



Manufacturer Serialization Readiness Survey

Executive Summary

Introduction

In 2013, the Drug Supply Chain Security Act (DSCSA) was enacted. The DSCSA preempted a 50-state patchwork of pedigree requirements to create one federal traceability solution for prescription medicines.

To aid in implementation of DSCSA's requirements, the Healthcare Distribution Alliance (HDA) has been conducting pilots on the 2019 saleable returns requirements and other activities to help prepare manufacturers and distributors for product serialization and data sharing deadlines. The next milestone is quickly approaching and, as mandated by the law, by **November 27, 2017, all manufacturers will need to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce.**

§582(b)(2)(A). However, on June 30, 2017, the FDA issued a Draft Guidance¹ announcing that the agency intended to exercise enforcement discretion and would not take action against manufacturers that, after November 27, 2017 but before November 27, 2018, introduce in a transaction into a commerce a product that is not serialized.

A Manufacturer Serialization Readiness Survey was conducted by the HDA Research Foundation to provide HDA and its members with unbiased, objective data about manufacturers' current readiness to meet the DSCSA's product serialization requirements in 2017 and beyond, and when distributors can expect to begin receiving serialized product and associated data.

The Foundation is most grateful to all who participated in the year's survey and to our sponsors who made it possible - [LSPediA](#), [TraceLink, Inc.](#), and [WDSrx – Woodfield Distribution, LLC](#).

Methodology

In July 2017, the HDA Research Foundation distributed confidential questionnaires via email to all manufacturer contacts in its database. HDA distributor members were also encouraged to distribute the survey link to their manufacturer trading partners.

All data were collected by Industry Insights (an industry-leading research firm that is not affiliated with HDA or the HDA Research Foundation) and entered into a proprietary system, where they were edited by Industry Insights' analysts for accuracy and consistency. The data were compiled and thoroughly reviewed to ensure responses were

¹ "Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy, Draft Guidance for Industry," June 2017, <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf>. See Federal Register notice at <https://www.federalregister.gov/documents/2017/07/03/2017-13979/product-identifier-requirements-under-the-drug-supply-chain-security-act-compliance-policy-draft>.

reasonable and responsive to the questions asked. Thus, manufacturer responses that were clearly inconsistent with the survey question were eliminated from the analyzed data.

The survey was fielded between July 13 and August 18, 2017. In all, 67 manufacturers responded to the survey and participation, including 15 of the 2016 top 20 pharmaceutical manufacturers by sales and eight of the top 20 pharmaceutical companies by prescriptions dispensed listed by QuintilesIMS.

The statistical information contained in this report is believed to be representative of the manufacturers responding to the survey. However, statistical validity of any given number varies depending upon sample sizes and the amount of consistency among responses for that item. Industry Insights, therefore, makes no representations or warranties with respect to the results of this study and shall not be liable to the HDA Research Foundation, its members or anyone else for information inaccuracies, errors or omissions in content.

Manufacturer Readiness Survey Results

Key findings:

Serialized Product

- 64 percent of manufacturers responding indicated that wholesale distributors will start to receive serialized products *before November 27, 2017*. Additionally, 33 percent indicated wholesale distributors will receive the first serialized product/SKU *between November 27, 2017 and November 27, 2018* (Figure 1 and Table 1).
- A little more than half — 51 percent — of manufacturers with fewer than 150 products/SKUs anticipate wholesale distributors will receive the first serialized product/SKU *by November 27, 2017*, whereas 91 percent of manufacturers with 150 or more products or SKUs anticipate sending the first product or SKU by that date (Table 1).
- Manufacturers reported that generic and branded product portfolios will be in varying states of readiness. First, 3 percent of *generic product* portfolios and 34 percent of *branded product* portfolios, anticipated that wholesale distributors will see 100 percent of serialized product units *by November 27, 2017*. Second, 69 percent of *generic product* portfolios and 91 percent of *branded product* portfolios reported that wholesale distributors will receive 100 percent of serialized *product by November 27, 2018*. (Figure 2 and 3, Tables 4 and 6).
- More respondents, 63 percent, as compared with 40 percent last year, indicated they had concerns with the requirement to serialize product *by November 27, 2017* (Table X). For those with concerns, 62 percent cited “delayed delivery of equipment”, 60 percent cited “contract manufacturing organizations (CMOs) knowledge of DSCSA” and 31 percent cited “operation or scheduling concerns” (Table XI).
- Most manufacturers — 86 percent — reported no concerns with serializing product *by November 27, 2018*, assuming FDA’s draft guidance on enforcement discretion is finalized (Table XII). Those with concerns ranked “lack of FDA guidance on serialization requirement” and “absence of FDA clarification on possible exemptions exceptions and waivers” as their top two reasons.

Serialized Data and Data Exchange

- Nearly one quarter, or 24 percent, of manufacturers anticipated sending *serialized data* to wholesale distributors upon shipment *by November 27, 2017*. One-third of the respondents (33 percent) indicated they plan to send serialized data *by November 27, 2018*. One-third (30 percent) indicated they will send serialized data *between November 2018 and November 27, 2023*. Some respondents (13 percent) are unsure when they will send serialized data. (Table XIII)

- Approximately 38 percent of manufacturers indicated they will aggregate data (units to case) in 2017. 32 percent indicated they would aggregate data *by November 27, 2018*. Six percent of manufacturers responded that they will not be aggregating data. Some (8 percent) reported they are awaiting FDA guidance to determine whether they will or will not aggregate, as compared to 27 percent last year. (Table XIV).
- About 15 percent of companies plan to exchange EPCIS data for all products with wholesale distributors by the end of 2017. Nearly half, or 49 percent, anticipate sending EPCIS data for all products in 2018. Meanwhile, 11 percent plan to exchange EPCIS data for all products in 2019. One-quarter of respondents (25 percent) anticipate exchanging EPCIS data for all products with wholesale distributors after November 27, 2019 (Table XV).

General

- Of the product manufacturing lines in scope for serialization reported in this survey, 42 percent were internal lines and 58 percent were external lines managed by a contract manufacturer. Companies reporting on external manufacturing lines were more likely to indicate that distributors will start receiving serialized product between November 27, 2017, and November 27, 2018.
- Approximately 40 percent of manufacturers are participating or conducting DSCSA-related pilots, the majority of which, either internal or external, are focused on 2017 requirements. Nineteen percent of internal pilots and 39 percent of external pilots are focused on 2019 returns verification (Table XVI).

Conclusions

Overall, the survey indicated that manufacturers are working diligently to serialize products by the November 27, 2017, milestone (now extended to November 27, 2018). However, based on these data, 100 percent of product will not be serialized by November 27, 2017. Currently, it also does not appear that all products will be serialized by November 27, 2018, when FDA's enforcement discretion expires. The top stated concerns that impact manufacturers' ability to serialize product include delayed delivery of equipment and CMO readiness (Table X). For manufacturers and distributors, this will mean using or developing training and processes to manage both concerns in the supply chain, posing the additional challenge of managing dual, serialized and non-serialized systems.

Manufacturers' ability to provide serialized data varies by SKU or product line. Most will capture and exchange serialized data as each SKU is serialized. Manufacturers will be sending serialized data to wholesale distributors upon shipment and exchanging EPCIS data at different points in the serialization process between now and 2023 (Tables XIII and XV) and 70 percent of manufacturers indicate that they plan to aggregate (unit to case) by November 27, 2018 (Table XIV).

Figures and Tables

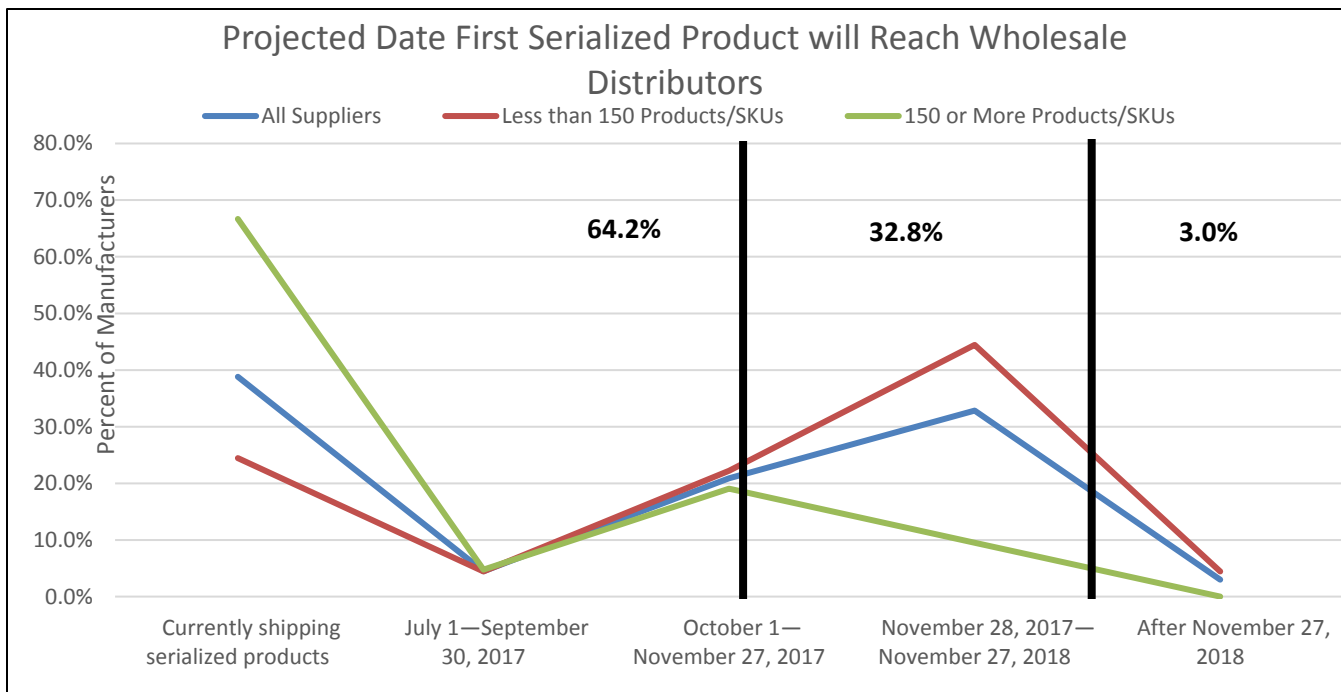


Figure I. The figure above shows the manufacturer-projected date when wholesale distributors will begin to receive serialized product. About 64 percent of manufacturers estimate they will be sending first serialized products by November 27, 2017.

| When will wholesale distributors receive the first serialized product/SKUs from your company? | | | | | |
|---|---------------|-------------------------|------------------|---------------------------------------|------------|
| | All Suppliers | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| | | Fewer than 150 SKUs | 150 or more SKUs | Fewer than 15 | 15 or more |
| (N) | 67 | 45 | 21 | 32 | 32 |
| Currently shipping serialized products | 38.8% | 24.4% | 66.7% | 18.8% | 59.4% |
| July 1–September 30, 2017 | 4.5% | 4.4% | 4.8% | 6.3% | 3.1% |
| October 1–November 27, 2017 | 20.9% | 22.2% | 19.1% | 18.8% | 21.9% |
| November 28, 2017–November 27, 2018 | 32.8% | 44.4% | 9.5% | 50.0% | 15.6% |
| After November 27, 2018 | 3.0% | 4.4% | 0.0% | 6.3% | 0.0% |
| We don't plan to introduce serialized product into the supply chain | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |

Table I. Manufacturer estimated date for when serialized product will first reach wholesale distributors. The data have been broken out by manufacturer reported SKUs and product manufacturing lines.

| When will wholesale distributors receive the first serialized product/SKUs from your company? | | | | |
|---|--------------|---------------|--------------|---------------|
| | Branded | | Generic | |
| | 50% of units | 100% of units | 50% of units | 100% of units |
| Present — November 27, 2017 | 51.0% | 15.7% | 40.7% | 3.1% |
| November 27, 2017–November 27, 2018 | 92.2% | 90.6% | 97% | 68.7% |

Table II. Manufacturer-estimated date for when serialized product will first reach wholesale distributors. The data have been consolidated to show a comparison of branded and generic manufacturer responses for when 50 percent and 100 percent of units will reach wholesale distributors.

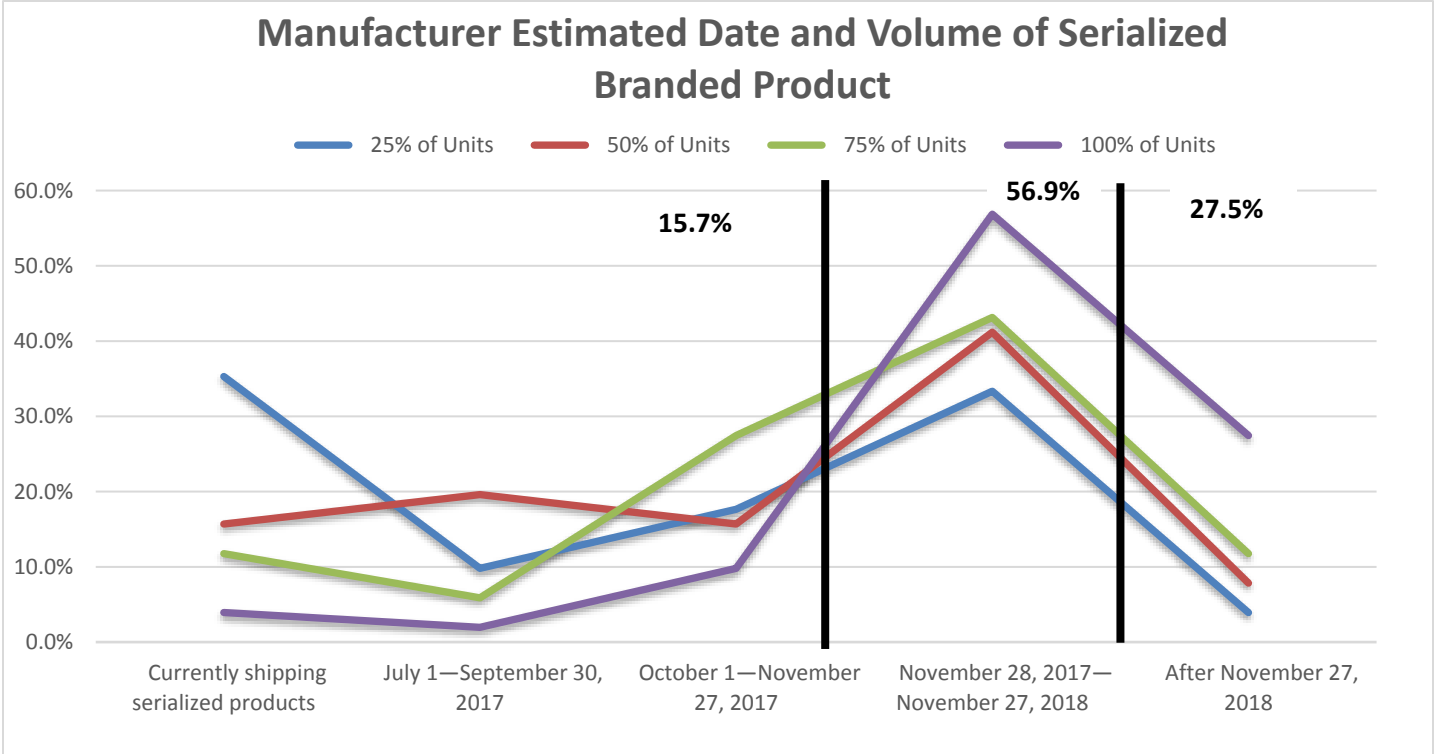


Figure II. Manufacturer-estimated date and volume of when wholesale distributors will receive branded product. About 16 percent of manufacturers reported 100 percent of their branded products will be serialized by November 27, 2017, 56.9 percent reported 100 percent of branded product will be serialized between November 28, 2017 and November 27, 2018, and 27.5 indicated 100 percent of serialized products will be released after November 27, 2018.

| When do you expect wholesale distributors will receive serialized units from your company's branded product portfolio? | | | | | |
|---|----------------------|--------------------------------|--------------------|--|-------------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| 50% of Units | All Suppliers | Fewer than 150 | 150 or more | Fewer than 15 | 15 or more |
| 50% of Units | | | | | |
| <i>(N)</i> | 51 | 35 | 15 | 26 | 23 |
| Currently shipping serialized products | 15.7% | 14.3% | 13.3% | 7.7% | 21.7% |
| July 1–September 30, 2017 | 19.6% | 17.1% | 26.7% | 15.4% | 26.1% |
| October 1–November 27, 2017 | 15.7% | 11.4% | 26.7% | 7.7% | 21.7% |
| November 28, 2017–November 27, 2018 | 41.2% | 51.4% | 20.0% | 61.5% | 21.7% |
| After November 27, 2018 | 7.8% | 5.7% | 13.3% | 7.7% | 8.7% |

Table III. Manufacturer-estimated date for when wholesale distributors will receive 50 percent of branded product portfolios. Data have been broken out by manufacturer-reported SKUs and product manufacturing lines. This table includes only companies with branded product.

| When do you expect wholesale distributors will receive serialized units from your company's branded product portfolio? | | | | | |
|---|----------------------|--------------------------------|--------------------|--|-------------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| 100% of Units | All Suppliers | Fewer than 150 | 150 or more | Fewer than 15 | 15 or more |
| <i>(N)</i> | 51 | 35 | 15 | 26 | 23 |
| Currently shipping serialized products | 3.9% | 2.9% | 6.7% | 0.0% | 4.4% |
| July 1–September 30, 2017 | 2.0% | 2.9% | 0.0% | 3.9% | 0.0% |
| October 1–November 27, 2017 | 9.8% | 11.4% | 6.7% | 7.7% | 13.0% |
| November 28, 2017–November 27, 2018 | 56.9% | 60.0% | 46.7% | 61.5% | 52.2% |
| After November 27, 2018 | 27.5% | 22.9% | 40.0% | 26.9% | 30.4% |

Table IV. Manufacturer-estimated date for when wholesale distributors will receive 100 percent of branded product. Data has been broken out by manufacturer reported SKUs and product manufacturing lines. This table includes only companies with branded product.

Manufacturer Estimated Date and Volume of Serialized Generic Product

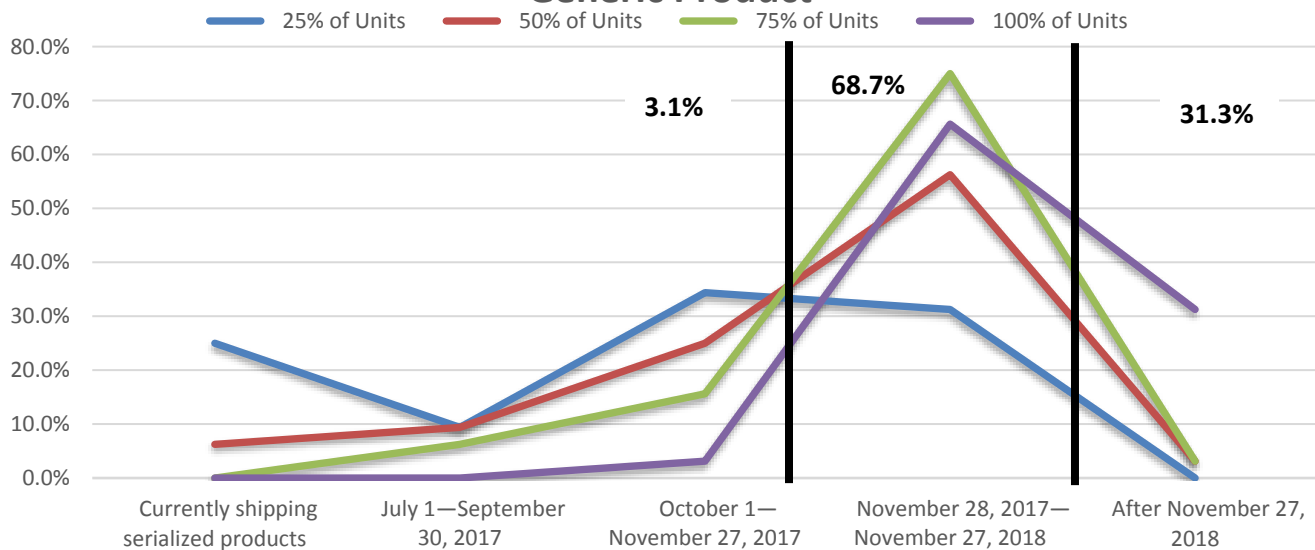


Figure III. Manufacturer-estimated date and volume of when wholesale distributors will receive generic products. 3.1 percent of manufacturers estimated 100 percent of their generic product portfolio will be serialized by November 27, 2017, 68.7 percent estimated 100 percent of products will reach wholesale distributors between November 28, 2017 and November 27, 2018, and 31.3 percent anticipate wholesale distributors receiving 100 percent of product after November 27, 2018.

| When do you expect wholesale distributors will receive serialized units from your company's generic product portfolio? | | | | | |
|--|---------------|-------------------------|-------------|---------------------------------------|------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| 50% of Units | All Suppliers | Fewer than 150 | 150 or more | Fewer than 15 | 15 or more |
| (N) | 32 | 16 | 16 | 10 | 21 |
| Currently shipping serialized products | 6.3% | 0.0% | 12.5% | 0.0% | 9.5% |
| July 1–September 30, 2017 | 9.4% | 12.5% | 6.3% | 20.0% | 4.8% |
| October 1–November 27, 2017 | 25.0% | 12.5% | 37.5% | 0.0% | 33.3% |
| November 28, 2017–November 27, 2018 | 56.3% | 75.0% | 37.5% | 80.0% | 47.6% |
| After November 27, 2018 | 3.1% | 0.0% | 6.3% | 0.0% | 4.8% |

Table V. Manufacturer-estimated date for when wholesale distributors will receive 50 percent of generic product. Data have been broken out by manufacturer reported SKUs and product manufacturing lines. This includes only companies with generic product.

| When do you expect wholesale distributors will receive serialized units from your company's generic product portfolio? | | | | | |
|---|----------------------|--------------------------------|--------------------|--|-------------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| 100% of Units | All Suppliers | Fewer than 150 | 150 or more | Fewer than 15 | 15 or more |
| <i>(N)</i> | 32 | 16 | 16 | 10 | 21 |
| Currently shipping serialized products | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| July 1–September 30, 2017 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| October 1–November 27, 2017 | 3.1% | 0.0% | 6.3% | 0.0% | 4.8% |
| November 28, 2017–November 27, 2018 | 65.6% | 81.3% | 50.0% | 70.0% | 61.9% |
| After November 27, 2018 | 31.3% | 18.8% | 43.8% | 30.0% | 33.3% |

Table VI. Manufacturer-estimated date for when wholesale distributors will receive 100 percent of generic product. Data have been broken out by manufacturer reported SKUs and product manufacturing lines. This table includes only companies with generic product.

| Will your company's ability to capture and exchange serialized data vary by product? | | | | | |
|---|----------------------|--------------------------------|--------------------|--|-------------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| | All Suppliers | Fewer than 150 | 150 or more | Fewer than 15 | 15 or more |
| <i>(N)</i> | 66 | 45 | 20 | 32 | 31 |
| We plan to capture and send serialized data as each SKU is serialized | 56.1% | 64.4% | 35.0% | 75.0% | 32.3% |
| We plan to capture and send serialized data as each product line is serialized | 4.6% | 6.7% | 0.0% | 6.3% | 3.2% |
| We plan to capture and send serialized data as each production line is serialized | 1.5% | 2.2% | 0.0% | 0.0% | 3.2% |
| We plan to capture and send serialized data once all SKU's within our DC have been serialized | 13.6% | 8.9% | 25.0% | 6.3% | 22.6% |

Table VII. Manufacturer ability to capture and exchange serialized data by product. Data have been broken out by manufacturer reported SKUs and product manufacturing lines.

| Will your company's ability to provide serialized data with an order to a wholesale distributor customer vary by SKU, product line, etc.? | | | | | |
|--|----------------------|--------------------------------|--------------------|--|-------------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| | All Suppliers | Fewer than 150 | 150 or more | Fewer than 15 | 15 or more |
| <i>(N)</i> | 67 | 45 | 21 | 32 | 32 |
| Yes | 34.3% | 28.9% | 47.6% | 28.1% | 40.6% |
| No | 44.8% | 51.1% | 28.6% | 50.0% | 40.6% |
| Unsure | 20.9% | 20.0% | 23.8% | 21.9% | 18.8% |

Table VIII. Manufacturer ability to provide serialized data to wholesalers with an order broken out by SKUs and product manufacturing lines.

| When do you anticipate sending serialized data to your wholesale distributor customers upon shipment? | | | | | |
|--|----------------------|--------------------------------|--------------------|--|-------------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| | All Suppliers | Fewer than 150 | 150 or more | Fewer than 15 | 15 or more |
| <i>(N)</i> | 67 | 45 | 21 | 32 | 32 |
| We plan to send serialized data with shipped by November 27, 2017 | 23.9% | 26.7% | 14.3% | 28.1% | 18.8% |
| We plan to send serialized data with shipped by November 27, 2018 | 32.8% | 33.3% | 33.3% | 40.6% | 28.1% |
| We plan to send serialized data with shipped product between November 28, 2018 and November 27, 2019 | 17.9% | 20.0% | 14.3% | 15.6% | 18.8% |
| We plan to send serialized data with shipped product between November 28, 2019 and November 27, 2023 | 11.9% | 4.4% | 28.6% | 3.1% | 21.9% |
| We are unsure of when we will send serialized data | 13.4% | 15.6% | 9.5% | 12.5% | 12.5% |

Table IX. Manufacturer estimated date of when serialized data will be able to be sent upon shipment broken out by product SKUs and product manufacturing lines.

| Do you have concerns or obstacles to meeting the DSCSA's original requirement to serialize product as of November 27, 2017? | | | | | |
|---|---------------|-------------------------|------------------|---------------------------------------|------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| | All Suppliers | Fewer than 150 SKUs | 150 or more SKUs | Fewer than 15 | 15 or more |
| (N) | 67 | 45 | 21 | 32 | 32 |
| Yes | 62.7% | 51.1% | 85.7% | 43.8% | 84.4% |
| No | 37.3% | 48.9% | 14.3% | 56.3% | 15.6% |

Table X. Manufacturers concerns with or obstacles to meeting DSCSA's original requirement of serializing product by November 27, 2017. Data have been broken out by manufacturer reported SKUs and product manufacturing lines.

| Why do you have concerns? (multiple responses allowed) | | | | | | | | |
|--|---------------|-------------------------|-------------|---------------------------------------|------------|--|--------------------------|-------------------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | | Date Distributors Will Start Receiving Serialized Products | | |
| | All Suppliers | Fewer than 150 | 150 or More | Fewer than 15 | 15 or More | Currently Shipping | Before November 27, 2017 | After November 27, 2017 |
| (N) | 42 | 23 | 18 | 14 | 27 | 20 | 10 | 15 |
| Lack of FDA Guidance on serialization requirement | 23.8% | 21.7% | 22.2% | 14.3% | 29.6% | 25.0% | 0.0% | 41.7% |
| Absence of FDA clarification on possible exemptions, exceptions, and waivers relevant to serialization requirement | 21.4% | 13.0% | 27.8% | 7.1% | 29.6% | 35.0% | 10.0% | 8.3% |
| CMO knowledge of DSCSA i.e. CMO ability to secure technical consultants needed for line upgrade | 59.5% | 39.1% | 83.3% | 28.6% | 77.8% | 65.0% | 50.0% | 58.3% |
| Operational/scheduling concerns i.e. access to lines (downtime) to upgrade | 31.0% | 39.1% | 22.2% | 42.9% | 25.9% | 25.0% | 30.0% | 41.7% |
| Delayed delivery of equipment | 61.9% | 56.5% | 66.7% | 64.3% | 59.3% | 65.0% | 60.0% | 58.3% |
| Internal constraints i.e. investment/approval/resources | 7.1% | 8.7% | 5.6% | 0.0% | 11.1% | 5.0% | 20.0% | 0.0% |
| Issues associated with graphics/labels | 11.9% | 13.0% | 11.1% | 14.3% | 11.1% | 10.0% | 30.0% | 0.0% |
| Other | 26.2% | 21.7% | 27.8% | 28.6% | 25.9% | 30.0% | 20.0% | 25.0% |
| | | | | | | | | |

Table XI: Responses from only those manufacturers who expressed concerns about their ability to serialize product by November 27, 2017.

| Do you have concerns or obstacles to serializing product by November 27, 2018, when FDA's enforcement discretion ends, assuming the Draft Guidance is finalized as proposed? | | | | | | | | |
|--|---------------|-------------------------|------------------|---------------------------------------|------------|--|--------------------------|-------------------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | | Date Distributors will Start Receiving Serialized Products | | |
| | All Suppliers | Fewer than 150 SKUs | 150 or more SKUs | Fewer than 15 | 15 or more | Currently Shipping | Before November 27, 2017 | After November 27, 2017 |
| (N) | 66 | 44 | 21 | 31 | 32 | 26 | 16 | 22 |
| Yes | 13.6% | 4.6% | 33.3% | 3.2% | 25.0% | 26.9% | 0.0% | 9.1% |
| No | 86.4% | 95.5% | 66.7% | 96.8% | 75.0% | 73.1% | 100.0% | 90.9% |

Table XII. Manufacturer concerns about serializing product by November 27, 2018, broken out by SKU, product lines and estimated date of serialization. Table X and Table XI. Shows responses from only those manufacturers who expressed concerns about their ability to serialize product by November 27, 2017.

| When do you anticipate sending serialized data to your wholesale distributor customers upon shipment? | | | | | |
|---|---------------|-------------------------|-------------|---------------------------------------|------------|
| | | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| | All Suppliers | Fewer than 150 | 150 or More | Fewer than 15 | 15 or More |
| (N) | 67 | 45 | 21 | 32 | 32 |
| We plan to send serialized data with shipped by November 27, 2017 | 23.9% | 26.7% | 14.3% | 28.1% | 18.8% |
| We plan to send serialized data with shipped by November 27, 2018 | 32.8% | 33.3% | 33.3% | 40.6% | 28.1% |
| We plan to send serialized data with shipped product between November 28, 2018 and November 27, 2019 | 17.9% | 20.0% | 14.3% | 15.6% | 18.8% |
| We plan to send serialized data with shipped product between November 28, 2019 and November 27, 2023 | 11.9% | 4.4% | 28.6% | 3.1% | 21.9% |
| We are unsure of when we will send serialized data | 13.4% | 15.6% | 9.5% | 12.5% | 12.5% |

Table XIII. Manufacturer-estimated timeframe for sending serialized data to wholesale distributor customers upon shipment, broken down by manufacturer reported SKUs and product manufacturing lines.

| Is your company planning to aggregate-data (unit to case)? | | | | | |
|---|----------------------|--------------------------------|--------------------|--|-------------------|
| | All Suppliers | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| | | Fewer than 150 | 150 or More | Fewer than 15 | 15 or More |
| <i>(N)</i> | 66 | 44 | 21 | 31 | 32 |
| Yes All SKUs by November 27, 2017 | 37.9% | 45.5% | 23.8% | 48.4% | 25.0% |
| Yes All SKUs by November 27, 2018 | 31.8% | 36.4% | 19.1% | 35.5% | 31.3% |
| Yes All SKUs by November 27, 2019 | 3.0% | 0.0% | 9.5% | 0.0% | 6.3% |
| Yes All SKUs by November 27, 2023 | 13.6% | 6.8% | 28.6% | 3.2% | 25.0% |
| No | 6.1% | 6.8% | 4.8% | 9.7% | 3.1% |
| Awaiting FDA guidance to determine whether or not we will aggregate | 7.6% | 4.6% | 14.3% | 3.2% | 9.4% |

Table XIV. Manufacturer estimated date for when they plan to aggregate data (unit to case) broken down by manufacturer reported SKUs and product manufacturing lines.

| When does your company plan to exchange EPCIS data for all products with wholesale distributors? | | | | | |
|---|----------------------|--------------------------------|--------------------|--|-------------------|
| | All Suppliers | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| | | Less than 150 | 150 or More | Less than 15 | 15 or More |
| <i>(N)</i> | 65 | 44 | 20 | 32 | 31 |
| Present – End of 2017 | 15.4% | 18.2% | 10.0% | 21.9% | 9.7% |
| January 2018 – June 2018 | 24.6% | 29.6% | 15.0% | 31.3% | 19.4% |
| June 2018 – December 2018 | 24.6% | 22.7% | 25.0% | 21.9% | 25.8% |
| January 2019 – November 27, 2019 | 10.8% | 13.6% | 5.0% | 9.4% | 9.7% |
| November 27, 2019 – Beyond | 24.6% | 15.9% | 45.0% | 15.6% | 35.5% |

Table XV. Manufacturer estimated date for exchanging EPCIS data for all wholesale distributor products broken down by manufacturer reported SKUs and product manufacturing lines.

| If your company is conducting or participating in DSCSA related pilots: | | | | | |
|---|---------------|-------------------------|-------------|---------------------------------------|------------|
| | All Suppliers | Number of Products/SKUs | | Number of Product Manufacturing Lines | |
| | | Fewer than 150 | 150 or More | Fewer than 15 | 15 or More |
| (N) | 67 | 45 | 21 | 32 | 32 |
| Yes | 40.3% | 28.9% | 61.9% | 28.1% | 53.1% |
| No | 59.7% | 71.1% | 38.1% | 71.9% | 46.9% |
| Internal (multiple responses allowed) | | | | | |
| (N) | 26 | 13 | 12 | 9 | 16 |
| 2017 serialization | 69.2% | 61.5% | 75.0% | 55.6% | 81.3% |
| 2019 returns verification | 19.2% | 23.1% | 8.3% | 11.1% | 25.0% |
| 2023 interoperability | 15.4% | 0.0% | 25.0% | 0.0% | 25.0% |
| Other DSCSA related pilot topics | 15.4% | 0.0% | 25.0% | 0.0% | 25.0% |
| External-with trading partners (multiple responses allowed) | | | | | |
| (N) | 26 | 13 | 12 | 9 | 16 |
| 2017 serialization | 53.9% | 61.5% | 41.7% | 55.6% | 50.0% |
| 2019 returns verification | 38.5% | 15.4% | 58.3% | 11.1% | 56.3% |
| 2023 interoperability | 26.9% | 7.7% | 41.7% | 0.0% | 43.8% |
| Other DSCSA related pilot topics | 26.9% | 7.7% | 41.7% | 0.0% | 43.8% |

Table XVI. Manufacturer responses to whether they are participating in DSCSA related pilots, categorized by topic area, internal and external.