

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 August 27, 2025—September 10, 2025

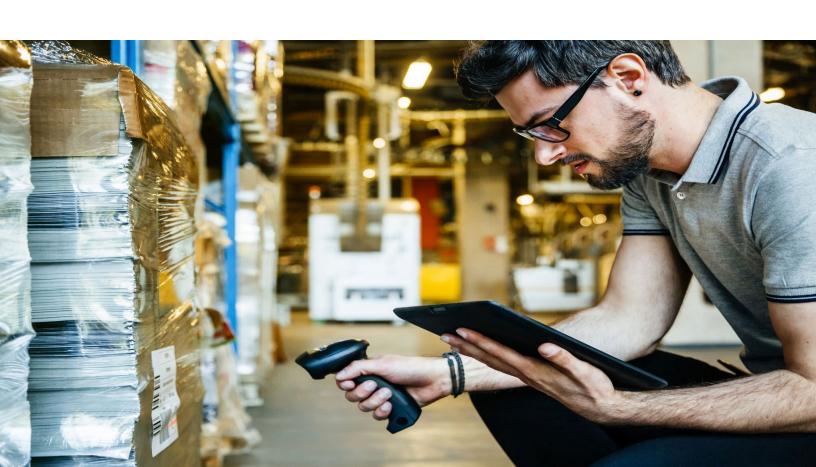


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EXECUTIVE SUMMARY

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 Compliance Policy, Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act, 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 the FD&C Act for Certain Trading Partners</u>, 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 <u>FDA-issued stabilization period</u>, 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 exempt 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 four iterations:

- May 23, 2024, to June 10, 2024;
- February 26, 2025, to March 12, 2025;
- May 28, 2025, to June 11, 2025; and
- August 27, 2025, to September 10, 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 four 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, June 2025, and September 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 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.

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.

110 trading partners responded to the September 2025 survey.

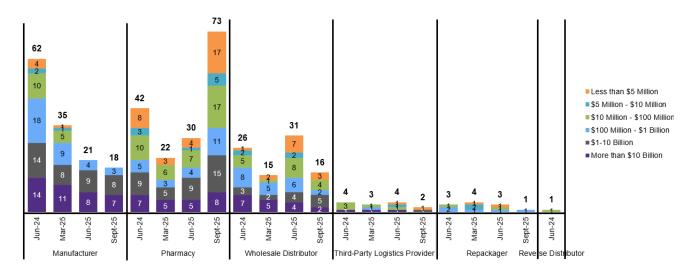
- There was a significant uptick in pharmacy responses, representing the highest rate of respondents and accounting for 73 out of 110 (66%). 32% of these pharmacies had annual revenues over \$1 billion. Smaller pharmacies with an annual revenue under \$10 million were the highest rate of respondents within the sector, making up 30%.
- Manufacturing accounted for 18 respondents, the lowest response rate from this sector out of all instances of the survey (16%). The majority of these manufacturers (83%) had an annual revenue of more than \$1 billion.
- 16 wholesale distributors responded to the September 2025 survey (15% of respondents). Just under half of these wholesale distributors (44%) had an annual revenue over \$1 billion.

Graph 2, below, reflects only the 15 organizations who responded to <u>each of the</u> June 2024, March 2025, June 2025, and September 2025 surveys. This control group represents approximately 14% 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

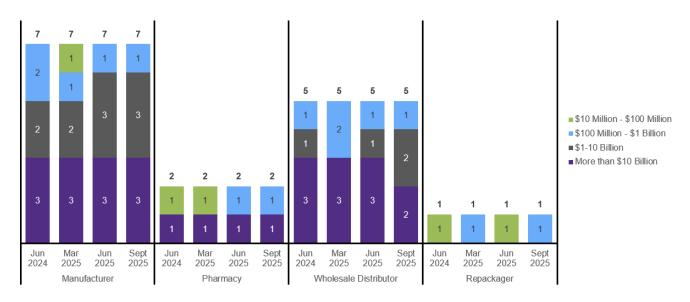
June 2024 N= 138 March 2025 N= 79 June 2025 N= 89 September 2025 N= 110



Graph 2 (Control Group)

Number of Respondents by Sector and Size

June 2024 N= 15 March 2025 N= 15 June 2025 N= 15 September N= 15



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 data below provides 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 <u>entity-level</u> readiness.

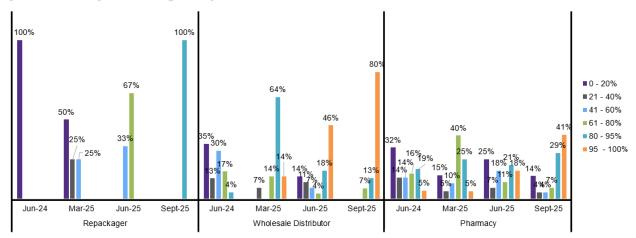
Graph 3 shows that across all sectors, the percentage of suppliers routinely providing complete serialized data has increased steadily since June 2024. This is noteworthy considering June 2024 and September 2025 had the highest number of respondents out of all four iterations of the survey. This is also informed by the fact that multiple sectors' exemptions had expired by September 2025, driving high rates of readiness/compliance.

In September 2025, wholesale distributors continued to show great progress. Just 4% of wholesalers were receiving complete serialized data from 80% or more of their suppliers in June 2024, and in September 2025, 93% were routinely receiving complete data from 80% or more of their suppliers. Pharmacies have seen similar, but less dramatic, increases in data received. 24% of June 2024 pharmacy respondents reported routinely receiving complete data from 80% or more of their suppliers, and by September 2025, that increased to 70% of pharmacy respondents indicating they routinely received data from 80% or more of their suppliers.

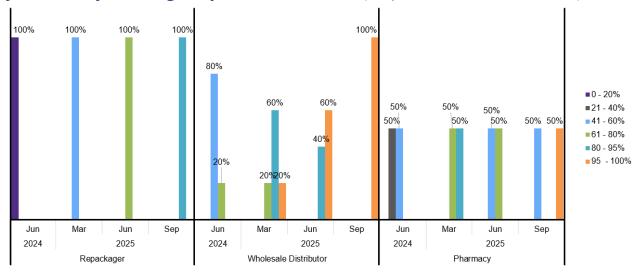
The control group (graph 4) shows a consistent steady increase in complete serialized data received from suppliers; however, the pharmacy control group only includes two pharmacies, which is too limited to draw clear conclusions.

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
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 <u>product</u> you purchase are you routinely receiving complete serialized data (i.e., transaction information)?

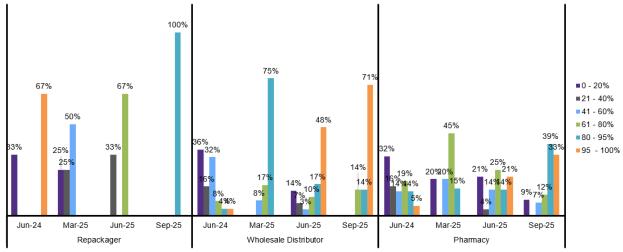
Graphs 5 and 6 provide insight on the percent of *product* (as opposed to suppliers) for which trading partners were routinely receiving complete serialized data. Unlike the prior graphs that focused on entity-level (supplier) readiness, these graphs focus on the volume of product accompanied by complete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

Wholesale distributors and pharmacies again reported significant increases in the percent of product for which they are routinely receiving complete serialized data for. In just three months, the number of wholesalers reporting that they are routinely receiving complete serialized data for 95% or more of product they purchased increased from 48% to 71% of respondents. Similarly, the number of pharmacies reporting that they are routinely receiving complete serialized data for 80% or more of product they purchased more than doubled, increasing from 35% in June 2025 to 72% of pharmacy respondents in September 2025.

Again, the control group in Graph 6 supports the upward trend indicated across all respondents in Graph 5.

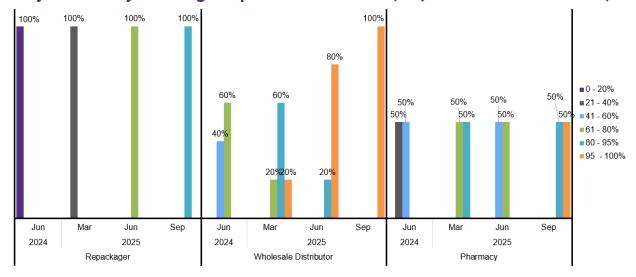
Graph 5 (All Respondents)

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 <u>customers</u> 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.

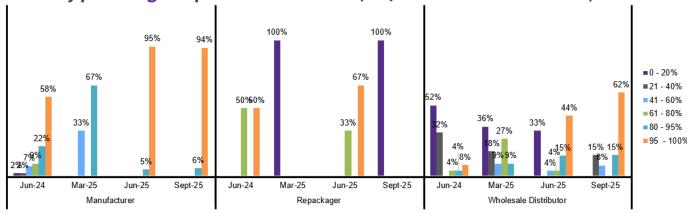
Across all respondents (Graph 7), manufacturer respondents continue to indicated they are consistently providing complete data to nearly all customers.

Wholesale distributors continue to improve their rate of outbound data as well. In the most recent survey, 77% of wholesaler respondents indicated they are routinely providing complete serialized data to 80% or more of their customers, up from 59% of wholesaler respondents three months prior.

The control group (Graph 8) supports the trends in graph 7. Manufacturers and wholesale distributors both showed consistent increases throughout 2025.

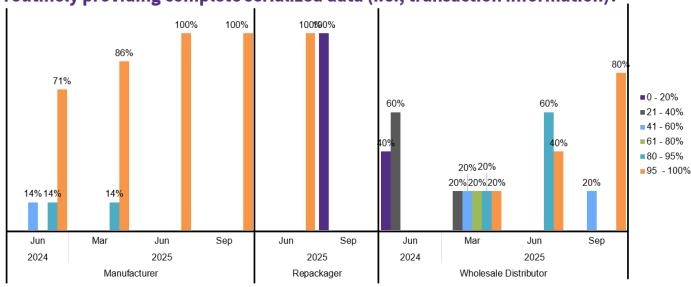
Graph 7 (All Respondents)

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



Graph 8 (Control Group)

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



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

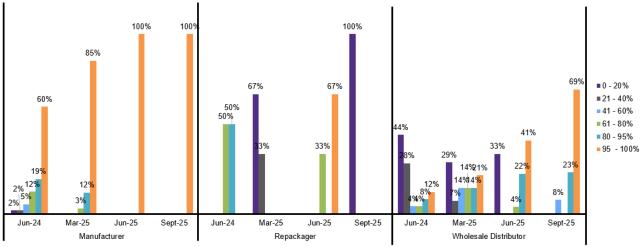
This question highlights the rate of data exchange as a percentage of *product* sold (as opposed to percentage of *customers*). Responses indicated a notable increase in outbound data exchange among both manufacturers and wholesalers.

Once again, Graph 9 shows manufacturers are consistently providing complete serialized data for product they sell, with all respondents indicating they are constantly doing so. Wholesale distributors also continue to report strong increases in data provided throughout each survey instance. In just the last three months, wholesaler respondents indicating they are providing complete serialized data for 95% or more of their product has increased from approximately 4 in 10 respondents (June 2025) to 7 in 10 respondents (September 2025).

The control group (Graph 10) continues to support the overall results and trends, with manufacturers and wholesale distributors reporting consistently high levels of data exchange, increasing throughout each instance of the survey.

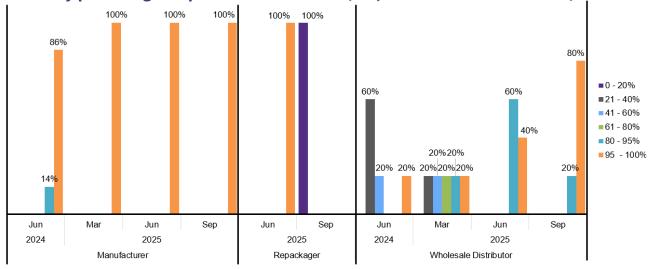
Graph 9 (All Respondents)

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.

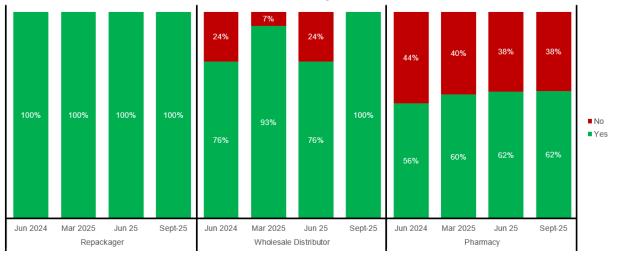
When Purchasing Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you receive?

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.

All repackager and wholesale distributor respondents in the most recent survey (September 2025) report that they are actively assessing the quality and accuracy of serialized data they receive (as shown in graph 11). Dispenser responses have been quite consistent across all survey iterations, with approximately 6 in 10 pharmacy respondents indicating they are actively assessing inbound data quality and accuracy and 4 in 10 indicating they are not doing so.

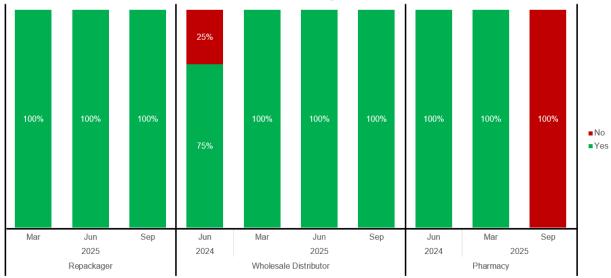
Graph 11 (All Respondents)

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



Graph 12 (Control Group)

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



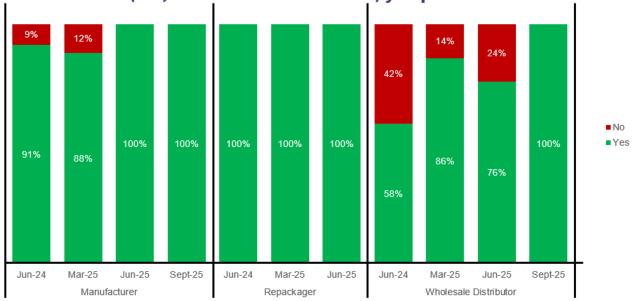
When Selling Product: Are you actively assessing the quality and accuracy of serialized data (i.e., transaction information) you provide?

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).

Responses in the most recent iteration of the survey (September 2025) are very strong, with 100% of respondents across all sectors actively reporting that they are actively assessing the quality and accuracy of serialized data they provide to their customers.

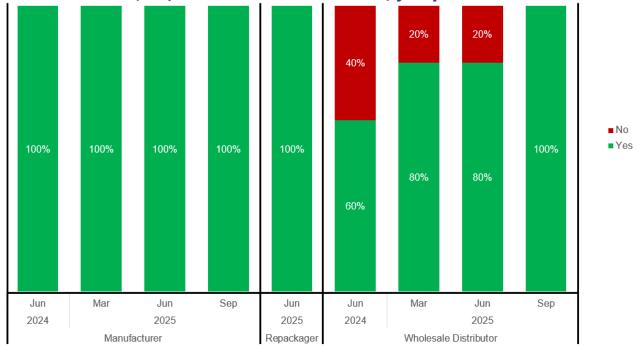
Graph 13 (All Respondents)

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.

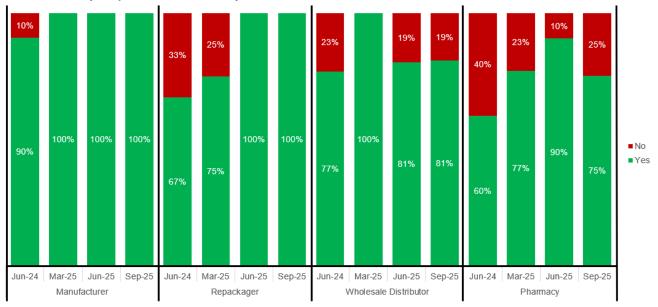
Do you have interoperable electronic systems and processes to verify product identifiers (i.e., serial number)?

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.

Graph 15 shows a significant majority of respondents in every sector have interoperable systems and processes to verify product identifiers throughout each survey occurrence. All manufacturer respondents report they implemented electronic systems and processes to respond to verification requests. A lower portion of wholesale distributor and pharmacy respondents report having interoperable electronic systems and process to verify product identifiers, without clear significant increases in those rates over time.

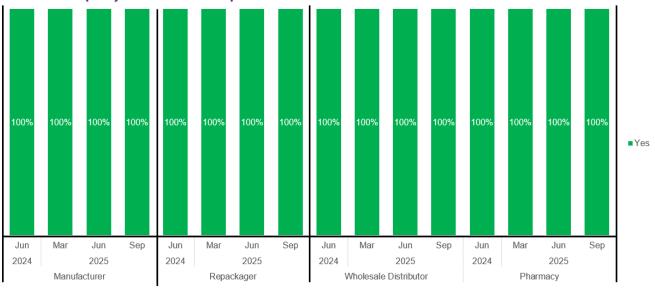
Graph 15 (All Respondents)

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



Graph 16 (Control Group)

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



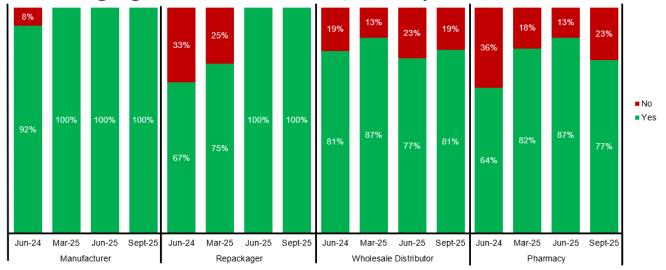
Do you have interoperable electronic systems and processes to facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer (i.e., trace product)?

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

Responses were very consistent with those related to implementation of interoperable electronic systems and process to verify product identifiers. All manufacturer respondents in the latest survey report having implemented interoperable electronic systems and processes for tracing. Most, but not all, wholesale distributor and pharmacy respondents indicated they have implemented interoperable electronic systems and processes to trace product.

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)?

