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Rise in Unsuccessful Serialization Implementations Prompts Pharmaceutical Companies to Replace Competitive Offerings with TraceLink Solutions

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 that a wide range of pharmaceutical companies experiencing unsuccessful lot-level and serialization project implementations are replacing competitive offerings with TraceLink's proven Life Sciences Cloud. Pharmaceutical companies ranging from large global manufacturers to smaller specialty and family-owned businesses cite long implementation delays, gaps in country compliance coverage, repeated unsuccessful validation attempts, and high costs as primary factors leading to the decision to move away from other vendors in order to meet compliance deadlines under the U.S. Drug Supply Chain Security Act (DSCSA), EU Falsified Medicines Directive (FMD) and in other countries.

“With over 650 global customers connected to 255,000 of their trading partners on our network, TraceLink’s proven success is demonstrated time and again through our customers’ seamless integrations and rapid serialization implementations. As deadlines approach, our competitors are increasingly challenged to meet serialization requirements, failing their customers on functionality, time, cost and quality,” said Shabbir Dahod, president and CEO, TraceLink. “Our track record in delivering a serialization solution with the shortest time to live production at the lowest possible cost, is unsurpassed by any other solution provider in the industry. We have successfully migrated various types and sizes of companies over to TraceLink, at different stages of their serialization projects and encourage any company, large or small, that is frustrated with their current implementation progress, to speak with us – and our customers.”

Switching to TraceLink: What’s Driving the Decision

Consistently, pharmaceutical companies that have chosen other serialization vendors are encountering significant challenges and unsuccessful results, including the inability to connect and exchange data with trade partners, limited solutions for multiple geographies with regulations, concerns around receiving timely and necessary software updates, unsuccessful validation attempts, and more. Some of the companies that have replaced other vendors’ serialization solutions with the TraceLink Life Sciences Cloud include:

- A top 25 pharmaceutical company specializing in neurological and autoimmune therapeutic treatments. After selecting another vendor's solution in 2013 for track and trace, the biotech company recognized that the solution was unable to accommodate its business need to serve multiple global markets. The company has since selected TraceLink for its comprehensive solution to help them meet global serialization requirements and provide long-term value-added applications and solutions beyond meeting compliance regulations.
- A mid-size generics and specialty branded pharmaceutical company. After experiencing difficulty integrating their edge solution with their previous serialization solution—and acquiring another generics pharmaceutical company that was already successfully using TraceLink for serialization, the company compared the two competing serialization solutions and their success trajectories. They chose to switch to TraceLink for its ease of implementation, low cost and ability to interoperate and achieve scale between the two companies.
- A global Indian-based pharmaceutical company with a diverse pipeline in various stages of clinical development. Using another vendor to comply with DSCSA lot-level requirements in 2015, the company realized that a different provider would be

required for serialization to support its operations in more than 80 countries. The manufacturer selected TraceLink as a single partner capable of providing DSCSA lot-level compliance and meeting serialization requirements for the US and other countries, while minimizing business risk and cost.

- A small family-owned and operated pharmaceutical manufacturer of prescription tablet and capsule formulations. Using another solution provider for DSCSA lot-level compliance, the company was unable to validate the solution with successful IQ, OQ or PQ results. After working on the same validation issue for two years with the competitor, a security bug exposed the pharmaceutical company, and it determined it could no longer assume this kind of risk with serialization. This led to the decision to select TraceLink for its proven reliability, cost-effective validation approach, and repeated success with live customers.
- A mid-size manufacturer of affordable generic medications. During the process of implementing another serialization solution, the company experienced major challenges when it was unable to connect its packaging lines to the solution. The provider did not execute promised customizations and product release dates on time, and was unable to provide a viable and cost effective solution for the

manufacturer. As a result, the company turned to TraceLink for its time-efficient and cost-effective integration expertise and proven ability with data exchange across hundreds of thousands of successful trade partner connections.

- A specialty pharmaceutical company with a robust portfolio of branded and generic drugs in multiple therapeutic areas. Numerous validation challenges with its former solution provider during DSCSA lot-level implementation caused a manual, time-intensive strain on internal resources. Realizing that updates and corresponding validation can be unpredictable, and that serialization would only bring increased complexity, the specialty manufacturer selected TraceLink for its unique network-tenant approach that eliminates validation complexity.

To hear first-hand about the factors leading to one pharmaceutical company's decision to replace another vendor's serialization offering with TraceLink, please visit [TraceLink](#).