

# HPE ALM e-Signature

## Meet regulatory compliance with electronic signature capabilities for HPE ALM/QC.

### Executive Summary

Managing the lifecycle of regulated applications can be a daunting and costly task. Paper-based processes—typically in place to ensure compliance, validate, and prove that everything has been executed as per regulations—are even more costly and inefficient. From requirements management, testing, release, and defects management, organizations with regulated applications need to ensure and prove to auditors that any changes and access to these regulated applications have undergone a rigorous and auditable process.



While HPE Application Lifecycle Management/Quality Center (ALM/QC) provides core functions such as Requirements Management, Deviation Management, Test Planning, Test Execution, Traceability Matrix Management, and Reporting—which are critical to managing an effective paperless testing effort—HPE ALM e-Signature complements these

features with an integrated workflow expressly designed to enhance the use of ALM/QC in regulated environments. For example, in environments where 21 CFR Part 11 compliance is required, HPE ALM e-Signature can drive a paperless yet fully traceable and auditable process where all ALM/QC project entities can be electronically signed following every human interaction, rejection, or approval of any change going into the system.

### HPE ALM e-Signature and regulatory compliance

HPE ALM e-Signature is a controlled workflow with electronic signature add-in for HPE ALM/QC. Based on HPE's Open Test Architecture and Workflow APIs, it ensures that the use of HPE ALM/QC conforms with health and life science 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 solution also ensures a repeatable testing process, and optimizes reviews and approvals across your organization while proving full traceability.

### Service overview

HPE ALM e-Signature implementation services are designed to implement and integrate a prepackaged software solution within your new or existing ALM/QC environment. The implementation process leverages a base intellectual property solution framework that is followed by a customization and integration phase to meet your organization's requirements and internal processes with respect to regulations in effect. The base template

follows FDA 21 CFR Part 11 guidelines but does not factor in existing customizations or requirements that could either interfere or are needed to coexist with the new functionality, hence the customization and integration phase. Service delivery typically ranges between three to seven weeks in duration directly impacted by the level of customization or requirement complexity indicated by the customer. HPE Software Services provides end-to-end solution delivery with minimal impact to the business.

### HPE ALM e-Signature service delivery approach

The first step to a successful e-Signature implementation is a revalidation of the requirements with an in-depth analysis of the implications. After sign-off on the requirements is obtained, software development begins.

Our recommended approach is to perform a preliminary implementation of the base solution in an ALM/QC software development environment with comparable data to production. This allows complete autonomy during the development process while offering a realistic framework to validate functionality. Upon completion of development, we will conduct an initial end-to-end testing phase and resolve any defects until the solution is determined ready for the user acceptance testing phase.

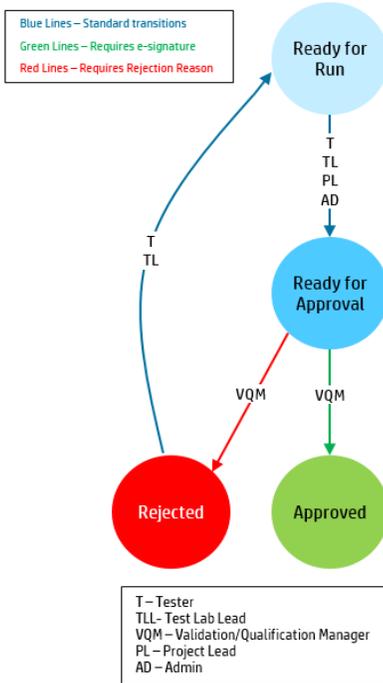
This phase is typically conducted in a user acceptance testing or staging environment with production-like data. While the user acceptance testing phase is owned by the customer, we will act as mentors and support personnel until production release sign-off is obtained.

After the ALM e-Signature solution is deployed to the ALM/QC production

## Service brief

instance(s), we will provide a production support period, fixing any defects while mentoring the larger user base.

Services are typically delivered using a best-shore approach to position a financially compelling solution; however, other software delivery models can be presented should your organization desire.



Sample test run workflow diagram

## HPE ALM e-Signature service deliverables

Upon signature of a Statement of Work, HPE will provide the following:

- Solution implementation project plan
- HPE ALM/QC project template containing governance workflows in accordance with regulatory compliance required by 21 CFR Part 11 regulations and other customizations agreed upon in the Statement of Work

- Deployment of the solution in up to two (2) HPE ALM/QC environments
- Documentation of the implemented HPE ALM software solution with an emphasis on workflow logical diagram and customized entities

## HPE ALM e-Signature benefits

While the primary benefit of HPE ALM e-Signature is to guarantee that regulatory compliance is met, many other benefits are gained:

- Flexible workflow customization allowing e-Signature to follow or blend into your existing ALM processes
- Significant reduction in time and costs associated with managing a paper-based process
- Fostering of reusable, repeatable, and predictable validation initiatives
- Ease and convenience of an embedded functionality within ALM/QC yielding up to 40% in time reduction post-execution review and approval of tests
- Up to 45% reduction of time in reporting activities
- Entirely built using out-of-the-box framework of ALM/QC, significantly reducing future upgrades or migration challenges

Equally supported to run in a SaaS environment or on premises

## The HPE Software Services difference

HPE provides unmatched capabilities with a comprehensive set of ALM consulting and implementation services and unique intellectual property that help you deliver high-quality applications faster and accelerate innovation. The unique HPE ALM e-Signature solution demonstrates how customers can take full advantage of their

existing or new HPE ALM/QC solution, avoiding the need to invest in a third-party solution. HPE Software Services consistently demonstrates:

- Expertise and knowledge in HPE tools and their practical usage to solve concrete problems
- Practitioner experience in integrating and implementing solutions within complex and regulated organizations
- Knowledge, expertise, and experience in management of change and transforming organizations
- Global reach with vast expertise in providing IT transformation consulting solutions to enterprise customers
- Extended professional and education services to address any phase of application lifecycle management.

Only HPE Software Services brings together a seemingly simple solution for what would be considered a sensitive and complex problem.

## For more information

Contact your HPE representative or email HPE Software Services in your region:

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