NEWSROOM



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.

TraceLink Inc., the leading digital network platform company enabling end-to-end product orchestration by connecting more than 290,000 healthcare and life sciences entities through its B2N Integrate-OnceTM network, is proud to announce its continuing support of Drug Supply Chain Security Act (DSCSA) 2023 readiness through its partnership with GS1 in the authoring of the GS1 US Addendum Guidance and XML Examples for GS1 US DSCSA Implementation Guideline R1.3. An early adopter of GS1 standards, TraceLink has now exchanged over one million DSCSA-compliance EPCIS transactions between trading partners on the TraceLink network, with over 1,075 companies now being EPCIS-enabled for DSCSA compliance data exchange in preparation for November 2023 deadlines.

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The latest implementation documents, published by GS1 US on May 26th, 2023, serve as an EPCIS serialized data exchange implementation blueprint for companies across the US pharmaceutical and healthcare supply chain. The expanded documentation provides detailed descriptions of end-to-end trading partner event choreographies for serialized item traceability use cases under DSCSA

“Given the sense of urgency for November 2023, we want to jumpstart EPCIS implementations and demystify the technical “wirings” for orchestrating DSCSA exchanges for the industry’s most common supply chain choreographies,” noted Elizabeth Waldorf, Director, Global Traceability and Standards for TraceLink, co-chair and editor of GS1 US RxSecureSupplyChain workgroup and member of the GS1 Healthcare US Executive Leadership Committee.

As part of the collaborative effort, the GS1 Rx Secure Supply Chain Workgroup identified and documented 21 supply chain scenarios that encompass the majority of business use cases within the industry. Among these scenarios, 11 have been meticulously detailed with comprehensive business event choreographies and XML examples of electronic data exchange, including critical use cases for dropship, co-licensing, repackaging, and 340B programs. Leveraging its deep industry experience, including its leadership in the recent FDA pilot program on product tracing, TraceLink played a key role in spearheading the creation of 50 XML examples that effectively illustrate each of the 11 end-to-end trading partner message exchange choreographies for shipping and receiving products.

Spanning 406 pages, the newly published GS1 US Addendum Guidance and XML Examples document offers an extensive yet structured approach that enables quick identification and reference to the specific business supply chain choreography that is most relevant for individual customer and product use cases. This invaluable resource will assist stakeholders across the US pharmaceutical industry in their preparations for the Drug Supply Chain Security Act (DSCSA), a

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vital regulatory framework aimed at enhancing patient safety through enhanced visibility and traceability of pharmaceutical products.

GS1 is a global, non-profit organization dedicated to the design and implementation of global standards for efficient business communication. As the administrator and provider of the GS1 system of standards, GS1 facilitates collaboration among trading partners, enabling the seamless exchange of information and goods throughout the supply chain. The GS1 US branch specifically focuses on the implementation of GS1 standards in the United States, promoting industry-specific guidelines and supporting organizations in achieving operational excellence.

As a member of the GS1 US Executive Leadership Committee, co-chair of the GS1 Healthcare US® Rx Secure Supply Chain Workgroup, and an active contributor to critical standards documentation such as the R1.3 Guideline, TraceLink continues to demonstrate its commitment to supporting the US pharmaceutical industry in its compliance efforts.

For more information about TraceLink and our DSCSA solution suite, visit https://www.tracelink.com/products/regulatory-compliance/us-dscsa-compliance.

To access the guidance from GS1 visit https://www.gs1us.org/industries-and-insights/by-industry/healthcare/standards-in-use/pharmaceutical/dscsa-implementation-guidelines

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