EPCIS IMPLEMENTATION BENCHMARKING SURVEY

HDA
Healthcare Distribution Alliance

TABLE OF CONTENTS

INTRODUCTION

In just a little over a year, the healthcare supply chain is required to fully implement the [Drug Supply Chain Security Act (DSCSA)](#). After this date, industry trading partners are required 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. In recent guidance, FDA named GS1's Electronic Product Code Information Services (EPCIS) as the recognized standard that allows trading partners to complete this task.[1]

By November 27, 2023, DSCSA requires transaction data with product identifiers to be provided with physical product. However, it became apparent to many industry stakeholders there is a long road toward compliance and that preparation was needed to guarantee:

- 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, 2023.

Accordingly, industry and service providers approached the Healthcare Distribution Alliance (HDA) to continue benchmarking progress of EPCIS adoption and trading partner plans for sending data. This edition of the HDA's *EPCIS Implementation Benchmarking Survey* is a follow-up to the survey conducted by the HDA Research Foundation in late 2021.

Through this survey, HDA 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.

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[1] "[DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry (July 2022)](#)," 87 Fed. Reg. 40258 (July 6, 2022; Interoperable Data Exchange Guidance).

METHODOLOGY

HDA conducted two surveys: in February 2022 (Q1) and June 2022 (Q2). Each survey was distributed via email, with 65 companies responding: 29 manufacturers, 14 distributors, and two 3PLs. (In some instances, companies fulfill multiple supply chain responsibilities; as an example, a distributor might operate its own 3PL.) All data collected by HDA are strictly confidential. Data were compiled and thoroughly reviewed to help ensure consistency and coherence. Additionally, due to the lower volume of 3PL respondents in this cycle, this report will not include data reflecting those responses, as it was not a significant amount of data to reflect the effort of that portion of the industry. Therefore, this report will address progress made by manufacturers and distributors for quarter one (Q1) and quarter two (Q2) of 2022.

RESULTS

Figure 1: Manufacturers Using EPCIS v1.2

Is Your Company Using EPCIS v1.2?
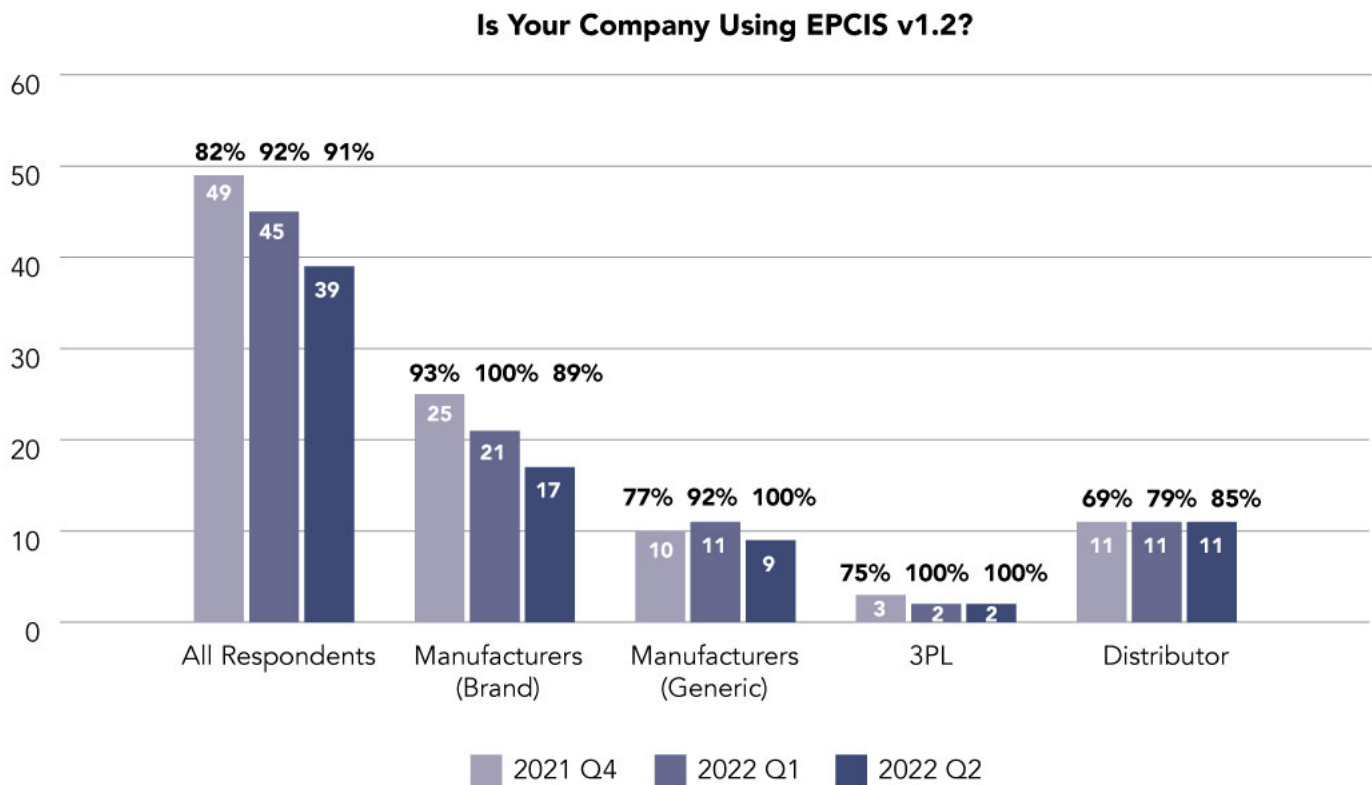
MANUFACTURERS

In recent months, the FDA endorsed EPCIS as the accepted standard for exchanging Transaction Information (TI) and the Transaction Statement (TS). Recognition of this standard came in good timing as survey results indicate the industry's move toward the use of EPCIS v.1.2 and later versions going forward. Most surveyed manufacturers (92 percent in Q1 2022 and 91 percent in Q2 2022) 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 2: Reported Connections between Manufacturers and Distributors
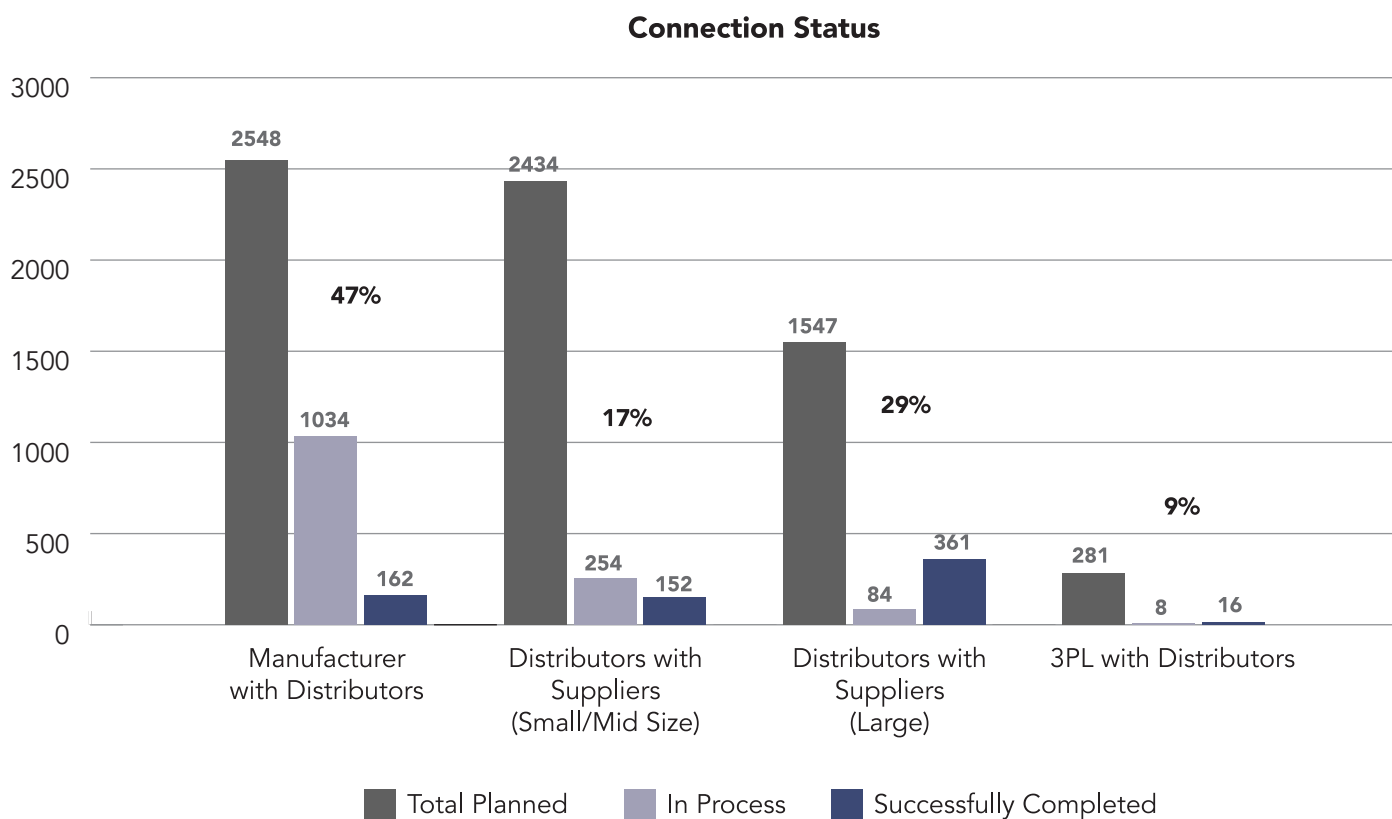
Connection Status

In 2022, manufacturers started connecting with partners downstream as distributors called for trading partners to begin the early phases of onboarding. The fourth quarter of 2021 closed with the survey tracking a total of 850 connections. Since then, there has been a significant upward trend in connections; manufacturers now report a total of 2,548 planned connections to distributors, with 47 percent either "in process" or "completed" as of the second quarter.

Key Obstacles to Implementation

Manufacturer respondents were asked to identify key obstacles to implementing EPCIS. In the first quarter, the top obstacle identified (at 56 percent of respondents) was "adequacy of employee resource/availability," followed by "other," at 46 percent. Additional responses were ranked accordingly:

- Trading partner understanding and commitment (40 percent);

- Ability to dedicate IT resources (36 percent);

- Lack of guidance (33 percent);

- Potential enforcement discretion (26 percent);

- Third-party provider availability (23 percent);

- Adequacy of financial resources (23 percent); and,

- Employee knowledge (13 percent);

Some of the "other" obstacles cited were:

- "Internal IT upgrades required to exchange data, and availability of internal and external resources due to COVID and resources residing in different time zones"

- "Lack of FDA clarity especially regarding their own timelines"

- "Also lack of guidance on exception handling scenarios"

- "Data alignment/master data share solution"

- "Aggregation"

- "Industry uncertainty - production procedures, ex: exceptions management"
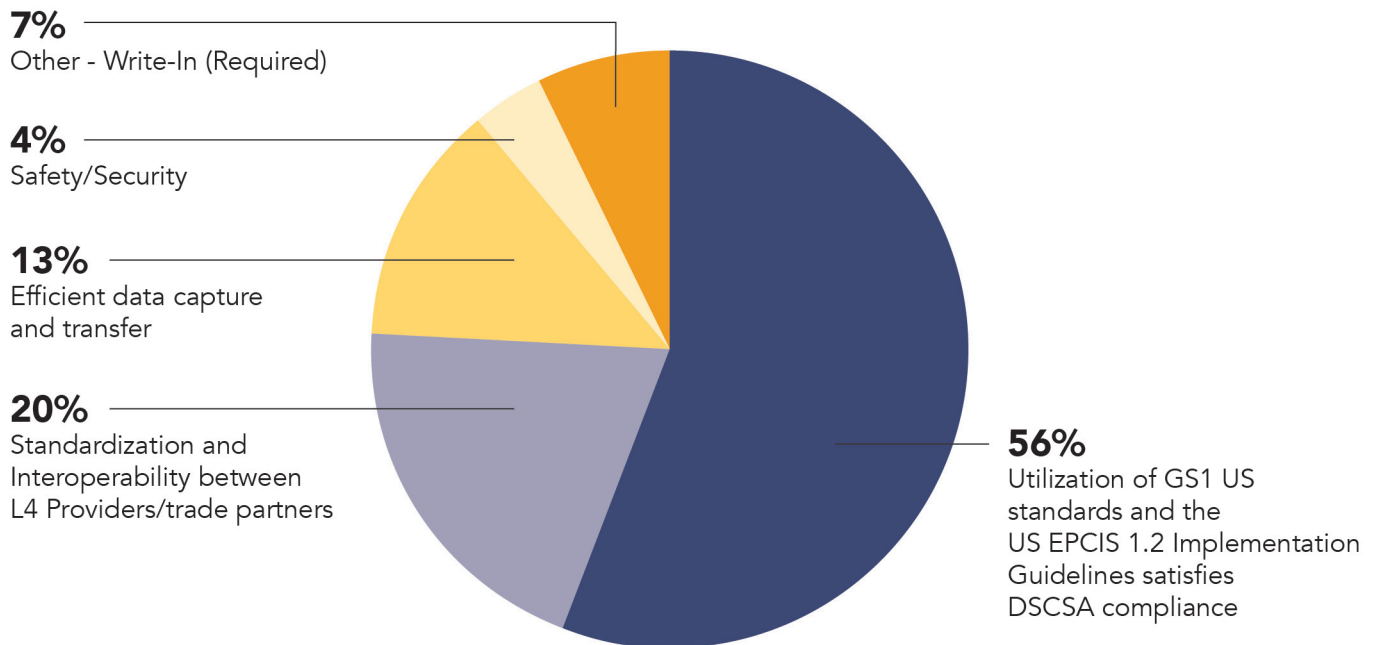
- "Time required for each implementation"

Likewise, the same question was asked in the second quarter following several months of onboarding. Sixty-two percent of manufacturers reported their top obstacle was a "lack of trading partner understanding and/or commitment"; thirty-seven percent reported "adequacy of employee resources/availability" and the "ability to dedicate out IT to testing and implementation" as challenges. Additional responses were ranked accordingly:

- Length of time to onboard trading partners (27 percent);

- Availability of consultants/service provider/solution provider (20 percent);

- Lack of aggregation (17 percent);

- Other (17 percent);

- Adequacy of employee knowledge (13 percent);

- Delaying due to past and/or potential future enforcement discretion (13 percent); and,

- Lack of guidance (6 percent);

Some of the "other" obstacles cited were:

- "Companies not responding"

- "System constraints, resource turnover, CMO delays"

- "Company spin-offs"

- "Currently upgrading internal serialization system"

- "Downstream partner readiness; partners changing architectures; industry standard revisions to comply with DSCSA 2023; interpretation of DSCSA and strategy changes between trading partners vary - everyone still tweaking processes, systems are not final even after qualification"

Figure 3: Perceived Benefits of Using EPCIS v1.2

7%
Other - Write-In (Required)

4%
Safety/Security

13%
Efficient data capture
and transfer

20%
Standardization and
Interoperability between
L4 Providers/trade partners

56%
Utilization of GS1 US
standards and the
US EPCIS 1.2 Implementation
Guidelines satisfies
DSCSA compliance

Perceived Benefits Of Adopting EPCIS

In the first quarter, manufacturer respondents indicated it was "too early to assess any benefits," yet noted that the key benefit for adopting EPCIS would be "safety/security." By quarter two, this perception had evolved, with results indicating that 35 percent of the participants "are seeing benefits" while 43 percent are still reporting that it is "too early to see benefits." Two percent of the respondents reported that they "have implemented and are not seeing benefits." Lastly, 20 percent have "not yet implemented EPCIS" and therefore are not reporting any benefits.

As onboarding is underway, manufacturers reported that they could see other key benefits aside from "safety/security," which dropped to 4 percent in Q2. Other key benefits reported were "utilization of GS1 standards and the US EPCIS 1.2 Implementation Guideline satisfies DSCSA compliance" (56 percent), "standardization and interoperability between L4 providers/trade partners" (20 percent) and "efficient data capture and transfer" (20 percent). Lastly, 7 percent indicated "other" key benefits.

DISTRIBUTORS

Figure 4: 2022 Trends for Distributor Connections

	2022 Trends							
	Mfres > Dist		**Dist > Supp (Small/Mid)**		**Dist > Supp (Large)**		**3PL > Dist**	
	Q1	Q2	Q1	Q2	Q1	Q2	Q1	Q2
Total Planned	64	2,548	162	2,434	528	1,547	141	281
% Complete/ In Process	30%	47%	10%	17%	23%	29%	6%	9%

Across both quarters, distributors are experiencing an uptick in connections. From Q1 to Q2, there was an increase from 162 to 2,434 total planned connections between distributors and small, middle-sized suppliers. Of those connections, 17 percent are reported being complete or in process at the end of the second quarter. For large suppliers, distributors have moved from 528 planned connections to 1,547, with 29 percent of those companies either completed or in process at the end of the second quarter. Nine percent of the total 281 planned connections were complete or in process as of the end of the second quarter. When asked to comment of their current connections, the open-ended responses were as follows:

- "A lot of manufacturers are not ready to test"

- "Suppliers are connected to send EPCIS, but our warehouses are still being implemented with technology to utilize the data; unknown at this point if suppliers are having trouble with EPCIS data accuracy"

- "There will be 150 customer connections comprising 20,000 customer accounts for chains, health systems and government customers"

- "Expect to ramp up a lot this year especially around September to end of the year"

As previously noted, respondents acknowledged how dispensers primarily have plans to use a portal provided by the wholesale distributor, therefore maintaining relatively slow numbers of direct distributor-to-dispenser connections. Rather, distributors reported that transaction data will be exchanged in an interoperable manner with manufacturers and posted to a portal that the wholesale distributor maintains on behalf of the dispenser and is ultimately accessed by the dispenser.

CONCLUSION

Overall, the industry continues to move toward DSCSA implementation as partners have ramped up onboarding efforts and begin testing solutions for EPCIS interoperability and data exchange. While many manufacturers have prepared internally to send data downstream with the transition to EPCIS 1.2, a notable increase in connections suggests that sending data in production today will continue to progress. However, the industry will need the more than 2,500 planned connection to go in an "in-process" or "completed" phase to accurately evaluate readiness for November 27, 2023.

Further, industry stakeholders still have significant work to do over the next year, and companies must continue to address lingering obstacles identified, such as a "lack of trading partner understanding/commitment" and "dedicated IT and employee resources." Assessing the increased percentage of respondents who answered, a "lack of trading partner understanding and/or commitment" and provided open-ended responses suggesting a need for more educational resources led HDA to add another question to the survey to probe the format of knowledge-sharing medium that would be most beneficial to trading partners. Sixty percent identified a webinar as the most beneficial tool. Face-to-face workshops (17.8 percent), articles (4.4 percent), a knowledge portal (13.3 percent) and "other" (4.4 percent) comprised the remaining responses. Responses imply that industry leaders and associations must play an important role in sharing information on requirements and processes, thus bridging the knowledge gap for supply chain partners. Commitment to these activities that share knowledge and empower stakeholders to engage with implementation efforts could stimulate progress and push the industry toward achieving DSCSA compliance by the fast-approaching deadline.

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