NEWSROOM

TraceLink Customers Receive EMVO Approval for Data Submission to EU Hub

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 it has developed a streamlined program for its more than 190 customers to rapidly complete conformance testing and successfully receive European Medicines Verification Organization (EMVO) approval to submit data to the EU Hub - a complex and lengthy process that requires each individual company to complete EMVO registration and provide a full set of test cases to be executed for conformance with the EU Hub.

In just one month, 34 companies have completed their conformance testing with TraceLink's conformance test kit. Of these, 11 companies have received EMVO approval to submit data to the EU Hub and 14 companies are awaiting review from the EMVO. In order to achieve final approval, all pharmaceutical companies must now submit a series of transactions to be reviewed by the EMVO, a process that can now take several weeks due to the surge of companies seeking to connect to the EU Hub before the EU Falsified Medicines Directive (FMD) deadline in February 2019. Once the transactions are approved by the EMVO, a pharmaceutical company will receive access to the certificates required for production and data submission to the EU Hub.

In order to accommodate the more than 190 customers that have selected TraceLink to help meet their EU Falsified Medicines Directive (FMD) requirements, TraceLink has developed a standard feature for its customers to execute the EMVO conformance testing successfully, including specific product functionality and services optimized to help guide customers through the EMVO approval process for connection to the EU Hub. After executing a conformance test, any TraceLink customer using the EU compliance module will receive automatically generated files that are ready to be submitted to the EU Hub for approval.

“The EMVO has stated that there is no longer a formal certification for pharmaceutical companies or solution providers to gain access to the EU Hub, so pharmaceutical companies that are still evaluating solutions should be skeptical of any vendor statements claiming they are ‘EMVO certified.’ The true test is demonstrating how many pharmaceutical companies have actually achieved EMVO approval using a particular solution provider, as this validates correct use of the EU Hub integration APIs,” said Shabbir Dahod, president and CEO of TraceLink. “TraceLink’s history integrating with the EU Hub dates back two years, with nearly 650,000 serial numbers submitted to the EU Hub by our customers since 2016. Today, while other solution providers are in the midst of conducting pilot tests and resorting to promotional discount strategies in an attempt to acquire new customers, TraceLink customers are out front, already live in production with serialization and officially approved to submit data to the EU Hub.”

“After working with TraceLink to successfully complete our conformance testing, we have received EMVO approval to begin submitting data to the EU Hub, nearly 10 months ahead of the EU FMD deadline,” said Ortwin Kottwitz, CEO of biosyn. “Gaining EMVO certification with the TraceLink conformance test kit was simple and straightforward, and with TraceLink’s multi-tenant approach, we are well-positioned for continued certification despite any unforeseen changes to our systems in the future.”

To learn more about TraceLink’s compatibility with the EMVO conformance testing and its EU FMD solutions for small, medium and large pharmaceutical companies, please visit: https://www.tracelink.com/solutions/eu/eu-fmd-overview.