

DSCSA Governance Group Reveals 2023 Interoperability Blueprint

Key takeaways

- The PDG Blueprint signals the industry to start planning and budgeting to meet 2023 requirements.
- The Blueprint includes recommendations for serialized data exchange, interoperability, and trade partner authentication.
- PDG recognizes “Direct-to-Source” verification of the product identifier against manufacturer data as an appropriate method of verification . “Direct-to-replicate” verification is recognized with limited applicability to specific circumstances. Verification against the packaging itself is not seen as a viable alternative.
- PDG will host public workshops to discuss the Blueprint and next steps toward successful implementation.

A critical step in achieving DSCSA interoperability

The Partnership for DSCSA Governance (PDG) is an industry consortium of more than 60 pharmaceutical supply chain stakeholders. Established in late 2019, PDG is a public-private partnership with the FDA “to establish and advance an industry consensus for an interoperable system to meet 2023 DSCSA requirements.” **The DSCSA 2023 requirements** comprise three interrelated statutory components

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that go into effect on November 27, 2023:

- **Interoperable Exchange.** Trading partners must exchange required transaction information (TI) and transaction statements (TS) in a secure, electronic, interoperable manner, and the TI must include the product identifier at the package level.
- **Interoperable Verification.** Trading partners must be able to verify the product identifier on a package or sealed homogeneous case in a secure, electronic, interoperable manner.
- **Interoperable Tracing.** Trading partners must maintain secure, electronic, interoperable systems and processes to provide TI and TS in response to a request for it and to promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer.

On July 14, PDG released the first chapter of its consensus-based industry Blueprint for secure, electronic, interoperable unit-level tracing, verification, and reporting, as required under DSCSA. Chapter 1 of the Blueprint, “Understanding of Compliance Requirements and Baseline Business Requirements” comprises 5 sections:

- Requirements and Recommendations to Support Serialized Transaction Information (TI) and Transaction Statement (TS) Data Exchange
- Requirements and Recommendations to Support Interoperable Verification
- Requirements and Recommendations to Support Interoperable Tracing
- Requirements and Recommendations to Support Credentialing and Trading Partner Authentication
- A glossary of industry and statutory terms

Addressing the authentication and verification challenge

The Blueprint provides a detailed, industry-driven foundation for meeting DSCSA interoperability requirements while achieving critical business requirements. It also represents an industry perspective on two outstanding issues regarding

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interoperable data exchange between trading partners:

- **Trade partner credentialing and authentication.** While DSCSA requires that transactions only take place between "Authorized Trading Partners (ATP)," it does not provide a prescriptive method for authenticating a partner before initiating an electronic data exchange. In place of existing manual authentication processes, the PDG Blueprint describes a more robust and operationally efficient method using a verifiable ATP Credential for validating the identity and ATP status of the requester or responder.
- **Product verification method.** The Blueprint assesses 3 options for meeting DSCSA verification requirements. While both "Direct-to-Source" and "Direct-to-Replicate" verification using product information provided by the manufacturer are recognized as appropriate methods of verification, "Direct-to-Replicate" is considered appropriate for certain specific circumstances listed in the PDG Blueprint requirements document. The third method, "Direct-to-Product" verification using data collected by the verifier by scanning the physical product, is not seen as an appropriate method for verification as defined under the statute.

PDG will host a series of public workshops to discuss the content of the Blueprint and next steps as industry works toward full compliance with the DSCSA 2023 requirements. The public workshops are open to all industry stakeholders.

The "starting gun" in the race to DSCSA 2023 interoperability

The PDG Blueprint signals the start of an industry-wide, cross-segment push to meet the final phase of DSCSA requirements. Because much of the solution design and development work is expected to take place in 2022, companies are advised to plan and budget accordingly for next year in order to be well positioned for implementation, testing, and "go-live" in 2023. Contact TraceLink to learn more and to schedule a consultative workshop.

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