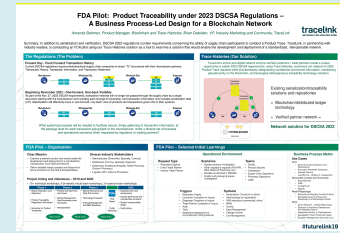




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Case Study: TraceLink | FDA Pilot - Product Traceability Under 2023 DSCSA Regulations - A Business Process-Led Design for a Blockchain Network



TraceLink's breakthrough blockchain solution, Trace Histories, can help pharma clients comply with US Drug Supply Chain Security Act regulations which go into effect in 2023. With Trace Histories, customers can respond to product trade requests while simultaneously safeguarding confidential commercial information. Read our new poster, which was featured at FutureLink Nashville, for additional details.

FDA Pilot: Product Traceability under 2023 DSCSA Regulations – A Business Process-Led Design for a Blockchain Network

Amanda Bettman, Product Manager, Blockchain and Trace Histories; Brian Daleiden, VP, Industry Marketing and Community, TraceLink

Summary: In addition to serialization and verification, DSCSA 2023 regulations contain requirements concerning the ability of supply chain participants to conduct a Product Trace. TraceLink, in partnership with industry leaders, is conducting an FDA pilot using our Trace Histories solution as a tool to examine a solution that would enable the development and deployment of a standardized, interoperable network.

The Regulations (The Problem)

Present Day - Push Forward Transaction History
Current DSCSA regulations require pharmaceutical supply chain companies to share "T3" documents with their downstream partners: Transaction History, Transaction Information, and Transaction Statement.

Beginning November 2023 - One-forward, One-back Visibility
As part of the Nov. 27, 2023 DSCSA requirements, transaction histories will no longer be passed through the supply chain as a single document starting with the manufacturer and including each change of ownership, and transaction information now includes serialization data (sTI). Stakeholders will effectively have a "one-forward, one-back" view of products and transactions given sTIs in their systems.

What systems/processes will be needed to facilitate secure, timely gathering of transaction information, at the package level for each transaction going back to the manufacturer, under a diverse set of business and operational scenarios when requested by regulators or trading partners?

Trace Histories (Our Solution)

TraceLink's end-to-end digital network and pre-verified customers / trade partners create a unique opportunity to satisfy 2023 DSCSA requirements; using Trace Histories, customers can respond to 2023 Product Trace requests while simultaneously safeguarding confidential commercial information, maintaining pseudonymity on the blockchain, and leveraging heterogeneous traceability technology solutions.

Existing serialization/traceability solutions and repositories

- + Blockchain/distributed ledger technology
- + Verified partner network =

Network solution for DSCSA 2023

FDA Pilot – Organization

Clear Mission

- Examine a network solution that would enable the development and deployment of a standardized, interoperable Trace Histories Network.
- Deliver detailed impact analysis and blueprint for future directions for the FDA and stakeholders.

Diverse Industry Stakeholders

- Manufacturers (Diversified, Specialty, Contract)
- Distributors (Full-line, Specialty, Regional)
- Dispensers (Healthcare/Hospital, Retail Pharmacy, Grocery Pharmacy)
- Logistics (3PL, Returns Processor)

Project timing and milestones – 2019 and 2020

- 10+ individual workshops, 9 bi-weekly virtual team workshops, 3 in-person team workshops

Phase 1	Phase 2	Phase 3	2020
Goals, Evaluation, and Objectives	Product and Data Flow Use Cases	Special Scenarios and Data Risk Factors	Expanded use case development
Product Traceability Regulations and Impact	Identity Management, Data Permissions and Ownership	Technology Evaluation	Industry governance and interoperable standards
Scenarios for Product Traceability	Interoperability	Change Management and 2023 Roadmap	System interoperability design
			Field piloting

Mock Trace Mock Trace Mock Trace

FDA Pilot – Selected Initial Learnings

Operational Environment

Request Type <ul style="list-style-type: none"> Regulatory Agency Direct Trade Partner Indirect Trade Partner 	Scenarios <ul style="list-style-type: none"> Suspect product investigation Other regulatory requests (FDA RFI, DEA, Board of Pharmacy, etc.) Recalls (as denoted in DSCSA) Quality and packaging issues investigation 	Teams <ul style="list-style-type: none"> Quality Product Security Compliance Supply Chain Operations Pharmacy Operations Legal
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Triggers

- Regulatory Inquiry
- Consumer Complaint or Inquiry
- Dispenser Complaint or Inquiry
- Trade Partner Complaint or Inquiry
- Audit
- Theft
- Suspicious appearance or circumstances (FDA guidance)

Systems

- Serialization (TraceLink or other)
- InfoExchange (or equivalent)
- ASN repository (commercial, other)
- WMS
- Quality
- Case Management
- Change Control
- Line Management

Business Process Matrix Use Cases

Core

- Direct Purchase Distribution from Manufacturer
- Secondary Wholesale Distribution
- Saleable Returns
- Loan/Borrow – Affiliate vs. Independent

Decoupled Custody and Ownership

- Drop Shipment
- 340B
- Consignment
- Staging

Resell/Repackage

- Manufacturer Reselling Finished Product
- Wholesaler Direct Purchase from Repackager and Repackager Resale

Other

- Direct Shipment – Global Military Base
- Shipment to Territories Saleable and Non-Saleable Returns
- Independent Broker or Clearinghouse
- Aggregated Product Flows/Use Cases
- Exception Management (short ship, etc.)

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DSCSA 2023 introduces significant regulatory compliance challenges and new operational complexities for drug manufacturers.

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