

EPCIS IMPLEMENTATION BENCHMARKING SURVEY

Third Quarter 2022

TABLE OF CONTENTS

- Introduction** 2
- Methodology** 3
- Manufacturers** 4
 - Key Obstacles to Implementation 5
 - Perceived Benefits Of Adopting EPCIS 5
- Distributors** 6
- Conclusion** 6

INTRODUCTION

The FDA will begin enforcing the Drug Supply Chain Security Act (DSCSA) of 2013 in a little more than 11 months, further securing the U.S. pharmaceutical supply chain against the threat of illegitimate product movement. Over the past 10 years, pharmaceutical supply chain stakeholders have been preparing for this complete overhaul of systems and processes for shipping and verification of medicines and drug products. After November 27, 2023, pharmaceuticals will travel through a multi-layered chain of custody — from manufacturers to dispensing pharmacies — with transaction data with product identifiers required to be provided with physical product.

Stakeholders have identified the standards for exchanging transaction data, which include product identifiers for the package(s) transacted in a secure, electronic, interoperable manner complying with all elements of the published FDA guidance. FDA has named GS1's Electronic Product Code Information Services (EPCIS) as the recognized standard that will allow trading partners to exchange transaction data.

The following key elements continue to be prioritized by trading partners:

- That 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.

HDA continues to benchmark progress of EPCIS adoption and trading partner plans for sending data through quarterly surveys. As the DSCSA deadline approaches, 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, repackagers and third-party logistics providers (3PLs) face in establishing those connections. This edition of HDA's EPCIS Implementation Benchmarking Survey is a follow-up to survey conducted in June 2022.

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 this survey in October 2022 to capture third quarter insights from supply chain partners. Each survey was distributed via email, with 70 companies responding: 45 manufacturers (27 brand and 18 generic), 18 distributors, four repackagers 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 HDA are entered into a proprietary system and are strictly confidential. Data were compiled and thoroughly reviewed to help ensure consistency and coherence.

This survey report will primarily address manufacturer and distributor progress in the third quarter of 2022. Due to the lower volume of repackagers and 3PL respondents this cycle, minimal data are included to avoid misrepresenting the work underway in this segment.

RESULTS

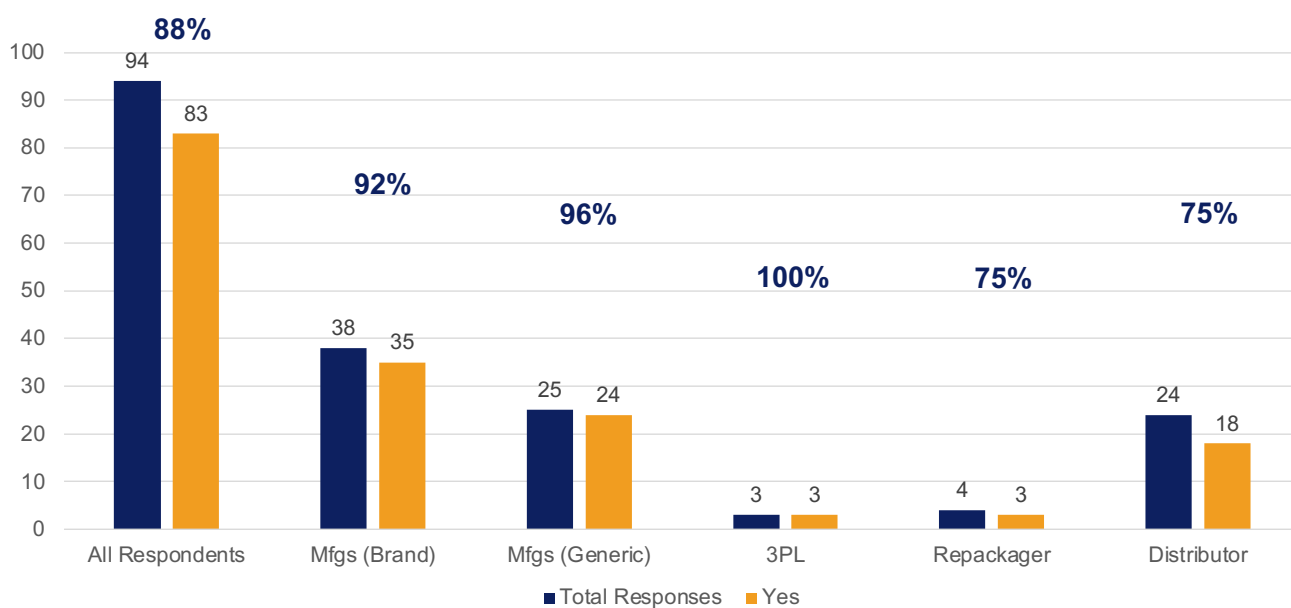
Figure 1. Total Responses and Business Categories

Surveys	Number of Responses	Categories				
	Total	Mfgs. (Brand)	Mfgs. (Generic)	3PL	Repackager	Distributor
Q3 2022	70	27	18	3	4	18
Q2 2022	41	20	9	2	New Category for Q3 survey	10
Q1 2022	47	21	10	2		14

MANUFACTURERS

As noted in prior report, in 2022 the FDA acknowledged EPCIS as the accepted standard for transaction information and transaction statement exchange. Survey results indicate the industry continues to move toward the use of EPCIS 1.2 and later versions going forward. Most surveyed manufacturers (88 percent) have already 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. Also noteworthy, there was a slight decline in the percentage from 92 to 88. To reduce survey fatigue, HDA proposed multiple changes in the format and distribution of the Q3 survey which resulted in a slight increase in respondents. The variance in the percentage of EPCIS use illustrated in the results can be attributed to the increase from 39 to 94 individual responses to this question.

Figure 2: Use of EPCIS 1.2



In 2022, manufacturers started connecting with partners downstream as manufacturers answered the call of distributors asking to begin the early phases of onboarding. Overall, the industry continues to make progress: manufacturers are now reporting 1,584 planned connections to distributors and 51 percent being either “in process” or “completed” as of Q3.

Figure 3: Connections Status

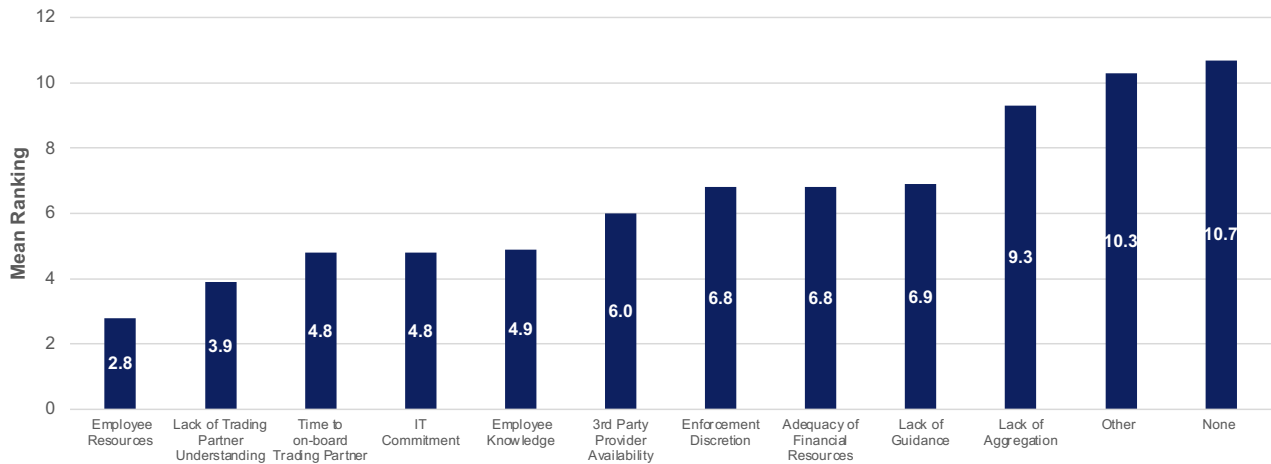
2022 Trends	Mfres to Dist			Dist (Small/Mid) to Suppliers			Dist (Large) to Suppliers			3PL to Dist		
	Q1	Q2	Q3	Q1	Q2	Q3	Q1	Q2	Q3	Q1	Q2	Q3
Total Planned	64	2548	1584 ↑	162	2434	2930 ↑	528	1547	1140 ↑	141	281	35 ↑
	30%	47%	51%	10%	17%	22%	23%	29%	56%	6%	9%	46%

Key Obstacles to Implementation

Over the last year, manufacturer respondents were asked to identify key obstacles to implementing EPCIS. Top obstacles reported in previous surveys were: “Lack of trading partner understanding and/or commitment” (62 percent); “adequacy of employee resource/availability” (56 percent); “other” (46 percent); and both “adequacy of employee resources/availability” and “ability to dedicate out IT to testing and implementation” (37 percent). In the third quarter, HDA revamped this question, asking respondents to rank their obstacles from 1 to 12 (with 1 having the greatest and 12 having the least impact on EPCIS Implementation). The top three obstacles are ranked as follows:

- Employee Resources (3)
- Lack of Trading Partner Understanding (4)
- Time to onboard Trading Partner/IT Commitment (5)

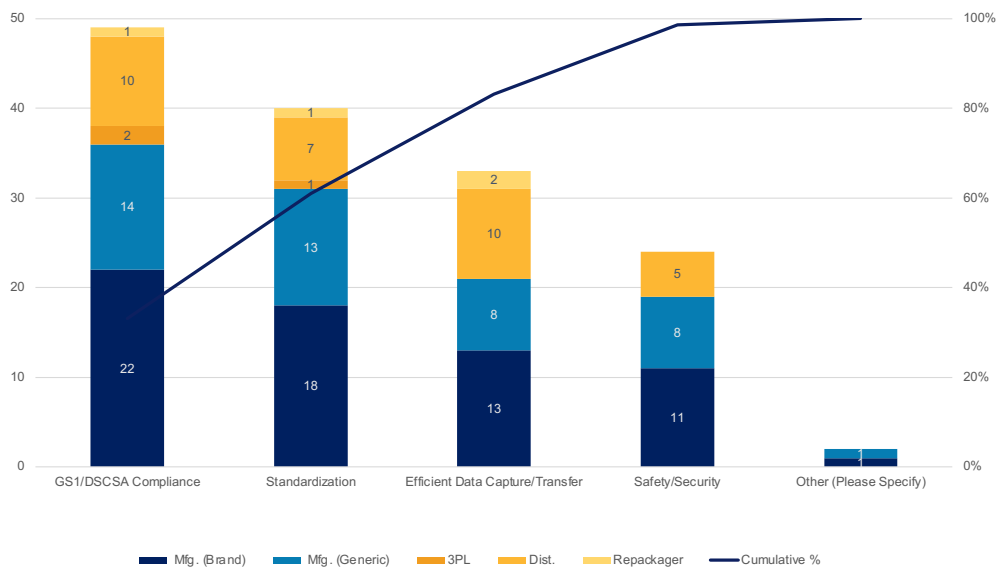
Figure 4: EPCIS ADOPTION OBSTACLES – Q3 2022



*Results may not be a whole number due to mean ranking based on the impact this issue has on on-boarding.

Perceived Benefits Of Adopting EPCIS

Thirty-one percent of manufacturer survey participants report they are seeing benefits while 37 percent report that it is still too early to see benefits. The top reported benefits of adopting EPCIS were the use of GS1 standards and that the US EPCIS 1.2 Implementation Guideline satisfies DSCSA compliance, standardization and interoperability, and efficient data capture and transfer.



DISTRIBUTORS

Over the last quarter, distributors moved from 2,434 to 2,930 total planned connections with small, mid-sized suppliers. For large suppliers, distributors have moved from 1,547 planned connections to 1,140. However, distributors have shown signs that they are moving steadily away from planned connections to completed. Survey results show an increase in the number of “in process” or “completed” connections from the first and second quarters, jumping from 17 to 22 percent for small, mid-sized suppliers and 29 to 56 percent large suppliers.

Most noteworthy is the increasing number of distributor connections to dispensers. In previous surveys, distributors indicated that dispensers primarily have plans to use a portal provided by the distributor, which revealed relatively slow numbers of direct distributor-to-dispenser connections. As of quarter three, “in process” and “completed” connections grew 9 percent to reach a promising 46 percent.

CONCLUSION

The supply chain is moving swiftly toward the final deadline for DSCSA compliance. As the third quarter 2022 *EPCIS Implementation Benchmarking Survey* highlights, the sector is progressing toward sharing transaction data in an efficient and interoperable manner. While survey results indicate the industry’s commitment to meeting that objective, they also illustrates the challenges that still remain to press forward on that commitment.

Overall, trading partners have made significant strides in aligning on the EPCIS standards, system implementation and onboarding, and connecting to partners as transaction data moves downstream. However, as 2022 ends, there are still major hurdles to overcome in the months ahead. Industry stakeholders must come together to address lingering obstacles identified, such as a perceived lack of trading partner understanding, commitment and engagement in the process of exchanging transaction data. There is also the issue of manpower and intellectual capital as the gaps in the IT workforce and employee resources continue to be problematic. HDA will continue to serve as a resource for industry knowledge by sharing survey insights and hosting educational activities — while empowering stakeholders to keep their foot on the gas to reach DSCSA compliance by the final deadline of November 27, 2023.



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