RESOURCES



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 reevaluate their vendor options. They had three major concerns:

- **Testing and validation failures**

For four months, the company made repeated attempts with their lot-level

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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

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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

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more than 140 that are sharing live serialization data with partners today. Contact us to learn more.

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Thank you for contacting us; we’ll be in touch shortly.

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