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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Late last week, the U.S. Food & Drug Administration (FDA) posted draft guidance on the Federal Register titled "Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs" to share their interpretation of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.

### **BlogDSCSA for ManufacturersRegulatory/ComplianceUnited States**

I want to learn more about verification from TraceLink.

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I want to learn more about verification from TraceLink.

### **Related Content**



**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

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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)

#### Essential 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.



#### Gaining November 2023 - One-forward, One-back Visibility

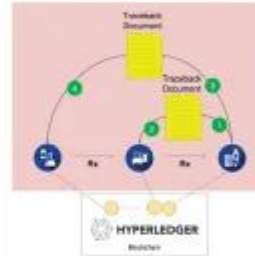
Part of the Nov. 27, 2023 DSCSA requirements, transaction histories will no longer be passed through the supply chain as a single document starting with the manufacturer and including each change of ownership, and transaction information now includes serialization data (i). Stakeholders will effectively 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)
- Dispensaries (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



### FDA Pilot – Selected Initial Learnings

Operational Environment			
Request Type	Scenarios	Teams	Business Process Matrix
<ul style="list-style-type: none"> <li>Regulatory Agency</li> <li>Direct Trade Partner</li> <li>Indirect Trade Partner</li> </ul>	<ul style="list-style-type: none"> <li>Suspect product investigation</li> <li>Other regulatory requests (FDA RFI, DEA, Board of Pharmacy, etc.)</li> <li>Recalls (as mandated in DSCSA)</li> <li>Quality and packaging issues investigation</li> </ul>	<ul style="list-style-type: none"> <li>Quality</li> <li>Product Security</li> <li>Compliance</li> <li>Supply Chain Operations</li> <li>Pharmacy Operations</li> <li>Legal</li> </ul>	<b>Use Cases</b> <ul style="list-style-type: none"> <li>Core               <ul style="list-style-type: none"> <li>Direct Purchase Distribution from Manufacturer</li> <li>Secondary Wholesale Distribution</li> <li>Secondary Returns</li> <li>Loan/Return – Active vs. Independent</li> </ul> </li> <li>Decoupled Custody and Ownership               <ul style="list-style-type: none"> <li>Ship (Shipment)</li> <li>JAR</li> <li>Consignment</li> <li>Shaping</li> </ul> </li> <li>Recall/Repackage               <ul style="list-style-type: none"> <li>Manufacturer Receiving Finished Product</li> <li>Wholesaler Direct Purchase from Repackager and Repackager Route</li> </ul> </li> <li>Other               <ul style="list-style-type: none"> <li>Direct Shipment – Global Military Base</li> <li>Shipment to Territories, Satellite and Non-Saleable Regions</li> <li>Independent Broker or Clearinghouse</li> <li>Aggregated Product Flow/Use Cases</li> <li>Exception Management (short ship, etc.)</li> </ul> </li> </ul>

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

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