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# Mutual Drug Discusses DSCSA Compliance Challenges



Wholesale distributor Mutual Drug began making a plan for a DSCSA solution as soon as the law was passed. Hear Andrew Meyer, Senior Systems Analyst & Traceability Lead, discuss their criteria for selecting a compliance partner plus some of the challenges they faced in working towards the May 1 deadline.

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### **Henry Schein: Manufacturers Must Stay Focused on Saleable Returns Verification**

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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 Daleiden, VP, Industry Marketing and Community, TraceLink

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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

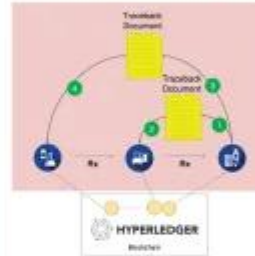
Part of the Nov. 27, 2023 DSCSA requirements, transaction histories will no longer be passed through the supply chain as a single document starting with the manufacturer and including each change of ownership, and transaction information now includes serialization data (i). Stakeholders will effectively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

Request Type	Operational Environment		Business Process Matrix
	Scenarios	Teams	
<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>Standalone Returns</li> <li>Loan/Returns – Active vs. Independent</li> </ul> </li> <li>Decoupled Custody and Ownership               <ul style="list-style-type: none"> <li>Ship (Shipment)</li> <li>3PL</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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## Building the TraceLink Network One Business Process Ecosystem at a Time

Josh Sheldon, Director of Services Products

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### Business Challenge & Solution

Companies within the pharmaceutical Supply Chain are assessing ways to take advantage of the hard work they have put into being compliant with serialization regulations. A lot of data, which is now available, never existed before and more companies are integrated with their trade partners than ever before, or companies within the pharmaceutical supply chain who want to glean insights from historical data sets and quickly build out ecosystems using a robust network, the digital Network Platform provides supply chain visibility, interoperability across trade partners and a platform to develop new applications.

### What is a Business Process Ecosystem?

TraceLink provides solutions that help our customers with their business processes. If business process has an ecosystem of trade partners that need to connect to exchange information, TraceLink's robust network enables our customers to quickly react to those trade partners so that they can scale up new Business Process ecosystems more quickly than ever.

### Team

Josh Sheldon  
Director of Services Products  
TraceLink



Role of Network Success Manager (NSM)



### Objectives

Enable hundreds of thousands of businesses and people to collaborate on new innovative digital solutions to maximize the efficacy, quality, safety, security, and availability of products that prove human life.

### Existing Business Process Ecosystems



### Milestones and Learnings



### Building New Business Process Ecosystems



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## Case Study: TraceLink | Building the TraceLink Network One Business Process Ecosystem at a Time

See how TraceLink's powerful digital supply network enables customers to quickly connect to trade partners for scaling up business process ecosystems.

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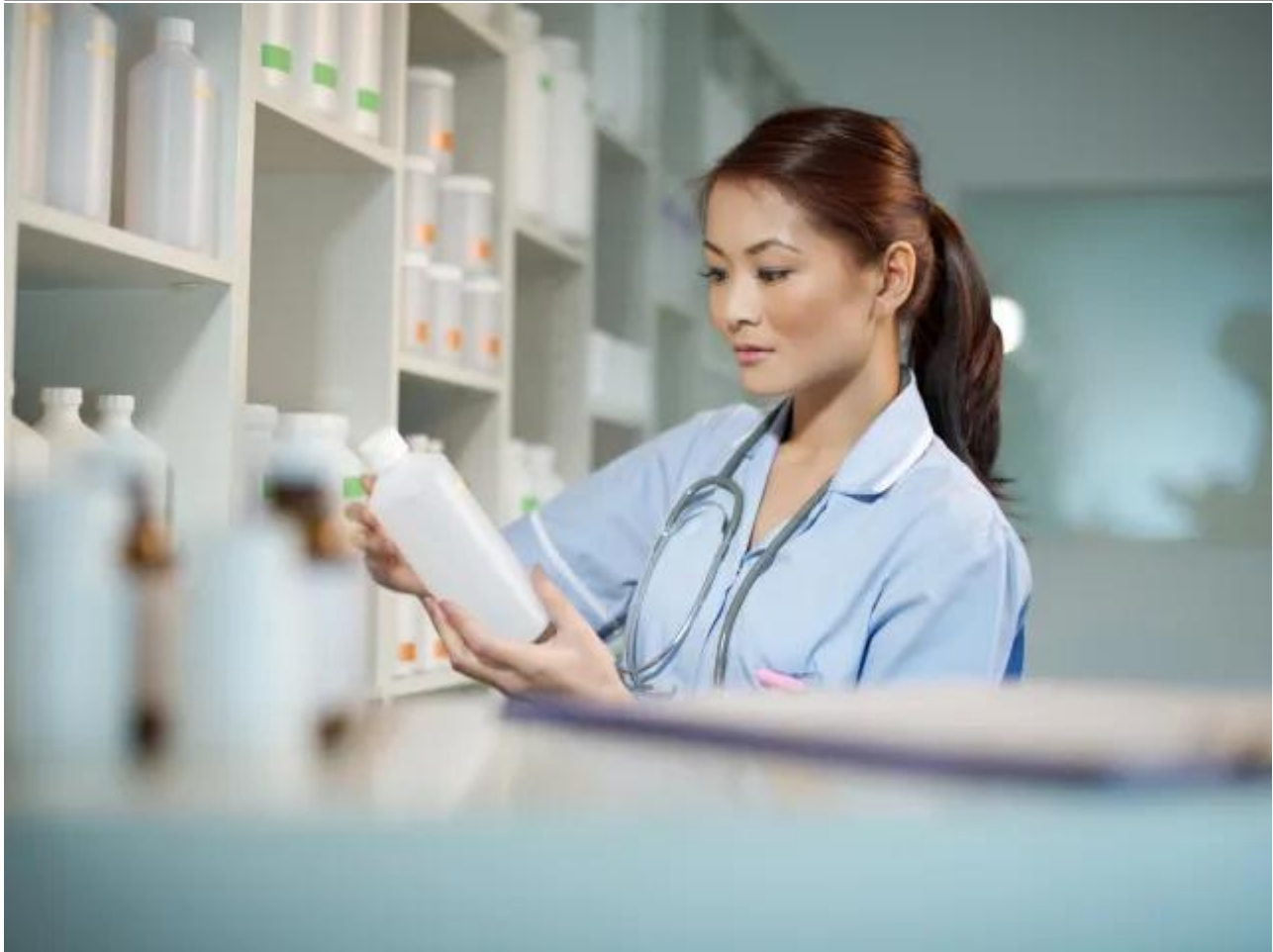
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### **Why An Open, Standards-Based Approach is Essential for the Pharmaceutical Supply Chain**

Learn five critical criteria to determine whether you want a trusted partner or just a vendor.

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### **Will Serialization Affect Minimum Order Quantity for Rx Products?**

Learn key definitions and requirements of how products are identified and sold under DSCSA, and how serialization can make product verification more accurate and efficient.

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