TraceLink Unveils Automated Validation Manager, Removing Burden of Validating Software Updates

TraceLink Inc., the World's Largest Track and Trace Network for connecting the life sciences supply chain and eliminating counterfeit prescription drugs from the global marketplace, today announced **Automated Validation Manager (AVM)** – a revolutionary web-based offering that automates the entire validation lifecycle of the TraceLink Life Sciences Cloud on an ongoing basis.

Customers using the Life Sciences Cloud already benefit from the only network-tenant solution that enables them to quickly adapt to rapid change in today's continuously evolving regulatory environment. By subscribing to TraceLink AVM, customers no longer have to deploy manual, labor-intensive, paper-based validation procedures and instead are assured that their current instance of the Life Sciences Cloud is automatically validated to meet GxP compliance requirements in accordance with industry standards, such as GAMP 5. Using nothing more than a browser, TraceLink AVM customers simply

login to a web portal and review any aspect of the validation lifecycle, including the validation plan, traceability matrix, test results and final validation certificates. Once validation is complete, TraceLink AVM customers will know that all required IQ, OQ, and PQ test scripts have been successfully executed in a dedicated validation environment.

"We introduced our network-tenant Life Sciences Cloud platform in 2009 as a revolutionary architecture that would enable life sciences companies in any geographic market to eliminate the risks associated with frequent technology updates resulting from continuously changing laws, data exchange requirements and trade partner demands," said Shabbir Dahod, president and CEO of TraceLink. "Automated Validation Manager is the next step in managing the complexity of computer systems validation for our customers, ensuring that they have an easy-to-use solution that removes the business and operational burdens of manual validation and keeps them continuously compliant."

TraceLink Automated Validation Manager: How It Works

 As regulatory demands evolve and changes occur, life sciences companies must be able to quickly adapt their track and trace solutions in order to maintain continuous compliance and prevent disruption to product flow. Technology solutions must also evolve to keep pace with these industry changes, and life sciences companies need to validate software updates to mitigate operational risk by confirming that all new software functionality is working as intended. With the unpredictability associated with

pharmaceutical supply chain compliance, companies face the challenge of managing and validating software updates more frequently – often resulting in the need for specific staff expertise and repeated labor intensive testing. Those who outsource validation because they do not have in-house expertise face high costs for consultants to manage the entire validation process for them.

TraceLink AVM removes both the in-house and outsourcing burdens of validation by automating validation testing and confirming that current TraceLink software capabilities perform as intended. The end result is a fully executed, 100% paperless package compliant with GxP compliance standards, such as GAMP 5. Every TraceLink AVM customer will benefit from:

- A functional risk assessment – highlighting the GxP, business and functional impact of each TraceLink software release;
- A validation plan – outlining the approach and methodology, related procedures and expected deliverables;
- A user requirements specification document – detailing the TraceLink Life Sciences Cloud functionality including requirement priority, type, and risk profile;
- Installation Qualification and Operational Qualification certificates – authenticating the installation and operational quality assurance processes executed in the validation environment;

- Comprehensive Performance Qualification – including hundreds of test scripts and their results;

- A traceability matrix – allowing users to view all requirements linked to their corresponding tests and results;

- A final Certificate of Release – confirming the successful validation of the Life Sciences Cloud against GxP requirements for computer systems validation; and,

- 24/7 real-time access to all validation resources and test results – using an interactive, searchable web-based portal.

TraceLink Automated Validation Manager is expected to be available by the third quarter of 2017 for TraceLink customers.

For more information, visit **http://www.tracelink.com/solutions/automated-validation**.