Life Sciences and Healthcare Supply Chain Leaders Achieve DSCSA Readiness with TraceLink



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Across the U.S. life sciences and healthcare industry, companies are required to comply with **U.S. Drug Supply Chain Security Act (DSCSA)** requirements while minimizing disruption and avoiding slowdowns to critical operations. Whether you're a global pharmaceutical manufacturer, a regional wholesaler, a hospital, or a local pharmacy, compliance today means far more than ticking regulatory boxes. It demands deep operational integration, data transparency, and synchronized collaboration across your trading partner ecosystem.

TraceLink is the proven solution partner that life sciences companies, wholesale distributors, health systems, and pharmacies count on to ensure DSCSA readiness. With more than a decade of delivering DSCSA success, the industry's largest end-to-end digital supply network, and an unmatched breadth of compliance solutions and services, TraceLink helps organizations across the supply chain meet regulatory requirements and unlock long-term strategic value.

EPCIS: The Foundation of DSCSA Readiness

DSCSA mandates serialized, interoperable data exchange via EPCIS transactions. Companies must not only exchange these files but also validate and apply them in

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operational workflows—without disrupting performance. Traditional point-to-point integration fails to support this need at scale, introducing delays, errors, and unnecessary cost.

TraceLink's B2N Integrate-Once™ architecture powers the industry's only EPCIS data exchange infrastructure to earn the GS1 US Rx EPCIS Trustmark—recognized for meeting the highest standards for DSCSA compliance. With thousands of customers already EPCIS-enabled on the TraceLink network, companies gain immediate access to a vast ecosystem of ready-to-exchange partners—reducing the cost, time, and risk of DSCSA implementation.

Proof Points:

- Over 14,900 live serialization links.
- 291,000+ authenticated and onboarded network members.
- Over 910 million DSCSA transactions exchanged on the TraceLink network.

DSCSA is Complex and Demands Deep Proven Capabilities

DSCSA compliance involves much more than EPCIS file exchange. Companies must support serialized shipping and receiving, master data sharing, product verification, exception management, and more—all without disrupting day-to-day operations.

TraceLink delivers the most comprehensive U.S. compliance solution on the market, with capabilities spanning every requirement of DSCSA. Designed for scalability, TraceLink ensures operational continuity even as regulations and business needs evolve.

Proof Points:

- 1,750+ customers on the TraceLink network.
- 41.1B+ serial numbers commissioned to date.
- 919M+ regulatory documents exchanged.

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- Comprehensive solution set includes Product Information Manager, Serialized Operations Manager, Smart Inventory Tracker, and more.

Leveraging a Network is a Force Multiplier in DSCSA Compliance

Building custom integrations with every trading partner is not sustainable. Companies must rapidly exchange DSCSA data with hundreds of diverse partners—many with unique formats, systems, and requirements.

TraceLink's network-based model allows companies to integrate once and interoperate with all. A single link to the TraceLink network links you to every customer and supplier, enabling seamless EPCIS data exchange without the delays of one-off integrations.

Proof Points:

- 7,300+ live CMO links across 1,300+ customers.
- $4.7B+ in customer savings from avoiding point-to-point integrations.
- 930+ distribution and logistics customers and partners on the network.

Resolve Exceptions at Scale with POET

As DSCSA compliance moves from setup to daily execution, managing exceptions—like unreadable barcodes, missing data, or product mismatches—emerges as one of the biggest operational challenges. Left unresolved, these issues can delay shipments, impact revenue, and erode partner trust.

Many companies still rely on spreadsheets and email to resolve exceptions—methods that are slow, inconsistent, and hard to scale.

TraceLink’s Process Orchestration for Empowered Teams (POET) replaces that manual chaos with structured, scalable exception management. POET delivers configurable workflows, automated routing, and real-time collaboration tools that help internal teams and external partners resolve issues quickly and keep product

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moving.

With POET, companies turn compliance bottlenecks into efficient, traceable business processes—ensuring DSCSA doesn’t disrupt daily operations.

Proof Points:

- 60+ pharmaceutical companies managing DSCSA exceptions through TraceLink.
- Aligned to HDA exception categories across 1,750+ customers.
- Built on the OPUS Platform with 290,000+ authenticated supply chain partners.

Certified Partner Ecosystem Ensures Rapid and Secure DSCSA Readiness

Many companies lack the internal resources to implement, test, and troubleshoot compliance systems. Without expert partner support, businesses risk missing deadlines or falling out of sync with trade partners.

TraceLink's certified partner ecosystem includes consultants, systems integrators, and service providers with proven DSCSA expertise. These partners extend TraceLink’s internal support capabilities to help customers deploy and maintain compliance solutions quickly and effectively.

Proof Points:

- 45+ solution and technology partners.
- 43 partner contacts with project management and technical consultant certifications.
- 200+ projects completed by partners this year.

Patient Safety Remains at the Heart of DSCSA

As companies navigate the complexities of DSCSA compliance, it's important to

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remember the law's foundational purpose: protecting patients by increasing visibility, traceability, and security in the supply chain.

TraceLink continues to innovate in support of this mission. Solutions like **Targeted Recalls** and **Serialized Product Verification** ensure that regulatory compliance directly contributes to safer outcomes for patients.

TraceLink's Targeted Recalls solution digitalizes FDA recall notices and matches them to serialized product data—enabling pharmacy teams to instantly determine if they're affected, where recalled products were distributed, and how much needs to be removed. This allows staff to act with speed and precision while staying focused on patient care. Serialized Product Verification provides dispensers and trading partners with instant confirmation of product authenticity at the package level, helping to stop potentially counterfeit, diverted, stolen, or expired drugs from reaching patients.

Proof Points:

- Targeted Recalls reduces pharmacy recall cycle time by up to 55%.
- One health system projects 8,000+ hours in annual time savings by eliminating manual shelf sweeps and paper tracking.
- 55,700+ GTINS owned by TraceLink customers ready for verification.

Standards and Industry Alignment are Critical Ingredients for Success

DSCSA compliance is about more than checking regulatory boxes—it requires confidence that systems are built on standards that ensure interoperability today and scalability tomorrow. The vendors best equipped to meet these expectations are those deeply involved in shaping the standards themselves.

TraceLink plays a central role in the development and advancement of DSCSA-related industry standards. As an active contributor to GS1, the Healthcare Distribution Alliance (HDA), and the Partnership for DSCSA Governance, TraceLink

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helps drive alignment on best practices that reduce implementation complexity and support long-term success across the entire supply chain.

Compliance Creates a Foundation for Strategic Advantage

The most forward-looking organizations recognize DSCSA compliance as more than a regulatory requirement—it's a springboard for digital transformation. When executed with the right partner, compliance becomes a powerful enabler of business value.

By implementing TraceLink's DSCSA solution on the TraceLink network—the most established and proven digital supply chain platform in the industry—companies not only meet critical regulatory deadlines but also activate a foundation for smarter, more agile operations. The same serialized product data, master data, and digital trade partner links used for compliance can be extended to drive inventory visibility, reduce manual processes, improve working capital, and enhance collaboration across the end-to-end supply chain.

Future-Proof Your ASN Strategy With MINT

As the industry moves to EPCIS as the mandated format for DSCSA compliance, the requirement to send DSCSA-specific ASNs will sunset. However, trading partners across the supply chain—especially wholesalers and pharmacies—continue to rely on standard ASNs to drive operational efficiency and visibility at the receiving dock. This creates a challenge: how can manufacturers meet regulatory requirements without disrupting downstream processes that still depend on ASNs?

TraceLink enables companies to solve this challenge with **MINT for Commerce**, allowing manufacturers to continue using their existing integrations while simultaneously sending EPCIS for compliance and standard ASNs to support trading partner operations. With more than 110 million ASNs exchanged across 15,000+ link profiles, TraceLink brings more than a decade of expertise to this critical business process.

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A Defining Moment for the Industry

The final phase of DSCSA readiness represents more than a compliance milestone—it’s a turning point for the future of pharmaceutical supply chains.

TraceLink is the industry’s most trusted partner for achieving DSCSA success and unlocking long-term value. With the most experienced team, the most comprehensive solutions, and the most proven network platform, TraceLink equips your organization to lead.

Contact TraceLink to ensure your organization is fully DSCSA-ready—and positioned to lead the next era of pharmaceutical supply chain excellence.

BlogUS Drug Supply Chain Security ActDSCSA for Dispensers, DSCSA for ManufacturersRegulatory/Compliance
Meet with TraceLink to learn more about DSCSA compliance.
Fill out the form to schedule a meeting now.

Thank you for contacting us; we’ll be in touch shortly.

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