

# ALM e-Signature

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

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 Micro Focus 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—Micro Focus 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, 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.

## ALM e-Signature and Regulatory Compliance

ALM e-Signature is a controlled workflow with electronic signature addin for ALM/QC. Based on Micro Focus’s Open Test Architecture and Workflow APIs, it ensures that the use of 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

ALM e-Signature implementation services are designed to implement and integrate a pre-packaged 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. Micro Focus Professional Services provides end-to-end solution delivery with minimal impact to the business.

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

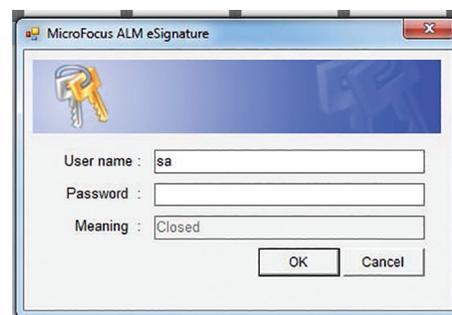


Figure 1. ALM e-Signature

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.



**Figure 2.** ALM e-Signature service deliverables

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

- Solution implementation project plan
- 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) ALM/QC environments
- Documentation of the implemented Micro Focus ALM software solution with an emphasis on workflow logical diagram and customized entities

### ALM e-Signature Benefits

While the primary benefit of ALM eSignature 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 Micro Focus Professional Services Difference

Micro Focus 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 ALM e-Signature solution demonstrates how customers can take full advantage of their existing or new ALM/QC solution, avoiding the need to invest in a third-party solution. Micro Focus Professional Services consistently demonstrates:

- Expertise and knowledge in Micro Focus 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 Micro Focus Professional Services brings together a seemingly simple solution for what would be considered a sensitive and complex problem.

### For More Information

Contact your Micro Focus representative or email Micro Focus Professional Services:

[e-sign-contact@microfocus.com](mailto:e-sign-contact@microfocus.com)

Micro Focus gives you the power to gain connected intelligence for the new style of enterprise IT—anytime, anywhere, quickly and securely.

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