NEWSROOM

Italian Pharmaceutical Manufacturer and CMO, IBI Lorenzini, Selects TraceLink to Comply with Global Serialization Regulations

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 IBI Lorenzini has selected TraceLink's solutions to ensure compliance with global serialization regulations.

IBI Lorenzini, IBIGEN group, is an Italian-based, family-run pharmaceutical company and contract manufacturing organization (CMO) that was founded over 100 years ago. IBI's pharmaceutical products are distributed in 20 countries across all five continents, including Europe, Australia and New Zealand, and the U.S., which accounts for 80% of its exports. In 1961, IBI obtained FDA approval for the production of sterile penicillin for the U.S. market.

"IBI Lorenzini is a unique business, operating as both a pharmaceutical company and a CMO in a number of markets, which adds an additional layer of complexity when implementing a serialization solution. After careful analysis of serialization solutions and a strong recommendation from our pharmaceutical brand customers, we selected TraceLink's Life Sciences Cloud platform to deliver the flexibility and scalability we needed to connect with both our partners and customers as quickly

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and efficiently as possible, while providing a simple connection into the EU Hub." said Luca Pezzano, Operations Director at IBI Lorenzini.

For its U.S. Drug Supply Chain Security Act (DSCSA) requirements, IBI has completed all serialization packaging line upgrades and partner connections in the U.S. In preparation for EU Falsified Medicines Directive (FMD), IBI has started the integration process with its CMO partners, discussing data exchange processes and redesigning artwork to include tamper evidence. The company aims to be ready for FMD serialization by the end of 2018, ahead of the February 2019 deadline.

"As a progressive company that consistently adopts innovative digital countermeasures to reduce the risks of falsified medicines and protect consumers' health, IBI Lorenzini recognized the urgency of EU FMD and began preparations early on, in order to ensure compliance and improve patient safety. With the EU FMD deadline on the horizon, there is relatively little time left for companies to have new technologies and processes fully implemented and connected into the EU Hub," said Shabbir Dahod, president and CEO of TraceLink. "TraceLink has a proven ability to simplify serialization challenges and we look forward to partnering with IBI Lorenzini to not only ensure EU FMD compliance but to explore and realize the wider potential of information sharing through digital network connectivity."

TraceLink has developed a streamlined program for its more than 190 customers with EU FMD requirements to rapidly complete conformance testing and successfully receive European Medicines Verification Organization (EMVO) approval to submit data to the EU Hub. With TraceLink's conformance test kit, 42 companies have been able to complete their conformance testing. Of these, 21 companies have received EMVO approval.

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