Qualio


>

Our validation approach

How Qualio follows industry best practice for fast, compliant and headache-free software assurance

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The perceived burden and stress of computerized system validation is one of the main blockers standing between life science companies and the fruits of digitization.

*Industry bodies like the FDA and ISPE don't want that. The latest industry guidelines, and the shift from a **validation** to an **assurance** focus, encourage software vendors to do the bulk of the heavy lifting themselves, freeing their customers to focus on a sensible, efficient, risk-based and 'least burdensome' assessment of the software systems they're onboarding.*

This document outlines how Qualio has absorbed and applied this best practice to offer our customers an assurance approach that doesn't involve weeks of work or mountains of paper.

With close support from our expert team, the use of modern tools and automation, and a clear, step-by-step approach, your business can implement and assure Qualio faster than any other eQMS platform — without compromising on compliance or integrity.

Kelly Stanton
Director of Quality, Qualio

What is computerized system validation (CSV)?

The FDA defines validation as:

> ***The confirmation by examination... of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.***

CSV is ultimately about answering this question:

? Is your software fit for your intended use in a regulated GxP environment?

What is computerized system assurance (CSA)?

The FDA's 2022 CSA guidelines emerged as a corrective to the perceived problems of and frustrations with CSV, which included:

01. Redundant, duplicated or unnecessary validation tasks performed by the customer in fear of regulatory punishment

02. Reliance on outdated validation documents like IQs, OQs and PQs, which don't reflect the non-linear nature of modern software development

03. A general industry perception of validation as a time-consuming, laborious and painful process

Although the name has changed, CSA shouldn't be seen as a dramatic or complex shift, and the word 'validation' can still be used interchangeably with 'assurance' when referring to the risk management and critical thinking activities connected to your company's software systems.

As Sion Wyn, GAMP 5 editor and FDA advisor puts it:

> ***The regulators aren't saying, 'we've defined this big and complex thing called CSA we want you to follow'.***
>
> ***They're saying: CSA means following GAMP truly... and dropping all this baggage of unnecessary documentation.***
>
> ***It doesn't really matter what it's called; it's about protecting the patient and, in the end, increasing the quality of your final product.***

CSA ultimately means:

Faster, simpler computerized system onboarding

Higher adoption

A more digitized life science world with modern tools and techniques

Computerized system assurance focuses on:

Critical thinking and risk-based adoption of computerized tools

Jettisoning of unnecessary legacy validation documents, like IQs, OQs and PQs

Eliminating fear of regulatory inflexibility as a blocker to the adoption of new technology

A return to the original 'spirit' of GAMP:

- Proving your computerized system is fit for intended use
- Ensuring your computerized system meets the basic baseline of compliance
- Managing any residual risk to patients and to the quality of the final medicinal product

Above all, CSA places the responsibility for most of the assurance activity on the vendor, not on you, the customer.

Rather than converting pre-existing vendor documentation into IQs, OQs or PQs, or simply repeating system tests already performed by the vendor as a tickbox compliance exercise, CSA is all about giving you the headspace and focus to critically evaluate and respond to the potential risk profile of the vendor and the software they're providing you.

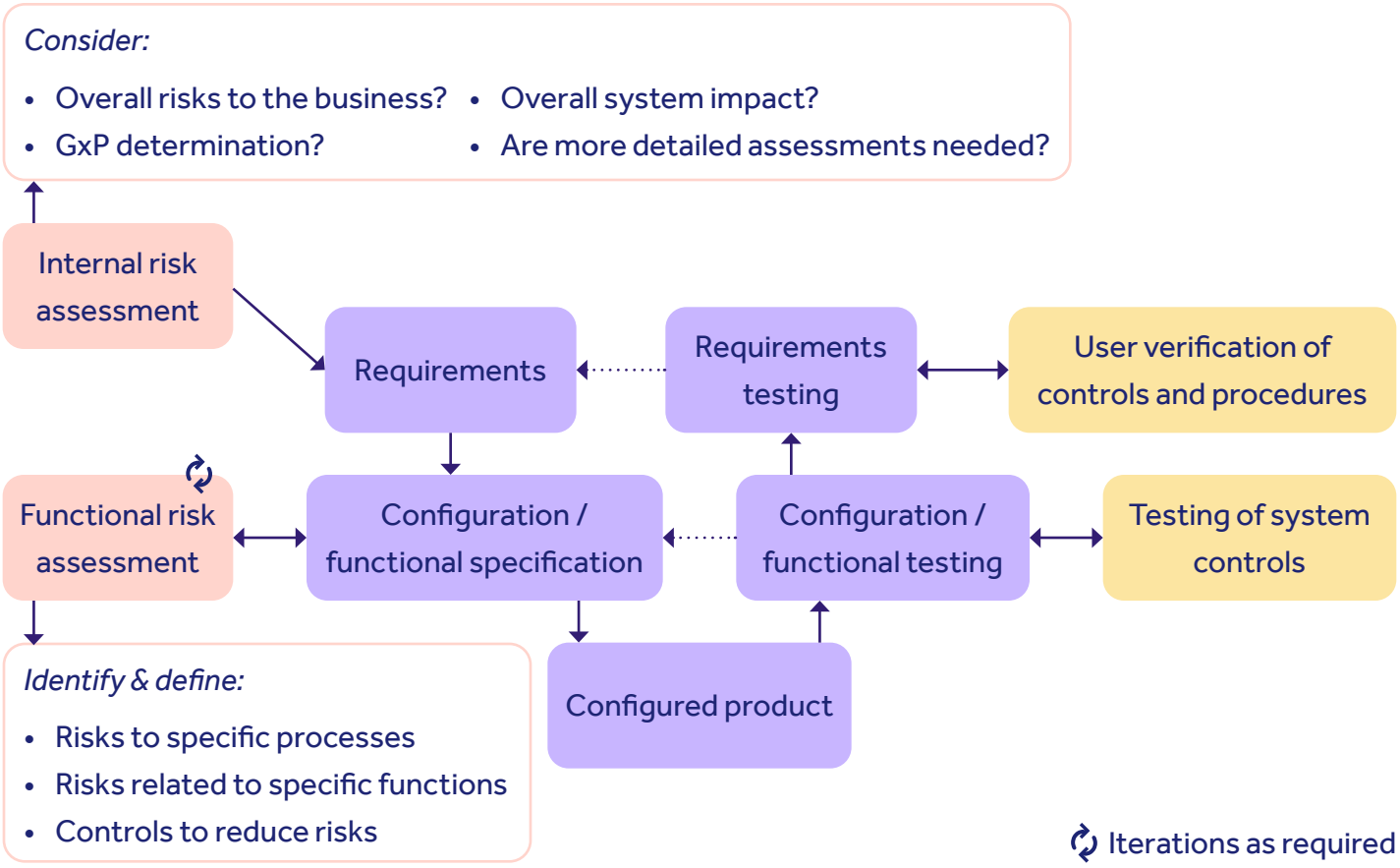
And because an eQMS like Qualio is defined as 'non-product software' without direct impact on product or patient safety, there's no need to perform the same rigorous assurance activities that, for instance, an FDA adverse event reporting system or manufacturing SCADA system would require. The majority of your assurance focus should always be spent on these direct-risk systems.

Learn more about the transition from CSV to CSA, and what it means for your business ›

Qualio's GAMP category

Because of the levels of configuration built into the **Events**, **Design Controls** and **Suppliers** functionality of the system, Qualio falls into **GAMP Category 4** as a configured software product. It therefore sits between the risk and assurance levels of Category 3, fixed off-the-shelf software, and Category 5, customizable software requiring deep levels of coding.

The Second Edition of GAMP 5, released in July 2022, offers a risk-based model for Category 4 product onboarding as follows:



GAMP 5, A Risk Based Approach to Compliant GxP Computerized Systems, Second Edition

How our assurance approach works

Qualio	You
Manages system	Manage configuration & data
Maintains a fully documented quality management system and software development lifecycle (SDLC)	Use Qualio-generated documentation to evaluate and demonstrate alignment with your needs
Documents user requirements of the software and related functionality	Document business processes and potential risks to these processes introduced by the software
Performs continuous system testing and document results	Perform and document any additional testing and risk treatment you think necessary, in line with the risk activity performed above

Modern computer system assurance is a shared exercise, with most of the work being performed by Qualio as your system vendor. **Qualio's responsibility** is to prove that the software we provide is robust, effective, operational, and frequently tested.

We therefore document the requirements and test activities of our system using a typical SaaS development methodology, and share this with you for determining Qualio's suitability for your intended use. The customer doesn't need to generate documents for user needs, functions, or testing of those needs. These are all covered and documented as part of Qualio's ISO 9001-certified quality management system.

The customer's responsibility is to understand your business processes and identify the key areas of concern where Qualio will touch, impact and transform these processes.

Qualio provides customers with templates to assist in this work, allowing you to focus solely on managing and testing your configuration as required by your unique risk profile.

Our end-to-end assurance process looks like this:

Supplier qualification

- Qualifying Qualio as your SaaS eQMS vendor of choice. We maintain certification for both ISO 9001 and 27001 to demonstrate our commitment to our customers and to a robust, optimized quality management system. We are happy to host a remote audit of our QMS as you become a Qualio customer, and annually thereafter if required.

Planning

- Laying out the plan and approach to the overall computer software assurance activities to be managed.
- Defining the responsibilities of both the customer and Qualio.

Business requirements and risk assessment

- Risk assessment of your business processes is recommended to help you scope any additional testing activities you may undertake. As we've seen, system activity like document control, training, CAPAs and supplier management do not generally have any direct impact to product quality or patient safety. With that in mind, it's your responsibility to pinpoint and work on any system processes you deem of higher risk.

Requirements, testing & traceability matrix

- → User requirements, functions built to meet those requirements, and tests executed to demonstrate meeting of requirements are all established in Qualio's software development lifecycle (SDLC) process and fully documented to make the entire process visible to our customers.
- → This testing covers the software as built. You should determine, through your own business process documentation and risk assessment, if any configurations require any further testing by you.

Qualio provides a bundle of validation documentation to you to accelerate this process and give you objective evidence of Qualio's integrity and suitability for purpose.

Validation pack ingredients

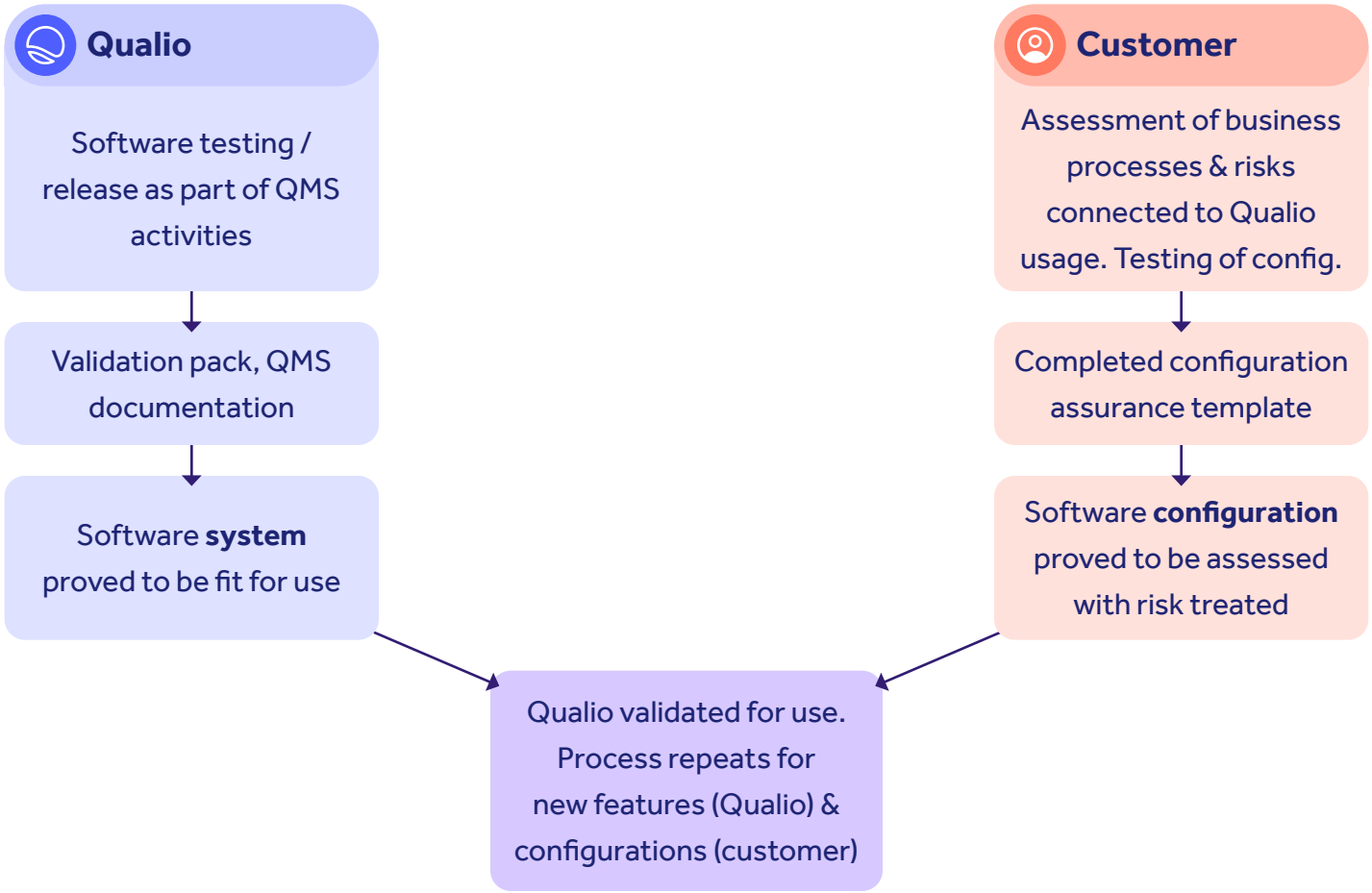
01. **Requirements traceability matrix (RTM) —** Visually represents the traceability between the user need, the "why" of the need (or user story), and the test for this need
02. **Test plan —** Summarizes how the automated test scripts have been written, the "passing results," and the date the testing was performed
03. **Requirement specification —** Lists all requirements
04. **Software design specifications —** Lists design requirements that were part of this release
05. **Video evidence —** Shows these tests being performed. You'll see two views within these videos:
    - On the left, you'll see the test script itself being run
    - On the right, you'll see the in-app view of this test being performed

System configuration

→ Receive a template to get you started on documenting the configuration of your instance. This becomes the baseline for change management for your instance going forward. The Qualio team will help you with this during your onboarding.

Validation Summary Report (VSR)

→ Summarizes the entire validation effort & your system's suitability for use



Re-assurance

Qualio owns the software. You own the configuration and the data within. Qualio will test every new change to the system before it is released to the customer, and document it in our impacted feature test documentation. These changes are then shared with you, before or as they happen, depending on the scope of the change.

Your job is to assess the impact of that change to your configuration and to your documented business processes. You may need to update your documents, and, if you previously chose to perform any configuration specific testing, you may need to assess the impact to that testing and decide if you need to test again.

However, the vast majority of Qualio system changes are small, incremental feature enhancements. We do this to limit the impact to our software and ultimately to minimize the ongoing re-assurance burden passed onto you, the customer. And while we're on the topic of re-assurance, here are some reassuring quotes from industry partners and happy customers!

Qualio has all the elements of a modern software development quality system. I was very happy to see those elements: modern processes with modern tools, information held in appropriate systems, the use of continuous monitoring, testing and building.

All the processes were well defined and described. I, as an external person, could understand them, so then I have faith that the internal person can follow and understand them as well.

— Sion Wyn, GAMP 5 editor

The validation documentation provided by Qualio was easy to understand and execute. It's easy to get in touch with Qualio's team with questions or concerns, and the team responds quickly.

Soni Mikkilineni, Director of QA/RA
NovoSource

It was super easy. Qualio did all the heavy lifting and we just grabbed the validation package. We're in the business of precision oncology. Certainly we need a QMS, but let the experts be the experts. Cut that check and move on!

Mike Trudnak, VP of IT & Information Security
xCures

I realized, 'oh my God, this is fantastic!' We could configure Qualio within its validated state almost unlimitedly. I realized I could set up any process flow that matches us, rather than having to adapt to a system. The flexibility has been mind-boggling.

Michael Holcomb, Quality Assurance Director
TriMed

When I recommend Qualio, one of the first things I say is: you're going to be able to get this thing in-house, validated, implemented and live in a short amount of time with limited resources. That's unique in this industry.

Beckinam Nowatzke, Quality & Regulatory Lead
Synthego

FAQs

01. If Qualio tests the software as part of its own quality management activities, does that mean I don't need to test it myself as part of our validation activities?

Qualio is a web-based, multi-tenant system that runs identically for all customers. It would therefore only be a waste of your time to repeat the functional tests already performed and documented by Qualio with tools like CircleCI and GitHub.

One customer expressed it like this: if you bought a piece of manufacturing equipment that had already passed through factory acceptance testing, there would be no need to immediately retest it yourself.

The only testing required by you comes from the ***specific system configurations*** *you build into Qualio, and how they might impact on your business processes and, by extension, the safety of your products and patients. Regulators like the FDA encourage a critical-thinking- and risk-based approach to testing, so it's appropriate to the business-specific risks you identify, and isn't overly excessive or burdensome.*

02. Why does Qualio require less rigorous assurance activity than other systems?

*An eQMS is an example of low-risk, non-product software with no **direct** impact on patient safety, product quality, or the integrity of the data underpinning these areas.*

Your auditors will expect your assurance activity to be focused proportionately based on the systems you're using, and an eQMS naturally demands less rigorous assurance than a high-risk system for these reasons.

Risk categories	
High	Directly impacts product quality Directly impacts human safety Could potentially cause or impede a product recall
Medium	Required for regulatory compliance (i.e. PHI, PII, PCI, SOx) Indirectly impacts product quality Indirectly impacts human safety
Low	Not categorized as **high** or **medium** (i.e. business risk)

03. A Qualio competitor is offering IQ, OQ and PQ documentation as part of their validation approach. Why aren't you? Are you less compliant?

No! Any modern software vendor providing IQ, OQ and PQ documentation as standard is simply sticking de rigeur *to 20-year-old outdated validation practice. Both FDA CSA and ISPE GAMP guidance have now diverged from this approach, understanding that 'linear' documentation like IQs, OQs and PQs doesn't reflect the non-linear, agile nature of modern software development.*

Simply put: a vendor pushing this approach is only interested in appeasing customers worried about ticking old boxes – and not interested in offering a modern, streamlined and least burdensome approach for their customers.

04. Why is your process better than the old methodology of IQs, OQs and PQs?

The foundation of modern CSA is demonstrating that the system meets your requirements for intended use with a minimum of burden and effort. With that as the basis, you're proving that the system meets the requirements defined during its inception and in subsequent updates.

If we map the traceability of requirements to functions to testing (which is what we used to do with IQs/OQs/PQs), we have proven our system is suitable for use leveraging our software development lifecycle process.

From there, you then configure the system to meet your needs and manage the configuration. Our partnership as your eQMS vendor ensures we are managing the system for you as the experts in QMS software.

Ditching time-heavy documents like IQs, OQs and PQs scrubs 2 weeks from our old set-up timeframe and lets you start extracting value from Qualio even more quickly. That's why our work wins awards for ease and speed of set-up and our 'go live' time is around 50% faster than our competitors.

05. How will you support me if I'd like to do the validation myself instead of accepting your tests?

Qualio provides test scripts and documentation on requirements for the system, and you can format them as your company or your policies require.

06. I've been used to IQs, OQs and PQs my whole career. Can you give those to me?

Qualio provides test scripts and documentation on requirements for the system, and you can format them as your company and your policies require.

We also provide a template for customers who require performance qualification. For example, customers may want to PQ their complaint workflow in Qualio's Events area, because this activity can impact patient safety. However, as we've seen, customers are responsible for configuring, documenting and testing system workflows themselves.

07. I don't believe regulators will accept this approach. How do you know they will?

Not only is the Qualio team highly experienced in modern quality and compliance, we aren't afraid of listening to industry experts and third parties to keep our approach aligned with the latest trends and expectations.

We asked Sion Wyn, editor of GAMP 5, FDA advisor and a leading expert on computerized system compliance, to interrogate our software assurance approach and advise us on the direction of travel from the FDA and ISPE.

You can hear Sion's thoughts on our assurance approach here. And you can read our breakdown guide of all the threads of modern computerized system compliance, and why we do what we do, here.

08. Qualio used to be GAMP Category 3. What changed?

When Qualio was a simple document and training platform with no configuration possibilities, it fell into Category 3. The evolution of Qualio into a flexible, scalable quality management platform for managing quality events, medical device design controls and suppliers naturally upgraded the product to Category 4.

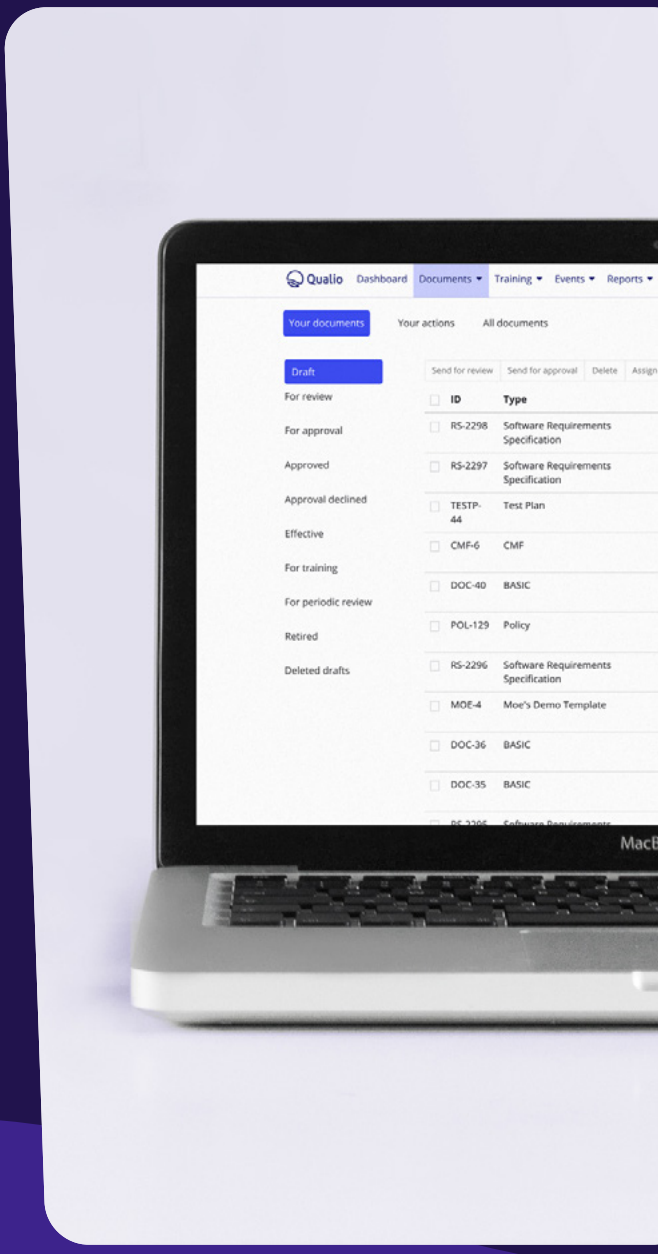
Although this new layer of configuration demands some critical thinking and risk assessment from customers, the low-risk nature of an eQMS (as above) means there's no reason this should be burdensome, time-consuming or painful.

Plus, the powerful business benefits of a flexible Category 4 system more than outweigh any extra assurance demands!

Qualio

Ask us about our validation approach

Schedule a demo with us



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