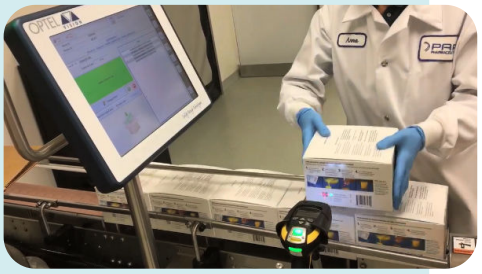
RESOURCES

Home

AVM Helps Virtual Manufacturer Automate Software Validation Across Diverse Supply Chain



Companies that rely on a global community of contract manufacturing organizations (CMOs) and third-party logistics providers (3PLs) to bring medicines to market and comply with government track-and-trace regulations must also be sure that their compliance solutions meet government qualification standards. Because compliance software must be frequently updated to meet changing regulatory and business requirements, companies need a reliable, efficient way to test and validate each new update and release.

To keep pace with changing regulations and plan for future growth, a leading biopharmaceutical manufacturer turned to TraceLink's Automated Validation Manager to help manage their software compliance requirements across a diverse, global supply chain.

Partnering with TraceLink to connect a virtual operation

As a virtual organization, the company relies on a network of CMOs to produce dozens of pharmaceutical products. The manufacturer realized the value of using TraceLink's integrated digital supply network to connect and share data with its CMOs, 3PL, and downstream distributors to comply with each phase of DSCSA regulations. According to the company's director of supply chain, "What's different about us is that we're a virtual manufacturer. To date, data exchange is strictly within the TraceLink cloud: suppliers send data directly to TraceLink, then it goes to the 3PL, then our 3PL sends data to downstream customers via the TraceLink network."

Ensuring software compliance across a diverse supply chain

As the DSCSA track-and-trace regulations evolved from lot-level identification to a unique identifier for each unit, the company's CMOs took on the task of managing and sharing vast amounts of serialization data. This presented a new challenge: validating the software deployed across a diverse CMO community every time it was updated to meet changing regulations. "With virtual production scenarios," notes the director, "it is a challenge to address and validate the various scenarios across the numerous systems that are exchanging data within the TraceLink Life Sciences Cloud."

To ensure continuous qualification aligned with the FDA's General Principles of Software Validation as well as the industry's Good Automated Manufacturing Practices (GAMP), the company utilizes TraceLink's Automated Validation Manager. AVM provides and runs the test scripts required for performance qualification (PQ) by both

the brand owner and its CMOs—and generates the documentation needed for internal and external quality assurance. “Prior to AVM, we had to create the scripts for what needed to be tested,” says the director, “As we introduced more diversity with serialization and the different systems that are being used, AVM became a huge benefit for us. It has minimized the workload of the testing that we needed to perform and was able to execute against a more extensive list of test scripts and user cases.”

“AVM ensures that we have a compliant, validated system.”

“AVM is allowing us to keep up with the ‘rapid fire’ changes in our industry,” adds the director, “As we add new use cases—customers, regions, languages, and systems—we expect that there will be a lot of compliance software updates and releases.” She also notes the complexity that comes with relying on multiple partners, “Working with our suppliers, we have a plethora of different scenarios. Some are aggregating, some using SOAP, some using SFTP. Again, various scenarios to test. AVM provides the additional support needed to successfully validate the system.”

Positioning virtual manufacturers for growth and business transformation

The company also points out the benefits of TraceLink’s information-sharing network and Automated Validation Manager as they looks to expand their global footprint: “There’s a push for growth. As we expand our focus beyond the U.S. market, we can utilize the efficiency of using one system, rather than multiple systems, for the different compliance scenarios, including validation.”

As the pharmaceutical industry moves toward all-digital track-and-trace solutions, the speed and efficiency of automated software validation will be essential to stay compliant and competitive in the global marketplace. AVM helps virtual companies focus their resources on delivering therapeutic medicines while giving them the freedom and flexibility to implement innovative go-to-market strategies and business models.

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