

Partnership for DSCSA Governance (PDG)

DSCSA Implementation Survey Results

Survey Conducted: May 23, 2024–June 10, 2024; February 26, 2025–March 12, 2025; May 28, 2025–June 11, 2025

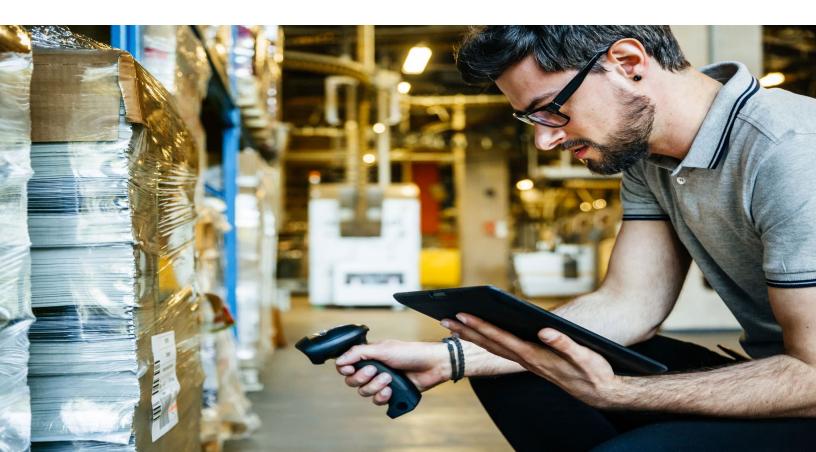


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EXECUTIVE SUMMARY

The Drug Supply Chain Security Act (DSCSA) required drug manufacturers, wholesaler distributors, dispensers, and repackagers (collectively, "trading partners") to implement secure, electronic, interoperable systems and process for enhanced product tracing by November 27, 2023. In August 2023, FDA published its <u>Compliance Policy, Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act</u>, which established a one-year stabilization period to afford trading partners the necessary flexibility to maintain patient access to medicines while maturing and stabilizing their interoperable systems and processes.

In October 2024, FDA published its <u>DSCSA Exemptions from Section 582(g)(1)</u> and <u>Other Requirements of</u> 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.

In addition to the phased exemption periods, dispensers with 25 or fewer full-time employees are also <u>exempt</u> until November 27, 2026.

In effort to better understand trading partner progress toward each of those deadlines and to inform any necessary action, the Partnership for DSCSA Governance (PDG) surveyed trading partners to better understand the industry's progress in achieving interoperable data exchange and traceability during the stabilization period. The survey was issued to trading partners in three iterations:¹

- May 23, 2024, to June 10, 2024;
- February 26, 2025, to March 12, 2025; and
- May 28, 2025, to June 11, 2025.

This report provides the results of these surveys. Each survey question is analyzed in two ways and presented in two graphs. The first graph summarizes the results from all three iterations of the survey. Because response rates were variable across the iterations of the survey, the second graph presents the responses of only those organizations who responded to <u>each of the</u> June 2024, March 2025, and June 2025 surveys, providing a control group to present clearer trends across consistent respondents.

The information in this report is organized into four sections:

- Respondent Demographics,
- Data Exchange Rates,
- Assessing Data Quality and Accuracy, and
- Implementation of Verification and Tracing.

¹ PDG also surveyed trading partners from October 14, 2024 to October 30, 2024, and that data has been included in prior PDG survey reports. However, because the October 2024 response rates were low, they have been omitted from this particular report.

DSCSA IMPLEMENTATION SURVEY RESULTS

Respondent Demographics

Graph 1 shows the demographics of participants for each survey occurrence. 138 trading partners responded to the June 2024 survey.

- Manufacturers were the most frequent respondents, representing 62 out of 138 respondents (45%). Of the 62 Manufacturers, more than 45% have annual revenue of more than \$1 billion.
- Pharmacies represented a total of 42 out of 138 respondents (30%). Pharmacy respondents also represented a diversity of organization sizes.
- Wholesale Distributors had a total of 26 (19%) of respondents. Wholesale distributor respondents also represented a diversity of organization sizes.
- Third-Party Logistics Provider had four (3%) respondents.
- Three repackagers responded (2%).
- One reverse distributor responded to the survey (1%).

79 trading partners responded to the March 2025 survey.

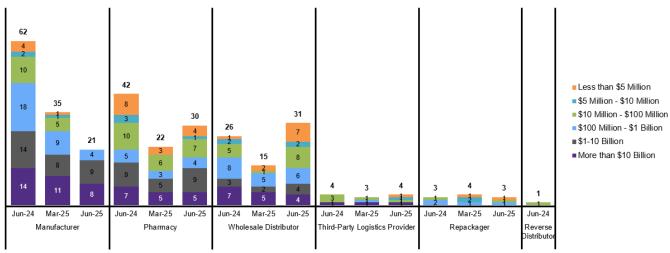
- Manufacturers again accounted for the most respondents with 35 respondents (44%). The majority (54%) of manufacturers have an annual revenue of more than \$1 billion.
- 22 pharmacies responded to the survey (28%), with a diversity of business sizes.
- 15 wholesale distributors responded to the March 2025 survey (19%). Nearly half (47%) have an annual revenue of more than \$1 billion.
- Three third-party logistics providers responded to this survey (4%).
- Four repackagers responded to this survey (5%).
- No reverse distributors responded to the March 2025 survey.

89 trading partners responded to the June 2025 survey.

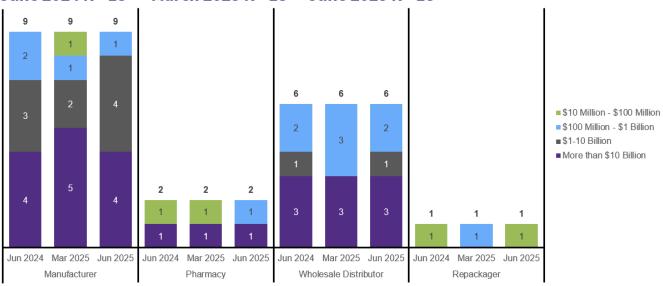
- Manufacturers made up 21 out of the 89 respondents (24%), a notable decrease from prior surveys. A majority of these manufacturers (81%) had an annual revenue over \$1 billion.
- 30 out of the 89 respondents were pharmacies (34%). Close to half of these pharmacies (47%) have an annual revenue over \$1 billion.
- Wholesale distributors had the highest number of respondents, with 31 respondents out of 89 (35%). This was a notable increase from prior surveys.
- Third-party logistics providers accounted for 4 respondents (5%).
- Three repackagers responded (3%).

Graph 2, below, reflects only the 18 organizations who responded to <u>each of the</u> June 2024, March 2025, and June 2025 surveys. This control group represents approximately one-fifth of the overall survey respondents. Across the sectors, the control group skews significantly toward manufacturers and wholesale distributors with light response rates among pharmacies and repackagers.

Graph 1 (All Respondents) Number of Respondents by Sector and Size June 2024 N= 138 March 2025 N= 79 June 2025 N= 89



Graph 2 (Control Group) Number of Respondents by Sector and Size June 2024 N= 18 March 2025 N= 18 June 2025 N= 18



THE FOLLOWING QUESTIONS QUANTIFY THE FREQUENCY OF DATA EXCHANGE OCCURRING AMONG TRADING PARTNERS.

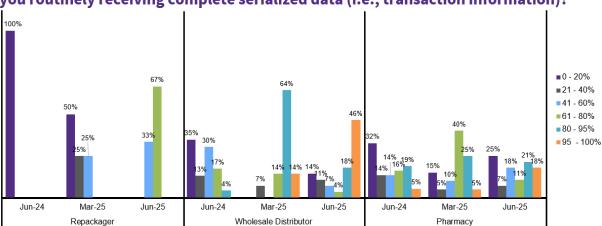
When Purchasing Product: For approximately what percent of your <u>suppliers</u> are you routinely receiving complete serialized data (i.e., transaction information)?

The graphs below provide insight into the percentage of <u>*suppliers*</u> from whom repackagers, wholesale distributors, and pharmacies are routinely receiving complete serialized data from their suppliers. The percent of suppliers (i.e., entities) that are providing data is a proxy for entity-level readiness.

Graph 3 shows repackagers exhibited a steady increase in data received from June 2024 to June 2025. Wholesale distributor responses indicate continued progress in inbound data receipt. In June 2024, no wholesaler respondents were receiving complete serialized data from 95-100% percent of their suppliers, but 14% of wholesaler respondents were receiving complete serialized data from 95-100% of their suppliers in March 2025 and 46% reported such rates in June 2025. This trend is even more significant among the control group (Graph 4).

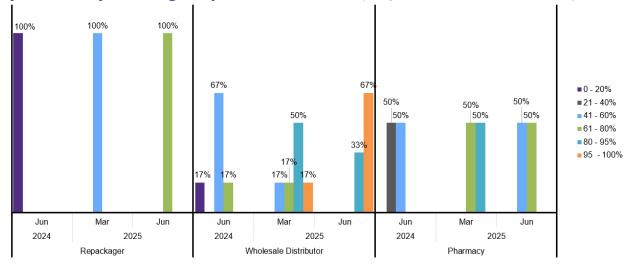
It should be noted that an increased number of wholesaler respondents (7% in March 2025 and 25% in June 2025) reported receiving complete data from less than 40% of their suppliers. However, this increase is likely due to the significant increase in wholesaler respondents in June 2025, as all respondents in the control group (Graph 4) reported receiving complete data from 80-100% of their suppliers in both the March 2025 and June 2025 surveys.

Pharmacy respondents also reported steady increases in data receipt across all survey instances. Only 24% of pharmacies reported receiving complete data from 80-100% of their suppliers in June 2024; that figure increased to 39% in June 2025.



Graph 3 (All Respondents) When Purchasing Product: From approximately what percent of your suppliers are you routinely receiving complete serialized data (i.e., transaction information)?

Graph 4 (Control Group) When Purchasing Product: From approximately what percent of your suppliers are you routinely receiving complete serialized data (i.e., transaction information)?



When Purchasing Product: For approximately what percent of *product* you purchase are you routinely receiving complete serialized data (i.e., transaction information)?

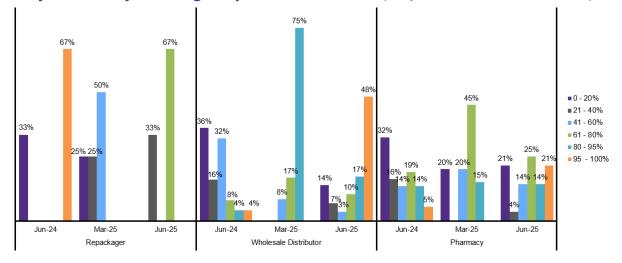
Graphs 5 and 6 provide insights on the percent of *product* (as opposed to suppliers) for which trading partners were routinely receiving complete serialized data. Unlike the prior graphs that focused on entity-level (supplier) readiness, these graphs focus on the volume of product accompanied by complete data, which serves as a proxy for overall supply chain readiness.

Graph 5 shows a marked improvement in inbound data rates among wholesaler respondents, with the vast majority of respondents reporting that data was being received for 80-95% of product in March 2025, and a significant plurality reporting data being received for 95-100% of product in June 2025. That same significant increase in wholesalers reporting data being received for 95% or more of product was borne out in the control group (Graph 6).

Graph 5 also demonstrates similar continued progress at the top ends for pharmacies. No pharmacy respondents were receiving complete serialized data for 95-100% of product in March 2025, but 21% reported receiving data 95-100% of product just three months later in June 2025.

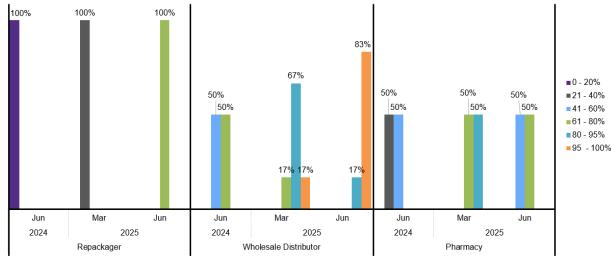
Graph 5 (All Respondents)

When Purchasing Product: For approximately what percent of product you purchase are you routinely receiving complete serialized data (i.e., transaction information)?



Graph 6 (Control Group)

When Purchasing Product: For approximately what percent of product you purchase are you routinely receiving complete serialized data (i.e., transaction information)?

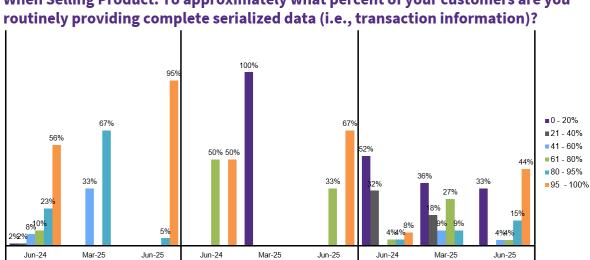


When Selling Product: To approximately what percent of your *customers* are you routinely providing complete serialized data (i.e., transaction information)?

This question, and the following question, seek to understand the rate of *outbound* data being provided by the seller of product in a transaction. Graphs 7 and 8 represent the percentage of *customers* to whom manufacturers, repackagers, and wholesale distributors routinely provide complete serialized data.

As expected with the passing of the May 27, 2025 expiration of the exemption for manufacturers, nearly all (95%) of manufacturer respondents report that they are sending outbound serialized data to 95-100% of their customers. All manufacturers in the control group (Graph 8) reported that level of data exchange.

Wholesaler respondents also reported marked improvements in the percent of customers to which they are routinely providing complete serialized data. As of March 2025, less than 1 in 10 wholesalers were sending complete serialized data to 80% or more of their customers, and by June 2025 nearly 6 in 10 wholesaler respondents were sending complete serialized data to 80% or more of their customers. The improvements were even more significant among the control group (Graph 8) with all wholesalers in the control group now reporting they are sending complete serialized data to 80% or more of their customers.



Graph 7 (All Respondents) When Selling Product: To approximately what percent of your customers are you

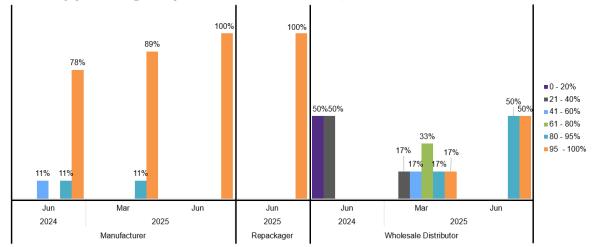
Graph 8 (Control Group)

Manufacturer



Repackager

Wholesale Distributor



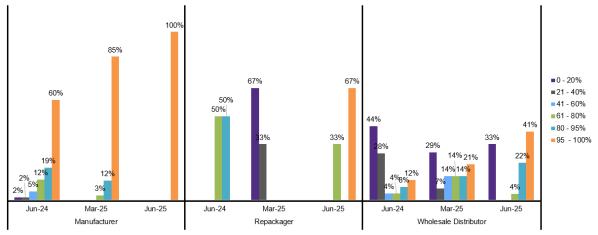
When Selling Product: For approximately what percent of *product* you sell are you routinely providing complete serialized data (i.e., transaction information)?

This question highlights the rate of data exchange as a percentage of *product* sold (as opposed to percentage of *customers*). Responses indicated a notable increase in outbound data exchange among both manufacturers and wholesalers.

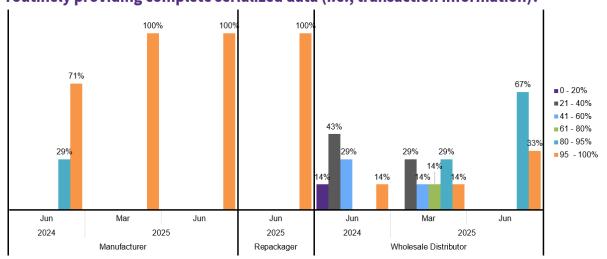
Similar to the prior graphs, Graphs 9 and 10 reflect the move into a full-compliance environment among manufacturers, with all responding manufacturers indicating they are sending complete serialized data for 95-100% of the product they sell.

Wholesaler respondents also reported notable improvements in the amount of outbound data they are sending. Twice as many respondents reported sending complete serialized data for 95-100% of product in June 2025 than in March 2025. However, one-third of wholesaler respondents continue to report they are providing complete serialized data for less than 20% of the product they sell. These improvements are also reflected in the control group (Graph 10), though the control group does not include the same tranche of respondents reporting low rates of data exchange.

Graph 9 (All Respondents) When Selling Product: For approximately what percent of product you sell are you routinely providing complete serialized data (i.e., transaction information)?



Graph 10 (Control Group) When Selling Product: For approximately what percent of product you sell are you routinely providing complete serialized data (i.e., transaction information)?



THE FOLLOWING QUESTIONS ASSESS TRADING PARTNERS' ADOPTION OF SYSTEMS AND PROCESSES TO ACTIVELY ASSESS THE QUALITY AND ACCURACY OF DATA.

When Purchasing Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you receive?

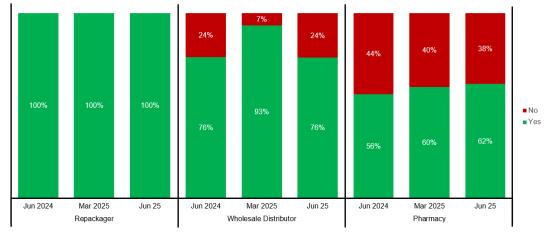
Graphs 11 and 12 represent the extent to which trading partners are actively assessing the quality and accuracy of serialized data they *receive*. This is critical because continued improvement of data accuracy and reliability is necessary for stabilization.

Overall, wholesaler respondents (Graph 11) reported a dip in practices of assessing data quality and accuracy, which likely reflects the increased number of respondents to the June 2025 survey. Among the control group, these practices were flat with 83% of control group (Graph 12) respondents reporting they are actively assessing the quality and accuracy of data they receive.

The practice of assessing quality and accuracy of inbound data was similarly flat among pharmacies, with modest increase among all respondents (Graph 11) and flat rates from March 2025 to June 2025 among control group respondents (Graph 12).

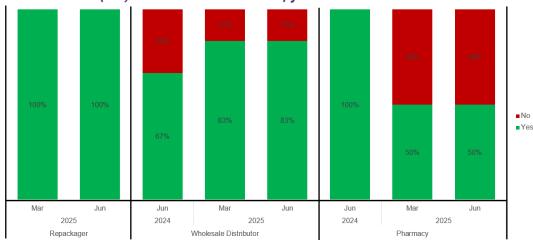
Graph 11 (All Respondents)





Graph 12 (Control Group)

When Purchasing Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you receive?

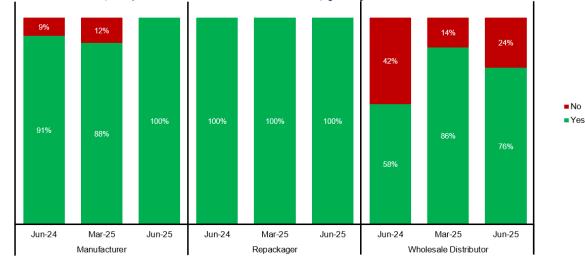


When Selling Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you provide?

Graphs 13 and 14 represent the extent to which trading partners are actively assessing the quality and accuracy of serialized data they *provide* (i.e., outbound data).

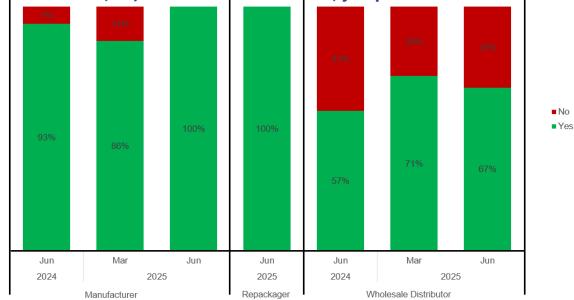
Manufacturers and repackagers exhibited significant and consistent progress, with all manufacturer and repackager respondents now reporting they are actively assessing the quality and accuracy of serialized data they provide. Wholesale distributors show slightly inconsistent results, with the highest rate of 'yes' responses provided in March 2025 across all respondents (Graph 13) and the control group (Graph 14).

Graph 13 (All Respondents) When Selling Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you provide?



Graph 14 (Control Group)

When Selling Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you provide?

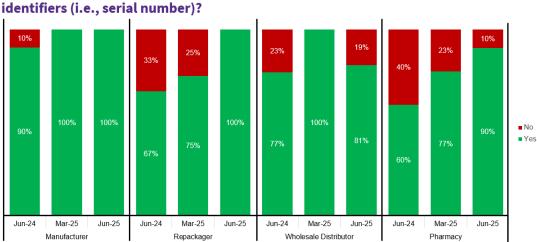


THE FOLLOWING QUESTIONS ASSESS TRADING PARTNERS' ADOPTION OF SYSTEMS AND PROCESSES TO VERIFY PRODUCT IDENTIFIERS AND TRACE PRODUCT.

Do you have interoperable electronic systems and processes to verify product identifiers (i.e., serial number)?

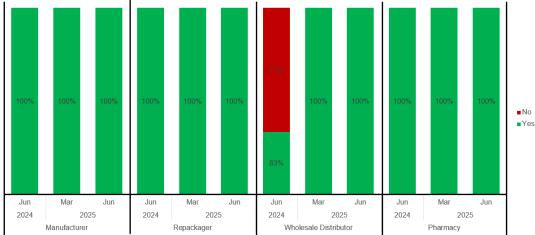
The DSCSA requires trading partners to implement electronic interoperable systems and processes for verification of product at the package level, including the serial number. This question highlights the progress of manufacturers, repackagers, wholesale distributors, and pharmacies in implementing such systems and processes.

Here again, all manufacturer and repackager respondents now report having interoperable electronic systems and processes to verify product identifiers. Pharmacies are steadily increasing in their implementation of such systems and processes, with only 10% responding 'no' to this question in June 2025. Wholesale distributors responses (Graph 15) are likely skewed by the increased number of respondents in June 2025, but among the control group (Graph 16), all wholesaler respondents report implementation of interoperable systems and processes for verification of product identifiers.



Graph 15 (All Respondents) Do you have interoperable electronic systems and processes to verify product identifiers (i.e., serial number)?



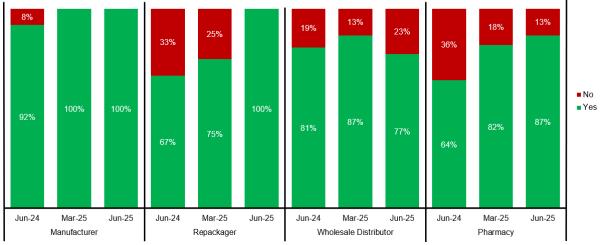


Do you have interoperable electronic systems and processes to facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer (i.e., trace product)?

The DSCSA also requires trading partners to implement electronic interoperable systems and processes to trace product back to the manufacturer.

Responses track closely with the implementation of systems and process for verification. All manufacturer and repackager respondents report having implemented interoperable systems and processes to trace product, and pharmacy respondents show continued progress in this regard. Trends among all wholesaler respondents (Graph 17) are again likely skewed by the increased response rate in June 2025, but among the control group (Graph 18), implementation of interoperable systems and processes for tracing has continued to increase as of June 2025.

Graph 17 (All Respondents) Do you have interoperable electronic systems and processes to facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer (i.e., trace product)?



Graph 18 (Control Group)

Do you have interoperable electronic systems and processes to facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer (i.e., trace product)?

