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 2021/2022 are to:

1. Develop and present a consensus-based industry functional design in alignment with PDG Blueprint requirements for the secure, electronic, interoperable unit-level TI/TS exchange, tracing and Product Information verification, as required under DSCSA, (referred to throughout as "interoperability") to the PDG Board for member approval. This work will define the following attributes for Authorized Trading Partner stakeholders (as defined by the DSCSA and regulator) and cover:
    a. the functional design 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 recommended business practices necessary to minimize potential operational exceptions

3. DELIVERABLES

1. Present to the PDG Board a work plan for a consensus-based functional design by milestones and deliverable
2. Produce the following documentation based on Committee and working group consensus and consideration:
    a. **Design principals:** Design principles are widely applicable laws, guidelines, biases and design considerations which designers apply with discretion.
    b. **Functional Design:** Definition of the functional system and process attributes, including identification of anyexisting or needed standards, for establishing and sustaining interoperability among authorized stakeholders based on the defined business requirements.
    c. **PDG Conformance Criteria:** Rules around the necessary governance for assuring that the industry consensus requirementsand functionality are maintained in a sustainable fashion in order for authorized stakeholders to stay compliant with DCSCA.
    d. **Trust Framework:** a common set of agreed upon standards for trading partners and solution providers to establish trust, ensuring all participating organizations meet the same agreements and requirements.
3. **Other Deliverables:**
    a. Post 2023 considerations: Document design elements, alternatives and recommendations that are unlikely to be implemented by 2023,
    b. Blueprint Change Requests: as the working groups move into design, all recommended changes to the Blueprint will be submitted to the Interoperability Committee
    c. Update Definitions: of key terminology (e.g., model, architecture, system and process, interoperability,electronic methods, tracing, prompt).
    d. Set a schedule to meet and align with organizations (GS1, HDA, etc.) that maintain guidelines. specifications, and standards that are instrumental to the PDG Blueprint requirements and functional designs.
    e. As needed, develop and submit change requests to organizations in 3(d).
    f. Quarterly updates to Board and General Membership.

4. SCOPE DEFINITION

The Interoperability Committee should develop industry consensus for an interoperable functional design 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 of 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.

MS1	Scope, objective, and metrics of Functional Areas presented to Interop Committee	Sept 7, 2021
MS2	Interoperability Committee Approval	Sept 21, 2021
MS3	Provide Charter to Board for review	Sept 24, 2021
MS4	Board approval of Charter	Oct 6, 2021
MS5	Design Principals approved by Interoperability Committee	Oct 19, 2021
MS6	Serialized TI Exchange Functional Design – WG Approved	11/29/2021
MS7	Serialized TI Exchange Functional Design – Publication	12/31/2021
MS8	PI Verification Functional Design – WG Approval	11/29/2021
MS9	PI Verification Functional Design – Publication	12/31/2021
MS10	Alerts Functional Design – WG Approval	1/5/2022
MS11	Alerts Functional Design – Publication	2/15/2022
MS12	Credentialing Functional Design – WG Approval	11/29/2021
MS13	Credentialing Functional Design – Publication	12/31/2021
MS14	Trust Framework Functional Design – WG Approval	2/15/2022
MS15	Trust Framework Functional Design – WG Approval	3/31/2022
MS16	TI/TS Tracing Functional Design – WG Approval	1/26/2022
MS17	TI/TS Tracing Functional Design – Publication	3/31/2022

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 Functional Design • 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 • FDA guidance and functional design alignment • FDA EDDS is in alignment and interoperable with functional design • FDA and other Regulators follow same credentialing approach as industry • • Member openness, willingness to think creativity, and willingness to compromise

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)
PDG Blueprint (https://dscsagovernance.org/wp-content/uploads/2021/07/PDG_Blueprint-v1.0-Final_071221.pdf)
Other relevant regulation and guidance

8. AUTHORIZATION

Approved by:	Board	Date
Approved by:	Committee Chair	Date