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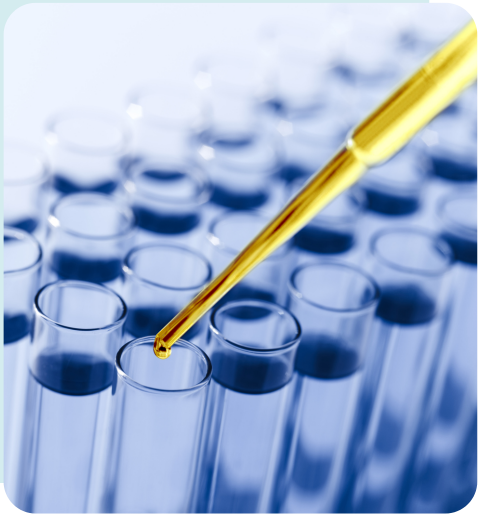
German Biotech Chooses TraceLink Network Over Point-to-Point Approach



When a family-owned, German biotech company started preparing for EU FMD compliance, they considered using an on-premise solution for serialization and reporting. Because it is a Marketing Authorization Holder (MAH), the company is required to connect to the European Hub and upload its product data. As a research-led manufacturer of specialized medicines with a relatively low number of contract manufacturing partners, the company assumed the best approach was to develop point-to-point connections with each CMO to receive the necessary product data.

However, the company realized how complex it would be to develop and maintain individual connections to its partners. Based on its need to connect to the European Hub and its CMOs by the February 2019 deadline—and to remain compliant thereafter to ensure product delivery—the company decided to reassess its approach.

Decision drivers: Fast CMO onboarding, continuous compliance, lower TCO

The company evaluated several solutions providers, including Arvato and Giesecke + Devrient, and decided to move away from point-to-point technology in favor of the cloud-based, multi-tenant solution and automated validation offered by TraceLink:

- **Efficient partner onboarding**

  The company found that all 10 of their CMOs were already being onboarded to the TraceLink network, saving them valuable time. In addition, TraceLink has an entire team dedicated to working with its customers' partners, managing much of the implementation work so that companies don't have to tackle it themselves. All the company will need is a single connection to the TraceLink network to exchange data with its CMOs.

- **A proven connection to the European Hub**

  Establishing a proven connection for reporting to the EU Hub before the 2019 deadline is crucial for this company. TraceLink was already sending data to the EU Hub via its live connection 18 months ahead of the deadline.

- **Automated validation to ensure GMP compliance**

  As the owner of two GMP-compliant manufacturing sites, continual software validation to ensure uninterrupted compliance is a top priority for this biotech company. TraceLink offered an unrivalled level of validation support via Automated

Validation Manager (AVM), which automates the entire validation life cycle of the TraceLink Life Sciences Cloud. AVM includes automatic testing and confirmation to ensure all current TraceLink software capabilities meet GxP compliance in accordance with industry standards such as GAMP 5.

- **Lower total cost of ownership (TCO)**

  The company initially believed an on-premise solution to be the most cost-effective approach. However, the company realized that a cloud-computing, network-tenant architecture could deliver lower TCO than any single-tenant or on-premises alternative and address the unpredictable costs of serialization in one subscription.

TraceLink network-tenant architecture accelerates compliance

By choosing TraceLink, the company is on track to connect to their partners and the European Hub to exchange serialization data by the EU FMD deadline. The network-tenant approach to software validation and upgrades will allow the growing company to respond to evolving regulations, insulating them from future delays and compliance risks. In addition, because the company also does business in Brazil and South Korea, they will be able to take advantage of TraceLink's compliance modules for those regions and manage all their serialization needs with one global vendor.

Throughout implementation, the 40 members of the TraceLink services team in Europe ensure its customers' projects run smoothly and to schedule. With a multi-lingual team

that includes 22 German speakers, TraceLink is committed to supporting customers at local, national and regional levels.

All of this will allow the company to focus its resources on its core missions of R&D and manufacturing. Contact us to learn how we could support your company’s serialization and compliance needs, enabling you to stay focused on your business.

Case Study | European Union Falsified Medicines Directive | Global Track & Trace | Regulatory/Compliance | Germany | European Union

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

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