

A world map is centered in the background, overlaid with a network of glowing blue lines and nodes. The background is filled with a dense field of binary code (0s and 1s) in a light blue color. The overall theme is global connectivity and data.

Compliance, Connectivity, and Customer References

Why Select Companies Chose TraceLink for EU FMD



Introduction

As pharmaceutical track and trace regulations take effect around the world—the next being EU FMD in February 2019—companies are learning valuable lessons about choosing a serialization partner. Select an unproven solution or a provider lacking the expertise and resources to connect you to your trade partners or the authorities in time, and your business may be at risk.

TraceLink has over 870 customers worldwide—including 280 in Europe—that range from small, family-run businesses to global enterprises. Regardless of size, they need to comply with serialization requirements, integrate their existing line management systems, and onboard their network of manufacturing partners.

Compare the business models and concerns of these 10 companies against your own, and then read their stories to see why they chose TraceLink over alternative solution providers—or switched to TraceLink after another solution provider let them down.

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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 solution 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.





Spanish Pharma Discovers All Its Partners Are Already On TraceLink Network

For a small Spanish pharma company, the potentially high investment required to comply with EU FMD represented a huge hurdle. The company operated a manufacturing site for its own products and to provide CMO services for its affiliate companies, and also outsourced manufacturing services to five CMO partners. The pharma company needed an EU FMD compliance solution that would:

- **Connect current and future supply chain partners**

The company needed a Level 4 – 5 serialization solution that would be able to exchange data seamlessly between its partners. Although they had a relatively small network, its future plans required a solution that could scale easily to add new partners as the company continued to expand.

- **Integrate with its existing Level 3 serialization solution**

As a small company with fewer resources than its larger peers, the pharma company needed a solution that would work well with its existing systems and processes, without compromising operational efficiency. As they evaluated Level 4 – 5 solution providers, they realized that the time required to develop an untested solution put them at risk of missing the February 2019 EU FMD deadline, and focused on companies with an existing interface to its Level 3 provider.

- **Maintain customer satisfaction and loyalty**

The pharma company needed to control costs but it also understood that taking a risk on an unproven compliance solution could jeopardize its ability to meet its obligations to customers and partners. The company viewed the solution as an important business investment in its brand and reputation.

Decision drivers: Network model reduces time, risk and total cost of ownership

As the pharma company evaluated solution providers who competed solely on price but could not offer proven results or references from similar pharma companies, it saw the benefits of selecting TraceLink:

- **All of its supply chain partners were already on the TraceLink network**

By joining the largest digital supply chain network, all the pharma company needed was one connection to TraceLink to be able to start exchanging data with all of its partners immediately. This meant the pharma company had no need to develop custom connections or workflows, which would have added time, risk, and complexity for the small business.

- **Proven integration to Level 3 solution for efficient operations**

TraceLink's unmatched number of out-of-the box integrations with leading business systems included the pharma company's existing Level 3 solution, eliminating the time and cost of development and testing.

- **Lower total cost of ownership (TCO) through all-inclusive subscription**

The TraceLink network's all-inclusive subscription model allowed the pharma company to eliminate many of the unpredictable costs of integration, customization, and service that they would have risked by basing their decision on low initial cost.

TraceLink network: A platform for growing companies

By choosing the TraceLink Life Sciences Cloud, the company is on track to achieve EU FMD compliance while minimizing the disruption to its business operations. And being part of the TraceLink network will simplify the onboarding of future partners as the company continues to expand. The network-tenant approach to software validation and upgrades will allow the growing company to respond to evolving regulations, and TraceLink's compliance modules for other regions give them the ability to manage all of their serialization needs on one platform, with one proven vendor.





French Pharma Selects TraceLink for Smooth LMS Integration, Lower Costs

Like many companies preparing for EU FMD, this mid-size French pharma company invested in a new line management system (LMS) to handle the upcoming serialization requirements for its own business and for the pharma customers it had taken on in a CMO capacity. The company had also diversified its own manufacturing in recent years, building a network of over 30 CMOs for its product portfolio.

Key criteria: Cost control and time constraints

The pharma company evaluated a number of serialization solution providers to integrate with its new technology and help it achieve compliance with EU FMD.

- Given their significant investment in the new LMS, the company wanted to control its initial cost outlay. However, they soon discovered that the seemingly lowest cost solutions could not offer a proven integration to their new LMS. If the LMS and serialization solution could not talk to one another, the pharma company would not be able to apply the serialized data to its products and, subsequently, upload it to the European Hub. Not only would this mean a complex, labor-intensive integration effort and potential business disruption, it also jeopardized their chances of being compliant by the deadline.
- The company realized that the resources required to create, test and maintain individual connections to its growing network of CMOs and manufacturing customers would also impact their budget. More important, the time needed to onboard their partners also put the company at risk of not being ready by February 2019.

Efficient data exchange would be crucial, not just between the company's internal systems but also with its trade partners. For those reasons, the company decided it could not take a risk on an unproven solution.

Decision driver: On-time implementation and low connectivity costs

To control implementation costs through out-of-the-box integration and streamlined partner onboarding—and ensure that its LMS investment would be producing serialized product by the deadline—the company turned to TraceLink for:

- **Seamless integration to line management systems**
TraceLink offered a ready-to-use integration to the pharma company's new LMS. Because this integration had already been tested in real-world production environments, the pharma company would benefit from a shortened implementation and user acceptance timeline. In addition to achieving compliance by the deadline, the company would more quickly begin to realize the business efficiencies it sought when it purchased the new LMS.

- **A network approach to streamline partner connections**

For EU FMD compliance, the pharma company needed to exchange product data with its network of over 30 CMOs, plus an additional 20 pharma companies who outsourced their manufacturing to the company. It discovered that 65% of their 50 partners were already on the TraceLink network, so all it needed was one connection to TraceLink in order to exchange data with them. In addition, TraceLink would onboard the remaining partners, meaning that the pharma company did not need to invest in developing point-to-point connections to its growing partner network.

TraceLink helps companies achieve efficiencies in addition to compliance

With the selection of TraceLink as its serialization solution provider, the pharma company is not only on track to achieve EU FMD compliance by the deadline, but to do so in a way that minimizes the impact on its day-to-day operations. While many solution providers charge for additional partner onboarding and service requests, TraceLink's all-inclusive subscription model will insulate the pharma company from unexpected development costs in the future. The pharma company saw the benefits of a proven solution, and will continue to benefit from being part of the TraceLink network as it continues to grow and diversify in the future.





EU FMD Express: The Perfect Partner for Virtual Pharma

For this virtual pharma company based in France, supply chain connectivity was vital to meeting the EU FMD requirements. With all of its manufacturing outsourced to CMOs, it needed an efficient way of generating and exchanging serialization data with its partners by February 2019. With just 8 months to the deadline, the company engaged three solution providers with the goal of selecting the one best suited to:

- **Help it meet the EU FMD deadline with minimal disruption**

As a small company without internal resources to dedicate to the project, it needed an easy-to-implement solution, from an established provider that offered local support and expertise. Given the tight timeframe, the company also wanted to minimize risk of delays—or even failure—by choosing a proven solution provider.

- **Integrate its virtual supply chain model**

The company counted on a network of CMOs and 3PLs to handle all its manufacturing and distribution, and needed a solution that would allow its entire partner network to exchange data on orders, recalls, and more.

- **Provide references from companies like them**

It was essential that the chosen provider understood the needs of a virtual company, and could demonstrate successful serialization projects for other small, virtual customers.

Decision driver: References highlight a proven solution with seamless deployment

The company concluded that two of the solution providers they were evaluating—while able to propose attractive pricing—could not meet these basic needs. It chose TraceLink for its ability to offer:

- **A cost-effective, off-the-shelf solution for rapid implementation**

TraceLink's solution for smaller pharma companies, EU FMD Express, provided proven functionality with fast, expert deployment at a low cost. With little time and limited resources, the pharma company saw the advantages of a robust off-the-shelf solution that included deployment, testing, and training services.

- **A network model for end-to-end supply chain connectivity**

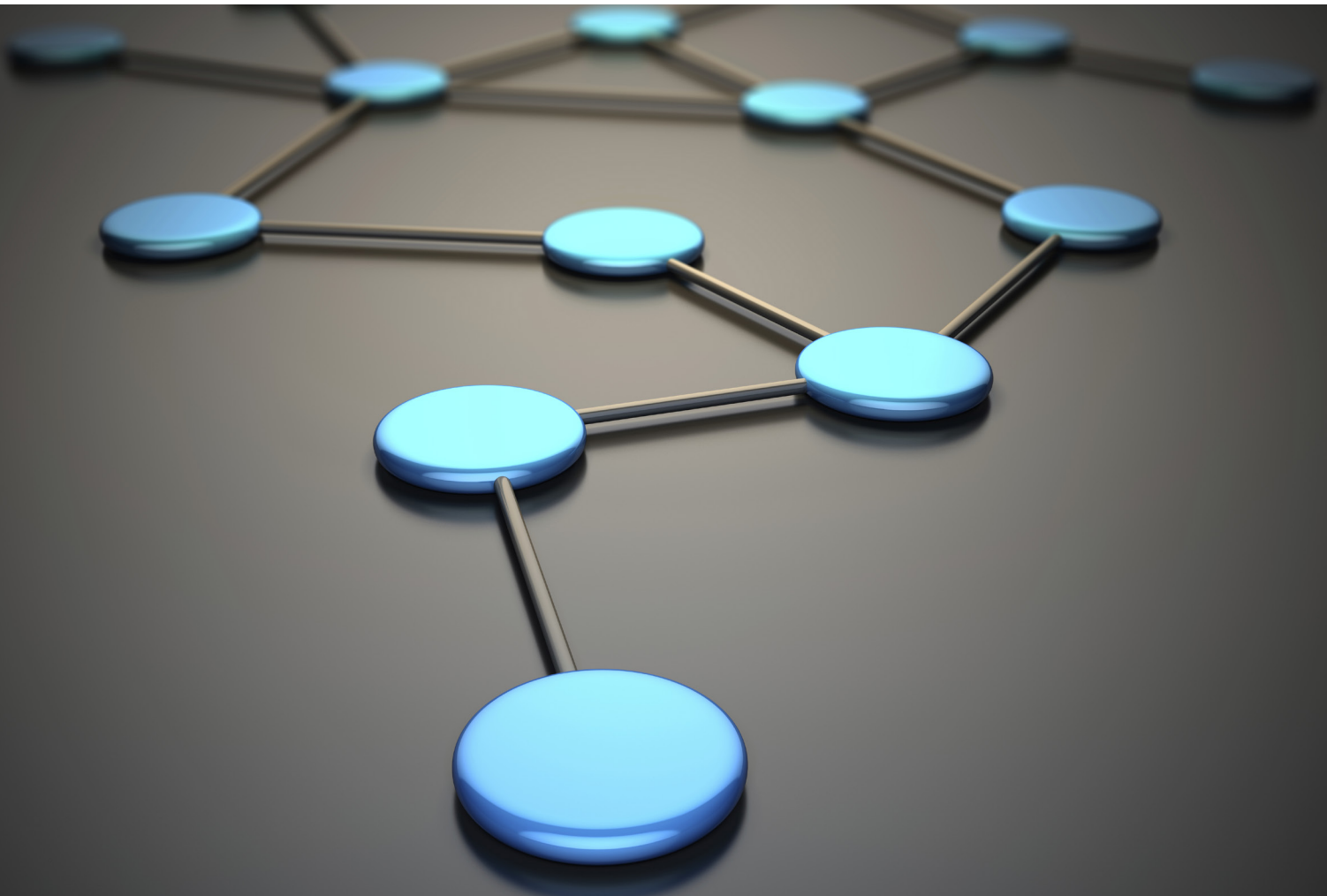
TraceLink's analysis of the pharma company's supply chain showed that 3 of the 4 company's CMOs were already on the TraceLink network. With one connection to TraceLink, the company could connect to all of them, eliminating the time and resources required to develop individual connections.

- **A proven record with similar companies**

TraceLink provided references from small and virtual pharma customers. With over 190 customers in Europe alone, TraceLink is proven to deliver on EU FMD compliance, and as of June 2018 had already helped 34 companies complete EMVO's new conformance tests. TraceLink's Europe-based implementation and services teams offered native-language support during and after deployment, to ensure a smooth implementation and business continuity.

EU FMD Express: Turnkey compliance for smaller pharma companies

By choosing TraceLink, this virtual pharma company is on track to achieve EU FMD compliance by the February 2019 deadline. EU FMD Express uses the same proven technology as TraceLink's enterprise-level EU FMD Compliance solution, while offering the streamlined configuration smaller companies need. And being part of the TraceLink Life Sciences Cloud will simplify the onboarding of additional supply chain partners if the pharma company chooses to expand.





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.



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.





European Pharma Chooses TraceLink over ERP Provider for Compliance & Connectivity

Like many companies, this European pharma needed an EU FMD compliance solution that would integrate seamlessly with the existing ERP and line management systems critical to its daily business operations. Given that its ERP provider also offered a serialization solution, the pharma company believed it would be the logical choice. However, with limited time to implement a compliance solution by the February 2019 deadline, the choice of provider would come down to who could offer proven serialization data exchange capabilities and streamlined partner onboarding.

The company needed a solution that would:

- **Interoperate with its existing business systems**

The pharma company had a strong relationship with its ERP solution provider, who also offered a serialization solution. In order to be considered, any alternative solution provider would have to demonstrate working Level 4 – 5 capabilities as well as seamless integration with the pharma company’s ERP and other business systems.

- **Onboard its 25 CMOs by the deadline**

In addition to its internal manufacturing plants, the pharma company had a network of 25 CMO partners producing its medicines. The chosen provider would have to demonstrate an efficient connectivity solution between the pharma company and all of its partners, in order to exchange the product data required by EU FMD.

- **Enable compliance in other markets**

As it operated across 80 markets worldwide, the pharma company needed a provider that could help it navigate the complexities of regulations for individual countries—in addition to EU FMD—and stay current with evolving compliance requirements in each market.

Decision driver: Live demo shows integration capabilities, network connectivity, and onboarding programs

To help it make an informed decision, the pharma company requested a live demo from all shortlisted solution providers. During those demonstrations, TraceLink was the only provider able to showcase proven Level 4 – 5 expertise. The pharma company selected TraceLink based on their ability to demonstrate:

- **Seamless ERP and line management system integration**

TraceLink had pre-existing integrations to the pharma company’s ERP solution and LMS, tested and optimized for a quick integration and smooth day-to-day operations, ensuring business continuity.

- **A global network with over 267,000 entities exchanging data**

TraceLink was able to show that pharma companies around the world were already exchanging data with their CMOs and other supply chain partners via the TraceLink Life Sciences Cloud. The pharma company's most important CMO partner was already on the network, and TraceLink presented an onboarding plan to show how it would streamline connections to any CMO partners not on the network in advance of the EU FMD deadline.

- **A single platform for future growth**

With its cloud technology and proven expertise in compliance solutions for the life sciences industry, TraceLink had the ability to offer the pharma company one platform to manage all of its track and trace needs in the future. This meant the pharma company would not need to develop new connections or purchase new systems, as it could all be managed through its one connection to TraceLink.

TraceLink's network ensures compliance today, adaptability for future growth

By selecting TraceLink for EU FMD, the pharma company can easily onboard its CMO partners, and is on track to achieve compliance by February 2019. TraceLink's proven integration with its existing ERP and line management systems means minimal impact on the pharma company's existing workflows and business efficiencies, and its suite of compliance offerings provide flexibility to adapt to evolving business requirements.





CPO Switches to TraceLink After Costly Integration Effort Fails

One contract packaging organization (CPO) believed their line equipment vendor, Systech, would be able to handle the company’s Level 4 – 5 enterprise and network solutions for serialization as well. But after spending more than one year and over \$1 million—and still failing to integrate with their customers—the CPO turned to TraceLink for its proven abilities in partner connectivity, serialization workflows, and regulatory compliance.

Four critical shortcomings

The vendor presented itself as a single point of contact that would manage “the full stack,” including enterprise serialization. The vendor has built its reputation as a Level 1 – 2 line management system (LMS) partner, providing the hardware, automation, and control solutions that manage the printing and inspection of serial numbers and aggregation. They had acquired a small company with the shell of a Level 4 – 5 solution, but those capabilities were never part of their native solution or expertise.

The CPO discovered that relying on the vendor for Level 4 – 5 meant:

- **Unprecedented licensing costs**

Licensing the vendor’s Level 4 – 5 solution resulted in costs of “hundreds of thousands of dollars.” In one year, the failed project became “the single largest investment they have ever made,” the company says.

- **Lack of support for unpacking and packing scenarios**

The CPO specializes in reworking batch product that has already been commissioned—and then serializing it with new serial numbers. But the vendor’s basic tools could not manage the Level 4 – 5 serialization requirements for rework, and the solution was continually interrupting their business processes.

- **Point-to-point integration complexities**

The vendor lacked point-to-point integration expertise, was not able to develop the complex connections in a timely manner, and could not manage the custom requirements of the CPO’s brand owners.

- **Failure to meet implementation milestones**

Despite an initial promise that integration time would be less than two months, the vendor missed go-live dates repeatedly—in August 2016, November 2016, and March 2017. Being “a small guy” with a dozen packaging lines meant the specialty CPO was never a priority for the vendor, the company says.

Decision driver: Proven partner integrations to save cost, ensure supply

After spending over \$1 million without ever being able to connect to their most important brand-owner customer for serialization, the company switched to TraceLink in April 2017 for:

- **Lower cost through an all-inclusive subscription**

Regardless of project size, TraceLink consistently delivers lower TCO than any other enterprise serialization alternative. Companies rely on the all-inclusive subscription model that TraceLink offers to eliminate many of the unpredictable hidden fees for integration, customization, and service they find with other solution providers.

- **A network model for faster partner connections**

Companies turn to TraceLink for its "integrate once, interoperate with everyone" network platform. The TraceLink Life Sciences Cloud enables them to onboard existing trade partners, manage all the unique brand requirements, and connect any new partners they begin working with in the future—at no additional charge.

- **Configurable workflows to support unique business requirements**

TraceLink uses configurable workflows to solve for all the unique business scenarios that companies have. For example, if a brand owner imposes a size limit on data files or requires a naming convention with custom data parameters, TraceLink will manage that.

- **A vendor-agnostic platform for serialization**

Working with TraceLink gives businesses flexibility and choice. Using an LMS vendor to manage network and enterprise serialization needs means companies are locked into that line system, without the ability to add in different equipment and systems to their operations.

Outcome: Leveraging interoperability with industry-leading expertise

Today, the CPO is able to easily connect with brands through the TraceLink network, depend on TraceLink to manage unique brand requirements, and rest assured that new pharma customers will also be seamlessly onboarded. They also have support for their own unique workflows, flexibility with line systems, and predictable costs—regardless of how their business may grow.

The TraceLink Life Sciences Cloud is the only purpose-built solution that digitizes the entire pharmaceutical supply chain to help drug manufacturers, distributors, hospitals, and pharmacies meet existing and emerging regulations in every geographic market. With 400 pharmaceutical and contract manufacturing customers on its network—including nearly 200 that are sharing live serialization data with partners today—TraceLink offers the only proven playbook for serialization-readiness.



Pharma Drops Vendor over Integration and Validation Failures, Joins TraceLink

After repeated unsuccessful attempts to upgrade their lot-level rfxcel solution, one U.S. pharma company made the decision to break their contract and switch to TraceLink—even though the vendor had offered to provide serialization at no additional cost. The discovery of a bug that exposed them to a serious security risk was the last straw in a string of integration and validation issues that plagued their project from day one.

The company determined that TraceLink would help them make up for lost time, achieve compliance, and maintain a validated and secure system, helping them move ahead in their mission to deliver the highest quality and safest medicines to their customers.

Three critical shortcomings

During the lot-level solution sales process, the vendor had offered a serialization solution for no additional fee. But the lot-level compliance issues were so frequent—and so severe—that the company instead decided to re-evaluate their vendor options. They had three major concerns:

- **Testing and validation failures**

For four months, the company made repeated attempts with their lot-level software to complete one single basic installation qualification (IQ)—without success. In an industry where evolving regulations necessitate frequent code changes, they realized that these failures compromised their ability to go live and maintain a validated system.

- **Infrastructure vulnerabilities**

Incorrect configurations that caused an upgrade to fail repeatedly made the company realize that their compliance—and their ability to ship 3 billion tablets annually—was in jeopardy. Security weaknesses further undermined their confidence in the solution.

- **Line integration issues**

For two years, the company was unable to configure their systems for lot-level compliance. When the time came to integrate their line equipment for serialization, the project got off to a bad start—“the initial XML files provided to us were a mess”—and the company decided not to proceed. They later discovered that the vendor was unsuccessful in getting any of its software customers integrated with their line vendor.

Decision driver: Purpose-built for regulatory compliance, security, and flexibility

The company realized that if they were unable to complete a single IQ, they might never successfully go live with their solution. Uncovering security flaws added fuel to the fire, and prompted the final decision to change vendors. They chose TraceLink because it offered a proven architecture and validation support to help them manage the complexities of serialization, including:

- **Automated, scalable validation for continuous compliance**

TraceLink offers automated validation for the entire validation life cycle of its Life Sciences Cloud, with automatic testing and confirmation to ensure all current TraceLink software capabilities meet GxP compliance, in accordance with industry standards such as GAMP 5. Documentation necessary to supplement specific processes according to each company's own validation strategy is also provided.

- **The power of Amazon Web Services for security and reliability**

The TraceLink Life Sciences Cloud is built on Amazon Web Services (AWS) infrastructure. The AWS platform maintains more than 1,800 security controls—validated and certified by an independent auditor—providing a more secure and reliable environment than other vendors' proprietary cloud solutions.

- **Out-of-the-box integrations for streamlined success**

Ready-to-use integrations with more than a dozen LMS providers enable quick connectivity with line vendors and other core business systems across the life sciences supply chain. Overall, the TraceLink network approach—allowing companies to integrate once and interoperate with every company on the network—speeds the overall time to serialization implementation.

Outcome: Delivering streamlined integrations and long-term security

With the move to TraceLink, the company has shifted their solution to a secure cloud platform that seamlessly handles changing regulatory and trade partner requirements, and automates its validation processes. Rapid deployment of new software and out-of-the-box integrations with third-party systems give the company the flexibility to grow and adapt as business requirements evolve.

The TraceLink Life Sciences Cloud is the only solution that digitizes the entire pharmaceutical supply chain to help drug manufacturers, distributors, hospitals, and pharmacies meet existing and emerging regulations around the globe. TraceLink offers a proven playbook for serialization readiness, with nearly 400 pharmaceutical and contract manufacturing customers on its network—including more than 140 that are sharing live serialization data with partners today.



Delivery Issues and High TCO Prompt Generics Pharma to Switch to TraceLink

When a mid-size U.S. manufacturer of generic medications acquired the U.S. generic arm of another global drug manufacturer, it prompted their global serialization team to reassess how they would collectively manage serialization and track and trace across the new enterprise. Up to that point, the parent company's solution vendor, Axway, had been unable to meet many of their functional requirements and timelines, and the acquired company had been struggling with an SAP implementation from their previous owner.

Given these pre-existing concerns, and with the company now doubling in size, they agreed a new approach was needed to address the tens of millions of serial numbers they would be jointly commissioning annually. To avoid further delays and risks, the growing business switched entirely to TraceLink for full-stack serialization, including the TraceLink Edge Track solution for managing serialization in the distribution process.

Four critical shortcomings

There were several key factors that spurred the company to look for a new serialization solution provider:

- **Massive infrastructure costs**
Relying on an on-premises architecture meant that the company had to make a significant investment in hardware infrastructure in order to support their serial number volumes, and would only have to invest more to store the tens of millions of serial numbers they were adding as a result of their acquisition.
- **Inability to scale for serialization performance**
The relational database architecture of the parent company's vendor was struggling to process lot-level transactions, in which a batch shipment of 10,000 units requires just four transactions. This led to concerns about their ability to manage serialization—the same batch requires 60,000 serialization transactions to be updated for every single unit. To keep up with processing, the manufacturer's only option would have been to spend more to acquire bigger, more powerful hardware.
- **Inefficient partner and packaging line connectivity**
Creating point-to-point connections with each CMO was taking longer than expected, and the acquisition meant six additional CMOs were being added to the list. In addition, establishing connectivity to the company's internal packaging lines was not successful and far behind schedule.

- **Lack of committed vendor resources**

The parent company's vendor was unable to provide adequate resources to custom build new functionality for serial number provisioning changes without a several-month delay.

Decision driver: Scalability at lower overall cost

When the company decided to reassess their vendor options, they quickly ruled out SAP based on the acquired company's experience where the All/OER solution had problems processing serial numbers. A leading independent systems integrator serving as an advisor for merger-related IT strategy cautioned them against using the new ATTP platform as an unproven system.

The company ultimately chose TraceLink for its ability to address all of their needs, including:

- **Lowest total cost of ownership**

By using a native cloud-computing, network-tenant architecture, TraceLink addresses many of the unpredictable costs of serialization within an all-inclusive subscription model, eliminating separate line items and unpredictable costs. Regardless of project size, TraceLink consistently delivers lower TCO than any other single-tenant or on-premises alternative.

- **Measurable performance and scalability gains**

Implementing a solution that can manage the massive amounts of serialization data and transactions is critical to getting product out the door and maintaining operational efficiencies. TraceLink uses a NoSQL database in the Amazon Web Services (AWS) cloud that distributes workload across many machines for virtually limitless scalability and continuous data availability.

This unique approach to speed, scalability, and efficiency allows TraceLink to add real-time processing power as needed for unrivaled benchmark results:

- Provision 100K random serial numbers in 56 seconds.
- Commission 100K serial numbers in under 1 minute.
- Send 100K DSCSA-compliant messages in 50 seconds.
- Total process, provision to reporting, of 5 minutes.
- Read 150K serial numbers per second.
- Write 10K serial numbers per second.

- **Rapid CMO connectivity**

The TraceLink network approach allows customers to integrate once, then interoperate with all 268,384 supply chain businesses that are on the network, eliminating the need for point-to-point connections. When the company turned to TraceLink, they found that 70% of their CMO partners were already on the network, saving them valuable time. In addition, TraceLink has an entire team dedicated to working with customers' partners, managing a lot of the implementation work so that companies don't have to tackle it themselves.

The company in turn also serves as a CMO to multiple brand owners. In their CMO capacity, they were able to follow the same streamlined TraceLink onboarding approach.

- **24/7 support**

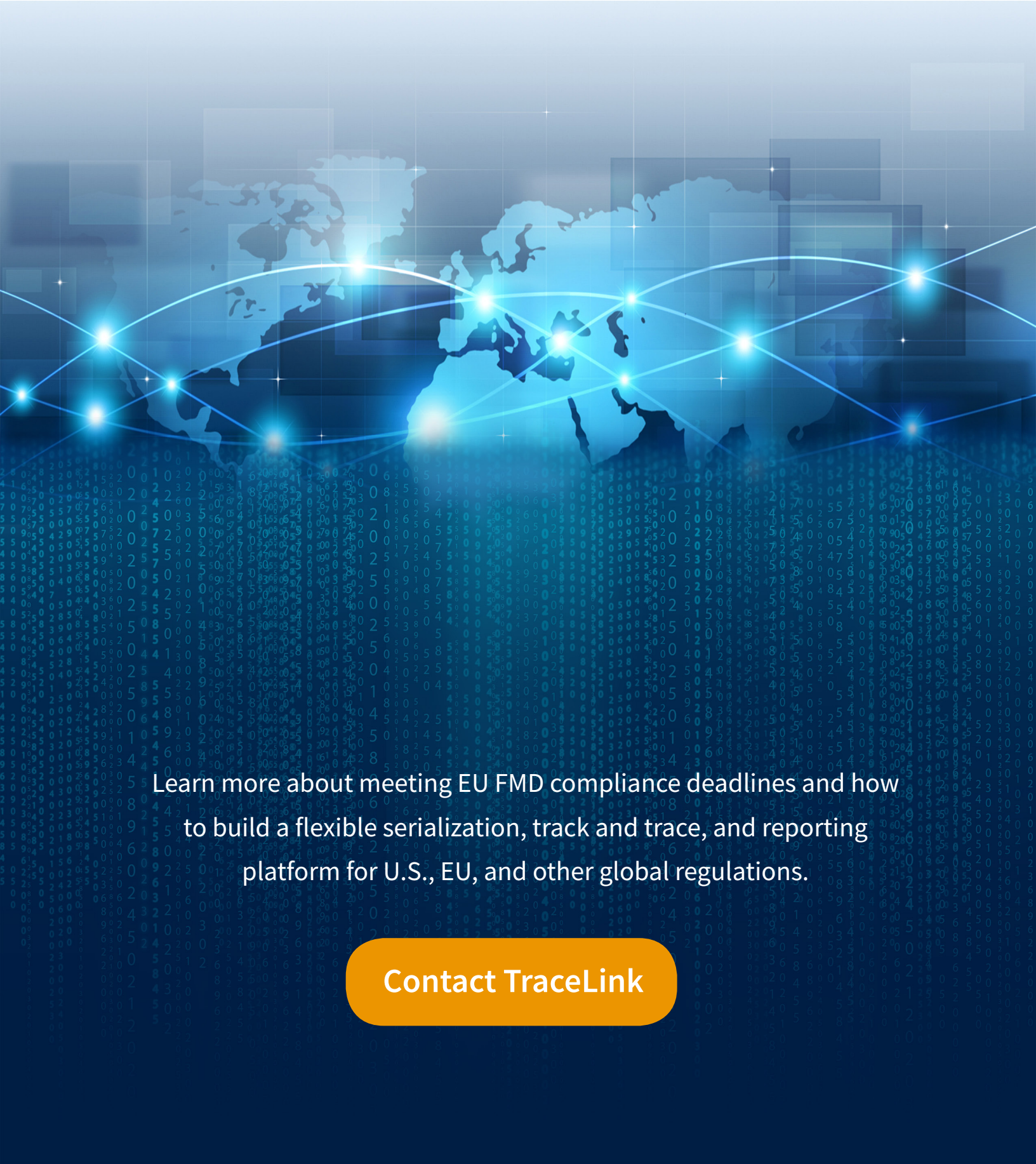
TraceLink customers get the support and attention they need to complete serialization implementation. With more than 400 employees around the world—and global R&D and Services teams of over 100 people—TraceLink service reps are available 24/7 and provide support in 15 languages.

Outcome: A platform built for complex integration and successful onboarding

Switching to TraceLink has enabled the company to rapidly integrate partners and conduct massive transaction processing at operational scale. At the same time, the TraceLink platform has insulated them from future delays and risk, so they can continue to exchange critical serialization information across their entire supply chain network.

The TraceLink Life Sciences Cloud is the only purpose-built solution that digitizes the entire pharmaceutical supply chain to help drug manufacturers, distributors, hospitals, and pharmacies meet existing and emerging regulations around the globe. With nearly 400 pharmaceutical and contract manufacturing customers on its network—including more than 140 that are sharing live serialization data with partners today—TraceLink offers the only proven playbook for serialization-readiness.





Learn more about meeting EU FMD compliance deadlines and how to build a flexible serialization, track and trace, and reporting platform for U.S., EU, and other global regulations.

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