



QC eApprove

Electronic signature-based approval workflow

 Designed for HP Quality Center

Provides controlled workflow and electronic signatures required to enable use of HP Quality Center in regulated environments where 21 CFR Part 11 compliance is required.

QC eApprove benefits

- With customization and validation, enables 21 CFR Part 11 compliance allowing HP Quality Center to act as the system of record for requirements, tests, and test results.
- Flexible workflow customization allowing QC eApprove and HP Quality Center to follow your process.
- Dramatically reduces time and costs associated with managing a paper-based process.
- Can be validated quickly with less cost thanks to customizable validation documentation from Genilogix.
- Officially endorsed by HP Software and produced by one of their top Platinum Partners.
- Can be delivered as a pre-validated virtual appliance.

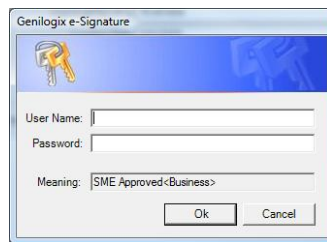
New features

- Biometric signatures
- Version control and baselining
- Release management support
- Risk-based quality management
- Enhanced reporting
- Dynamic approval configuration

The business problem

Using paper-based processes to manage your validation testing is costly and inefficient, causing delays and additional cost when deploying regulated applications.

By providing a controlled and enforceable workflow with electronic signatures, Genilogix QC eApprove enables your testing teams to employ HP Quality Center in regulated environments.



QC eApprove electronic signature

HP Quality Center

HP Quality Center is the industry-leading application lifecycle management tool that provides the ability to:

- Gain real-time visibility into requirements coverage and the associated defects
- Better understand the business risks related to software quality assurance
- Manage the release process and make more informed decisions with real-time KPIs and reports
- Collaborate in the software quality lifecycle with a unified global platform
- Manage manual and automated testing assets centrally
- Facilitate standardized testing and quality processes to boost productivity through controlled workflow
- Lower costs by using QA testing tools to capture critical defects before they reach production

Using HP Quality Center for validation testing enables paperless test management and helps to lower validation testing costs.

On-demand reporting allows efficient tracking of requirements and tests and helps to quickly locate critical information during regulatory audits.

With **QC eApprove**, we were able to meet all of the 21 CFR Part 11 requirements and customize the design to meet our existing internal procedures. This provided a significant savings in both time and costs.

- **Bayer Healthcare**

HP Quality Center 10 enhancements

HP Quality Center 10 provides new features useful for regulated industries, including native version control, shared libraries and improved reporting capabilities.

QC eApprove complements these features with through integrated workflow expressly designed to enhance the use of Quality Center in regulated environments.

Administration enhancements include new back-up and recovery features,, which assure your projects are protected and available long-term.

Implementation enhancements include the option of purchasing Quality Center 10.0 delivered via flash drive, in an FDA validated state, and the use of application-specific libraries of tests.



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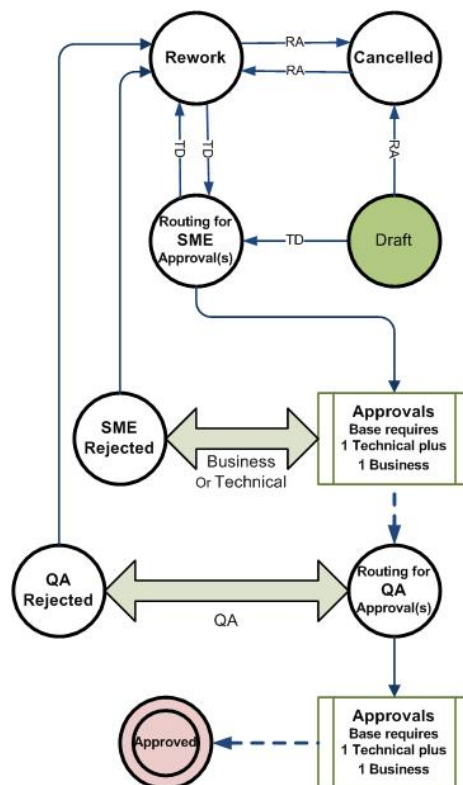
System requirements

- Quality Center 9.0 or greater
- Internet Explorer 6.0 SP1 or greater
- Microsoft .NET Framework 2.0 or greater (client)

Regulatory compliance

QC eApprove is the controlled workflow with electronic signature add-in from Genilogix for HP Quality Center. Based on HP's Open Test Architecture and Workflow APIs, it ensures that the use of Quality Center conforms with life science and health regulatory requirements and industry guidelines such as 21 CFR Part 11, GAMP5, SOX, and HIPAA.

The controlled workflow supports regulatory compliance by providing the technical controls required by 21CFR Part 11. This also ensures a repeatable testing process and optimizes review and approvals across your organization.



Biometric authentication for Health and Life Sciences

Genilogix biometric authentication tools provide an added level of security and convenience for users, by automating the signature process using biometric identification methods. The technology uses fingerprint or palm vein patterns to authenticate users, eliminating the need to remember and maintain PINs or passwords. Biometric Authentication can be combined with passwords or smartcards for 2-factor authentication, supports PKI, and integrates with SSO Single Sign On systems and LDAP directories.



Siemens Biometric Mouse for QC eApprove

About Genilogix

Genilogix, an HP Software Platinum and VMware Enterprise Partner, offers innovative software and services for application lifecycle management in regulated industries. We resell the full product suites from HP Software and VMware allowing us to put together complete solutions for our customers.

To get QC eApprove, or for additional information, call: +1 (800) 780-5110

www.genilogix.com