New GS1 Implementation Guide Addendum Addresses EPCIS Interoperability Issues to Ensure DSCSA Compliance



A new addendum to the DSCSA implementation guide from the GS1 standards organization promises to help U.S. pharmaceutical supply chain stakeholders implement fully interoperable, multienterprise data exchange in the Electronic Product Code Information Services (EPCIS) format. The guideline offers examples and guidance for EPCIS data exchange between trading partners in compliance with the **final phase of the U.S. Drug Supply Chain Security Act (DSCSA)** for the upcoming Nov. 27 deadline.

This article explores why ensuring interoperability when implementing EPCIS can be complicated and how the newly released addendum to "**Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability**" can help. TraceLink played an important role in the creation of this addendum by contributing 50 XML examples, highlighting our commitment to driving standards development and supporting our customers and partners in their compliance efforts.

EPCIS enhances supply chain traceability and visibility

Developed by GS1 with input from pharmaceutical industry leaders, EPCIS is an open traceability event messaging standard. It enables supply chain partners to

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capture information about supply chain events and share that information with their trading partners—securely, electronically, and in near real time.

To make the transition from exchanging lot-level product information to serialized item-level data, as required by the DSCSA 2023 mandate, the pharmaceutical industry rallied around the EPCIS standard. While the use of the EPCIS standard is not required under the DSCSA, the FDA nonetheless recommends its use among industry trading partners to provide and maintain the data associated with Transaction Information (TI) and Transaction Statements (TS) in compliance with the DSCSA.

Given the fast-approaching deadline, the industry is focused on ensuring EPCIS data can be exchanged smoothly between trade partners. While EPCIS is a flexible standard that can be leveraged for many different business needs, every entity across the pharmaceutical supply chain has a unique tech stack with its own applications and environments. The flexibility of the EPCIS standard means there are numerous options for how it can be implemented, which can create interoperability issues in supporting the exchange of serialized item-level traceability data between partners.

Overcoming the interoperability pitfalls of EPCIS implementation

Members of the U.S. pharmaceutical industry recently joined together to assess various business processes and business requirements and develop a new resource to provide a standardized implementation approach.

Spearheaded by GS1 U.S. and the Rx Secure Supply Chain Work Group, the new Implementation Guideline addendum identifies 21 supply chain scenarios that encompass the majority of business use cases. It offers detailed choreographies that demonstrate the alignment between the physical movement of products and the corresponding data flows of EPCIS events capturing TI/TS data, complete with examples of EPCIS messages, which are based on the XML data format, for several scenarios, including drop shipping, co-licensing, repackaging, and 340B

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transactions.

TraceLink played an active role in the release of this addendum. TraceLink led the creation of 50 XML examples, which illustrate 11 end-to-end trading partner message exchange choreographies for receiving and shipping products. Companies in the pharmaceutical supply chain preparing for DSCSA 2023 can reference this addendum to quickly identify specific business supply chain choreography that is most relevant for their own specific customer and product use cases.

TraceLink: An active leader in standards development

The creation and implementation of standards like EPCIS is vital to facilitating the exchange of critical product information and preventing illegitimate medications from entering the supply chain. TraceLink fully understands this—we strive to **be a leader in standards development so we can better support our customers and partners** in their compliance efforts.

For more than 10 years, TraceLink has worked with industry committees to develop standards and educate the TraceLink customer community about EPCIS. TraceLink is a member of several committees at GS1, PDG, and OCI, and an active participant and industry presenter at HDA. TraceLink has also authored and edited standard implementation guidelines and industry specifications, including the GS1 U.S. DSCSA Implementation Guideline addendum.

TraceLink provides continuous compliance

TraceLink works with customers, partners, regulatory agencies, and government system providers to understand new requirements and specifications, and update TraceLink solutions to ensure continuous compliance for all customers across the network. TraceLink deploys new functionality across its network simultaneously in a highly controlled manner compliant with GxP and related regulations, ensuring that everyone is operating with the same functionality.

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Compliance isn’t a one-time activity, it’s an ongoing process and, as a quick scan of the GS1 Implementation Guideline shows, it is very complex. TraceLink subject matter experts track the details that lead to this complexity in order to create simple-to-use solutions that scale for operational efficiency so you can concentrate on running your business.

If you’d like assistance with preparing for the rapidly approaching DSCSA deadline, contact TraceLink to **review your DSCSA readiness** today.

Learn More about US DSCSA Compliance

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

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