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New FDA Guidance: Verification Systems for DSCSA



Late last week, the U.S. Food & Drug Administration (FDA) posted draft guidance on the Federal Register titled "Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs" to share their interpretation of the Drug Supply Chain Security Act (DSCSA) requirements for verification systems, processes in suspect or illegitimate product scenarios and saleable returns verification, and recommendations for cleared product notifications.

Read the [summary of this DSCSA guidance](#), which was designed to help all industry stakeholders involved in verification processes to:

- Understand the information and business process expectations from the FDA given DSCSA requirements.
- Learn the FDA recommendations for managing verification.
- Determine how to manage the quarantine and investigation/disposal of suspect and illegitimate product.

Blog DSCSA for Manufacturers Regulatory/Compliance United States

I want to learn more about verification from Tracelink.

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I want to learn more about verification from Tracelink.

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FDA Pilot Report: Digital Recalls Network and DSCSA 2023 Traceability with Blockchain

See the results of TraceLink's FDA pilot project that focused on two workstreams; digital recalls and blockchain with participants from 22 companies across the supply chain

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DSCSA 2023: How Does the FDA Define “Suspect Product”?

Learn how recent FDA guidance provides more detailed definitions to help dispensers identify a suspect product.

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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 Daidein, 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.

Regulations (The Problem)

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



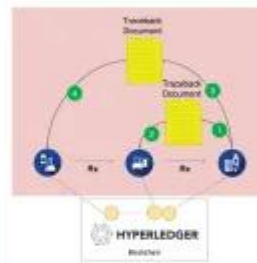
Beginning November 2023 - One-forward, One-back Visibility
Part of the Nov. 27, 2023 DSCSA requirements, transaction histories will no longer be passed through the supply chain as a single document starting with the manufacturer and including each change of ownership, and transaction information now includes serialization data (I). 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, maintain 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, 8 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 Requirements and Impact	Identity Management, Data Permissions and Governance	Technology Evaluation	Industry governance and interoperable standards design
Scenarios for Product Traceability	Interoperability	Change Management and 2023 Readiness	System interoperability design
			Facilitating Public Workshop

FDA Pilot – Selected Initial Learnings

Request Type	Operational Environment	Business Process Matrix
<ul style="list-style-type: none"> Regulatory Agency Direct Trade Partner Indirect Trade Partner 	<p>Scenarios</p> <ul style="list-style-type: none"> Suspect product investigation Other regulatory requests (FDA RFI, DSA, Board of Pharmacy, etc.) Recalls (as denoted in DSCSA) Quality and packaging issues investigation <p>Triggers</p> <ul style="list-style-type: none"> Regulatory Inquiry Consumer Complaint or Inquiry Dispenser Complaint or Inquiry Trade Partner Complaint or Inquiry Audit Theft Suspicious appearance or inconsistencies (FDA guidance) <p>Systems</p> <ul style="list-style-type: none"> Serialization (TraceLink or other) Interchange (or equivalent) ASN repository (commercial, other) WMS Quality Case Management Change Control Line Management 	<p>Use Cases</p> <ul style="list-style-type: none"> Direct Purchase Distribution from Manufacturer Secondary Wholesale Distribution Seasonal Returns Loan/Forms – Active vs. Inactive Decoupled Custody and Ownership Gap Shipment 3088 Consignment Shading <p>Receipt/Repackage</p> <ul style="list-style-type: none"> Manufacturer Receiving Finished Product Wholesale Direct Purchase from Repackager and Repackager Process <p>Other</p> <ul style="list-style-type: none"> Gap Shipment – Global Military Base Shipped to Territories, States and Non-Saleable Regions Independent Broker or Clearinghouse Aggregated Product Flow User Cases Exception Management (short ship, etc.)

#futurelink

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 customers comply with US DSCSA regulations that go into effect in 2023.

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