

Micro Focus e-Signature for ALM Octane and ALM/QC

Fulfill regulatory compliance within your Application Lifecycle

Executive Summary

Title 21 CFR Part 11 is a section in the Code of Federal Regulations (CFR) that sets forth the United States Food and Drug Administration's (FDA) guidelines on using electronic records and electronic signatures. Any organization with regulated applications that fall under the Title 21 CFR Part 11 need to ensure that any changes and access to these regulated applications have been conducted through a rigorous and auditable process.

Managing the lifecycle of these regulated applications can be a complex and costly task. Paper-based processes in place for such compliance is often costly, inefficient and labor intensive to administer. From requirements, backlog, testing, release and defects, organizations with regulated applications need to be able to provide evidence to auditors that changes and application access have undergone a rigorous and auditable process.

The Micro Focus e-Signature solution for Application Lifecycle Management (ALM) drives a paperless yet full traceable and auditable process where Micro Focus ALM entities can be electronically signed post every human interaction, rejection or approval. Micro Focus e-Signature runs on either ALM Octane or ALM/QC enabling e-Signature through the app lifecycle in requirements, backlogs, defects, tests, test plans, execution and pipelines.

e-Signature and Regulatory Compliance

The Micro Focus E-Signature solution handles workflow for Micro Focus ALM/QC or ALM Octane including an electronic signature that

conforms with health and life science regulatory requirements and industry guidelines such as Title 21 CFR Part 11, GAMP5, SOX, and HIPAA.

The workflow supports regulatory compliance by providing the technical controls required by Title 21 CFR Part 11. This solution also ensures a repeatable validation and testing processes, and optimizes reviews and approvals across your organization with full traceability and auditing native within Micro Focus ALM/QC and ALM Octane.

e-Signature for ALM Service Delivery Approach

The Micro Focus e-Signature solution for ALM implementation comprises of the following key events within the delivery approach:

- A kick off to align customer stakeholders and the implementation team with the delivery approach and timeline
- A customer workshop to validate and adapt requirements and plan the delivery backlog
- The preliminary implementation of the base solution in an ALM/QC or ALM Octane software development environment with comparable data to production.

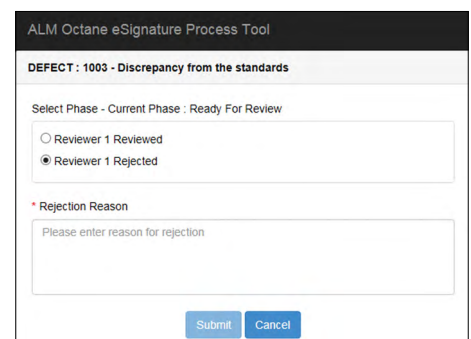


Figure 1. Example e-Signature

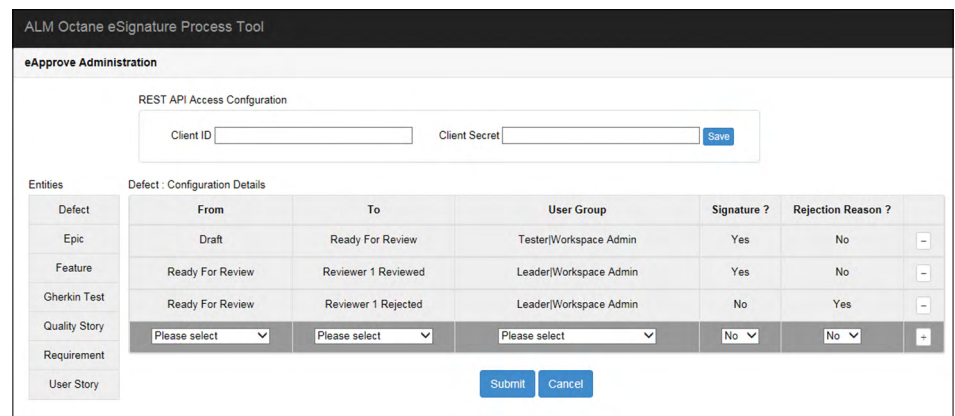


Figure 2. ALM Octane E-Signature Workflow Configuration

- Agreed number of sprints or cycles (depending on the delivery method agreed to) for the elaboration, development and testing of stories to deliver the solution.
- Initial end-to-end testing and resolution of any defects until the solution is determined ready for user acceptance.
- User acceptance testing in a 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.
- Deployment of the solution into a production instance
- A production support period, fixing any defects while mentoring the larger user base
- Post production Solution Management Service for a period of 1 year

Services are typically delivered using a best-shore approach to position a financially compelling solution; however, other software delivery models are an option.

Deliverables

As a part of the general deliverables included during this engagement Micro Focus will provide:

- A Solution implementation plan (either in backlog format or a traditional project plan)
- ALM/QC project template OR ALM Octane solution software containing governance workflows in accordance with regulatory compliance required by Title 21 CFR Part 11 regulations and other customizations agreed within the Statement of Work
- Deployment of the solution in up to two (2) environments
- Documentation of the implemented Micro Focus ALM software solution with an emphasis on the workflow logical diagram and customized entities
- Solution Management Service for a period of 1 year

e-Signature on ALM/QC or ALM Octane?

Micro Focus can deliver our e-Signature solution on either ALM/QC or ALM Octane. Although there are differences in the solution operation, the features of the solution provide

customers with effective features to manage the requirements for testing and managing applications by Title 21 CFR Part 11.

e-Signature Benefits

While the primary benefit of 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 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 significantly reducing future upgrades or migration challenges
- Equally supported to run in a SaaS environment or on-premises

Customers receive SMS for 1 year to help manage and support the solution:

About Solution Management Service (SMS) for e-Signature

New implementations of e-Signature for ALM are supplied with 1 year of SMS. This part of the solution provides extended support and management of e-Signature including:

- A single point of contact for incident and problem management across the entire solution
- Ongoing maintenance and operations, including system admin, proactive monitoring, health checks, patch management, app restarts, license key admin and recurring reports
- Proactive guidance: investigate-assess-recommend
- Enhancements, continuously improving the solution through new configurations, upgrades and integrations that increase value and adoption

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