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



Under the FDA Pilot Project Program, TraceLink led a cross-industry, cross-functional team of industry leaders from each segment of the United States pharmaceutical supply chain to study, analyze, and prepare recommendations on two key challenges facing all stakeholders.

Pilot members included:

- **Contract Manufacturers:** Thermo Fisher/Patheon; Sharp Packaging
- **Pharmaceutical Manufacturers:** Agios; A-S Medication Solutions; Bristol-Myers Squibb; Flexion; Johnson & Johnson; Merck; Par Pharmaceuticals; Sagent; Sandoz; Novartis
- **Wholesale Distributors:** McKesson; Value Drug Company
- **Retail Pharmacies/Healthcare:** CVS Health; Novant Health; Wegmens; Yale New Haven
- **Logistics Providers:** DHL; PharmaLink; Woodfield Distribution

The Digital Recalls workstream analyzed how pharmaceutical recalls are executed today and examined how a digital recalls network could be realized to improve the rapid and precise communication, management, execution, and closure of product recalls across the supply chain.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

The Traceability workstream analyzed how the industry will be impacted by the upcoming DSCSA 2023 regulations, to research the critical capabilities and requirements for a network solution to meet these requirements, and to study the potential role of blockchain/distributed ledger technology combined with serialization, traceability, and other existing technology solutions.

The team's findings for both workstreams were submitted to the FDA. To receive the full 50 page report via email, enter your information in the form. Executive summaries for each workstream can be viewed below.

Digital Recalls Executive Summary
2023 Traceability Executive Summary

BlogTargeted RecallsUnited States
Fill out the form below to receive the full report.
Download Now
Fill out the form below to receive the full report.

Thank you. Check your email for a copy of the content you requested.

More Serialization and Compliance Resources

© TraceLink Inc. 2009 - 2025 All Rights Reserved



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
View More

© TraceLink Inc. 2009 - 2025 All Rights Reserved



Preparing for DSCSA Saleable Returns Verification

Understand the impact of the upcoming DSCSA saleable returns verification requirement for both pharma companies and wholesale distributors.
View More

© TraceLink Inc. 2009 - 2025 All Rights Reserved