HOSPITALS, PHARMACIES, AND SERIALIZATION: THE STRATEGY OF EARLY ADOPTION

Key findings from the 2017 Global Drug Supply, Safety and Traceability Report

tracelink
Life Sciences Cloud

SERIALIZATION: WHY SOME PHARMACIES AREN'T WAITING FOR THE DSCSA DEADLINES

TraceLink's 2017 Global Drug Supply, Safety and Traceability (GDSST) Report is the largest survey ever conducted on pharmaceutical track and trace readiness with results from 660 respondents across the pharmaceutical supply chain, including 270 U.S. hospitals and retail pharmacies.

Serialization is driving a massive transformation across the industry. While a surprising number of U.S. hospitals and pharmacies are still not fully aware of the upcoming DSCSA regulations for serialization and electronic data exchange, some "early movers" are actively exploring new opportunities to improve operations and deliver better patient outcomes using serialization data and real-time information sharing.

This report focuses on the small subset of the pharmacies and hospitals surveyed for the 2017 GDSST Report that have already begun to explore the potential value of serialized data. It provides insight into the steps these early movers are taking to manage serialized product ahead of the DSCSA deadlines, and offers learnings you can use to assess and prepare your own serialization strategy from both a compliance and business value perspective.
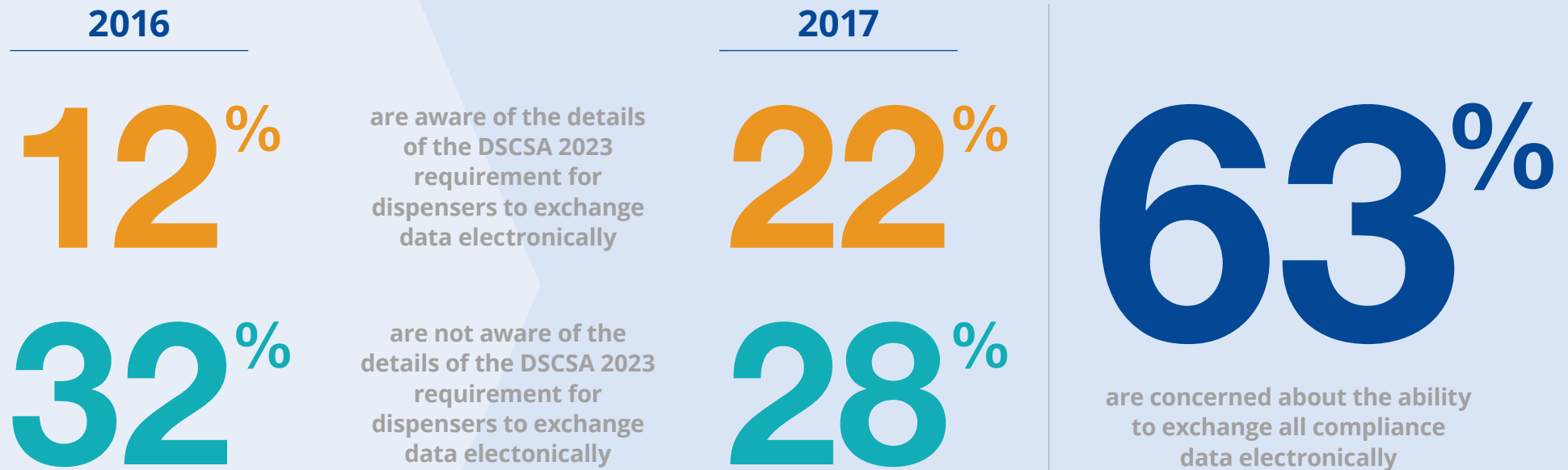
AWARENESS OF SERIALIZATION IS UP, BUT PHARMACIES HAVE CONCERNS ABOUT ELECTRONIC COMPLIANCE

While manufacturers are already shipping serialized product to wholesalers and, in some cases, directly to pharmacies, all hospitals and pharmacies will be directly affected by three upcoming DSCSA deadlines. In November 2019, wholesale suppliers will only be able to ship properly serialized product. One year later, in 2020, hospitals and pharmacies will only be able to receive serialized product—and must verify that it is properly serialized before they take ownership. Finally, in 2023, they must be able to exchange all compliance data electronically with their trade partners.

Compared to the 2016 GDSST Report, U.S. hospitals and pharmacies demonstrated an encouraging 10 percentage point increase in respondents that were familiar with the details around their DSCSA 2023 requirement. At the same time, 63% of respondents are concerned about their organization's ability to exchange all compliance data electronically in five years.

2016

12%
are aware of the details of the DSCSA 2023 requirement for dispensers to exchange data electronically

32%
are not aware of the details of the DSCSA 2023 requirement for dispensers to exchange data electonically

2017

22%

28%

63%
are concerned about the ability to exchange all compliance data electronically

WHAT ARE THE CHARACTERISTICS OF AN EARLY MOVER?

Of the 270 hospitals and pharmacies surveyed for the 2017 GDSST report, 11% are already taking steps to take advantage of serialization and electronic data exchange.
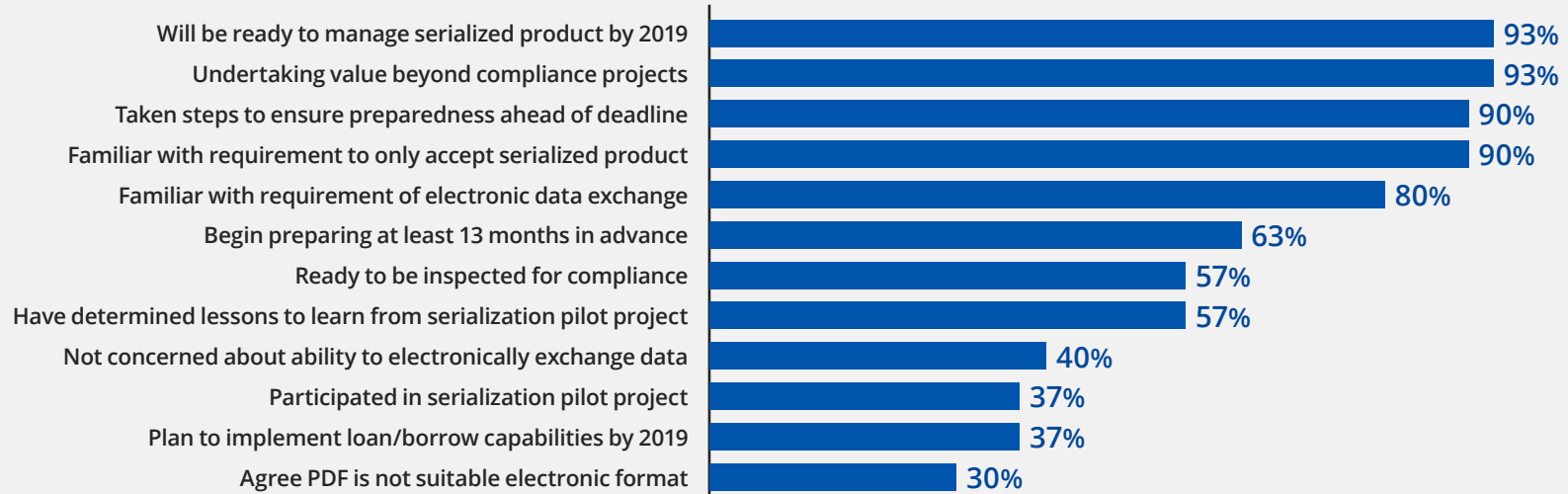
The vast majority of these early movers expect to manage serialized product when they start receiving it from their wholesale distributors in 2019. The same number are undertaking "value beyond compliance" projects to explore how they can use serialization data to improve operational efficiency and deliver greater business value.

Early movers, like all hospitals and pharmacies, are dependent on the efforts of their upstream trade partners in eliminating paper-based documentation. Surprisingly, only 30% agree that PDF is not a suitable format for electronic data exchange. This indicates that a significant portion of the dispenser segment still considers PDF as a viable electronic format, and may not realize that there are data formats specifically designed to exchange serialization data.

For example, the Electronic Product Code Information Service (EPCIS) standard has been cited by the FDA as an acceptable electronic format for reporting transactional information and exchanging serialization data to help meet DSCSA requirements.

Steps Taken
Showing % Have Taken the Step

Step	%
Will be ready to manage serialized product by 2019	93%
Undertaking value beyond compliance projects	93%
Taken steps to ensure preparedness ahead of deadline	90%
Familiar with requirement to only accept serialized product	90%
Familiar with requirement of electronic data exchange	80%
Begin preparing at least 13 months in advance	63%
Ready to be inspected for compliance	57%
Have determined lessons to learn from serialization pilot project	57%
Not concerned about ability to electronically exchange data	40%
Participated in serialization pilot project	37%
Plan to implement loan/borrow capabilities by 2019	37%
Agree PDF is not suitable electronic format	30%

Hospitals & Pharmacies 'Early Movers' (n=30)

VALUE OPPORTUNITIES OF MOST INTEREST TO THE INDUSTRY

Early movers are exploring how a product's unique product identifier—which will include a product code, lot number, expiration date, and serial number—can provide greater visibility into product inventory; recalled, stolen, or withdrawn product; and diverted or damaged product.

While any single company can gain a basic level of insight from its own serialized product data, the opportunity to leverage real-time information sharing across a digital supply chain network stands to truly unlock hidden business value and better patient outcomes.

Inventory management tops the list of potential value opportunities, with collective interest across the supply chain: pharma companies, CMOs, wholesalers, hospitals, and pharmacies. The ability to use serialization data for recall management is also of primary interest among pharma, CMOs, hospitals, and pharmacies.

Bolded items represent themes that are of interest by more than one group.

|	Pharma (n=124)	CMO (n=144)	Wholesale Distributors (n=43)	Hospitals and Pharmacies (n=216)	3PL (n=11)
Long-term Opportunities	**Inventory Management (27%)**	**Inventory Management (18%)**	**Inventory Management (53%)**	**Inventory Management (44%)**	Product Tracking (36%)
	Returns Management (27%)	Demand Forecasting (18%)	**Product Authentication (42%)**	Pharmacy Management Inventory (44%)	**Secure Product Distribution (27%)**
	Product Recall Management (25%)	**Product Recall Management (18%)**	**Secure Product Distribution (33%)**	**Product Recall Management (43%)**	**Product Authentication (27%)**

# INDUSTRY IS ALREADY STARTING ON VALUE-ADDED SERIALIZATION PROJECTS

Of all segments surveyed, CMOs and 3PLs are the most progressive of those already working on value-based projects.

And while only small percentages of pharma, wholesale distributors, hospitals, and pharmacies are currently working on value-based projects, these three segments are all planning to address this in the future.

Already working on projects

- Pharma: 19%
- CMO: 78%
- Wholesale Distributors: 24%
- Hospitals and Pharmacies: 17%
- 3PLs: 73%
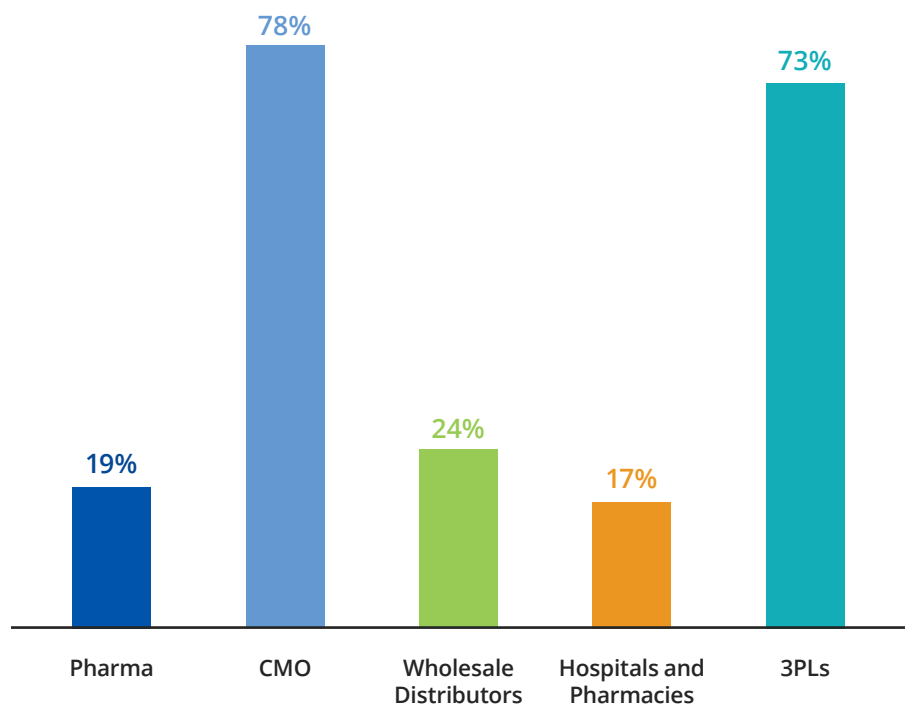
Planning to in the future

- Pharma: 52%
- CMO: 15%
- Wholesale Distributors: 62%
- Hospitals and Pharmacies: 62%
- 3PLs: 27%
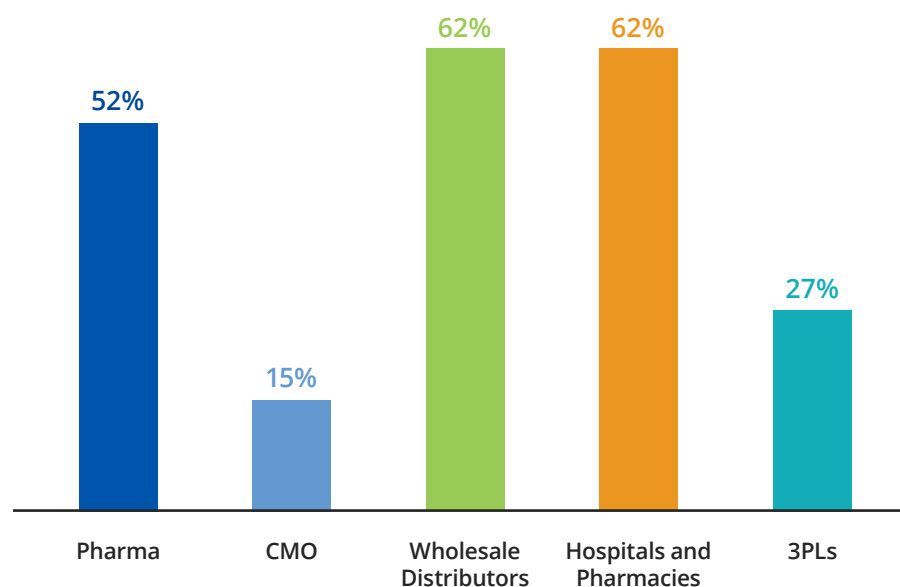
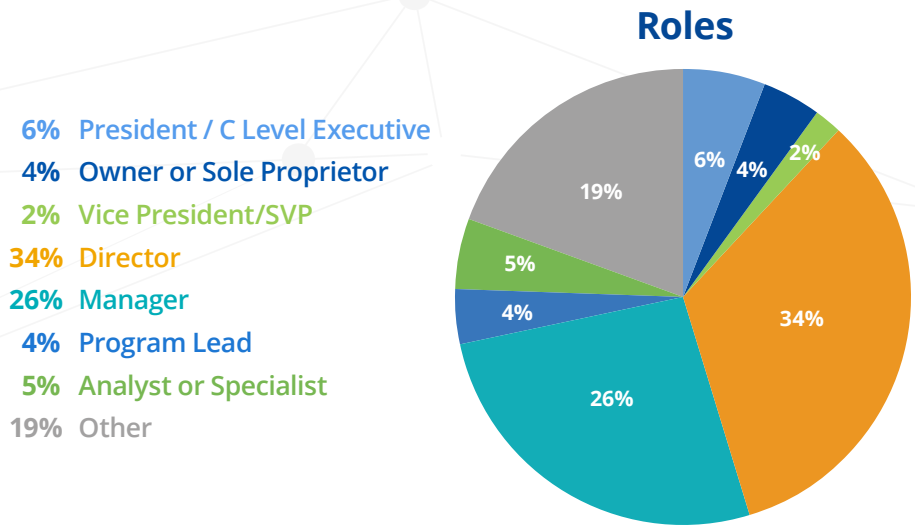**Pharma** (n=174)   **CMO** (n=155)   **Wholesale** (n=50)   **Hospitals/Pharmacies** (n=270)   **3PL** (n=11)

APPENDIX: ROLES AND FUNCTIONS

Among the 270 hospitals and pharmacies surveyed, respondents reflected a wide range of roles and functions. The wide overlap of functions indicates that decision making is shaped by operational, compliance, and financial concerns and shared across multiple departments.

Hospitals & Pharmacies (n=270)

Roles

- **6%** President / C Level Executive
- **4%** Owner or Sole Proprietor
- **2%** Vice President/SVP
- **34%** Director
- **26%** Manager
- **4%** Program Lead
- **5%** Analyst or Specialist
- **19%** Other

Functions

- **38%** Supply Chain
- **54%** Track and Trace
- **56%** Compliance / Regulatory
- **9%** Serialization
- **24%** IT
- **89%** Pharmacy
- **54%** Procurement
- **17%** Sales
- **11%** Marketing
- **36%** Quality / Validation
- **2%** Other

All respondents were able to choose multiple functions.

ABOUT TRACELINK

With more than 267,000 pharmaceutical companies, distributors, hospitals and clinics on its network, TraceLink Inc. is the World's Largest Track and Trace Network for connecting the life sciences supply chain and providing real-time information sharing for better patient outcomes. TraceLink facilitates the fastest and most comprehensive trade partner and system integrations for serialization, and eliminates the complexities associated with point-to-point connections.

www.tracelink.com

ABOUT PSB RESEARCH

TraceLink partnered with independent research firm, PSB Research, to conduct the survey and produce the report analysis. PSB Research is a world renowned market research and strategic advising firm. PSB advises Fortune 100 companies in a variety of sectors, and the Healthcare Practice serves clients in life sciences, health IT, payer and provider markets, public agencies, and NGOs.

For more information, email questions@tracelink.com

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