Solution Flyer

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Achieve Compliance Excellence in Healthcare and Life Sciences Industry—ALM-Based Computer System Validation

The healthcare and life sciences industry is entering a digital age where innovations happen at a fast pace. With so many opportunities in front of you, don't let inefficient Computer System Validation drag you down. Gain momentum with ALM-based digital processes to continuously stay compliant.

ALM-based Computer System Validation at a Glance:

- **Requirement and risk-based lifecycle approach**
  Use a risk-based approach for more effective testing and leverage risk analytics to identify focus areas
- **Complete traceability and audit log**
  Trace from regulatory requirements to tests and defects, and track the relationship and history of all validation artifacts
- **Solid processes with e-signature**
  Protect digital records with e-signatures and embed automated workflows and rules in your daily quality assurance activities
- **Data transparency and real-time insights**
  Apply advanced analytics on your validation data to gain insights for continuous improvement and informed decision-making
- **Integrated electronic records from all sources**
  Use a REST API to feed real-world data from devices and digitize offline manual testing results with QoT.
- **Collaborative platform for stakeholders around the globe**
  Collaborate with employees, partners, and suppliers on validation, from anywhere

State of Software Validation in Regulated Industries

Computer System Validation (CSV) is the bottom line for regulated industries. Medical device vendors, healthcare providers, pharmaceutical companies, and others must maintain scrupulous records on all aspects of their development, manufacturing, QA, and supply chain processes. These records help them comply with regulations, such as HIPAA, US Food and Drug Administration (FDA) Title 21 CFR Part 11, Part 820, Part 210 and 211 (CGMP), Eudralex Vol. 4 Annex 11 (EU Annex 11), and others. Failing to comply may lead to lost lives, hefty penalties, and a damaged reputation.

Staying compliant isn't easy. Computer systems in this industry are highly complex and have many components. The traditional paper-based process consumes large amounts of labor and takes weeks to months to complete, depending on the number of documents. There are also other problems, like the difficulty in ensuring data integrity, security, and archiving. Though regulations like 21 CFR Part 11 allow using electronic records, CSV is still a challenge. Whenever you install a patch, perform an upgrade, or make other changes, you need to validate again. Some organizations face audits often and struggle to keep the pace of CSV.

Moreover, CSV often sees the following issues:

- Difficult to establish linkage between records and ensure consistency
- No real-time visibility of overall quality status
- Lack of process standardization

It's time to solve these issues. The COVID-19 pandemic accelerated digital transformation—we are entering a digital-first era. The healthcare and life sciences industry faces increased pressure to move fast and let a distributed workforce collaborate productively. It's time to embrace a new digitized way to achieve high efficiency in CSV.

Managing Validation with Application Lifecycle Management

GAMP 5, the guideline adopted worldwide for CSV, defines four lifecycle phases for computerized systems—conception, project, operation, and retirement, which matches well with the Application Lifecycle Management (ALM) approach of continuous quality throughout the entire software lifecycle. **OpenText ALM/Quality Center** is a leading test management and ALM tool with functionalities for managing CSV and Computer Software Assurance (CSA):

- Requirements management
- Test management
- Defect management
- Workflow with e-signature
- Versioning and baselining
- Audit log
- Templates
- End-to-end traceability

- Reporting and analytics
- Archiving capability

With a proven track record of serving thousands of customers for over a decade, ALM/Quality Center is a highly stable, scalable, and secure management tool that's ideal for regulated industries.

Requirement and Risk-Based Lifecycle Approach

Efficient validation starts with defining quality criteria as requirements during the concept phase. Then use a risk-based approach to create an effective testing strategy and focus on the most critical requirements, for instance, requirements that affect patient safety and privacy. Leverage risk assessment to back up your reasoning objectively.

Define your validation scripts as test cases with a step-by-step procedure and expected result for each step. That way, you can reuse them whenever validation is needed, during any lifecycle phase. Information on all historical validation cycles is kept together so that you can retrieve it at any time.

Libraries and baselining let you work on different releases in parallel, for example, developing a new version while validating an older version.

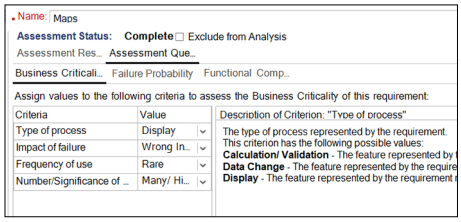

Figure 1. Requirement risk assessment in ALM/Quality Center

Complete Traceability and Audit Log

Complex computer systems in the healthcare and life sciences industry make traceability harder. ALM/Quality Center links requirements through dependency and business models and establishes traceability between requirements, test cases, test runs, test results, and defects. All these become electronic records to prove your compliance. Using the Traceability Matrix, you can track all requirements to their validation artifacts and their relationship and identify changes to the scope of your requirements when they occur.

ALM/Quality Center automatically generates audit trails on electronic records with details about who, when, and of what events—such as creation, deletion, and modification.

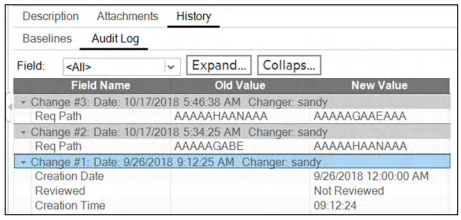

Figure 2. Audit log in ALM/Quality Center

Solid Processes with E-Signature

Governance of activities is key in CSV. Even the strongest teams suffer software quality setbacks and timeline slippage without solid processes. ALM/Quality Center helps you enforce processes with templates, library sharing, automated workflows, and rules embedded in your daily quality assurance activities. Using cross-project customization, you maintain a consistent way of working across your organization and synchronize all stakeholders.

You can apply e-signature on electronic records in ALM/Quality Center when they are created, modified, maintained, archived, retrieved, or transmitted along the workflow.

Governance also includes preventing unauthorized access to your records. ALM/Quality Center uses enterprise-level security measures to protect them, including Single Sign-On (SSO) authentication, LDAP-based user management, role-based access control, and data encryption in databases and during transmission.

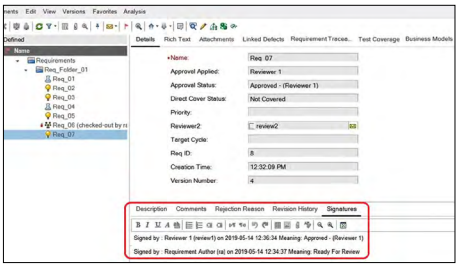

Figure 3. Requirement signed with e-Signatures

Data Transparency and Real-Time Insights

The most important deliverable in CSV is the final report declaring that the system is fit for use. With all the evidence well preserved and organized in your ALM tool, this task becomes much easier by using customizable, built-in graphs and reports.

Reporting and analytics not only help with the final report but also with the day-to-day tracking and visibility of quality status. Transparency gives the validation team confidence in the progress and predictability of completion timelines. Further, you can gain valuable insights through advanced analytics for continuous improvement and data-based decision-making.

Integrated Electronic Records from All Sources

Efficient use of electronic records requires capturing data in electronic format from the beginning. The portable offline testing tool QoT enables manual testing in all sorts of places and lets you digitize test results on the spot and then sync them into your ALM server repository.

> "Although our paper-based test processes worked, it would be time-intensive to deliver the required information during authority inspections. Now, our transparent system shows our inspectors we are in control of our processes and fully confident in the information we share."
>
> **PER BISCHOFF KRISTIANSEN**
> QA IT Compliance Specialist
> Xellia Pharmaceuticals

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OpenText CEO Mark Barrenechea's blog

An exploratory test is an indispensable approach, but people often lose track of what was done before encountering issues. The Sprinter tool solves this problem by automatically documenting the steps and their results in exploratory tests—you do not need to manually describe them later. These records can become formal test cases in your regression test set for future validations.

ALM/Quality Center's rich built-in integrations enable synchronizing electronic data with other tools you use, including OpenText test automation tools or 3rd-party ones. Its REST API makes various integrations possible, for example, feeding real-world data from devices.

Collaborative Platform with Flexible Deployment Options

CSV always involves SMEs and business users, and often partners and suppliers as well. ALM/Quality Center lets them collaborate smoothly on the validation project no matter where they are.

You can deploy ALM/Quality Center off cloud, on a private or public cloud, or with a SaaS subscription, depending on your business case. SaaS ensures business continuity in unusual times and reduces operational costs.

ALM/Quality Center is also highly scalable, helping you tackle complicated CSVs with a large number of requirements and test cases, in a well-organized, efficient way.

Choose Your ALM Tool

Though GAMP 5 describes using the V-model in validation, regulated companies are finding the benefits of Agile and DevOps in CSV. If you are adopting them, consider one of the following related products of ALM/Quality Center:

- ALM Octane (off cloud, cloud BYOL)
- ValueEdge Quality (SaaS)

They both share the same characteristics with ALM/Quality Center in stringently managing software quality, but better support Agile and DevOps practices. ValueEdge Quality brings you to the ValueEdge cloud platform, which further accelerates DevOps through modern quality management capabilities and value stream management.

Resources

- Analyst report: GigaOm Radar for Regulated Software Lifecycle Management
- ALM/Quality Center Use Cases in Regulated Industries
- E-Signature Implementation and Management Service

Learn More

ALM-based Computer System Validation Homepage

ALM/Quality Center Homepage

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