EPCIS IMPLEMENTATION BENCHMARKING SURVEY

HDA RESEARCH FOUNDATION

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Antares Vision is recognized as the world's leading provider of serialization-based track and trace solutions for the pharmaceutical industry, with more serialization systems installed worldwide than all major competitors. Antares Vision has installed solutions on over 1,300 production lines in 200 plants around the world. Antares Vision offers a one stop solution spanning from level 1 (line automation) to level 4 (data communication). The company features a complete track-and-trace solution for warehouses, distribution centers and re-packagers.

LSPediA provides SaaS solutions to the pharmaceutical industry. Manufacturers, wholesale distributors, dispensers, and healthcare providers partner with LSPediA to make, move, track, verify, and protect the drug products in their care for patient safety. LSPediA is different because our solution potential is limitless. Built with user efficiency, automation, and data security at their core, our solutions are transforming compliance and supply chain efforts. LSPediA's OneScan VRS, EPCIS & Investigator technologies enable error-free and keyboard-free capabilities for ASN, EPCIS, VRS, issue tracking, and interoperability.

BRONZE

Two Labs, founded in 2003 and headquartered in Columbus, Ohio, has offices and operations across the US and UK, and is a leading pharmaceutical services company that partners with pharma/biotech companies. At Two Labs, we understand no two product paths are alike. We deliver integrated and customized commercial solutions, helping to chart the path from clinical to commercial for a new product launch and provide strategies for continued market viability for drugs on the market. Our suite of DSCSA and Trade Management services specifically offer manufacturers compliance security, operations improvement and increased productivity. Two Labs has a proven track record of successful launches (250+ and counting) across all major therapeutic areas with unmatched client satisfaction.

Introduction

On November 27, 2023, the Drug Supply Chain Security Act 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 HDA Research Foundation to benchmark the 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. The Foundation aims to conduct this survey biannually, but future surveys are subject to funding availability.

Methodology

The Foundation's research partner, Industry Insights — a leading, independent research firm — hosted the survey from April 20 to June 4, 2021. The survey was distributed via email, with 70 companies responding: 52 manufacturers, 21 distributors, and five 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.

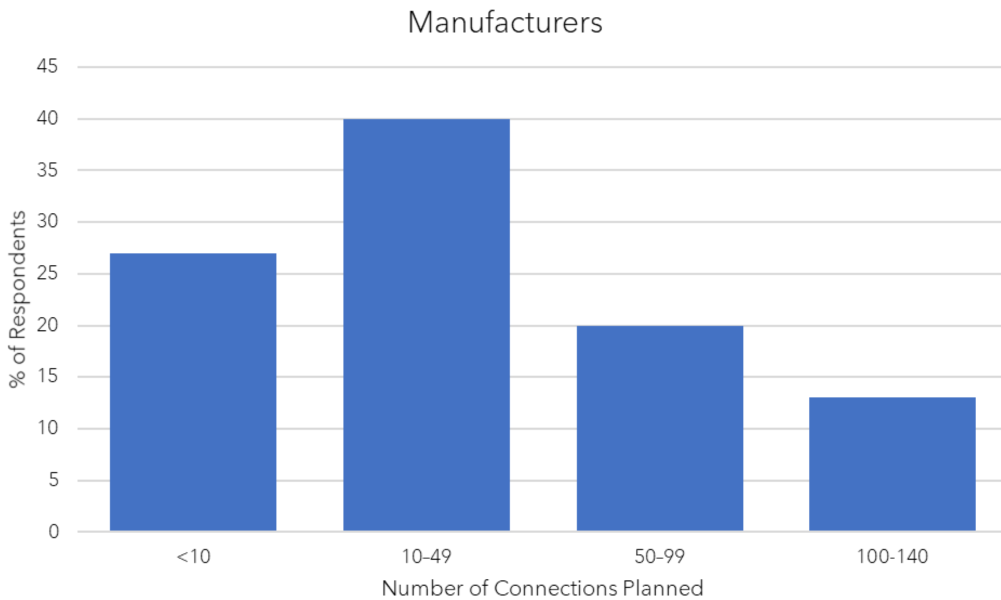
1 In 2014, FDA recognized that EPCIS was a compliant electronic-based method for the interoperable exchange of transaction data. *Draft Guidance for Industry, DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product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

Results by Company Type

Manufacturers

A majority (84 percent) of surveyed manufacturers 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



Nearly two-thirds (62 percent) of manufacturers are planning to connect directly with distributors, while 38 percent are planning to use a 3PL to manage connections downstream. A majority of manufacturers do not have connections with dispensers. Only 16 percent currently are directly connected to dispensers. One-quarter plan to use a third party to connect with dispensers.

Nearly half (49 percent) of manufacturers report they are not currently in the process of connecting with distributors. Thirty-five percent of manufacturers are in the process of connecting with between one and nine distributors, while 16 percent are in the process of connecting with more than 10. More than half (57 percent) of manufacturers have no successful connections in a production environment today. One-third (32 percent) have between one and nine successful connections in a production environment today. Just 10 percent have between 10 and 40 successful connections in a production environment today.

Twenty-seven percent of manufacturers plan to have fewer than 10 connections with distributors once fully implemented. Forty percent plan to have between 10 and 50 connections. Twenty percent plan to have between 50 and 99 connections. Thirteen percent plan to have between 100 and 140 connections in total once fully implemented.

Most manufacturers (59 percent) are not sending data to distributors. Nearly one-third (29 percent) are sending data to between one and six distributors. Ten percent are sending data to between 20 and 40 distributors.

Key Obstacles to Implementation

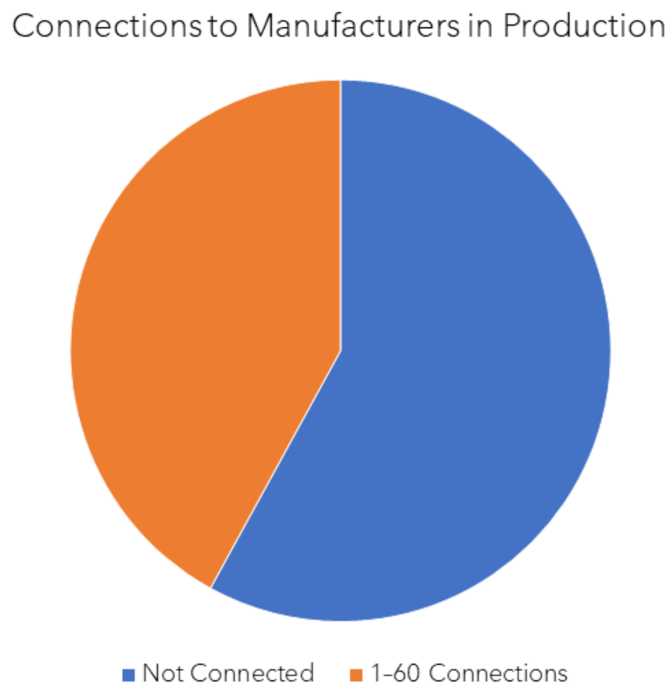
Manufacturer respondents were asked to identify key obstacles to implementing EPCIS. The top obstacle respondents identified was a delay due to either past or potential future enforcement discretion (43 percent). Thirty-nine percent cited "other," indicating:

- The industry is moving slowly to implement EPCIS;
- The company lacks the resources to adopt the standard;
- A lack of standards or lack of adherence to standards (GLN, EPCIS, etc.)[2];
- A need for internal IT upgrades first (line, packaging, aggregation and vendor upgrades); and,
- The company needs to focus on internal error resolution first.

Other obstacles cited were a lack of trading partner understanding or commitment (35 percent), lack of guidance (31 percent), adequacy of employee resources or availability (29 percent) and the ability to dedicate IT staff to testing and implementation (22 percent).

Distributors

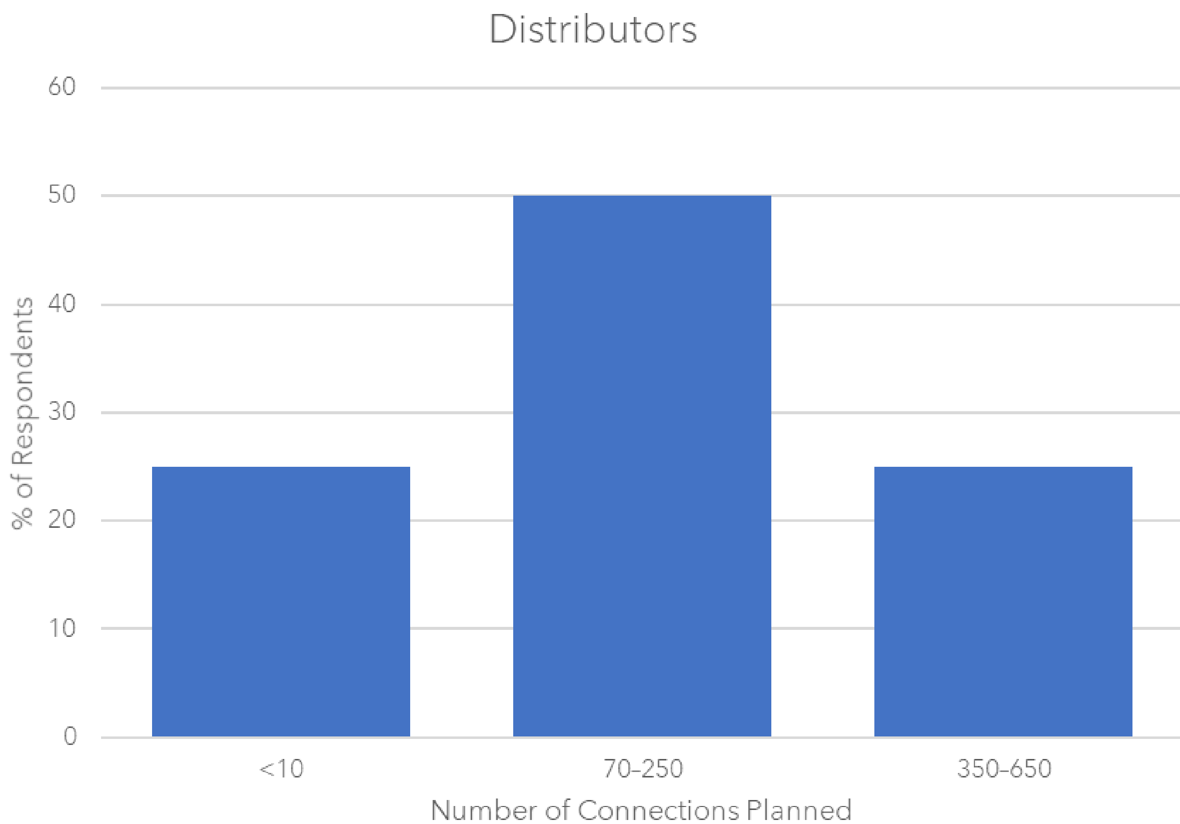
Figure 2: Distributor Connections with Manufacturers



Most distributors (58 percent) are not connected to manufacturers in production. Forty-two percent have between 1 and 60 connections in a production environment. Once fully implemented, one-quarter of distributors anticipate having fewer than 10 connections. Half of distributors expect to have somewhere between 70 and 250 connections, and a quarter plan to have between 350 and 650 connections.

2 Alignment on, and adherence to a common standard is a prerequisite to achieving interoperability. Recognizing this, DSCSA requires provision of transaction data in accordance with the standards of an international standards development organization. For exchanging transaction data and master data, industry has aligned on the use of GS1 standards. EPCIS is the only standard of an international standards development organization capable of passing product identifiers in transaction data, which the DSCSA requires in 2023. The Global Location Number (GLN), Global Company Prefix (GCP) and Global Trade Item Number (GTIN) are considered master data elements required for EPCIS implementation. For more details on the GS1 suite of standards for DSCSA visit GS1 US here.

Figure 3: Distributors' Planned Connections with Dispensers



Only half of distributors 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, 45 percent of distributors do not plan to have direct connections to dispensers, while one-quarter 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 interoperably with dispensers and posted to a portal that the wholesale distributor maintains on behalf of the dispenser and accessed by the dispenser.

In open-ended comments, respondents noted that COVID-19 has slowed adoption of EPCIS. Additionally, some companies noted that it is difficult to determine how many of their dispenser partners will want direct connections for EPCIS, rather than portal connections. Those numbers could vary widely if they are based, for example, on how many Advance Ship Notice connections they have today.

The top obstacle that distributors reported (75 percent) was a "lack of trading partner commitment." Other concerns included the ability to dedicate an IT team to testing and implementation (35 percent), and employee resources, lack of guidance and past or future enforcement discretion (25 percent).

Third-Party Logistics Providers

A typical 3PL currently is working to connect an average 67 manufacturer clients. On average, a 3PL has 10 successful connections today and is in the process of connecting with five customers. Key obstacles cited included delays due to past or potential future enforcement discretion and lack of trading partner understanding or commitment, limited guidance or not having a dedicated IT team.

In comments, 3PLs cited the readiness of their clients to proceed as a hurdle, as well as wholesale distributors often not articulating clear deadlines to trading partners for taking necessary steps — which they believe is slowing integration.

Conclusion

Overall, the industry is in an initial stage 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 nearly 40 percent of manufacturers are relying on 3PLs, sharing information on the timing of connections and data send with distributors will be critical, as this additional connection adds a layer of complexity to the process.

Only half of distributors 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 seven quarters to meet this deadline, and addressing obstacles identified, such as “lack of trading partner commitment” and “adherence to standards” will be essential.

Data Tables

Figure 4: Manufacturer Data

	Manufacturer	Company Focus	
		Brand	Generic
Is your company…			
(N)	*52*	*33*	*19*
a Manufacturer	100.0%	100.0%	100.0%
a 3PL	3.9%	0.0%	10.5%
a Distributor	7.7%	3.0%	15.8%
Is your company using EPCIS v1.2 or higher?			
(N)	*51*	*33*	*18*
Yes	84.3%	78.8%	94.4%
No	15.7%	21.2%	5.6%
Are your company sales...			
(N)	*50*	*31*	*19*
Over $1B	70.0%	77.4%	57.9%
Under $1B	30.0%	22.6%	42.1%
Is your company primarily…			
(N)	*52*	*33*	*19*
Brand	63.5%	100.0%	0.0%
Generic	36.5%	0.0%	100.0%
Do you have direct connections with distributors?			
(N)	*50*	*31*	*19*
Yes	62.0%	64.5%	57.9%
No, I am using a 3PL	38.0%	35.5%	42.1%
Do you have connections with dispensers?			
(N)	*51*	*32*	*19*
Yes, via a direct connection	15.7%	18.8%	10.5%
Yes, via a third party (e.g., 3PL or solution provider)	19.6%	15.6%	26.3%
No, I do not maintain connections with dispensers	64.7%	65.6%	63.2%

	Manufacturer	Company Focus	
		Brand	Generic
How many distributors are you currently in the process of connecting with in a production environment?			
(N)	*49*	*31*	*18*
Average	10	7	15
Median	1	1	1
75th Percentile	4	3	6
25th Percentile	0	0	0
How many successful connections do you have with distributors in a production environment?			
(N)	*49*	*31*	*18*
Average	4	2	6
Median	0	0	1
75th Percentile	5	3	6
25th Percentile	0	0	0
How many connections with distributors do you plan to have once fully implemented?			
(N)	*45*	*28*	*17*
Average	39	30	54
Median	30	23	50
75th Percentile	50	37	80
25th Percentile	8	8	25
How many distributors are you currently sending data?			
(N)	*48*	*30*	*18*
Average	4	2	6
Median	0	0	1
75th Percentile	2	2	3
25th Percentile	0	0	0

	Manufacturer	Company Focus	
		Brand	Generic
What obstacles are you facing with build, integration or adoption of EPCIS?			
(N)	*49*	*30*	*19*
Adequacy of financial resources	18.4%	6.7%	36.8%
Adequacy of employee resources/availability	28.6%	23.3%	36.8%
Availability of consultants/service provider/solutions provider	16.3%	10.0%	26.3%
Adequacy of employee knowledge	12.2%	6.7%	21.1%
Ability to dedicate our IT to testing and implementation	22.5%	20.0%	26.3%
Lack of trading partner understanding and/or commitment	34.7%	30.0%	42.1%
Delaying due to past and/or potential future enforcement discretion	42.9%	33.3%	57.9%
Lack of guidance	30.6%	33.3%	26.3%
Other	38.8%	46.7%	26.3%

Figure 5: Distributor Data

	Distributor
Is your company…	
(N)	*21*
a Manufacturer	19.1%
a 3PL	19.1%
a Distributor	100.0%
Is your company using EPCIS v1.2 or higher?	
(N)	*21*
Yes	47.6%
No	52.4%
Are your company sales...	
(N)	*20*
Over $1B	35.0%
Under $1B	65.0%
How many suppliers do you have successful connections with, in a production environment?	
(N)	*19*
Average	11
Median	0
75th Percentile	15
25th Percentile	0
How many suppliers do you plan to have connections with once fully implemented?	
(N)	*20*
Average	202
Median	192
75th Percentile	275
25th Percentile	54
How many suppliers are you currently in the process of connecting with in a production environment?	
(N)	*20*
Average	5
Median	1
75th Percentile	5
25th Percentile	0

	Distributor
How many dispenser customers are you currently in the process of connecting with?	
(N)	*20*
Average	0
Median	0
75th Percentile	0
25th Percentile	0
How many dispenser customers do you have successful connections with in a production environment?	
(N)	*19*
Average	0
Median	0
75th Percentile	0
25th Percentile	0
How many dispenser customers do you plan to have connections with once fully implemented?	
(N)	*14*
Average	62
Median	0
75th Percentile	21
25th Percentile	0
Of the manufacturers that you have successfully connected with, how many are having difficulties with the EPCIS event data?	
(N)	*15*
Average	3
Median	0
75th Percentile	5
25th Percentile	0

	Distributor
What obstacles are you facing with build, integration, or adoption of EPCIS?	
(N)	*20*
Adequacy of financial resources	15.0%
Adequacy of employee resources/availability	25.0%
Availability of consultants/service provider/solutions provider	15.0%
Adequacy of employee knowledge	15.0%
Ability to dedicate our IT to testing and implementation	35.0%
Lack of trading partner understanding and/or commitment	75.0%
Delaying due to past and/or potential future enforcement discretion	25.0%
Lack of guidance	25.0%
Other	25.0%

Figure 6: 3PL Data

	3PL
Is your company…	
(N)	*5*
a Manufacturer	40.0%
a 3PL	100.0%
a Distributor	80.0%
Is your company using EPCIS v1.2 or higher?	
(N)	*5*
Yes	60.0%
No	40.0%
How many manufacturer suppliers do you have?	
(N)	*
Average	*
Median	*
75th Percentile	*
25th Percentile	*
How many successful connections do you have with distributors on behalf of your manufacturer customers in a production environment?	
(N)	*5*
Average	10
Median	1
75th Percentile	*
25th Percentile	*
How many connections with distributors do you plan to have once fully implemented?	
(N)	*5*
Average	67
Median	30
75th Percentile	*
25th Percentile	*

	3PL
How many distributors are you currently in the process of connecting with?	
(N)	*5*
Average	5
Median	1
75th Percentile	*
25th Percentile	*
Do you have connections with dispensers?	
(N)	*5*
Yes, via a direct connection	40.0%
Yes, via a third party	20.0%
No, I do not maintain connections with dispensers	40.0%
What obstacles are you facing with build, integration, or adoption of EPCIS?	
(N)	*5*
Adequacy of financial resources	0.0%
Adequacy of employee resources/availability	0.0%
Availability of consultants/service provider/solutions provider	0.0%
Adequacy of employee knowledge	0.0%
Ability to dedicate our IT to testing and implementation	20.0%
Lack of trading partner understanding and/or commitment	20.0%
Delaying due to past and/or potential future enforcement discretion	40.0%
Lack of guidance	20.0%
Other	60.0%

HDA RESEARCH FOUNDATION

HDA Research Foundation
901 North Glebe Road, Suite 1000
Arlington, VA 22203

(703) 787-0000
(703) 812-5282 (Fax)

www.hda.org/foundation