## **Press Release**



## Genilogix Announces Availability of Validation Accelerator with e-Signature for the latest version of HP Quality Center

Solution to allow FDA regulated companies to use the latest automated testing software from HP

**Dec 5, 2008.** Responding to a growing demand for automated testing software by Life Sciences companies, Genilogix LLC announces the release of their Validation Accelerator with e-Signature for use with HP Quality Center software. This next generation of the Validation Accelerator with e-Signature solution is the most recent upgrade to the Genilogix family of tools for use by FDA-regulated customers. This solution enables clients to leverage the power of HP software to optimize the computer validation process.

The Validation Accelerator with e-Signature solution includes the following components:

- ➤ Validation Accelerator Base Project Template, which contains workflow based on standard computer systems validation process
- > e-Signature Add-in for HP Quality Center, to facilitate compliance with 21 CFR Part 11 requirements
- Comprehensive validation documentation set, which include Validation Plan (VP), System Requirements Specification (SRS), Design and Configuration Specification (DCS), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), Requirements Traceability Matrix (RTM), Project Administration Guide and Project User Guide
- Computer System Validation process integration services, including adaptation of tool to existing client validation process, validation of the tool, development of supporting procedures, as well as training, mentoring, maintenance, and support

New features of the Genilogix Validation Accelerator solution include:

- ➤ Pre-configured PDF reports for Pre-Execution and Post Execution
- eSignature Verification Report
- ➤ Batch approvals for requirements
- ➤ Automated Test Script locking
- > Test Case cloning
- > Test Case supersede functionality

The Genilogix e-Signature Add-in enables clients to comply with 21 CFR Part 11 while aligning the functionality of HP Quality Center with the client's internal validation procedures. This solution has already been installed at over 30 Life Science companies throughout North America and Europe.

## **About Genilogix**

Genilogix LLC is an information technology company with a mission to help Clients optimize quality, performance and availability in business applications. As one of HP's select "Platinum" partners, Genilogix is also one of HP's top resellers. The Genilogix Life Sciences practice is focused on deploying HP tools to increase our customers' ROI when performing Computer Systems Validation.

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