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Proven CMO Connectivity Prompts Pharma to Switch to TraceLink



For a large European pharma company selling a high volume of in-scope medicines—in addition to operating as CMO for a high profile pharma giant—finding a solution to exchange serialization data with more than 100 CMOs by the EU FMD deadline was crucial. So, when they discovered that their original solution provider had made little progress in the six months since they signed the contract, the company decided to re-evaluate their choice of provider.

Three critical shortcomings

The company's project team in Germany believed that selecting a fellow German solution provider was the most efficient option. However, the chosen provider's solution was still under development, which exposed three fundamental issues:

- **Lack of a proven EU FMD compliance solution**

Despite operating in the life sciences supply chain space, the original provider did not have the level 4 – 5 serialization software technology needed to meet the data exchange and reporting requirements of EU FMD. When the pharma company discovered that—six months on—the solution was still not ready, they realized they were at risk of not achieving compliance by the deadline.

- **No efficient way to connect to partners and customers**

Given that they had over 100 CMO partners and several brand customers to

connect to before the deadline, the pharma company realized that the original provider's plan to build and test point-to-point connections to all of them from scratch was not viable in the given timeframe.

- **No experience in connecting to the European Hub**

In addition to exchanging data with its CMOs and brand customers, the pharma company also needed a connection to the European Hub. Even if the provider were able to develop its solution, it would still need to complete EMVO's testing, QA and certification process before the company could begin using its connection to upload data.

Decision driver: Customer references confirm level 4 - 5 capability, live production, and expert service

After their original solution provider overpromised on their capabilities—and under-delivered—the company knew they needed an experienced solution provider who could quickly onboard them and all of their partners. They sought references from pharma companies who were live in production and able to provide reviews of their solution provider. With over 300 pharma companies as customers, TraceLink was able to provide references that confirmed its serialization expertise:

- **A proven solution to achieve compliance quickly**

As a leading level 4 - 5 solution provider with customers shipping serialized product, TraceLink offered a proven serialization playbook and a purpose-built EU FMD compliance module that could be quickly integrated with the company's systems. In addition, TraceLink was one of the first EU FMD solution providers to exchange data with European Hub—18 months ahead of the 2019 deadline.

- **A network model for swift partner onboarding**

With the TraceLink Life Sciences Cloud, all the company needed was one connection to TraceLink to exchange data with all of their CMOs and pharma

customers, as opposed to developing over 100 point-to-point connections. In fact, the pharma company discovered that 66% of their CMOs were already on the TraceLink network and ready to exchange data. Furthermore, TraceLink's team would onboard the remainder, so the pharma company didn't have to handle it themselves.

- **Dedicated, expert teams for smooth implementation**

TraceLink's Europe-based implementation and services teams are providing local, native-language support to onboard the company's remaining partners and ensure business continuity. Unlike the original solution provider, a dedicated project manager keeps company stakeholders updated on progress, minimizing uncertainty and helping them make informed decisions.

TraceLink delivers on its promises for timely compliance and onboarding

TraceLink offers a proven playbook for serialization readiness, with nearly 400 pharmaceutical and contract manufacturing customers already on its network. By taking advantage of a single connection to the TraceLink Life Sciences Cloud to exchange data with its CMOs and customers, the company is now on track to ship serialized product by the February 2019 EU FMD deadline. Becoming part of the TraceLink network also sets them up to maintain continuous compliance and plan for future growth with dedicated modules designed for regional and international markets.

Case StudyEuropean Union Falsified Medicines DirectiveGlobal Track & TraceRegulatory/ComplianceEuropean Union

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Learn more about TraceLink's serialization and compliance solutions for the pharmaceutical industry.

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