

Foundational Blueprint for 2023 Interoperability

Key Terminology

DSCSA 2023 Requirements are the requirements in Section 582(g)(1) of the FDCA, which go into effect Nov. 27, 2023 and include interoperable exchange, interoperable verification, and interoperable tracing.

Interoperability is the ability of systems and processes to exchange and use information accurately, efficiently, and consistently among trading partners.

PDG-Defined EDDS Network is a collection of industry systems that achieve interoperability through conformance to the PDG Blueprint.

Business Requirements are the technical characteristics of a proposed system that are operationally necessary to meet compliance requirements.

Compliance Requirements are the characteristics of a proposed system that are necessary to meet statutory obligations under the DSCSA.

The *Blueprint* represents years of input from 70 of the leading organizations throughout the supply chain to define the most effective and efficient approach to DSCSA compliance.

Why It Matters: Interoperability requires a common, standards-based framework and the *Blueprint* is the only *comprehensive* standards-based framework for DSCSA implementation.

Five Things to Know

1

The *Blueprint* incorporates, by reference, standards and the work of other stakeholder groups wherever possible.

2

The *Blueprint* defines compliance, business, and functional requirements for (i) TI Exchange, (ii) verification, (iii) tracing, and (iv) credentialing.

3

While conformance to the *Blueprint* is not a legal or regulatory requirement, it does represent the best thinking of the industry's leading organizations.

4

The *Blueprint* does not call for the development of shared industry infrastructure; rather, it is built on the assumption of a distributed data architecture.

5

All trading partners should be familiar with the *Blueprint*, but implementation of it will occur at the solution-level.