NEWSROOM



TraceLink Becomes First Solution Provider to Secure All 16 GS1 US Conformance Trustmarks for EPCIS File Support

Boston, MA — August 22, 2024 — TraceLink, the largest end-to-end digital network platform for intelligent orchestration of the life sciences and healthcare supply chain, proudly announces it has become the first and only solution provider to secure all 16 GS1 US Conformance Trustmarks for EPCIS file support. These trustmarks certify that a company's systems meet stringent criteria for accurately and securely exchanging traceability data, ensuring compliance with the Drug Supply Chain Security Act (DSCSA) requirements for tracking and tracing prescription drugs through the supply chain. This landmark achievement sets a new industry standard in the U.S. pharmaceutical supply chain's efforts to meet the DSCSA requirements.

This comprehensive certification encompasses 7 trustmarks supporting manufacturers to downstream trading partners and 9 trustmarks aiding wholesalers to dispensers. The attainment of all available trustmarks underlines TraceLink’s commitment to excellence and compliance in the pharmaceutical industry, providing assurance that the EPCIS messages sent on behalf of our clients—manufacturers, wholesalers, and dispensers—are in full compliance with

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the application standards set by GS1 US, the publisher of the GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2. This ensures that TraceLink customers can seamlessly track and trace their products, reducing operational risks, enhancing supply chain transparency, and ultimately improving patient safety.

Focused on Standards and Compliance

The GS1 US Rx EPCIS Conformance Testing Program plays a crucial role in the pharmaceutical supply chain, ensuring the interoperability and compliance of data exchanges required by the DSCSA.

"TraceLink's dedication to standards has been a cornerstone of our mission for over 15 years," said Shabbir Dahod, President and CEO of TraceLink. "Our active participation and leadership in various standards working groups, such as the GS1 US Healthcare Executive Leadership Team, GS1 Global Healthcare Leadership Team, and the GS1 Global Architecture Team, make evident our commitment to driving massive adoption and interoperability across the supply chain. Our own Elizabeth Waldorf, Director of Global Traceability and Standards, has served as co-chair of the GS1 US RxSecureSupplyChain Workgroup and the GS1 EPCIS/CBV Standard MSWG and Visibility Standards Mission Group and was also recognized with the 2022 GS1 Ken Traub Industry Award. Our ongoing investment in these initiatives is crucial for ensuring the delivery of safe, effective, and authentic medicines to patients worldwide."

Utilizing the DSCSA Stabilization Period

During the Enhanced Drug Distribution Security Stabilization Period from November 2023 to November 2024, the FDA recommended using this time to "implement, troubleshoot, and mature their systems and processes while supporting the continued availability of products to patients." Achieving all 16 GS1

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US Conformance Trustmarks is a great demonstration of how to best utilize this stabilization period, showcasing our commitment to interoperability through enhanced drug distribution and secure electronic tracing of products at the package level.

A Commitment to Excellence

"According to GS1 US, the goal of the Rx EPCIS Conformance Testing Program is to support and streamline trading partner onboarding with a mechanism to provide a level of confidence about readiness, implementation quality, and consistency. The voluntary program is designed to validate that an EPCIS event file follows the format and structure defined in the GS1 US Implementation Guideline to support interoperable EPCIS baseline functionality for the purposes of serialized item data exchanges." TraceLink's commitment to aligning with GS1 standards ensures a reliable and interoperable pharmaceutical supply chain, benefiting all stakeholders from manufacturers to dispensers.

As we celebrate this milestone, we continue to innovate and support our customers through exceptional service and compliance expertise. We have created solutions, such as Digital Recalls, to expand the usage of EPCIS data, enhancing patient safety.

For more information about TraceLink and our compliance solutions, please visit our website at https://www.tracelink.com/legal-and-trust/certifications.

For more information about the GS1 US Rx EPCIS Conformance Testing Program visit: GS1 US Rx EPCIS Conformance Testing Program.

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TraceLink: Leading Industry Readiness with More than 26,000 Companies Already Enabled for DSCSA Compliance

TraceLink leads DSCSA implementation with 26,000 companies enabled.
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TraceLink Collaborates with GS1 US to Author GS1 US Addendum Guidance and XML Examples for GS1 US DSCSA Implementation Guideline R1.3 to Support EPCIS Data Exchange

Publication of the GS1 standard guidelines and technical examples provide a strong foundation to help companies accelerate their network connectivity and EPCIS-based sTI/TS data exchange to meet forthcoming November 2023 DSCSA deadlines.

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