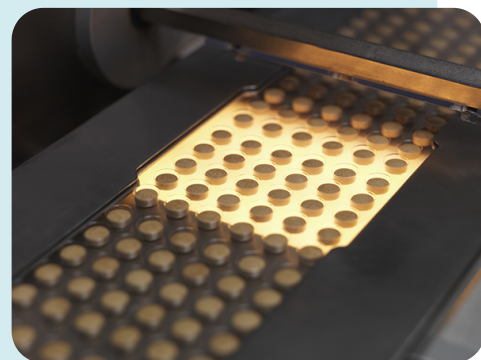


RESOURCES

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Small Italian CMO Sees Growth Opportunities with TraceLink



A family-run CMO in Italy saw emerging track and trace regulations as an excellent opportunity for business growth. They recognized that some of their CMO peers would struggle to adapt to serialization requirements, opening the door for them to acquire new customers. They also understood that being part of a supply chain network would put them in prime position to connect with pharma companies that need to achieve EU FMD compliance by the February 2019 deadline. Given that, their top criteria when evaluating serialization solutions included:

- **Easily connect to current and future customers**

EU FMD requires the CMO's pharma customers to upload their product data to the European Hub before shipping. In order to exchange that data with those customers, the CMO had to establish a digital connection to each of them. As it had limited internal resources to dedicate to implementation—and with the EU FMD

deadline approaching—the CMO required a solution that could connect to current and prospective partners in an efficient and timely manner.

- **Enable operational efficiency and handle diverse data requirements**

The CMO needed a solution that would send and receive its customers' product data seamlessly, with minimal disruption to its production. And because the CMO was investing in a solution to attract new customers, it had to accommodate the wide variety of data and reporting formats that those pharma companies might request.

- **Integrate with its line management system (LMS)**

Like most small companies, the CMO had tight profit margins, and therefore the chosen serialization solution needed an out-of-the-box integration with its LMS to ensure minimal downtime on its production lines.

Decision drivers: proven network platform the key to efficient data exchange

The CMO considered three providers for its serialization solution:

1. Its LMS vendor;
2. Its LMS vendor plus an IT service partner;
3. TraceLink.

Options 1 and 2 could not demonstrate the proven Level 4 – 5 capabilities that the CMO required. The CMO understood that data exchange—not serialization—was the bigger challenge and held the key to EU FMD compliance for pharma companies, so it selected TraceLink for its:

- **Proven solution for intelligent data exchange**

As the leading level 4 – 5 solution provider with customers already shipping serialized product, TraceLink offered purpose-built serialization and compliance modules that could be quickly implemented into the CMO's business. The TraceLink Life Sciences Cloud will enable the CMO to exchange product data with its customers in a secure and efficient manner through a single connection.

- **Large network of potential new customers**

With one connection to TraceLink, the CMO became part of a digital network of over 267,000 entities across the pharma supply chain. This opened the door to hundreds of potential new customers with whom the CMO could exchange data without needing to establish an additional connection, reducing the time and cost of growing its business.

- **Out-of-the-box integration with leading LMS vendors**

TraceLink's unmatched number of out-of-the box integrations with leading business systems included the CMO's existing line management system. This meant that the CMO did not have to pay for development work, or worry that its business systems might not be compatible.

TraceLink network sets growing companies up for success

By choosing TraceLink, the CMO has put itself in prime position to support its existing customers with their upcoming regulatory requirements, as well as to acquire new customers. As compliance deadlines draw closer, pharma companies may need to find new manufacturing partners if their existing CMOs aren't able to ship serialized product by the EU FMD deadline. Being part of the TraceLink Life Sciences Cloud is a major advantage, as companies can interoperate with any other company on the network, eliminating the time and cost of developing and maintaining point-to-point connections.

Case Study

European Union Falsified Medicines Directive

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