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Virtual Manufacturer Streamlines Software Validation with AVM

Staying compliant with continuously evolving track and trace regulations is challenging for all pharmaceutical companies, including virtual manufacturers with limited internal resources. When a leading oncology-focused biotechnology company based in the United States needed a solution to reduce the complexity of its software validation and documentation, they chose TraceLink's Automated Validation Manager (AVM).

Managing fast-changing compliance requirements

The company's senior director of information technology described the initial decision to partner with TraceLink: "We are 100% outsourced in terms of manufacturing and clinical trials, so we rely on our partners. The TraceLink cloud platform was selected to leverage a hosted service based on its established integration with our suppliers."

To validate its compliance software in a regulatory landscape that changes constantly, the company replaced the more resource-intensive software development lifecycle

[SDLC] process with a leaner change management paradigm, using AVM to automate its software testing and to generate the required documentation.

Supporting a risk-based approach to validation

In the classic validation approach, functional risk is not assessed and all requirements are essentially assigned the same risk level of "high." A risk-based approach enables companies to execute a higher volume of use cases and a more thorough validation of systems than classic methodologies while minimizing lengthy validation processes.

"As a pharmaceutical company, we are accustomed to a risk-based approach, and it applies to our business systems as well," notes the IT director, "Automated validation helps us follow a risk-based approach."

Automating test plans and documentation

By partnering with TraceLink, the company is able to minimize the resources required for validation and reporting, including Installation Qualification (IQ) and Operational Qualifications (OQ) summary documentation for each release. The IQ process includes the full set of installation activities for each software component in the TraceLink network, including software release version, date, listing of components, and migration tasks when required.

According to the senior IT director, "Looking at this from an IT perspective, our responsibilities are two-fold: systems administration and validation documentation. We

did not want internal staff to develop documentation for every release. We focus our resources on roadmap releases [and] rely on AVM for the validation plan as well as the summary reports associated with each release."

AVM gives this virtual manufacturer access to the full range of validation documentation to ensure TraceLink software capabilities are performing as intended, including:

- Functional risk assessment
- Validation plan
- Test cases and results
- User Requirements Specifications (URS)
- Traceability matrix
- Summary report

TraceLink: Partnering for continuous compliance

Whether a company relies solely on a partner network, maintains a fully in-house operation, or follows a hybrid business model, the speed and efficiency of automated software validation will be essential to stay compliant and competitive in the global pharmaceutical marketplace. Automated Validation Manager helps innovative companies take full advantage of TraceLink's integrated compliance platform and

flexible, scalable network-tenant architecture to meet changing regulatory requirements and go-to-market strategies.

Contact us to learn more about Automated Validation Manager from TraceLink.

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