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Partnership for DSCSA Governance (PDG) Interoperability Blueprint Publication

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Leading industry-wide collaboration forum and workgroup publishes an extensive set of interoperability guidelines and frameworks for meeting DSCSA 2023 requirements.

In November of 2019, the Partnership for DSCSA Governance (PDG) was formed. A not-for-profit organization, PDG's mission was to provide an end-to-end supply chain collaborative forum dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S. to help meet the requirements of the Drug Supply Chain Security Act (DSCSA). The members of PDG, composed of industry leaders from all segments of the supply chain, and the FDA through a public-private partnership agreement, were focused on establishing a technical and process interoperability foundation to help companies plan for and meet the upcoming final November 2023 phase of the DSCSA regulatory deadlines. TraceLink was a founding member of PDG in 2019 and has been a continuing thought leader and contributor across PDG workgroups and committees.

Compliance with the final phase of DSCSA regulations requires that stakeholders

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across the United States pharmaceutical supply chain meet substantial new and complex regulatory and operational requirements. Pharmaceutical manufacturers, 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 interoperability is critical, include:

- Serialized TI and TS data exchange (leveraging GS1 EPCIS and Core Business Vocabulary) 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

DSCSA regulations describe at a high level the “what” companies need to do to comply, but not the “how” to configure and implement their data management and exchange systems, operational processes, and more to meet both the regulatory and business requirements stemming from these regulations. This is where PDG comes in. The focus of PDG has been to develop an “Interoperability Blueprint” for the industry that describes a technical and operational framework for implementation of the interoperable systems and processes necessary to meet DSCSA requirements.

PDG members have created, through a series of virtual meetings, workshops, and pilots, a set of requirements and implementation guidance documents which are freely available for the industry to leverage. Known as the Foundational Blueprint for 2023 Interoperability, these documents include:

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- Understanding of Compliance Requirements and Baseline Business Requirements (Chapter 1).
- Interoperability Functional Design (Chapter 2).
- Transaction Information (TI)/Transaction Statement (TS) Exchange Functional Design (Chapter 3).
- Product Identifier Verification Functional Design (Chapter 4).
- Product Tracing Architectural Functional Design (Chapter 5).

TraceLink believes that PDG's interoperability work is a critical component in ensuring that the pharmaceutical supply chain has the knowledge and direction it needs to securely and efficiently prepare for DSCSA 2023 deadlines. To this end, TraceLink has deeply invested over the past several years in sharing developing PDG insights and technical documentation with our customers, and in partnering with our customers to take their knowledge and input back into PDG's work. TraceLink educational programs in this area include:

DSCSA 2023 webinar series where we have reviewed several parts of the PDG Interoperability Blueprint and their relevance to companies preparing for DSCSA 2023. Specific webinars discussing PDG guidelines include:

- The Importance of Standards to Industry DSCSA Success (PDG's role and focus).
- Preparing for Electronic, Interoperable Exchange of DSCSA Compliance Information (Interoperable Exchange requirements).
- Preparing for Electronic, Interoperable DSCSA Verification Requirements (Verification requirements and Authorized Trade Partner/Credentialing concepts).
- Preparing for Electronic, Interoperable Product Tracing (Product Tracing requirements/expectations).

TraceLink Community where we have held a regular series of meetings over the past several years breaking down and reviewing PDG work and documents, and

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discussing special topics like the February PDG, HDA, FDA workshop on DSCSA compliance exceptions.

FutureLink 2023 conference (May 22-24) where PDG will lead a panel of industry leaders in discussing the state of the supply chain and what companies should be doing right now to prepare for November 2023 deadlines.

End-to-end supply chain interoperability is a critical challenge in successfully meeting the regulatory and business requirements for DSCSA. TraceLink has helped drive industry DSCSA success from the beginning, helping define in 2014 the initial data exchange guidelines for lot-level DSCSA Transaction History exchange and creating Product Track, the industry's leading DSCSA compliance data management system. TraceLink has processed almost 1 billion Transaction Histories since 2015 and over 800,000 DSCSA EPCIS transactions, giving us unsurpassed insights into DSCSA transaction management and data exchange. Drawing on our experience with managing the commissioning of over 1 billion serialized product identifiers a month, supporting serialized product compliance reporting for over three dozen countries globally, and managing over 60% of the GTINs in the U.S. VRS network, we have deep expertise in understanding the implications of managing serialized products and their identities across large and high volume supply chains to meet track and trace compliance requirements.

We look forward to having a conversation with you about your unique DSCSA needs.

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