NEWSROOM

TraceLink Unveils EU FMD Express, a Purpose-Built Compliance Solution for Smaller Pharmaceutical Companies

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 EU FMD Express – a cost-effective, simplified solution designed specifically to address the needs of smaller pharmaceutical companies complying with the EU Falsified Medicines Directive (FMD.)

With far greater resource and budget constraints than their larger counterparts, many small pharmaceutical companies face extreme challenges with serialization, including master data management and data exchange with their contract manufacturing organizations (CMOs), making it difficult to meet the EU FMD deadline by February 2019. TraceLink's EU FMD Express provides these companies with a simple approach to meet EU FMD compliance while controlling costs and minimizing business impact. With over 40,000 users regularly accessing the Life Sciences Cloud system, TraceLink's EU FMD Express is a complete, easy to use solution that allows smaller manufacturers to comply with EU FMD and integrate with the EU Hub through a single, secure connection, while removing the burden of software maintenance and upgrades, and insulating companies from regulatory changes.

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“Due to its size and vast number of companies spread across various countries, Europe is one of the largest and most complex markets, leaving hundreds of small companies grappling with how to achieve EU FMD compliance within the next 11 months,” said Shabbir Dahod, president and CEO, TraceLink. “As the market leader, we feel that is our responsibility to help every company comply, regardless of size, and therefore developed this cost-effective, easy to use offering to streamline the ability for smaller companies to become compliant on time, with no disruption to their business operations. Through our investment in services and support in the EU and unique network architecture to accelerate company on-boarding, TraceLink is the only company positioned to provide such an offering for this market.”

EU FMD Express: Key Benefits for Small Pharmaceutical Companies

Designed specifically for smaller pharmaceutical companies with simple supply chains, EU FMD Express utilizes purpose-built templates and compliance modules for faster implementation and predictable costs. TraceLink executes the entire deployment, including system configuration and data entry. Every EU FMD Express customer will benefit from:

- **Easy to Use and Proven Solution That Is Purpose-Built for Smaller Companies –** Enabling portal access for line management systems and CMOs with integration options available; access to TraceLink’s serial number and event repository; and direct integration into the EU Hub;

- **Simplified Deployment, Set-Up and Configuration –** TraceLink Services will help EU FMD Express customers define and manage their master data, on-board and train their CMOs, configure the EU compliance module, support for QA testing and validation, and user training;

- **Ongoing Training and Education –** All EU FMD Express users will have full

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access to TraceLink configuration templates for master data and serial number templates. TraceLink also provides an online collaboration workspace for companies to exchange customer configuration documents and full access to TraceLink University for tutorials and e-learning courses.

To learn more about EU FMD Express and see how TraceLink provides smaller pharmaceutical companies with unmatched flexibility and predictability while eliminating the uncertainty of high costs from CMO integrations and time-intensive implementations, please visit: https://www.tracelink.com/solutions/global-compliance/eu-fmd-for-small-pharma.

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