etq Quality Creates.™

ETQ QMS validation approach and solution options

Expedited validation with minimal disruption

EXECUTIVE SUMMARY

Validation of software is not a choice for customers in the life science, pharmaceutical and medical device industries. It is a requirement set by agencies around the world. For many regulated companies today, validation has become a costly and time-consuming aspect of installing or upgrading Quality Management Software (QMS). But validation does not need to be a burden that prevents companies from investing in software that can improve product quality, safety and efficiency.

Validation must be looked at in a practical way-- a way that is not time consuming or cost prohibitive. At ETQ, our validation approach looks at defining the intended use and potential risk, while minimizing the validation effort by using the "least burdensome approach."

ETQ's validation offerings for life science companies are fully aligned with regulations and industry guidance and offer a comprehensive approach based on guidance like GAMP 5.

Validation

Validation is the process of using objective evidence to verify that the user needs, requirements and intended uses are met by software solutions for regulated industries like life science, biotech, medical devices and food and beverage. To do this, organizations must pursue a different path to validation if the software in question is "off the shelf" ready-to-use or configured in some fashion by in-house IT and quality teams. The intended use of the software matters, too, whether it is deployed for the production of pharmaceuticals or medical devices, embedded as part of a medical device, or software that supports either of those functions, like quality management software, such as ETQ Reliance. Therefore, the approach and methodology used to validate software will vary based on the above factors and the level of validation required must be commensurate with the level of risk posed.

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How can ETQ help with validation?

The U.S Food and Drug Administration (FDA) has noted that existing approaches to validation have created several roadblocks for the life sciences industry. As software has evolved, there has been a need to ensure that managing a company's digital capability is at the top of the list. With that in mind, ETQ's Reliance™ Software-as-a-Service (SaaS) solution can help life sciences companies clear existing barriers to validation with ease.

ETQ offers life sciences companies several approaches to comprehensive and simple validation including SaaS-based deployment benefits, a continuous release software update program, a validation process solution, and validation services that take on the heavy lifting required in validation and risk management. Each of these components comes with benefits that range from enhanced functionality and a reduction in operating costs to more efficient testing and stronger cloud-based security capabilities.

Take a deep dive into what ETQ provides

ETQ Continuous Release Update Program

The first component of ETQ's validation service is a continuous release software update program that makes software upgrades faster, less disruptive and more efficient. Continuous release ensures that ETQ

Reliance stays current in a dynamic landscape and delivers the business edge that quality-centric companies demand. The release comes with release notes that detail the changes, their impact and our vendor testing for each release. This allows ETQ customers to make decisions for their testing but, most importantly, allows them to leverage our documentation to streamline their validation effort.

Benefits

- Deploy enhancements and new functionality faster
- Reduce validation effort and disruption
- Accelerate improvements to quality programs
- Reduce regulatory and compliance risk

ETQ Reliance Release Management application

ETQ Reliance Release Management is a core application that delivers easy-to-use forms, workflows and reports to manage every step of the release and validation process. This ensures that ETQ Reliance customers know that their QMS is current regardless of the changes that take place in the regulatory and IT worlds.

Software Development

ETQ is committed to employing agile software development practices that enable ETQ Reliance to stay in lockstep with fast-moving regulatory changes and technology trends. ETQ is also ISO 9001:2015 certified and provides document traceability and auditability for all software development and release processes. The validation plan details how ETQ Reliance is developed in accordance with quality software engineering principles and how validation will be handled to ensure the software meets the functional capabilities required by users today and in the future.

ETQ AWS Cloud

Many customers in regulated industries choose to deploy ETQ Reliance as SaaS in order to take advantage of the always-on, always-backed-up, lower total cost, faster time-to-value and trusted security offered by cloud installations. ETQ provides a cloud-based infrastructure that meets the needs of the most stringent compliance requirements:

- Multi-layer security with AWS
- Monitoring and threat prevention
- Always on
- Executed installation qualifications (IQ) for validated installs and upgrades

Benefits:

Deploy enhancements and new functionality faster

Reduce validation effort and disruption

Accelerate improvements to quality programs

Reduce regulatory and compliance risk

The ETQ Approach to Expedited Validation

The least burdensome approach for non-product related software

The FDA acknowledges that existing approaches to computer system validation (CSV) are a significant barrier to improving digital capability. To mitigate these issues, the FDA recommends using a risk-based approach and customer leverage of vendor documentation and methodologies to ensure that IT installations are tested with regard to critical risk in their intended use. Validation is not a one-time event. Software must be maintained as validated throughout its life cycle. Therefore, using the least burdensome approach to validation and change management is critical and will help you to implement technology more easily and bring greater value to your company quickly.

1. **Critical thinking approach:** There is value in documenting your decision-making process, though, in the past the industry has gone about this in a "check-box" purely compliance-driven way. The FDA is asking the industry to shift this paradigm back to a critical thinking approach, focusing on patient risks with more concise testing and less documentation.

2. **Leveraging vendor documentation:** Even with a trusted and audited vendor or supplier, companies tend to needlessly reproduce a vendor's validation documentation that may already be in place. If the documentation is of good quality, then it should not be reproduced. Instead, effort should focus on making sure that the software works "for the intended use" in the customer's environment.

3. **Focus on the intended use only:** The FDA wants companies to focus on a system's intended use. That means limiting your risk assessments to clearly defined scenarios of the system's usage. You should be able to demonstrate and have confidence that the system meets your intended use, and the features and functions perform as expected without impacting patient safety and device quality.

4. **Streamlined risk assessment:** The use of risk-based testing ties into the focus of the system's intended use with an emphasis on product quality, product safety, and direct patient safety risks. The recommended risk assessment process looks at two variables:

    a. Potential impact on patient safety and product quality

    b. The implementation method of the functionality

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1.
Self-Validate with ETQ's Validated Platform and Documentation

ETQ uses agile development practices to enable faster response time to regulatory changes and technology trends. For each release of the product, ETQ provides all the necessary documentation to show evidence that the system platform capabilities are thoroughly tested using a risk-based approach.

Leveraging our vendor Validation Package documentation

ETQ Reliance QMS is certified to the ISO 9001:2015 ISO 27001:2013 standards. These systems include controls, processes and documentation that can be leveraged by your company as part of your critical thinking and risk-based approach.

As part of our software development cycle we make sure that our releases are tested and validated. To smooth the validation process, ETQ provides the ETQ Reliance Validation Execution Package that shows our robust development, testing and documentation approach for our platform and out-of-the-box (OOB) configurations. This package is aligned with the GAMP5 methodology and, reduces the time and expense associated with validation.

Validation Package executed artifacts

General

- Certification of Validation
- ETQ Software Release Notes

Platform

- Validation Plan/Test Plan
- Functional Requirements Specifications (sFRS)
- Functional Test Scripts (sOQ)
- Traceability Matrix (sFRS > sOQ)
- Validation Summary Report

Applications

- Application Requirements Specifications (URS)
- Application Test Scripts (PQ)
- Traceability Matrix

2.
Use ETQ's Validation Toolkit to Streamline Validation of Configured Qms Solutions

ETQ has simplified the validation process for our customers by delivering a platform in the cloud with vendor documentation. However, customers will need to validate the processes that they have configured to ensure that any changes they make still meet the system's intended use. ETQ Reliance is an extremely powerful configurable tool. The ability to adapt to not only internal changes but external changes is absolutely needed these days. Configuration in a validated environment can be a headache, but ETQ has a simple and efficient solution that avoids these issues.

The ETQ Validation Templates Toolkit is the aspirin for this potential headache. It provides you with procedural and validation templates required for an organized review your validation process. The templates are based on the out-of-box application and are a starting point for your own validation of ETQ Reliance. The Configuration Specifications (CS) template allows you to mock up the change you want as part of the configuration process and verify these changes with the Configuration Test Script (CQ).

The Requirement Specification (URS) template reflects our validated out-of-box application and can be updated to document your requirements and intended use. You can then use our prefilled Risk Assessment (RA) template to begin to apply critical thinking by using a risk-based approach to assess the new requirements and features, focusing on direct impact to patient safety/product quality and the level of coding complexity in a configured solution.

Finally, the Requirements Testing (PQ) template can be updated to test your specific application configuration and intended use.

Other useful templates are available as part of the toolkit to help you from validation planning phase all the way to maintaining your system thru procedure.

Validation Templates Toolkit

General

- Validation Plan/Test Plan template
- Validation Summary Report Template
- Defect Reports Template
- 21 CFR Part 11 and Annex 11 Assessment
- Vendor Quality Checklist (FAQ)

Application Templates

- Configuration Specifications (CS)
- Requirements Specifications (URS)
- Risk Assessments Creation (RA)
- Configuration Test Scripts (CQ)
- Requirements Test Scripts (PQ)

Procedural Templates

- Procedure for Validation and Change Management
- Procedure for Maintenance Procedure

3. Leave the Heavy Lifting to Us: Expertise, Best Practices and Quicker Time to Value

ETQ also offers validation services from our team of expert validation consultants. This services approach is risk-focused and based on current regulatory requirements. Our goal is to help you be compliant without duplicating effort while focusing on high-risk areas. Our services team will also help you understand our vendor test records and methodology so you can use these elements most efficiently.

ETQ will help you become validated, stay validated and allow you to derive value from your QMS faster.

Our Validation Services will provide you with support to:

- Leverage ETQ validation documentation
- Document requirements and intended use
- Assess the risk
- Document the requirement testing

Stay Validated with Change Management

As you configure and update your processes in ETQ Reliance, you will need to ensure that these processes stay validated. Having an ongoing change management process is an important part of maintaining your software solution. The ETQ Validation Consulting team can help by supporting and documenting your changes, while seeking to minimize and control risk, so that any configuration changes made after your initial validation are assessed and documented for traceability.

We also provide new release impact assessments that highlight new software features that could potentially impact your system's validation status. ETQ also documents the assessment and regression testing of the Reliance platform.

ETQ Validation Advantages and Benefits...

ETQ's validation offering and services can meet all your validation needs more conveniently and cost-effectively than hiring additional staff or new third-party validation professionals. Beyond simply meeting regulatory and vendor validation, ETQ's validation offering will enable you to gain confidence in your software capabilities and compliance.

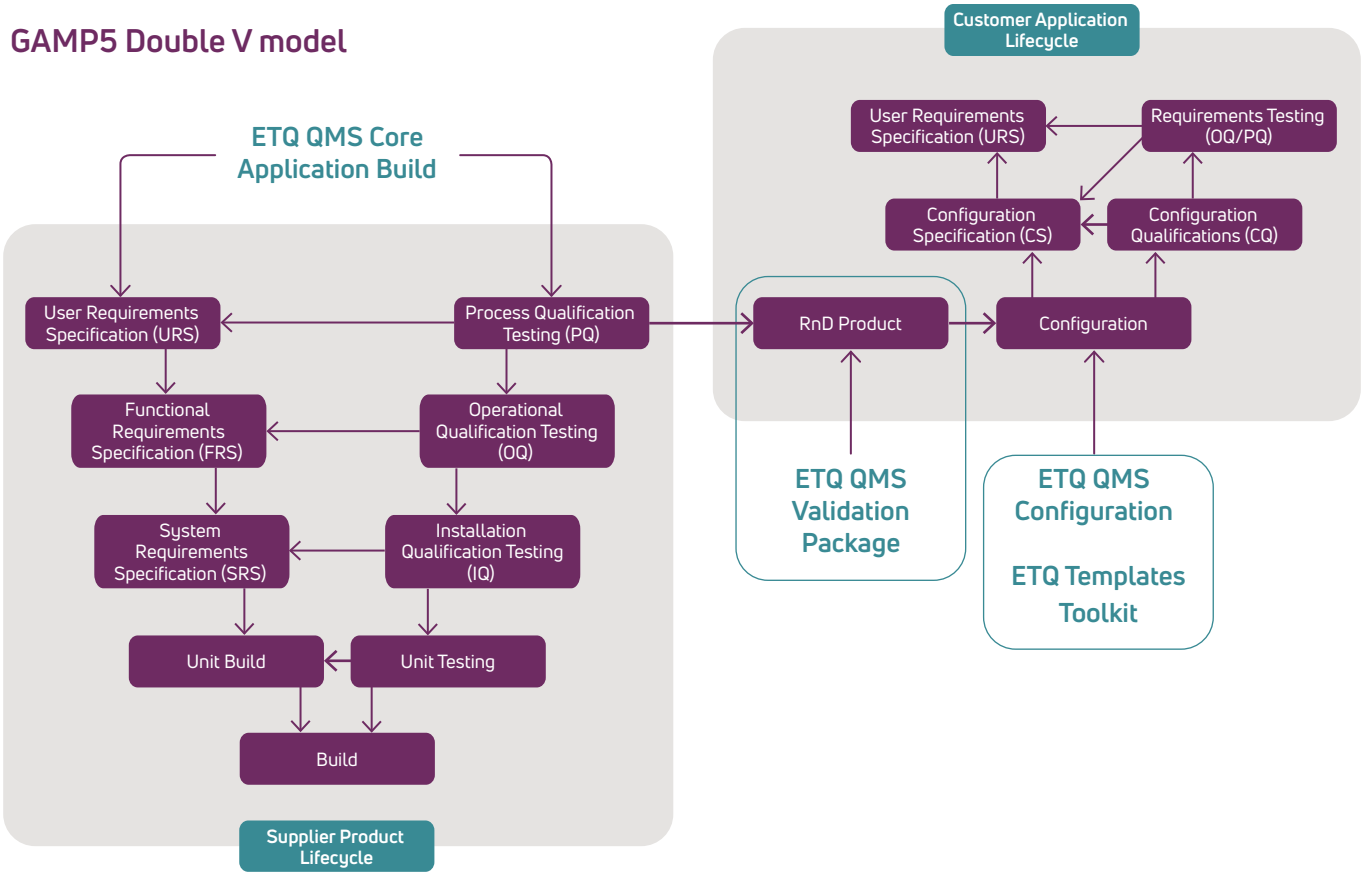
- **Validation expertise:** Our team has years of experience with validation services and has helped numerous life sciences customers reach compliance. Our validation consultants can provide a wide range of services to help customers become validated, stay validated, and allow customers to get value out of your system faster.
- **ETQ Reliance application expertise:** No one knows more about ETQ Reliance than we do. So, we waste no time "getting to know" your systems – we get to work quickly, efficiently and expertly to validate your configured or "out-of-the-box" implementation better than anyone in the industry.

Below are the typical documents that the ETQ Validation Implementation Consultant would provide for your validation.

Validation Service Artifacts

- Validation/Test Plan and Summary Report
- IQ Review
- Procedure for administration and maintenance
- Documentation that reflects your changes
  - Configurations Specifications (CS)
  - Executed Configuration Qualification (CQ)
  - Requirements Specifications (URS)
  - Application Risk Assessment (RA)
  - Executed Test Scripts (PQ)
  - Traceability Matrix

- **Industry best practices, least cumbersome approach:** Our team approach to validation aligns with agency regulation, GAMP 5 and industry best practices. Our method encourages the use of risk assessment to determine the appropriate level of validation evidence required.
- **Lower Cost:** ETQ has a long track record of helping life science and other highly regulated companies reduce their overall validation costs by ensuring that the right QMS system is efficiently deployed and functions as intended to meet the customer's needs.
- **Quicker time to value:** ETQ's validation offerings have been proven to reduce the time and effort required to validate your QMS.



About ETQ

ETQ is the leading provider of quality, EHS and compliance management software, trusted by the world's strongest brands, like Kimberly-Clark, Jazz Pharmaceuticals, Herman Miller and Chobani. More than 500 global companies, spanning industries including automotive, biotech, food and beverage, manufacturing and medical devices, use ETQ to secure positive brand reputations, deliver higher levels of customer loyalty and enhance profitability. ETQ Reliance offers built-in best practices and powerful flexibility to drive business excellence through quality. Only ETQ lets customers configure industry-proven quality processes to their unique needs and business vision. ETQ was founded in 1992 and has main offices located in the U.S. and Europe. To learn more about ETQ and its product offerings, visit www.ETQ.com.