NEWSROOM

TraceLink Publishes Full Analysis from the Global Drug Supply, Safety and Traceability Report, Industry's Largest Survey on Life Science Companies' Readiness for Serialization Deadlines

Report Includes Data from 660 Respondents in the Pharmaceutical Supply Chain, Revealing Disparity in Industry's Readiness to Comply with Track and Trace Regulations in the U.S. and EU

TraceLink Inc., 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, today unveiled the second annual Global Drug Supply, Safety and Traceability report, including results from 660 respondents across the pharmaceutical supply chain - the largest survey ever conducted on pharmaceutical track and trace.

The report highlights a massive gap in industry readiness for drug serialization, with only one-third of respondents stating that they are "very prepared" to comply with serialization deadlines in the U.S. and EU. The in-depth analysis also reports that not one survey respondent has completed all of the fundamental steps for serialization compliance.

Key Findings From the Global Drug Supply, Safety and Traceability Report Include:

- Only one-third of the 146 respondents from pharmaceutical companies with U.S. Drug Supply Chain Security Act (DSCSA) requirements believe they are "very ready" for serialization, a regulation that went into effect in November 2017, which requires pharmaceutical companies to place unique identifiers, or serial numbers, on each saleable unit of product sold into the United States;
- Compared to their pharma counterparts, half of the 88 respondents from contract manufacturing organizations (CMOs) serving customers with DSCSA

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requirements believe they are “very ready” for serialization;

- In both the DSCSA pharmaceutical company and CMO groups that feel “very ready,” not one respondent has completed all of the necessary basic steps for serialization;
- For pharmaceutical companies and CMOs with EU Falsified Medicine Directive (FMD) requirements, only one-third of respondents believe they are “very ready” for their serialization deadline in February 2019;
- After applying the basic steps to serialization in the analysis, the report found that only 15 percent of the EU FMD respondents are truly ready for serialization;
- The report also found that one-quarter of wholesale distributor respondents and 11 percent of hospital and pharmacy respondents are “early movers” in serialization, due to their progressive serialization preparations and ability to be ready ahead of their respective DSCSA deadlines.

“This year, serialization becomes a true reality for many pharmaceutical companies. As the leader in the market, we feel that TraceLink has a corporate responsibility to provide insight into the state of serialization as it stands today, by leveraging our unique ability to reach the entire supply chain, from end-to-end, through our 266,000+ trade partner network,” said Shabbir Dahod, president and CEO of TraceLink. “These survey results are startling. Despite goodwill efforts by industry and regulators to meet compliance on time, the industry is extremely behind in being ready for serialization. In 2018, as we reach the final hours of serialization in both the U.S. and EU, the industry-wide lag in full serialization implementations remains a concern and emphasizes the criticality of trade partner connectivity within the supply chain.”

TraceLink partnered with independent research firm, Penn Schoen Berland, to conduct the survey and produce the report analysis.

The 65-page Global Drug Supply, Safety and Traceability Report can be **downloaded here** at no charge. The full report includes global serialization readiness results, as well as industry-wide insights on differing preparation timelines between EU FMD and DSCSA, disparities between pharmaceutical companies and CMOs, and how all companies across the supply chain are managing network connectivity, data exchange, and aggregation. The report also includes a peek into the highest value-added benefits companies are looking to leverage from their serialization data.

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