

OpenText e-Signature for ALM Octane and ALM/Quality Center

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

e-Signature and Regulatory Compliance

The OpenText E-Signature solution handles workflow for OpenText ALM/Quality Center 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 OpenText ALM/Quality Center and ALM Octane.

e-Signature for ALM Services Summary

Our e-Signature for ALM services can be purchased as packaged services with fixed price and scope or as a custom service.

Figure 1. Example e-Signature

e-Signature for ALM Packaged Services

Our e-Signature for ALM packaged services are provided in a small, medium and large size. The packages are designed to suit customer requirement size and complexity.

Entities	From	To	User Group	Signature ?	Rejection Reason ?	
Defect						
Epic	Draft	Ready For Review	Tester/Workspace Admin	Yes	No	-
Feature	Ready For Review	Reviewer 1 Reviewed	Leader/Workspace Admin	Yes	No	-
Gherkin Test	Ready For Review	Reviewer 1 Rejected	Leader/Workspace Admin	No	Yes	-
Quality Story	Please select	Please select	Please select	No	No	-
Requirement						
User Story						

Figure 2. ALM Octane E-Signature Workflow Configuration

Service Flyer

OpenText e-Signature for ALM Octane and ALM/Quality Center

Find out more information about our e-Signature for ALM Packaged Services [here](#).

e-Signature for ALM

Service Delivery Approach

The OpenText 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/Quality Center or ALM Octane software development environment with comparable data to production.
- 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 Value+ Management Service for a period of 6 months

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 OpenText will provide:

- A Solution implementation plan (either in backlog format or a traditional project plan)
- ALM/Quality Center 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 OpenText ALM software solution with an emphasis on the workflow logical diagram and customized entities
- Value+ Management Service for a period of 6 months

e-Signature on ALM/Quality Center or ALM Octane?

OpenText can deliver our e-Signature solution on either ALM/Quality Center 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

The e-Signature solution is sold with 6 months of Value+ Management Services to help manage and support the solution:

About Value+ Management for e-Signature

New implementations of e-Signature for ALM are supplied with 6 months of Value+ Management Services. 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

The OpenText Professional Services Difference

OpenText provides unmatched capabilities with a comprehensive set of consulting and implementation services and unique intellectual property that help you drive innovation through streamlined and efficient software delivery:

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- Proven OpenText software solution implementation expertise
- More than 20 years of experience helping large, complex, global organizations realize value from their OpenText software investments
- Rich intellectual property and unparalleled reach into product engineering
- Technology-agnostic implementation approach with no vendor lock-in, no rip-and-replace
- Education and support services to ensure adoption

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