NEWSROOM



# Pioneering German Biotechnology Company, biosyn, Selects TraceLink to Comply with EU FMD 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 biosyn Arzneimittel GmbH has selected TraceLink's serialization solutions to ensure compliance with the EU Falsified Medicines Directive (FMD) requirements.

As one of the first biotechnology companies in Germany, biosyn was founded in 1984 and specializes in keyhole limpet hemocyanin products and high-dose selenium injectable pharmaceuticals. Since its founding, the company has developed into a pharmaceutical enterprise with subsidiaries in Liechtenstein, Austria and the U.S., and has customers in over 25 countries.

With a large customer base in Europe, biosyn needed a serialization solution that would ensure on-time compliance with the EU FMD regulations through a simple and direct path to the European hub. As biosyn works with multiple contract manufacturers, the chosen solution would need to simplify connectivity and enable the seamless exchange of data. The solution also needed to meet requirements in South Korea, Brazil and other future markets.

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“We have customers and partners located all over the world and could not afford to lose time and resources by establishing individual point-to-point connections. After a thorough evaluation of solution providers, it was clear that TraceLink’s network approach would deliver the scalability we needed while providing a simple and fast connection into the EU hub,” said Ortwin Kottwitz, CEO of biosyn.

“EU FMD compliance is becoming a stark reality for companies that need to have new technologies and processes fully implemented and connected into the EU hub by the February 2019 deadline. biosyn values our expertise on EU FMD and country compliance and chose TraceLink for its enterprise scalability and ability to simplify serialization challenges,” said Shabbir Dahod, CEO of TraceLink. “We look forward to partnering with the biosyn team to ensure they achieve EU FMD compliance and help them explore the wider potential of information sharing through digital network connectivity.”

TraceLink has already processed compliance reports for more than 150 million units of product in the EU, China, Brazil, India and South Korea. The TraceLink European Union Compliance module supports traceability reporting requirements from a single platform, providing customers with a tested integration to the European hub for reporting information about their product master data, serialized product pack data, and status changes for products targeted for distribution across all Member States.

To learn more about meeting global pharmaceutical compliance deadlines and how to build a flexible serialization, track and trace, and reporting platform for the U.S., the EU, and other global regulations, please visit: www.tracelink.com.

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