

GS1 US Publishes New DSCSA Implementation Guideline to Support Pharma Supply Chain Preparations for DSCSA Nov. 2023 Deadlines

TraceLink Inc., the leading digital network platform company connecting more than 290,000 entities across the Healthcare and Life Sciences industry, today announced that GS1 US has published its updated GS1 US DSCSA Implementation Guideline R1.3, another critical component in helping the pharmaceutical supply chain prepare for the upcoming November 27, 2023 deadlines of the Drug Supply Chain Security Act. This updated implementation guideline, focused on item-level serialized traceability required for DSCSA 2023 supply chain interoperability with efficiency optimizations for implementations, lays a broad standards-based technical foundation for EPCIS data exchange of serialized Transaction Information (TI) and Transaction Statements (TS), for verification of serialized product identifiers for saleable returns, and more. Deploying DSCSA 2023 Compliance solutions, TraceLink customers have been ramping up quickly to prepare for DSCSA 2023 deadlines, with over 800,000 DSCSA EPCIS transactions having been processed to date on the TraceLink Network.

Compliance with the final phase of DSCSA regulations requires that stakeholders across the United States pharmaceutical supply chain meet substantial new and complex regulatory and operational requirements. Pharmaceutical manufacturers,

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repackagers, wholesale distributors, healthcare providers, and retail pharmacies are faced with orchestrating DSCSA compliance solutions internally and with network partners for a broad range of critical capabilities. These capabilities, for which GS1 standards form a major supply chain interoperability foundation, include:

- Serialized TI and TS data exchange (leveraging GS1 EPCIS and CBV) and matching to product shipments
- Product tracing
- Product identifier verification for saleable returns, suspect and illegitimate products
- GTIN and product pack-level master data sharing
- Exception management across receiving, shipping and other inventory operations
- Recall status, investigations, and supply network alerting
- Authorized trade partner credentialing

“GS1 has been at the forefront in working tightly with the pharmaceutical industry for the past decade in developing data and interoperability standards to help companies and solution providers prepare for DSCSA requirements,” said Elizabeth Waldorf, Director of Standards and Traceability at TraceLink Inc. It is important to recognize that the EPCIS standard by itself is not enough. You must follow the specifications in the GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.2 or 1.3 in order to create data that meets DSCSA requirements and that will be interoperable with other trading partners in the U.S. pharmaceutical supply chain. “In support of this effort, TraceLink has invested heavily both in helping inform GS1 workgroups on the technical, operational process, and network integration requirements created by DSCSA regulations, and in implementing deep support for GS1 standards across our OPUS supply chain network digitalization platform and DSCSA compliance solutions.”

"Working closely on DSCSA compliance with our customers and their trading

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partners on the TraceLink Network, it is clear that network connectivity and standards-based interoperability is a must-have for companies to get ready for DSCSA 2023 deadlines," said Dan Walles, General Manager, Track and Trace/Compliance at TraceLink Inc. “TraceLink started early in developing our support for GS1 EPCIS standards, anticipating the need for the tens of thousands of network connections that would be required as companies implement serialized TI and TS data exchange for the massive volume of serialized product flowing through the U.S. pharma supply chain under DSCSA regulations. Elizabeth’s efforts as a leader in the GS1 US Executive Leadership Team and GS1 US RxSecureSupplyChain workgroup have been crucial in helping push this effort along and ensuring that TraceLink is always well prepared to meet our customers’ diverse needs under DSCSA.”

“TraceLink’s efforts as a trusted advisor in partnering with our customers to deeply understand the regulatory requirements and business needs for compliance mandates like DSCSA have been a critical part of our investment in customer success,” added Walles. “The diligent effort that Elizabeth put forward as editor of this standard and co-chair of the working group, collaborating closely with colleagues to develop and publish a strong implementation guideline, will help companies confidently move forward on their DSCSA 2023 preparations.”

To learn more about TraceLink DSCSA compliance solutions and OPUS supply chain network digitalization platform, please visit tracelink.com.

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