EPCIS IMPLEMENTATION BENCHMARKING SURVEY

HDA RESEARCH FOUNDATION

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Introduction

On November 27, 2023, the Drug Supply Chain Security Act (DSCSA) requires healthcare supply chain trading partners to exchange transaction data that includes product identifiers for the package(s) transacted in a secure, electronic, interoperable manner in accordance with standards published in FDA guidance. Those standards shall comply with a form and format developed by a widely recognized international standards development organization.[1] Currently, the only widely recognized standard of an international standards development organization that allows trading partners to exchange transaction data is GS1's Electronic Product Code Information Services (EPCIS).

While the DSCSA requires transaction data with product identifiers to be provided with physical product on November 27, 2023, many industry stakeholders have realized that they must prepare well in advance of this date to ensure:

- Business-to-business AS2 connections are made;
- Master data are transmitted;
- Data are properly formatted and received;
- Processes are established for when errors occur; and,
- Existing inventory has corresponding data when shipped after November 27.

Accordingly, industry and service providers approached the Healthcare Distribution Alliance (HDA) Research Foundation to benchmark progress of EPCIS adoption and trading partner plans for sending data. Through this survey, the Foundation seeks to inform industry trading partners on the status of successful connections — defined as a connection that is fully integrated and working in a production environment — and the key obstacles that manufacturers, distributors and third-party logistics providers (3PLs) face in establishing those connections.

This edition of the HDA Foundation's *EPCIS Implementation Benchmarking Survey* is a follow-up to survey conducted in spring 2021.

Methodology

The Foundation's research partner, Industry Insights — a leading, independent research firm — hosted the survey from October 20 to December 3, 2021. The survey was distributed via email, with 54 companies responding: 40 manufacturers, 16 distributors, and four 3PLs. (In some instances, companies fulfill multiple supply chain responsibilities; as an example, a distributor might operate its own 3PL.)

All data collected by Industry Insights are entered into a proprietary system, where they are blinded by the organization's analysts to maintain confidentiality. Data were compiled and thoroughly reviewed to help ensure consistency and coherence.

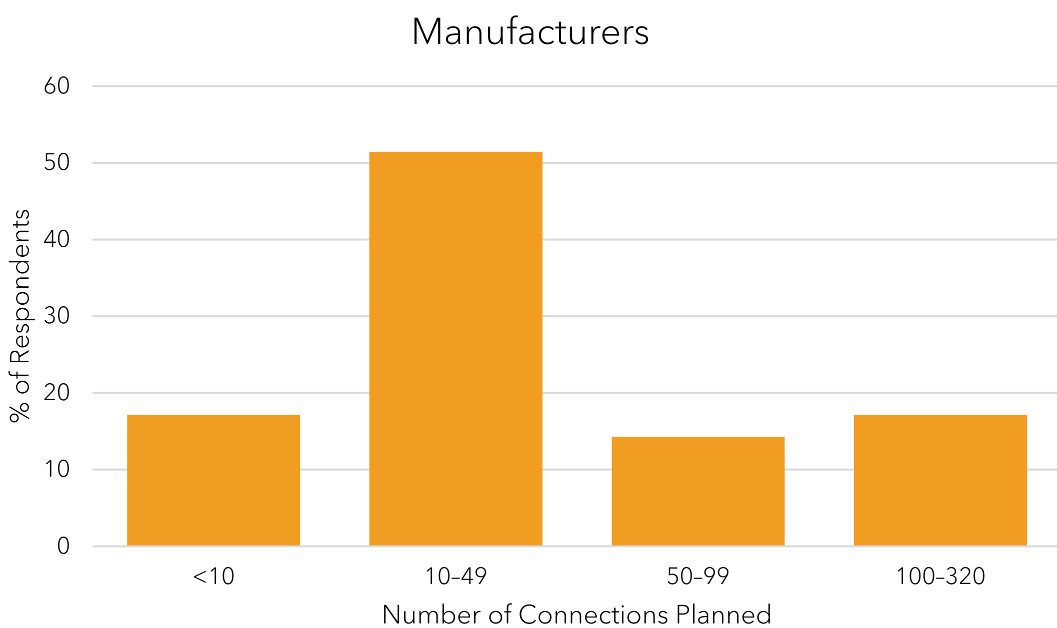
1 In 2014, FDA recognized that EPCIS was a compliant electronic-based method for the interoperable exchange of transaction data. See: draft guidance for industry, "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information" 79 FR 70878 (November 28, 2014), https://www.fda.gov/media/90548/download.

Results by Company Type

Manufacturers

Most surveyed manufacturers (88 percent) already have transitioned to EPCIS 1.2, the minimum version of the standard required for secure, electronic, interoperable exchange of data. While those manufacturers have implemented this current version of the standard, this does not necessarily mean data are being exchanged, and the transition to EPCIS 1.2 should only be viewed as a necessary, preparatory step.

Figure 1: Manufacturer Connections with Distributors



Just over a quarter (26 percent) of manufacturers are planning to connect directly with distributors via their own system; nearly two-thirds (69 percent) are planning to use a third party (e.g., a 3PL or a solution provider). Many manufacturers (60 percent) do not have or plan to have connections with dispensers. More than a quarter, 28 percent, have or plan to connect via a third party 3PL or solution provider, whereas 13 percent have or plan to directly connect with dispensers.

More than half (55 percent) of manufacturers report they are not currently in the process of connecting with distributors. Thirty-four percent of manufacturers are in the process of connecting with between one and nine distributors, while 11 percent are in the process of connecting with more than 10. More than half (55 percent) of manufacturers have no successful connections in a production environment today. More than one-third (37 percent) have between one and nine successful connections in a production environment today. Just 8 percent have between 10 and 40 successful connections in a production environment today.

Seventeen percent of manufacturers plan to have fewer than 10 connections with distributors once fully implemented. Fifty-one percent plan to have between 10 and 50 connections. Fourteen percent plan to have between 50 and 99 connections. Seventeen percent plan to have between 100 and 320 connections in total once fully implemented.

Most manufacturers (68 percent) are not sending data to distributors. Nearly one-quarter (22 percent) are sending data to between one and six distributors. Eleven percent are sending data to between seven and 20 distributors.

Key Obstacles to Implementation

Manufacturer respondents were asked to identify key obstacles to implementing EPCIS. The top obstacle identified was "other," followed by "adequacy of employee resources and availability" (32 percent). Responses shared in "other" include:

- Complexity of exception management;
- Current EPCIS solution does not have functionality to support full data exchange with 3PL (shipping, unpack, etc.);
- Clarity of regulatory and legal requirements versus good to have requirements;
- Enabling of aggregation;
- Focusing on other priorities in 2021, including internal project constraints and priorities;
- Lack of feedback from smaller wholesaler partners on their plans to support 2023 requirements;
- Lack of standards and adoption of standards;
- 3PL fees increasing once implemented;
- PDG and FDA adoption;
- Solution readiness; and,
- Implementation plans include sending EPCIS 1.2 data to wholesalers between second/third quarter of 2022 after implementing with 3PL and sharing data through a third-party solution provider.

Other obstacles cited were:

- Lack of guidance (29 percent);
- Delay due to past and/or potential future enforcement discretion (26 percent);
- Ability to dedicate IT team to testing and implementation (26 percent);
- Lack of trading partner understanding or commitment (24 percent);
- Adequacy of employee knowledge (13 percent);
- Availability of consultants/service provider/solutions provider (11 percent); and,
- Adequacy of financial resources (3 percent).

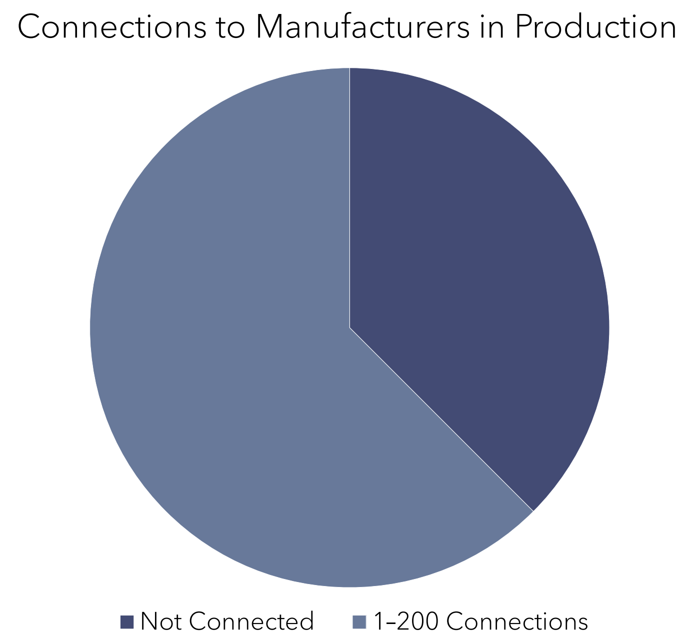
Third-Party Logistics Providers

A typical 3PL currently is working to connect 81 manufacturer clients on average. A 3PL typically has four successful connections as of today and is in the process of connecting with four customers. Once fully implemented, 3PLs plan to have connections with 104 distributors. At present, two have connections with dispensers via a direct connection, one has a connection via a third party and one does not maintain a connection with dispensers. Key obstacles cited included lack of trading partner understanding or commitment, delays due to past or potential future enforcement discretion, adequacy of employee resources or availability, adequacy of financial resources and "other."

In comments, 3PLs cited the "readiness of their clients to proceed" as a hurdle, "lack of resources or knowledge required to support a serialization implementation" and "upgrading warehouse management systems (WMS)" before implementing serialization data.

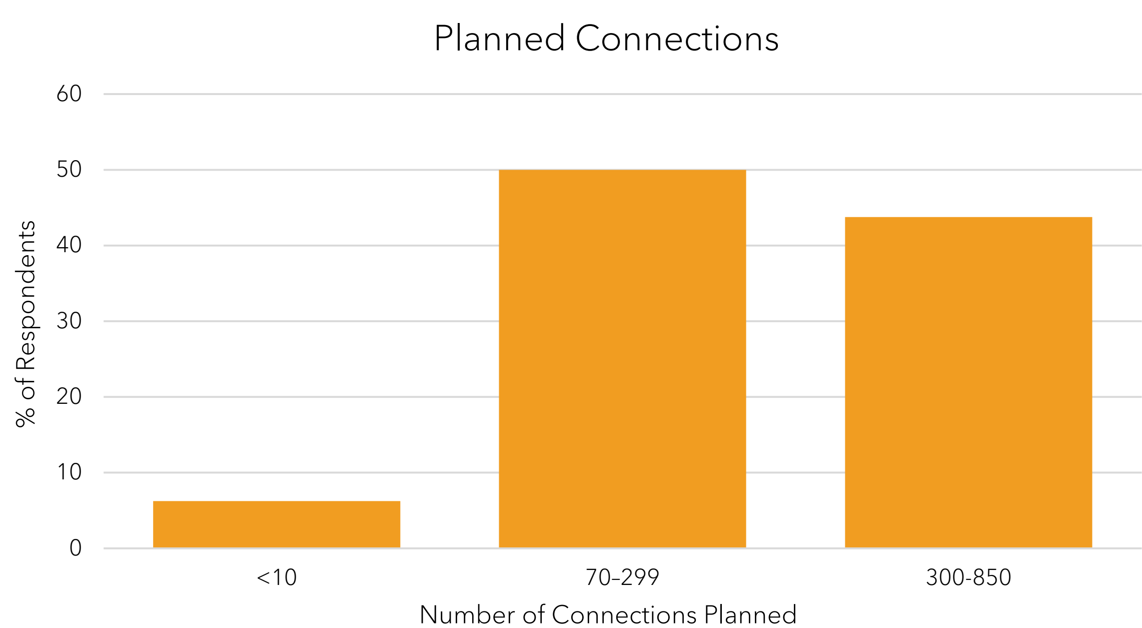
Distributors

Figure 2: Distributor Connections with Manufacturers



Thirty-eight percent of distributors are not connected to manufacturers in production, down from 58 percent in the last survey. Sixty-two percent, up from 42 percent, have between 1 and 200 connections in a production environment. Once fully implemented, 6 percent of distributors, down from a quarter in the last survey, anticipate having fewer than 10 connections. Half of distributors expect to have somewhere between 70 and 299 connections, and 44 percent, up from a quarter in the last survey, plan to have between 300 and 850 connections.

Figure 3: Distributors’ Planned Connections with Manufacturers



More than two-thirds of distributors (69 percent), up from 50 percent, are in the process of connecting to manufacturers in a production environment, with between one and 35 connections. Currently, no connections with dispensers exist today, whether in process or in a production environment. Note that there may be other test environments where connections exist. Once fully implemented, 31 percent (down from 45 percent) of distributors do not plan to have direct connections to dispensers, while more than half (54 percent), up from a quarter in the last survey, will have somewhere between 10 and 400 connections.

Respondents noted that many dispenser customers are planning to use a portal provided by the wholesale distributor, which explains the relatively low number of direct distributor-to-dispenser connections. Rather, distributors reported that transaction data will be exchanged interoperable with manufacturers and posted to a portal that the wholesale distributor maintains on behalf of the dispenser and accessed by the dispenser.

In open-ended comments related to connections, respondents noted:

- It is still unclear how many dispensers want direct connections versus those that will rely on a portal. It is anticipated that larger chains and hospitals may request EPCIS files, but most others will use a portal.
- Setting up AS2 connections with trading partners for EPCIS has been a more time-consuming piece of implementation.
- Availability and quality of master data from manufacturers specifically for packaging above the "each" continues to be a problem.
- Zero suppliers are fully ready to connect with EPCIS, so none have difficulties.
- One distributor noted recently switching service providers and being in the process of setting up connections. Currently, they are tracking all serial numbers and lot numbers outbound, as well as all that are being returned.

A third of manufacturers with successful connections are not experiencing difficulties with EPCIS event data, while two-thirds are facing challenges. The top obstacle that distributors reported with build, integration or adoption of EPCIS (88 percent) was "lack of trading partner commitment." Concerns also included the "ability to dedicate an IT team to testing and implementation" (31 percent), and "adequacy of employee resources" (31 percent), "lack of guidance" (31 percent) and "past or future enforcement discretion" (31 percent).

Open-ended responses under "other" included:

- Difficulty of connecting to dispensers without having full data flowing in from manufacturers;
- Lack of employees because of hiring issues;
- Finding appropriate scanners to handle all the various bar codes; and,
- Holding off on implementation of serialized data flows until a WMS upgrade is complete.

Conclusion

Overall, the industry continues to be in the initial stages of achieving EPCIS interoperable connections and data exchange with each other in a production environment. While many manufacturers have prepared internally to send data downstream with the transition to EPCIS 1.2, very few are sending data in production today. Additionally, since 69 percent of manufacturers are relying on 3PLs or solution providers, it will be critical that information is shared downstream to distributors on the timing of connections and sending data, as that additional connection adds a layer of complexity.

More distributors (69 percent as compared to half in the last survey) are setting up connections today, and it will be important that the rest of the sector also begins to make those connections to be able to meet the goal of interoperability by 2023. Industry stakeholders will have a significant amount of work to do over the next six quarters to meet this deadline, and addressing obstacles identified, such as "lack of trading partner commitment" and "dedicated IT and employee resources" will be critical.

Figure 4: Is Your Company Using EPCIS v1.2?

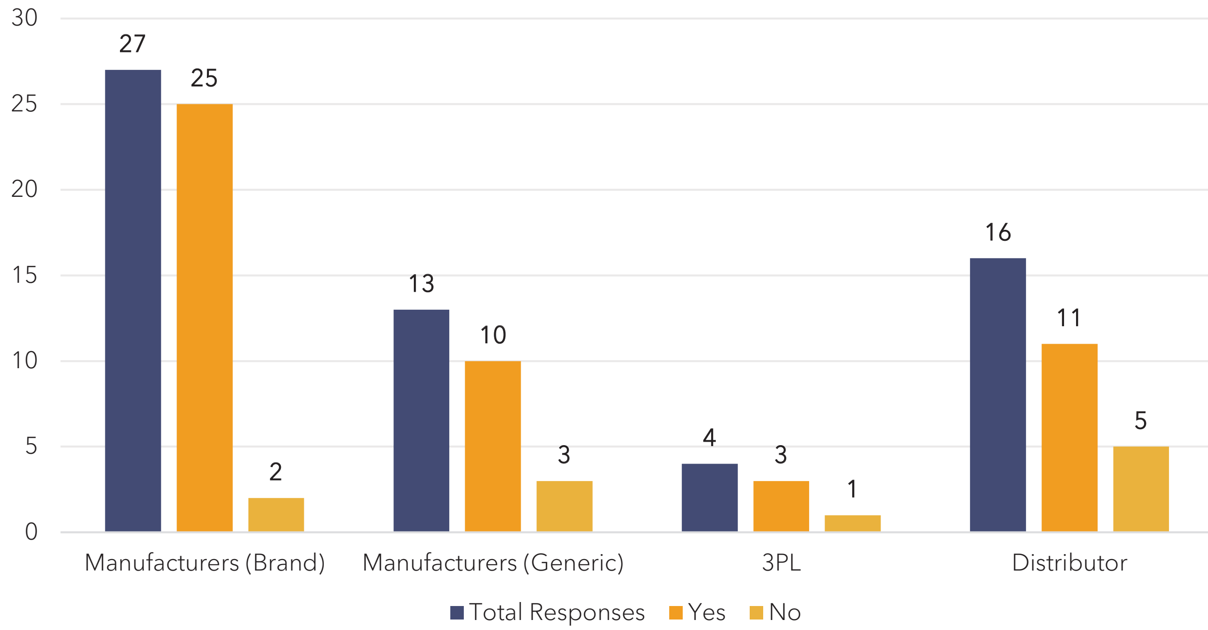


Figure 5: Connection Status - Average by Company Category

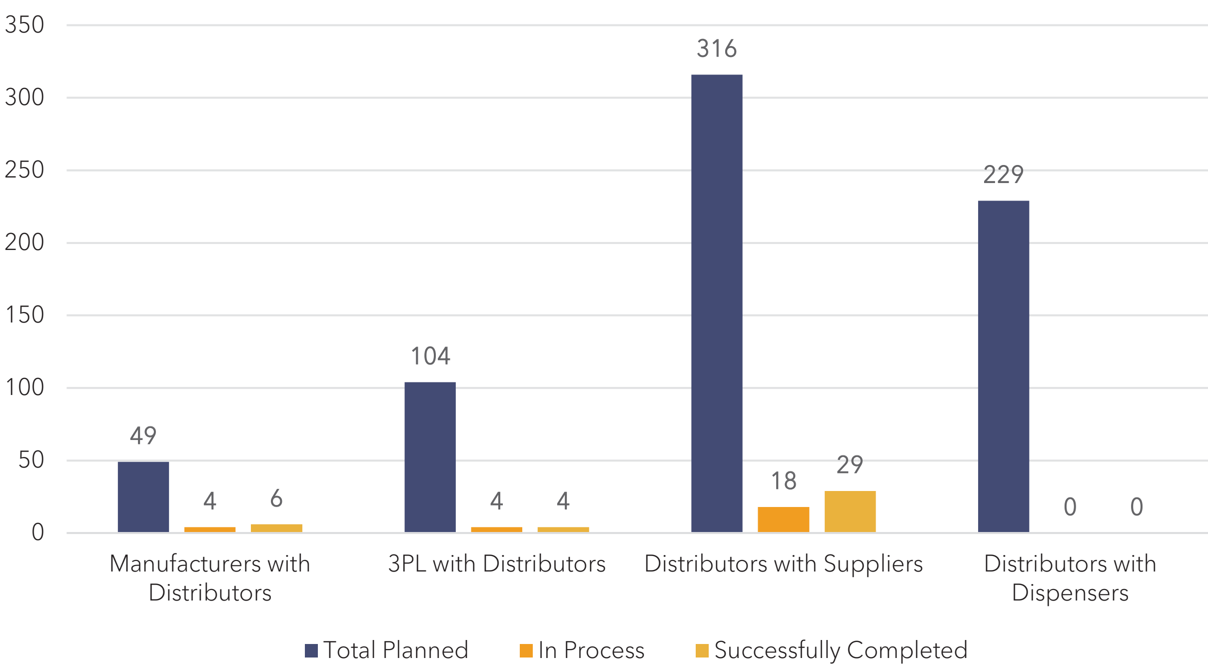
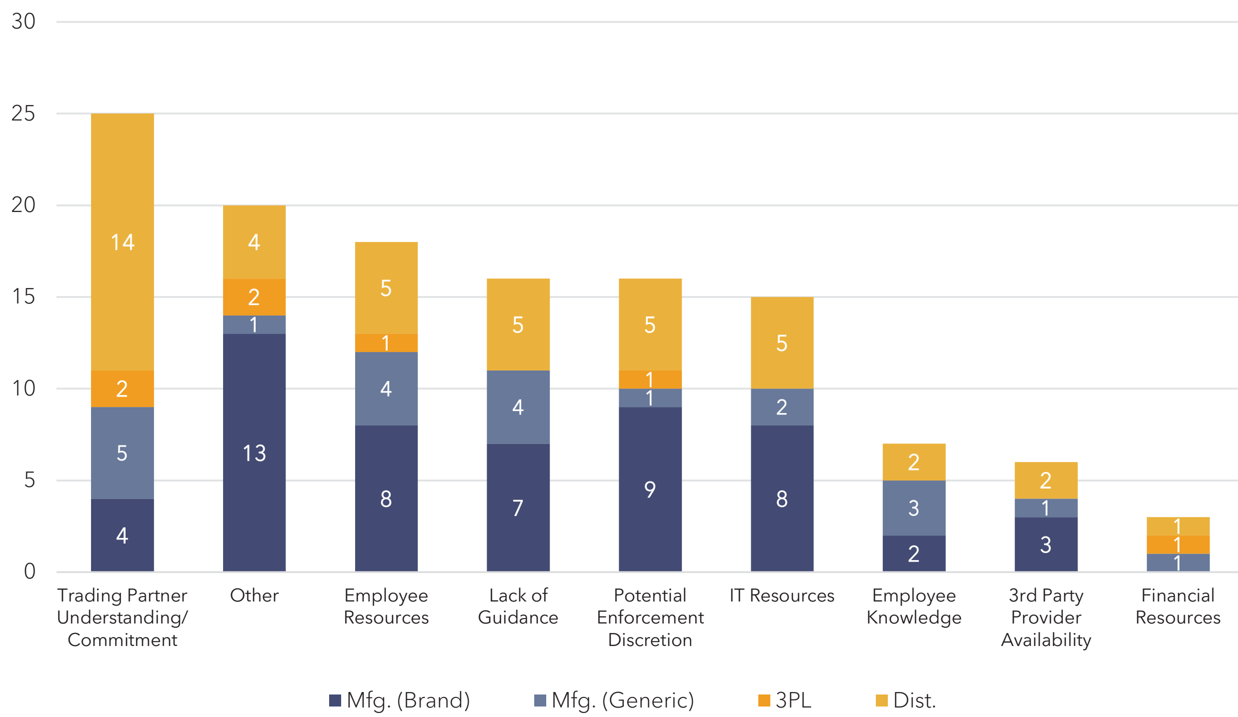


Figure 6: Adoption Obstacles



Data Tables

Table 1: Manufacturer Data	Manufacturer	Company Focus	
		Brand	Generic
Is your company…			
(N)	*40*	*27*	*13*
a Manufacturer	100.0%	100.0%	100.0%
a 3PL	5.0%	3.7%	7.7%
a Distributor	7.5%	3.7%	15.4%
Is your company using EPCIS v1.2 or higher?			
(N)	*40*	*27*	*13*
Yes	87.5%	92.6%	76.9%
No	12.5%	7.4%	23.1%
Are your company sales...			
(N)	*40*	*27*	*13*
Over $1B	67.5%	81.5%	38.5%
Under $1B	32.5%	18.5%	61.5%
Is your company primarily…			
(N)	*40*	*27*	*13*
Brand	67.5%	100.0%	0.0%
Generic	32.5%	0.0%	100.0%
Do you have or plan to have EPCIS connections with distributors?			
(N)	*39*	*26*	*13*
Yes, via own system	25.6%	23.1%	30.8%
Yes, via a third party (e.g. 3PL or solution provider)	69.2%	73.1%	61.5%
No	5.1%	3.9%	7.7%
Do you have or plan to have EPCIS connections with dispensers?			
(N)	*40*	*27*	*13*
Yes, via a direct connection	12.5%	11.1%	15.4%
Yes, via a third party (e.g., 3PL or solution provider)	27.5%	22.2%	38.5%
No, I do not maintain connections with dispensers	60.0%	66.7%	46.2%
How many distributors are you in the process of connecting with in a production environment?			
(N)	*38*	*27*	*11*
Average	4	5	1
Median	0	0	0
75th Percentile	3	3	3
25th Percentile	0	0	0

Table 1 (continued)	Manufacturer	Company Focus	
		Brand	Generic
How many successful connections do you have with distributors in a production environment?			
(N)	*38*	*27*	*11*
Average	6	7	5
Median	0	0	0
75th Percentile	5	5	3
25th Percentile	0	0	0
How many connections with distributors do you plan to have once fully implemented?			
(N)	*35*	*24*	*11*
Average	49	34	83
Median	25	25	50
75th Percentile	50	40	120
25th Percentile	10	10	13
How many distributors are you currently sending data?			
(N)	*37*	*26*	*11*
Average	2	2	3
Median	0	0	0
75th Percentile	1	1	1
25th Percentile	0	0	0
What obstacles are you facing with build, integration or adoption of EPCIS?			
(N)	*38*	*27*	*11*
Adequacy of financial resources	2.6%	0.0%	9.1%
Adequacy of employee resources/availability	31.6%	29.6%	36.4%
Availability of consultants/service provider/ solutions provider	10.5%	11.1%	9.1%
Adequacy of employee knowledge	13.2%	7.4%	27.3%
Ability to dedicate our IT to testing and implementation	26.3%	29.6%	18.2%
Lack of trading partner understanding and/or commitment	23.7%	14.8%	45.5%
Delaying due to past and/or potential future enforcement discretion	26.3%	33.3%	9.1%
Lack of guidance	29.0%	25.9%	36.4%
Other	36.8%	48.2%	9.1%

Table 2: Distributor Data	Distributor
Is your company…	
(N)	*16*
a Manufacturer	18.8%
a 3PL	18.8%
a Distributor	100.0%
Is your company using EPCIS v1.2 or higher?	
(N)	*16*
Yes	68.8%
No	31.3%
Are your company sales...	
(N)	*16*
Over $1B	50.0%
Under $1B	50.0%
How many suppliers do you have successful connections with, in a production environment?	
(N)	*16*
Average	29
Median	9
75th Percentile	28
25th Percentile	0
How many suppliers do you plan to have connections with once fully implemented?	
(N)	*16*
Average	316
Median	257
75th Percentile	459
25th Percentile	163
How many suppliers are you currently in the process of connecting with in a production environment?	
(N)	*16*
Average	18
Median	4
75th Percentile	13
25th Percentile	1

Table 2 (continued)	Distributor
How many dispenser customers are you currently in the process of connecting with?	
(N)	*15*
Average	0
Median	0
75^{th} Percentile	0
25^{th} Percentile	0
How many dispenser customers do you have successful connections with in a production environment?	
(N)	*15*
Average	0.07
Median	0.00
75^{th} Percentile	0.00
25^{th} Percentile	0.00
How many dispenser customers do you plan to have connections with once fully implemented?	
(N)	*13*
Average	229
Median	40
75^{th} Percentile	200
25^{th} Percentile	0
Of the manufacturers that you have successfully connected with, how many are having difficulties with the EPCIS event data?	
(N)	*12*
Average	8
Median	3
75^{th} Percentile	16
25^{th} Percentile	0

Table 2 (continued)	Distributor
What obstacles are you facing with build, integration, or adoption of EPCIS?	
(N)	*16*
Adequacy of financial resources	6.3%
Adequacy of employee resources/availability	31.3%
Availability of consultants/service provider/solutions provider	12.5%
Adequacy of employee knowledge	12.5%
Ability to dedicate our IT to testing and implementation	31.3%
Lack of trading partner understanding and/or commitment	87.5%
Delaying due to past and/or potential future enforcement discretion	31.3%
Lack of guidance	31.3%
Other	25.0%

Table 3: 3PL Data	3PL
Is your company…	
(N)	*4*
a Manufacturer	50.0%
a 3PL	100.0%
a Distributor	75.0%
Is your company using EPCIS v1.2 or higher?	
(N)	*4*
Yes	75.0%
No	25.0%
How many manufacturer suppliers do you have?	
(N)	*4*
Average	81
Median	39
75th Percentile	*
25th Percentile	*
How many successful connections do you have with distributors on behalf of your manufacturer customers in a production environment?	
(N)	*4*
Average	4
Median	2
75th Percentile	*
25th Percentile	*
How many connections with distributors do you plan to have once fully implemented?	
(N)	*4*
Average	104
Median	80
75th Percentile	*
25th Percentile	*

*Insufficient data

Table 3 (continued)	3PL
How many distributors are you currently in the process of connecting with?	
(N)	*4*
Average	4
Median	2
75th Percentile	*
25th Percentile	*
Do you have connections with dispensers?	
(N)	*4*
Yes, via a direct connection	50.0%
Yes, via a third party	25.0%
No, I do not maintain connections with dispensers	25.0%
What obstacles are you facing with build, integration, or adoption of EPCIS?	
(N)	*4*
Adequacy of financial resources	25.0%
Adequacy of employee resources/availability	25.0%
Availability of consultants/service provider/solutions provider	0.0%
Adequacy of employee knowledge	0.0%
Ability to dedicate our IT to testing and implementation	0.0%
Lack of trading partner understanding and/or commitment	50.0%
Delaying due to past and/or potential future enforcement discretion	25.0%
Lack of guidance	0.0%
Other	50.0%

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