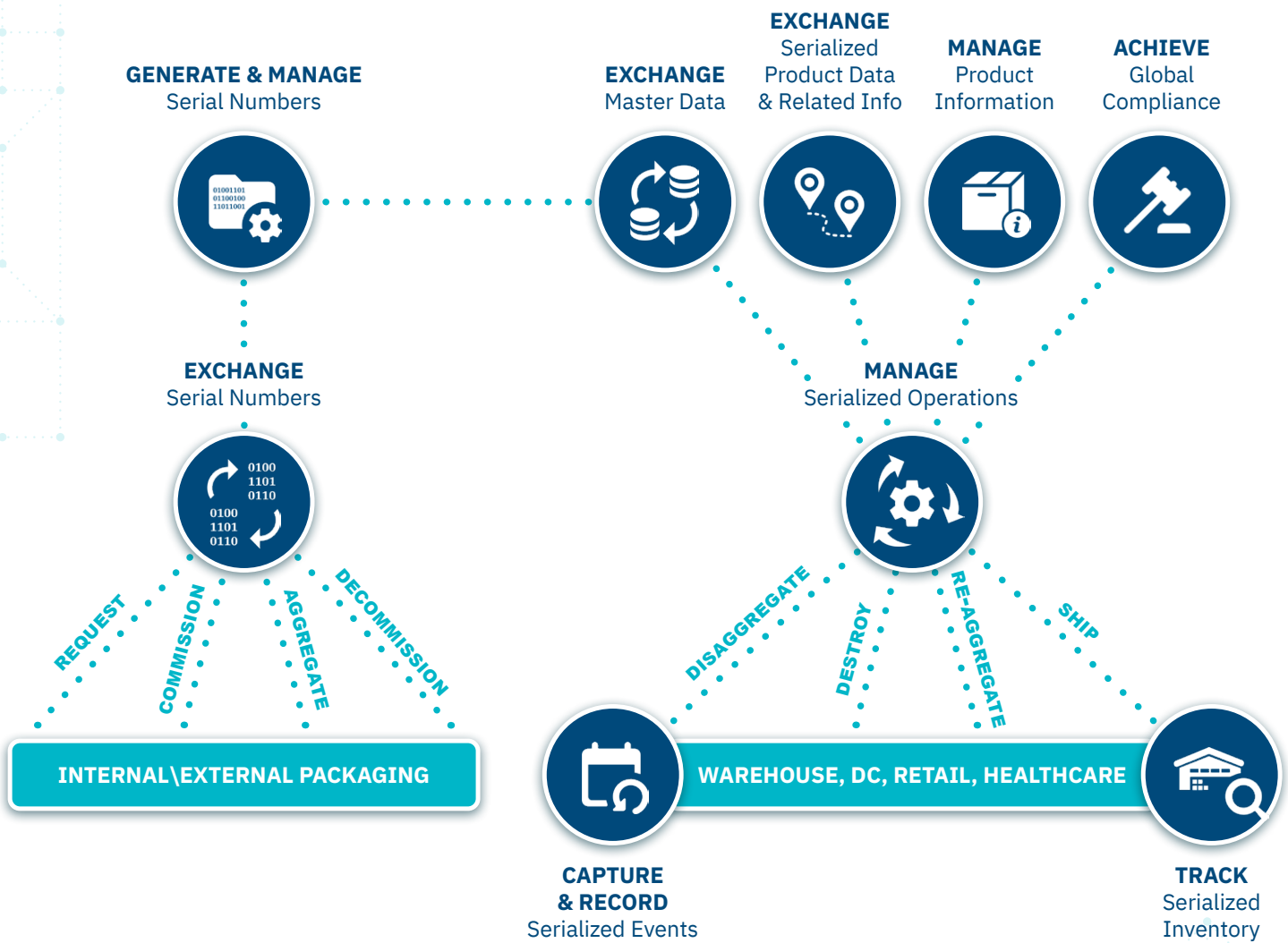$25 billion/year

BUSINESS CHALLENGES:

- Ensure compliance for exchanging EPCIS transactions and product verification.
- Onboarding and integrating over 1,500 regional customers; current solution provider unable to onboard supply chain partners at scale.
- Avoid replacing the existing Level 4 system.

SOLUTION:

- TraceLink Track and Trace for Pharmaceutical Manufacturers

RESULTS:

- 37 days to implement the TraceLink solution.
- $22.5 million in savings by eliminating point-to-point integrations.
- 93% of supply chain partners were already on the TraceLink network, enabling seamless connectivity.

GENERATE & MANAGE
Serial Numbers

EXCHANGE
Master Data

EXCHANGE
Serialized
Product Data
& Related Info

MANAGE
Product
Information

ACHIEVE
Global
Compliance

EXCHANGE
Serial Numbers

MANAGE
Serialized Operations

REQUEST
COMMISSION
AGGREGATE
DECOMMISSION

DISAGGREGATE
DESTROY
RE-AGGREGATE
SHIP

INTERNAL\EXTERNAL PACKAGING

WAREHOUSE, DC, RETAIL, HEALTHCARE

**CAPTURE
& RECORD**
Serialized Events

TRACK
Serialized
Inventory

About the TraceLink Network

TraceLink Track and Trace 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 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 Track and Trace for Pharmacutical Manufacturers.

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