Pharma Industry Traceability Mandates are Predictably Unpredictable! Ensure Continuous Validation with TraceLink AVM

Pharmaceutical industry quality standards and regulatory mandates are constantly changing, and track-and-trace systems must be updated to ensure continuous compliance. U.S. Food and Drug Administration (FDA) guidelines for software validation require manufacturers to validate that updated software works as intended in their environment. This validation process results in the need for specialized in-house expertise in software validation and lengthy, labor-intensive testing processes. Manufacturers that outsource validation processes typically end up paying expensive consulting fees.

Today, there is a faster and cost-effective way to manage track-and-trace software validation. **TraceLink Automated Validation Manager** is an automated validation service for pharmaceutical companies and contract manufacturers seeking to meet stringent regulatory and GxP compliance standards. Automated Validation Manager helps organizations ensure continuous compliance while maintaining the integrity of validation and quality processes in today's complex and ever-changing regulatory environment. Watch this quick video to learn more:

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Automated Validation Manager helps manufacturers reduce in-house and outsourcing burdens associated with validation by automating tests and confirming that TraceLink software and platform capabilities perform as intended for your environment. The solution delivers a fully executed, paperless package to ensure compliance with GxP standards such as GAMP 5. Key business benefits include:

- **Faster:** Eliminate manual validation processes, including the need to write and execute validation scripts against new releases. With the automation built into AVM, it runs at least 10x faster than could be done by manually running tests. This minimizes the risks of non-compliance by simplifying and automating validation processes.

- **Better:** AVM runs a full suite of more than 860 automated tests continually executed against platform and application releases to help pharmaceutical companies and contract manufacturers ensure continuous validation.

- **Low Total Cost of Ownership (TCO):** The TraceLink subscription model gives pharmaceutical companies and contract manufacturers the ability to control and predict costs. Running the more than 860 tests could take as much as 400 hours for a customer to execute per month. With AVM, this cost is eliminated and TraceLink maintains a thoroughly validated infrastructure for your organization at the lowest TCO.

- **Future Proof Compliance:** Ensure compliance with both internal and GMP validation requirements while keeping pace with industry compliance changes and emerging business needs; evolving regulations; new and changing data and technology standards; and diverse supply and trade partner requirements.

More than 485 TraceLink customers currently use Automated Validation Manager to execute automated testing and validation. Automated Validation Manager is the

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key to ensuring continuous validation across your organization’s TraceLink solutions.

Contact TraceLink to learn more

VideoAutomated Validation Manager
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Fill out the form to contact us now.

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

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