

# E-Signature for Application Lifecycle Management

Fulfill regulatory compliance within your application lifecycle with E-Signature for OpenText Application Quality Management and OpenText Software Delivery Management

## Benefits

- Simplify information access with powerful content management
- Drive productivity using intelligent automation
- Ensure comprehensive, trusted governance; privacy; and security
- Drive agility with a highly configurable and flexible platform

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 under Title 21 CFR Part 11 needs to ensure that any changes and access to these regulated applications have been conducted through a rigorous and audit-able process. Managing the lifecycle of these regulated applications can be a complex task. Using paper-based processes for compliance requirements is often costly, inefficient, and labor-intensive. From requirements, backlog, testing, release, and defects, organizations with regulated applications need to provide evidence to auditors that meet the requirements of the FDA regulations.

The OpenText E-Signature solution drives a traceable and auditable process within our ALM platforms. Entities within the application lifecycle can be electronically signed with every human interaction, whether rejection or approval. OpenText E-Signature runs on either OpenText Application Quality Management or OpenText Software Delivery Management enabling E-Signature for requirements, backlog items, defects, tests, test plans, execution, and pipelines.

Our E-Signature solution 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 that Title 21 CFR Part 11 requires. This solution also ensures repeatable validation and testing processes and optimizes reviews and approvals across your organization. Full traceability and auditing are native within OpenText Application Quality Management and OpenText Software Delivery Management.

## E-Signature for ALM Implementation

The OpenText E-Signature solution for ALM implementation includes:

- Kick-off meeting to align customer stakeholders and the implementation team on the delivery approach and timeline.
- Customer workshop to validate and adapt requirements and plan the delivery backlog within the selected scope (small, medium, or large).
- Preliminary implementation of the base E-Signature solution in an OpenText Application Quality Management and OpenText Software Delivery Management environment.
- Implementation of requested changes to the application lifecycle workflow, user roles, approval roles and levels, in-scope custom reports, in-scope integrations, bulk upload, and bulk approval. (See table x for service inclusions for each scope.)

- Initial end-to-end testing and resolution of any defects until the solution is ready for user acceptance.
- Support for user acceptance testing, performed by the customer, acting as mentors and supporting the customer's efforts to test functionality.
- Deployment of the solution into a production instance.
- Production support period, fixing any defects while mentoring

## Deliverables

Deliverables include:

- Solution implementation plan, either in backlog format or a traditional project plan.
- OpenText Application Quality Management project template or OpenText Software Delivery Management solution software containing governance workflows in accordance with regulatory compliance required by Title 21 CFR Part 11 regulations and other customizations included in the scope of the selected service.
- Deployment of the solution in environments as per the selected service.
- Documentation of the implemented OpenText ALM software solution with an emphasis on the workflow logical diagram and customized entities.

## Service Inclusions

The E-Signature for ALM service is available as medium or large for OpenText Application Quality Management small and medium for OpenText Software Delivery Management. The scope of each is detailed in the table below:

### E-Signature Service Size & Inclusions

	OpenText Application Quality Management		OpenText Software Delivery Management	
	Medium	Large	Medium	Large
Environments	2	3	1	2
WF	4	5	3	8
Roles	5	8	3	10
Approval roles/ levels	4	5	3	10
Custom reports	3	5	○	○
SSO authentication	●	●	●	●
Templates (incl. GXP Templates)	3	5	2	3
Non GXP project customization (not recommended)	○	○	○	○

	OpenText Application Quality Management		OpenText Software Delivery Management	
	Medium	Large	Medium	Large
Migration from other solution	○	○	○	○
Upgrade & migration (3 Proj)	○	●	○	○
UFT integration	●	●	○	●
Other integrations	○	○	○	○
Bulk upload	●	●	○	○
Bulk approval (WF)	●	●	○	●
Bulk approval (Excel)	●	●	○	●

● Included   ○ Not included   # Maximum values

## Duration

The duration of this service depends on the size:

Service	Duration in months
Small (OpenText Software Delivery Management only)	2
Medium (OpenText Application Quality Management or OpenText Software Delivery Management)	3
Large (OpenText Application Quality Management only)	4

## Service Limitations

The Service must be sold with Value+ Management for ADM ([see the Value+ Management for ADM Datasheet](#)) matched to the size of the E-Signature for ALM implementation. Value+ Management for ADM is charged separately and commences immediately following the implementation of E-Signature.

The customer must have licenses for one of OpenText Application Quality Management or OpenText Software Delivery Management.  
The service does not include:

- Troubleshooting existing performance issues or defects in the target environment or for any integrations or third-party products.
- Procuring licenses.
- Managing communications within or between your teams.
- Creating user acceptance test cases and scripts and executing user acceptance testing.
- Performing any integrations that OpenText doesn't support out of the box.

# Customer Requirements

To complete the service, you must:

- Provide our team with remote access to your environment, data, and solution.
- Assign a Service Sponsor who can help solve issues.
- Assign managers and other personnel to work with OpenText throughout the service.
- Provide access to subject matter experts and administrators who are responsible for your product.
- Participate in the knowledge transfer between the implementation team and your staff.
- Provide network connectivity, rack space, power, and cooling at the customer site (or equivalent capacity in a cloud service provider) to support the OpenText solution.
- Perform backups before our team makes any changes and back up the target systems and work.
- Provide support for planned and emergency changes as part of your change management process.
- Approve any changes planned for the environment.

## Terms

OpenText Customer Terms-Professional Services. The services described in this data sheet ("Services") are subject to the [OpenText Customer Terms—Professional Services](#) (the "Terms"). All capitalized terms used in this data sheet, but not otherwise defined, will have the meaning set forth in the Terms.

**Rescheduling.** Customer may reschedule Services by providing written notice ten (10) or more business days in advance of the scheduled delivery but only if the revised schedule results in completion of delivery within one year from the purchase date. If Customer notifies OpenText of rescheduling less than ten (10) business days prior to the offering startdate, the obligations of OpenText to deliver the Services are considered fulfilled and the rights of Customer to receipt of the Services will expire.

**Change in Scope.** Changes in scope to the Services are not allowed. Customer may request additional or different services, if available and at additional cost, through a mutually executed statement of work.

**Services; Acceptance.** Services do not include hardware maintenance and repair, software maintenance, or other standard support services provided by OpenText; software as a service; managed print services; or outsourcing services. Deliverables are deemed accepted upon delivery. Any acceptance criteria or procedures set forth in this data sheet apply only to the Services specified herein and do not apply to any other products or services OpenText may supply or has supplied to Customer, regardless of whether such products or services be used in connection with the Services.

**Authorization to Install Software.** During the provision of Services, OpenText may be required to install copies of third-party or OpenText-branded software and may be required to accept license terms accompanying such software ("Shrink-wrap Terms") on behalf of Customer. Shrink-wrap Terms may be in electronic format, embedded in the software, or contained within software documentation. Customer hereby acknowledges its responsibility to review Shrink-wrap Terms at or prior to installation and hereby authorizes OpenText to accept all Shrink-wrap Terms on Customer's behalf.

## Resources

[OpenText Professional Services >](#)

[OpenText Consulting Services >](#)

[OpenText Homepage >](#)

## SKUs

- **PS-AB205** E-Signature (ALM) Small—Service
- **PS-AB206** E-Signature (ALM) Medium— Service
- **PS-AB207** E-Signature (ALM) Large—Service

**Existing License & Support Agreements.** Services may be in support of a Customer license to software under a separate agreement and, in such case, the separate agreement shall govern all use by Customer of such software and these terms shall relate solely to the Services. These terms are not intended to modify, amend or in any way affect the licensing, warranty, or other provisions applicable to software products separately licensed by Customer from OpenText or any other party unless expressly provided for in the applicable data sheet.

**Payment; Validity.** The Services will be pre-billed. Pricing for the offering may vary by country. Customer must schedule delivery to be completed within a period of one (1) year from the date of purchase. Notwithstanding the previous sentence, OpenText's obligations to deliver the Services are considered fulfilled and Customer's rights of receipt of the Services will expire one (1) year from the date of purchase.

Pricing for the offering may vary by country.

## The OpenText Professional Services Difference

OpenText provides unmatched capabilities with a comprehensive set of Advisory, Solution Realization, and Optimization Services. You receive access to unique intellectual property that helps you drive innovation through streamlined and efficient software delivery. With OpenText you get:

- Proven OpenText software solution implementation expertise.
- More than 45 years of experience helping large, complex organizations around the world 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 and no rip-and-replace.
- Education and support services to ensure adoption