COMMITTEE CHARTER

1. PURPOSE

The Interoperability Committee is responsible for substantive, tactical, and technical work needed to establish and advance an industry consensus for an interoperable system to meet 2023 DSCSA requirements.

2. GOALS/OBJECTIVES

The Interoperability Committee's primary objectives for 2020 are to:

1. Develop and present a consensus-based industry blueprint for the secure, electronic, interoperable unit-level tracing, verification and reporting, as required under DSCSA, (referred to throughout as "interoperability") to the PDG Board. This work will define the following attributes for authorized[1] stakeholders of US DSCSA and cover:
   a. the business requirements and vision for 2023 interoperability
   b. the technical means of, and identification of standards for, establishing / sustaining interoperability
   c. the necessary governance to assure compliance to the business requirements
   d. the obligatory business practices necessary to minimize potential operational exceptions

   Note: The Interoperability Committee will also identify, for Board consideration and action, outside technical advisors that may be needed to support its work.
2. Develop and execute the FDA pilot on governance, with learnings to be shared with PDG Board and FDA.

3. DELIVERABLES

1. Present to the PDG Board a work plan for a consensus-based blueprint by milestones and deliverable dates that includes:
   a. A vision and key principles for interoperability.
   b. Definition of key terminology (e.g., model, architecture, system and process, interoperability, electronic methods, tracing, prompt).
   c. Definition of business requirements for key use cases which clearly define the minimum requirements of authorized stakeholders for complying with the 2023 DSCSA statute and associated FDA guidance (final or draft).
   d. Definition of the functional system and process attributes, including identification of any existing or needed standards, for establishing and sustaining interoperability among authorized stakeholders based on the defined business requirements.
   e. Rules around the necessary governance for assuring that the industry consensus requirements and functionality are maintained in a sustainable fashion in order for authorized stakeholders to stay compliant with DCSCA.
   f. A Committee meeting schedule.
   g. Project plan and key interim milestones.
   h. A final comprehensive "Blueprint" document capturing these deliverables.
2. Establish and execute the FDA-approved governance pilot on a schedule and cadence that meets both PDG and FDA's expectations.
   a. Test the structure and organization of PDG, including any lessons learned and recommendations to PDG Board to help further refine governance model.

[1] The term authorized is used in the context of DSCSA sec 581 (2).

b. Leverage a use case for determining "authorized" status of a trading partner to define system and processes to support interoperability.

3. Quarterly updates to Board and General Membership.

4. SCOPE DEFINITION

The Interoperability Committee should develop industry consensus for interoperability that meets the following expectations.

1. Interoperability that complies with applicable legal requirements (*e.g.*, DSCSA Phase II, FDA guidance on DSCSA, antitrust requirements, data integrity guidance, etc.).
2. Focuses on feasible methods of meeting the statutory requirements for 2023, though it should enable and may note additional business benefits that could be considered in the future.
3. Maximize efficiency and cost-effectiveness for all without regard to company size.
4. Maximize opt-ins (*i.e.*, encourage broad voluntary adoption of systems and processes that are based on the vision).
5. Not favor any particular stakeholder or constituency.
6. Focuses on U.S. (DSCSA) requirements, but should not hinder (*i.e.*, should account for) global harmonization.
7. Consideration to studies or outputs from other constituencies that offer a means of leveraging the work but not necessarily bound to the prior work of any such constituencies.

Interoperability should address the architecture of systems and processes for interoperability. Such architecture should:

1. Define an interoperable system(s) for electronic tracing of product at the package and homogenous case level which:
    a. Provides means of TI and TS to be exchanged in a secure, interoperable, electronic manner.
    b. Identifies method(s) to assure the integrity of the product identifier data for each package in the transaction contained within the TI.
    c. Addresses common practices, leading to processes, which facilitate verification of a product's identifier at the package level to the source data of the verification.
    d. Facilitates gathering the information necessary to produce the TI for each transaction going back to the manufacturer, including when, where and by whom gathering is to occur, who may request to gather, and how gathering is accomplished to assure secure the information gathered for the purpose of confidentiality.
    e. Facilitates trading partners ability to respond with TI & TS for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect or illegitimate product.
    f. Considers the needs of large and small business (fewer than 25 FTEs) among all sectors of the pharmaceutical distribution supply chain.
    g. Supports scalability of systems and processes as more users come on board and new use cases are developed.
    h. Clearly allows for identification of the source of truth or information pertaining to a product's identifier.
2. Define where and by whom governance is necessary to sustain the operations and technical characteristics of an interoperable system among authorized stakeholders once said system is established.
3. Define technical work groups necessary to fulfill the requirements and functionality necessary to establish an industry consensus interoperable system.

5. PROJECT MILESTONES

See project timeline.

Milestone	Description	Date
MS1	Scope, objective, and metrics of FDA pilot established	Jan '20
MS2	Approve Charter	Feb '20
MS3	Definition of baseline lexicon	Feb '20
MS4	Pilot activity concluded and report available	May '20
MS5	Establish and operate work group structure consistent with a general work plan	May '20
MS6	Publish detailed Work Group work plans	Jul '20
MS7	Credentialing (ATP) Framework presented to Interoperability Committee for review and approval	Aug '20
MS8	Credentialing (ATP) Framework presented to general membership for ratification	Sep '20
MS9	Serialized TI Exchange Framework presented to Interoperability Committee for review and approval	Sep '20
MS10	Credentialing (Identity) Framework presented to Interoperability Committee for review and approval	Oct '20
MS11	Serialized TI Framework presented to general membership for ratification	Oct '20
MS12	Accreditation (Verification) Framework presented to Interoperability Committee for review and approval	Oct' 20
MS13	Accreditation (Tracing) Framework presented to Interoperability Committee for review and approval	Oct' 20
MS14	Credentialing (Identity) Framework presented to general membership for ratification	Nov '20
MS15	Accreditation (Verification) Framework presented to general membership for ratification	Nov '20
MS16	Accreditation (Tracing) Framework presented to general membership for ratification	Nov '20
MS17	Interoperability Committee presents full Vision Framework (*i.e.*, User Requirements LITE) to PDG Board for review and comment	Dec '20
MS18	PDG Board presents full Vision Framework to PDG Membership for ratification and publication	Dec '20
MS19	Collection and discussion of broader (non-PDG) stakeholder feedback on full Vision Framework	Jan-Feb '21
MS20	Develop of full technical requirements based on stakeholder feedback	'21

6. ASSUMPTIONS, CONSTRAINTS, DEPENDENCIES, and DEFINITIONS

Assumptions	Constraints	Dependencies
• A single industry governance model • Unlikely to achieve industry-wide alignment on a single technology to meet 2023 interoperability • Routine work product review and feedback with Board &	• Lack of clarity on 2023 requirements could lead to multiple interpretations of DSCSA impacting interoperability • Lack of Membership growth / participation across all sectors • Funding • Identifying SMEs	• 2023 timeline as specified in DSCSA • Alternate methods of compliance • Participation and collaborative approach from all sectors, including Technology providers • FDA engagement • Standards development/adoption

FDA on both FDA pilot and blueprint development • Disruptive new technologies will not be introduced midstream • Work should focus on how to meet 2023 requirements and not business value adds	• Time and availability/competing demands	• Timely FDA input • Member openness, willingness to think creativity, and willingness to compromise

Definitions: The following terms have the meaning set forth in/as used in the Drug Supply Chain Security Act (DSCSA):

- Transaction Information (TI)
- Transaction Statement (TS)
- Trading Partner
- Interoperability
- Tracing
- Verification
- Systems and Processes

7. RELATED DOCUMENTS

DSCSA (21 U.S.C. 360eee, et seq.)
DSCSA Guidances (https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies)
Other relevant regulation and guidance

8. AUTHORIZATION

Approved by:	Board	Date
Approved by:	Committee Chair	Date