NEWSROOM

TraceLink Announces Russia Compliance Solution, Designed to Meet Complex Track and Trace Requirements for Customers Supplying to Russian Market



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 announced its Russia compliance solution, providing companies with the ability to meet requirements for serialization, traceability, and compliance reporting for all pharmaceutical manufacturers that supply medicines to the Russian market, in advance of the country's December 2019 enforcement deadline.

Under Russian Federal Law No. 425-FZ, medicines are required to be uniquely identified, or serialized, at multiple packaging levels including both aggregation and an expected application of cryptographic protections. Companies across the supply chain, from manufacturer to pharmacy, are also required to track and capture a wide range of product movements and packaging changes for these medicines between transfers of custody, and report these events into the Russian central system—the Federal State Information System for Monitoring Drug Circulation (FSIS MDC)—via digitally-signed data exchange. Manufacturers, including both those producing medicines outside of Russia as well as those with

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domestic production, will be responsible for up to 36 transactions, product events and notifications, including those impacting the product as it moves through internal distribution centers, customs, and third-party logistic providers serving the Russian market.

“Russia has one of the most complicated track and trace regulations in the world, requiring three times the amount of transactions than Europe. With proven experience developing compliance solutions for countries with similarly complex requirements, such as China, South Korea and Brazil, we already have customers that have invested in our Russia compliance solution, including the largest global pharmaceutical manufacturer that supplies to the Russian market,” said Shabbir Dahod, president, and CEO of TraceLink. “Because the Russian authorities are still evolving the regulatory requirements and technical guidelines, TraceLink has, and will continue to invest heavily in dedicated resources to continuously monitor and interpret the regulations, which is critical in order to implement timely software updates and accommodate any regulatory changes.”

Built on TraceLink’s existing network tenant platform and instrumented with the core serialization, master data, integration, and compliance functionalities seen in all other TraceLink compliance solutions, the Russia solution gives customers a single destination to manage all of their global track and trace and serialization requirements. Designed to meet the complex data choreography requirements for Russia compliance, TraceLink’s pre-configurable workflows and application logic enable companies to report on serialized events, and manage import, export, receipt, transfer, and shipment processes. The solution also securely and efficiently manages the complex reporting and notification capture process, supporting the complicated data schema and electronic signature process for Russia, employing a new level of technical sophistication not seen in other markets.

With TraceLink’s Russia solution, companies can leverage key components from TraceLink’s proven compliance platform, which are critical for a comprehensive

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system to comply with Russian requirements, including: Serialization, Master Data, and Compliance Reporting. To learn more about TraceLink’s Russia Compliance solution, please visit https://www.tracelink.com/solutions/global-compliance/russia.

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