Partnership for DSCSA Governance

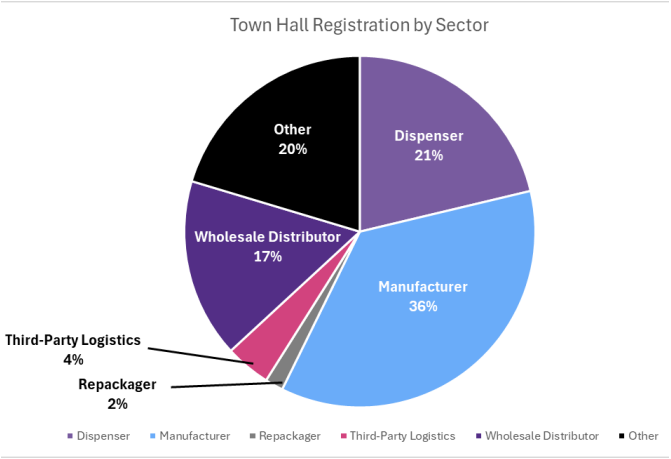
FDA-PDG Town Hall: Progress Toward End of Manufacturer Exemption

SUMMARY

PDG's role in the town hall summarized in this report was primarily facilitation of the exchange of information among industry stakeholders and FDA. This report summarizes the comments and recommendations of *participants* in the town hall. PDG TAKES NO POSITION ON THE COMMENTS OR RECOMMENDATIONS MADE BY THOSE PARTICIPANTS AND SUMMARIZED IN THIS REPORT.

Throughout 2025, the Partnership for DSCSA Governance (PDG) and FDA are hosting three virtual, public town halls, each scheduled two months prior to the expiration of the Drug Supply Chain Security Act (DSCSA) phased exemption periods for trading partners.[1] Each town hall is preceded by a meeting with FDA and PDG membership. The first set of these meetings occurred on March 25 and 26, 2025. This report summarizes major themes and findings from both meetings. More than 1,300 individuals registered for the town hall, representing the broad diversity of the supply chain and related stakeholders, as shown in the chart below.

This town hall was designed to provide a forum for trading partners across the supply chain and other interested parties to share information on continued implementation of DSCSA interoperability and areas of remaining concern, with a focus on the **impacts of the upcoming (May 27, 2025) expiration of the exemption for eligible manufacturers and repackagers**. The town hall provided interested parties with an opportunity to share information to support all trading partners in achieving **enhanced product tracing together**.



[1] In October 2024, FDA published its DSCSA Exemptions from Section 582(g)(1) and Other Requirements of the FD&C Act for Certain Trading Partners, which exempts eligible authorized trading partners from certain DSCSA requirements. These phased exemption periods provide trading partners with additional time as they work towards full DSCSA implementation while maintaining patient access to medicines. The exemption periods follow the FDA-issued stabilization period, which ended on November 27, 2024. The exemption periods expire on different dates based on sector, as follows:

- **Eligible Manufacturers and Repackagers** – May 27, 2025.
- **Eligible Wholesale Distributors** – August 27, 2025.
- **Eligible Dispensers with 26 or more full-time employees** – November 27, 2025.

Collectively, these exemptions are referred to as "the phased exemption periods" in this document.
In addition to the phased exemption periods, **dispensers with 25 or fewer full-time employees** are also exempt until November 27, 2026.

During the town hall, participants shared the **substantial progress** that has been made since the stabilization period, reiterated the **significant value the phased exemption periods have provided** in supporting continued DSCSA implementation, and emphasized the importance of **relationships with trading partners**. Stakeholders also provided important detail on the ongoing role of **continuous improvement**. **The majority of manufacturers engaged in the town hall expressed confidence in their ability to be ready for the end of the exemption period for eligible manufacturers and repackagers on May 27, 2025.**

The phased exemption periods were necessary to ensure continued access to medicines, and they are proving highly valuable to trading partners as organizations work towards full enhanced traceability.

Participants in the town hall confirmed that the phased exemption periods have provided, and continue to provide, trading partners across the supply chain with critical additional time to **refine and strengthen their processes** for enhanced traceability and mitigate potential risks to public health. Trading partners highlighted multiple ways in which they have been able to **successfully use the phased exemption periods** so far to progress toward enhanced traceability:

- **Data connections** have been established and tested with the majority of remaining manufacturers. Participating wholesale distributors reported that connections for exchange of serialized transaction information (TI) have been successfully established except for a small minority of manufacturers, and many of the remaining manufacturer connections are due to specific considerations (*e.g.*, a relatively new manufacturer entering the market) rather than general disengagement. The efficiency of establishing new connections, where needed, has also improved.
- Trading partners have used, and continue to use, the period to **train their employees** and afford them the opportunity to learn in a production environment. Participants highlighted the important human role in data management, as well as the complexity and time it takes to onboard and train personnel.
- Trading partners have improved, and continue to improve, systems, process, and collaboration to **substantially increase the amount of TI and data being exchanged** and to work more rapidly to **identify, understand, and resolve data errors and discrepancies** when they occur. The additional time has also provided organizations and their staff an opportunity to identify the data issues that are occurring and adopt preventive actions to limit their recurrence.

As trading partners approach the end of the manufacturer exemption period on May 27, 2025, it is clear that the phased exemption periods are allowing trading partners to make **significant strides toward robust and accurate exchange of serialized TI**, and trading partners are poised to continue making progress throughout the remainder of the phased exemption periods. The phased exemption periods are helping trading partners improve their systems and processes for enhanced drug distribution security, promote access to medicines, improve the resiliency of the pharmaceutical supply chain, and protect the country's public health.

Cross-sector communication and collaboration have been instrumental in the progress made to date and will remain critical to continued improvement and refinement of DSCSA implementation efforts.

Trading partners emphasized the importance of **building, leveraging, and maximizing relationships** with their trading partners. Established relationships and enhanced communication across the supply chain are essential to improving data quality, and these improvements have positively impacted the progress made throughout the stabilization and phased exemption periods.

Continued process improvement depends on regular communication and collaboration. For example, when a discrepancy in serialized TI data is identified, the processes needed to understand the cause of the data discrepancy and how it should be resolved are highly dependent on trading partner collaboration and communication. **Open lines of communication and regular feedback** are needed to quickly investigate, respond, and resolve issues that arise.

During the town hall, manufacturers recognized that data quality starts with them and must be supported by their own well-controlled, risk-based processes for data management. However, manufacturers also emphasized that their ability to continuously improve their systems and processes is dependent on **feedback from downstream partners** upon their receipt and use of that data. Without such cross-sector, bidirectional collaboration, manufacturers cannot fully understand their internal or external gaps. Consistent and proactive feedback and sharing of data reports are important to enable upstream trading partners to improve their systems and processes, which will benefit downstream trading partners and, ultimately, the security of the supply chain itself.

Substantial progress has been made across the supply chain, and manufacturers expressed confidence in their ability to comply with the expiration of the exemption for eligible manufacturers without significant disruption to patient access.

Manufacturers participating in the town hall reported that their **connections for exchange of serialized TI are largely established and stabilized, the volume of data transmission is high, and the quality of serialized TI data continues to steadily improve**. PDG presented survey results confirming this increase in data transmission. In May 2024, 49 of 62 manufacturer respondents were providing serialized TI data for more than 80 percent of their transacted product, and only 37 of 62 respondents were providing serialized TI data for more than 95 percent of their transacted product. In March 2025, 34 of 35 manufacturer respondents were providing serialized TI data for more than 80 percent of their transacted product, and 30 of 35 respondents were providing serialized TI data for more than 95 percent of their transacted product. Manufacturers—in collaboration with their trading partners—have focused on continually improving their systems and processes during the phased exemption period, and **no manufacturers participating in the town hall expressed a need to further extend the exemption for eligible manufacturers**. Instead, manufacturers are shifting into a refinement stage, with a focus on improving rapid data issue resolution as they receive feedback from downstream partners.

The confidence expressed by participating manufacturers was validated by downstream partners who reported a significant increase in the volume and quality of serialized TI data being received from manufacturers. Based on a survey of a subset of its members, the Healthcare Distribution Alliance reported that the percentage of product that could experience disruption due to inaccurate or missing

data from upstream trading partners has appeared to decrease from roughly 25 percent in September 2024 to roughly 9 percent in February 2025. Wholesale distributor participants in the town hall also noted that the lack of connections and/or complete disengagement by certain manufacturers that had previously been experienced has not been a significant issue during the phased exemption period.

While data discrepancies remain, and continued improvement is needed, **the process for managing discrepancies has significantly improved, and the types and scope of discrepancies are narrowing.** Through dedicated efforts and the tremendous cross-company and cross-sector collaboration noted above, trading partners have refined their exceptions handling processes and are now often able to resolve data discrepancies more quickly and more efficiently. In parallel, and because of those efforts, the data-related challenges faced by all levels of the supply chain are increasingly shifting from larger, higher-impact data issues to smaller volumes of product in less common and more complex distribution channels. For example, the prevalence of master data issues that impact distribution of large volumes of product have significantly decreased, and trading partners are increasingly focusing on narrow one-off exemptions and difficult channels, such as 340B replenishment product and drop shipments.

Continuous improvement of systems and processes to support data quality and information exchange is occurring, and stakeholders anticipate it will continue to occur for an extended period.

Stakeholders, including FDA, reinforced a key point from the May 2024 PDG-FDA Joint Public Meeting: **managing expected data imperfections is a key to success**. 100 percent accuracy of serialized TI data is not attainable, even in the long-term, given the volume and granularity of transactions and data exchange required by the DSCSA. Recognizing this reality, trading partners reported significant progress in two critical aspects of managing expected imperfections:

1. Trading partners have significantly progressed in **establishing well-controlled, risk-based processes for managing the expected errors** (*i.e.*, exceptions) in serialized TI data.
2. Manufacturers, as well as other trading partners, have undertaken **continuous improvement efforts**—ongoing processes to analyze data quality, identify the root causes of errors, and make incremental changes to systems and processes to address those root causes—needed to progress toward the maximum achievable level of accuracy.

Manufacturers emphasized that, while progress in these respects has been significant, **additional progress and refinement is expected to continue beyond the expiration of the exemption for eligible manufacturers**. For example, some stakeholders emphasized the **importance of staffing and training** as a crucial business strategy to ensuring ongoing compliance with DSCSA requirements. The value of trained and sophisticated staff to work on data quality and information exchange is significant and will become increasingly important as the subsequent exemption periods end in 2025.

Stakeholders identified remaining potential risks, but those risks are generally difficult to confirm or address until the subsequent phases of the exemption period are reached.

Town hall attendees identified several *potential* risks that remain, but ultimately, the scope and impact of those risks can only be fully understood once manufacturers move beyond the current exemption period and into full compliance. Potential remaining risks identified through the town hall included:

- Significant progress has been made stabilizing the quality of data based on *inbound* receipt of manufacturer data by the manufacturer's direct trading partners. However, **more granular visibility of data quality at the package level** (*i.e.*, serial number level) will be achieved as those direct trading partners further transact the product and manage the data *outbound*. Until the supply chain advances through the future phases of the exemptions, it is difficult to predict whether further data quality issues will be uncovered and how significant they will be.
- The increased visibility and feedback on data quality noted above will also inform **appropriate staffing levels**, and the ability to meet those staffing needs is difficult to predict until that time.
- Continued progress through the phased exemption periods is enabling manufacturers and wholesale distributors to more strictly enforce the DSCSA's prohibition on **returning saleable product** to a trading partner other than the direct trading partner from whom it was purchased. Additional education and awareness of this requirement among dispensers is needed, and a lack of awareness could significantly disrupt current product return processes.
- While they represent a small volume of product in the full supply chain and progress has been significant, there are outstanding pockets of **disengaged or unprepared manufacturers.** It is anticipated that those manufacturers will pursue **individual company-specific waivers or exemptions**, but managing those waivers and exemptions is a burden on the full supply chain. The volume and scope of such waivers and requests *could* create potential risks to product access and public health.

While each of these potential risks *could* negatively impact product access and public health, their actual impact will only be understood by continuing to advance through the phased exemption period.

About 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). Through our public-private partnership with FDA, we collaborate to develop, advance, and sustain an effective and efficient model for interoperability.

PDG 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 United States.

For additional information, visit www.DSCSAgovernance.org.