pdg Partnership for DSCSA Governance

# Partnership for DSCSA Governance (PDG)

# Member Prospectus - 2025

## Why does Governance matter?

PDG plays a pivotal role in two overarching functions:

1. **Industry Decision-Making:** PDG acts as the platform for trading partners to define and harmonize their interoperability business requirements under DSCSA, setting minimum standards for commercial DSCSA services.
2. **Public-Private Collaboration:** PDG serves as the nexus where industry stakeholders, the FDA, and state regulators collaborate to align their expectations and facilitate interoperable systems for investigations and recalls.

## Member Benefits

- **Direct Input:** Members have a direct voice in shaping the industry's business requirements outlined in the PDG Blueprint.
- **Engagement:** Access to work groups allows for discussions on industry challenges and queries during the stabilization period.
- **Monthly Updates:** Participation in the only current recurring stabilization period status updates with the FDA and NABP as part of the PDG Interoperability Committee.
- **Workshop Participation:** Involvement in public-private workshops, including an upcoming session focusing on collaboration throughout the suspect/illegitimate product investigation process, trading partner notification process, and 3911 reporting process.
- **Industry Leadership:** PDG offers an opportunity to assume a leadership role within the industry.

## Who is PDG?

PDG is an independent, balanced, sector-neutral nonprofit industry governance body that supports the secure, electronic, interoperable tracing, and verification of prescription drugs in the U.S. supply chain, as required by the Drug Supply Chain Security Act (DSCSA).

PDG's membership includes leading authorized manufacturers, repackagers, wholesalers, third-party logistics providers, and dispensers (hospitals and retail and independent pharmacies), as well as leading industry trade associations and technical experts. Together, these members are working to establish a comprehensive vision for industry's implementation of secure, electronic systems and processes for drug traceability in the U.S.

For additional information, visit www.DSCSAgovernance.org.

***PDG serves as a vital nexus for industry stakeholders to shape and align their efforts toward achieving the goals of DSCSA, promoting transparency, and safeguarding the integrity of pharmaceutical supply chains.***

## PDG: A Public-Private Partnership with FDA

PDG operates as a public-private partnership in collaboration with the FDA. While the FDA cannot explicitly endorse PDG's efforts, it actively engages with the PDG Interoperability Committee, contributing to discussions that inform the PDG Blueprint and related initiatives. Notably, the Interoperability Committee serves as the primary recurring monthly platform for public-private updates on the ongoing stabilization period and the exemptions set to extend into 2025. Additional information about the general guidelines governing this public-private partnership can be found here.

## The PDG Blueprint: Guiding Interoperability

The PDG Blueprint governs interoperable verification and tracing, as mandated by DSCSA, and encompasses practices and processes that impact the integrity and reliability of these operations. This scope includes practices and processes related to creating, storing, and transmitting data intended for exchange under DSCSA, though it excludes internal company-specific processes and practices. More specifically, the Blueprint for interoperability:

**Defines a Vision:** Outlines a vision for interoperability, encompassing models for transaction identifier (TI) exchange, credentialing, verification, and tracing.

**Specifies Use Cases:** Clearly defines the use cases, compliance requirements, and business requirements integral to achieving DSCSA interoperability.

**Identifies Standards:** Highlights the standards and/or functional specifications necessary to facilitate DSCSA interoperability.

## Who Can Participate In The Governance Body?

PDG membership is reserved for key pharmaceutical supply chain entities, known as "trading partners" under DSCSA, who have legal obligations. These members, which include authorized manufacturers, repackagers, wholesalers, third-party logistics providers, and dispensers, possess full decision-making authority.

PDG's strategic direction is managed by a 14-member Board, elected by the membership, overseeing day-to-day operations. The organization heavily relies on open committees and work groups for substantive work, including the creation of interoperability blueprints, welcoming participation from all general members.

In addition to the general membership, PDG recognizes two types of members who hold voting rights and privileges:

- **Trading Partner Members:** This category includes any trading partner, as defined in the DSCSA, who holds authorization under the DSCSA. They are eligible for full general membership rights and privileges.
- **Association Members:** Association members encompass trade associations or societies whose membership primarily consists of trading partners as defined in the DSCSA, along with professional societies that represent healthcare providers. These members also enjoy full voting rights and privileges within PDG.

Furthermore, PDG extends an invitation to technical or process experts, including thought leaders and service providers, to actively participate in all work groups where participation is not restricted to general members. This inclusive approach fosters collaboration and expertise sharing among industry stakeholders.

## Our Work

PDG's core work is carried out by several committees, each with a specific focus. Currently, there are three committees in operation:

1. **Membership Committee**
2. **Finance Committee**
3. **Interoperability Committee**

All general members are welcome to participate in PDG committees, except for the Finance Committee, which comprises Board members.

The Interoperability Committee takes the lead in executing substantive, tactical, and technical work essential for creating and advancing a consensus within the industry. This consensus aims to establish an interoperable system that aligns with the requirements of DSCSA, enhancing traceability and interoperability.

The Interoperability Committee is supported by several work groups, including:

- **Credentialing and User Authentication Work Group:** This group defines the systems and processes by which trading partners/users can demonstrate permission to request and exchange data within the governed environment, including establishing "authorized" status.

- **Serialized TI/TS Data Exchange Work Group:** Responsible for defining systems, processes, business requirements, and identifying messaging standards essential for enabling interoperable electronic verification and tracing.
- **Verification Architecture Work Group:** This group defines systems and processes that allow trading partners to implement verification requirements for products in an interoperable, secure electronic manner.
- **Tracing Architecture Work Group:** Responsible for defining systems and processes enabling trading partners to implement tracing requirements for products in an interoperable, secure electronic manner.
- **Validation Matrix Work Group:** This group focuses on developing matrices that solution providers can use to validate to trading partners that their systems adhere to the requirements specified in the PDG Blueprint.
- **Exception Root Cause Work Group:** This group discusses and explores the root causes of DSCSA data exceptions and preventive actions that can help mitigate and reduce future exceptions.

The work conducted by these diverse work groups is synthesized by the Interoperability Committee to create a comprehensive vision for interoperability. This vision forms the foundation for achieving enhanced traceability and interoperability in line with DSCSA requirements.

## Membership Dues

Membership dues for 2025 have been reduced by 20% from the 2024 dues (more than a 60% reduction since 2022). The membership dues set out below are proposed to be similar (but not identical) among sectors and account for ability-to-pay, based on annual **U.S. pharmaceutical revenue**. A small-business rate is available to trading partners with 25 or fewer full-time employees. A single fee applies to Association Members, and technical expert dues are tiered by number of employees.

| | FY 2025 MEMBERSHIP DUES | | | | |
|---|---|---|---|---|---|
| | **Manufacturers/ Repackagers** | **Wholesalers/ 3PLs** | **Dispensers** | **Associations** | **Technical Experts** |
| **Tier 1** | $19,200 | $19,200 | $19,200 | $96 | $5,760 |
| **Tier 2** | $11,520 | $11,520 | $5,760 | | $2,880 |
| **Tier 3** | $3,840 | $1,920 | $960 | | |
| **Small Business** | $384 | $384 | $96 | | $384 |

| | TIER DEFINITIONS | | | | |
|---|---|---|---|---|---|
| | **Manufacturers/ Repackagers** | **Wholesalers/ 3PLs** | **Dispensers** | **Associations** | **Technical Experts** |
| **Tier 1** | > $10 B | > $10 B | > $10 B | N/A | 101+ EEs |
| **Tier 2** | $1 B - $10 B | $1 B - $10 B | $1 B - $10 B | | 26-100 EEs |
| **Tier 3** | < $1 B | < $1 B | < $1 B | | |
| **Small Business** | 25 or fewer full-time employees | | | | 25 or fewer EEs |

Membership dues cover the period from January 1, 2025, through December 31, 2025. Membership dues will be invoiced on a schedule that provides flexibility to make payment in late 2024 or early 2025.

Any questions can be directed to PDG staff at admin@dscsagovernance.org.