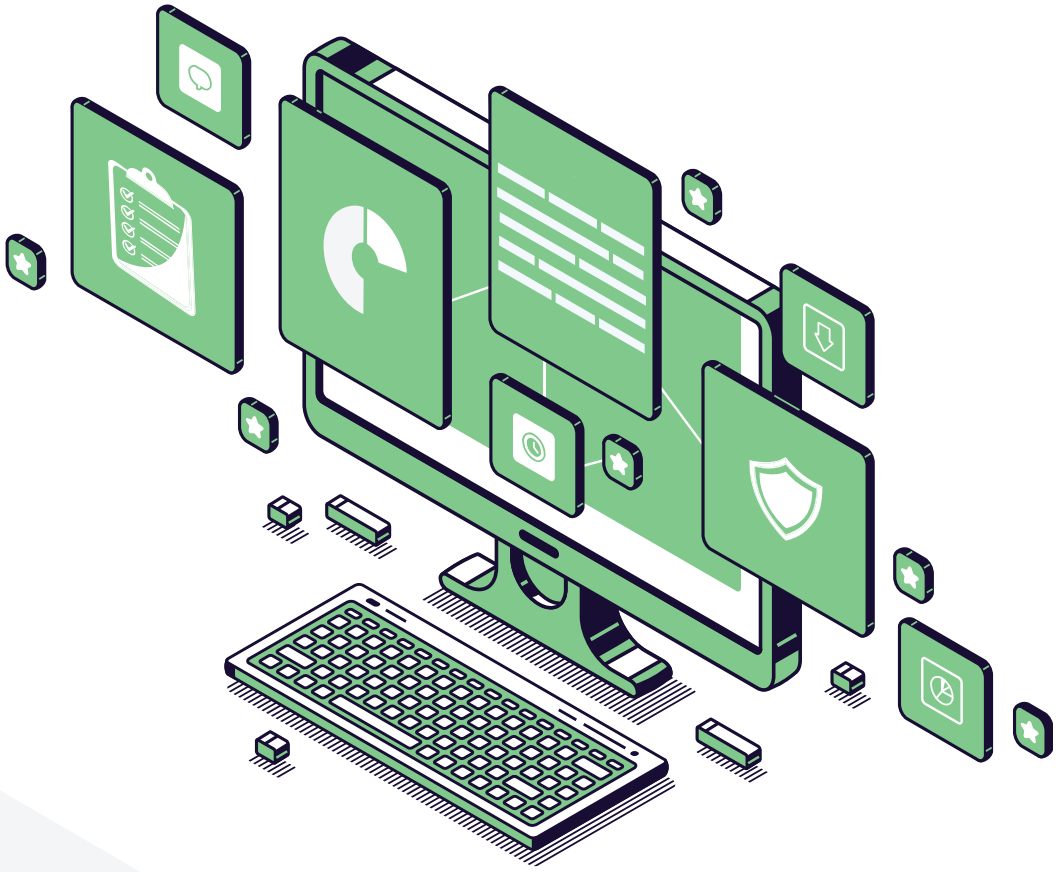

eBook

eQMS 301

Best practices for eQMS revalidation, data security, and quality ROI

ZENQMS

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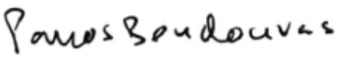
A note from Panos Boudouvas, CEO ZenQMS

Quality teams carry an incredible responsibility. They're tasked with not only bringing a company's commitment to safety and trust to life, but with upholding a culture of Quality that serves as the foundation of consumer safety.

So why are they so often denied the tools and investment they need to succeed? It's simple. Quality teams deserve more resources, more support, and less stress. That's why we released our eQMS 101, 201, and now 301 eBook series, as well as eQMS University. In eQMS 101, we covered the basics for choosing and getting buy-in for the tool you need.

In 201, we shared tips on how to implement and configure your eQMS so you hit the ground running. And in this eBook, we're going in-depth on keeping your eQMS efficient and impactful for years to come. With insights sourced from Quality leaders who have been – and still are – in your shoes, we hope this eBook is a helpful resource on your Quality journey.



Section 1

Quality Metrics & Reporting

Data is Power: Metrics that Quality teams can track to drive continuous improvement and prove ROI

Quality metrics matter

Quality metrics matter – and they matter to more than just the Quality team.

Why? Data analysis and improvement go hand in hand, and few teams have access to more GxP critical data than the Quality department.

From trend data on deviations to reports on quality practices and compliance, Quality teams get an inside look at what's working and what's not in the organization.

And with the right quality metrics, they provide leadership with actionable insights on where to invest more resources, where efforts are paying off, and where potential problems may be hiding... before they impact operations.

Plus, for Life Sciences investors conducting due diligence, these metrics can indicate a company's commitment to quality, a low tolerance for risk, and ultimately, its long-term stability, making it a more attractive asset for investment, partnerships, and more.

In fact, Quality teams are more than just compliance gatekeepers, they're the driving force behind a culture of continuous improvement for the entire organization. Music to the C-suite's ears.

> **What is continuous improvement?**
>
> Continuous improvement is a business process that encourages everyone in the organization to regularly examine and refine their work processes. Over time, these incremental improvements should lead to better processes, products, and overall business performance.

What metrics should Quality teams track?

When it comes to continuous improvement, figuring out the right metrics to track for improvement is half the battle. For Quality teams, metrics can be broadly divided into two main categories: quality-specific and organizational metrics.

Quality-Specific Metrics:

Quality-specific metrics are those directly under the control of the Quality team. They reflect the effectiveness of quality processes and provide insight into how well the Quality team performs its core functions. These are important not just for showcasing your team's wins, but they're also particularly useful when making the case to leadership for adding personnel to the team, updating quality processes, or getting more robust tools to make your job easier. Some key quality-specific metrics could include:

- **Document Accessibility:** How quickly and easily can team members find the documents they need? Document accessibility has a direct impact on audit speeds and overall productivity. Track the time it takes to locate any given document and use this data to determine if it's time to invest in a better document management system, like an eQMS.

- **Audit Efficiency:** How many audits does your Quality team host and/or conduct? How long does it take your team to navigate through them? If your team is drowning in audits or each one is taking an unusually long time, it could indicate it's time to hire or invest in efficiency solutions.

- **Document Approval Time:** How long does it take for a document to go from draft to final approval? What's the average time between when a signature is requested and received? Delays in document approval can bottleneck operations across the entire organization.

- **Audit Observations:** How many major and minor observations did the company receive this year? How long did it take to address audit findings? Tracking the number and severity of audit findings can serve as a pulse check for the overall health of the company's quality practices.

Organizational Metrics

Organizational metrics are those which are technically under the control of other departments.

As a secondary owner of these metrics, the Quality team plays a crucial role in tracking, reporting, and providing insights to help drive continuous improvement, but it's ultimately up to each individual department to act on these insights.

Which organizational metrics you track will heavily depend on your specific company operations – a CMO won't track the same exact data as a Biopharma organization – but some examples could include:

- **Training Compliance:** Your HR department may oversee training, but Quality can track company-wide training compliance percentages, spot patterns that lead to overdue assignments, and make suggestions for improvement, such as utilizing an eQMS for training management.

- **Batch Failure Rates:** Monitoring the number of batches that fail to meet quality standards is crucial. While the root cause may lie outside the Quality department, such as in manufacturing or supply chain, the Quality team can help identify trends and support corrective actions.

- **CAPA (Corrective and Preventive Action) Effectiveness:** Tracking CAPAs ensures that issues are addressed quickly and that preventive measures are actually successful in mitigating future risk. Take a look at time taken to implement corrective actions, the recurrence rate of similar issues, and the percentage of CAPAs deemed effective.

Tips for better quality data reporting

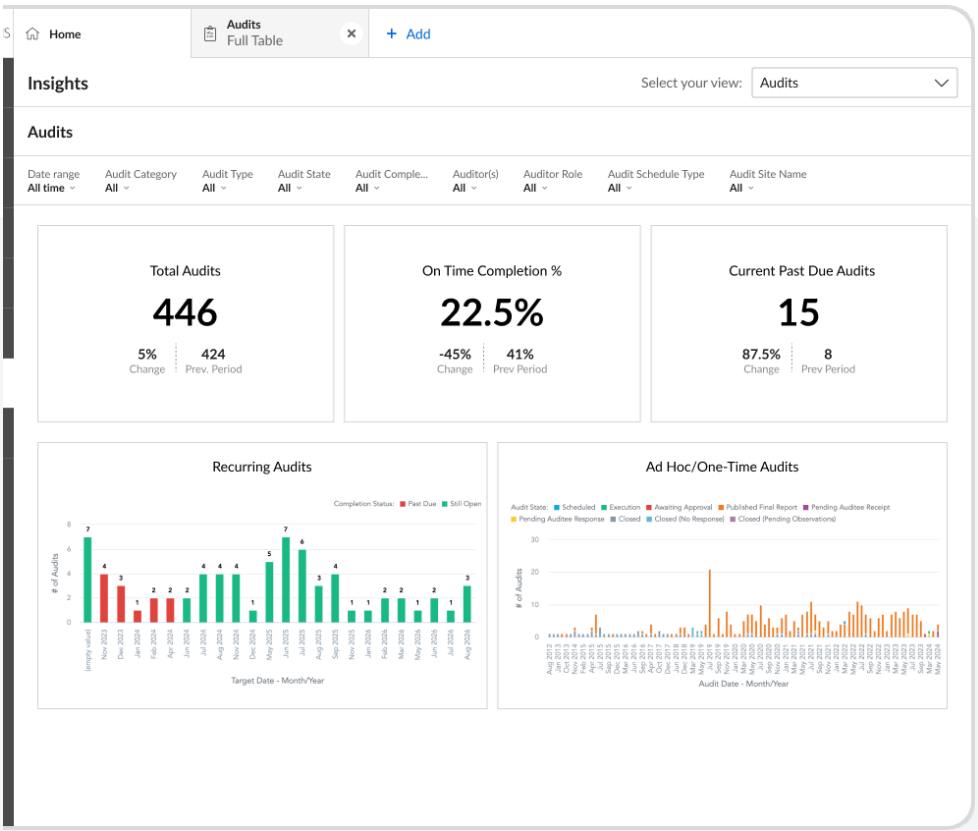
Reporting out on data can be a whole separate beast entirely. Here are some tips to help ensure your tracking efforts actually make an impact:

- **Set benchmarks:** Before you can judge whether or not quality efforts are improving, you have to have a baseline to measure against. How long does it currently take you to find a document? What percentage of employees are training compliant right now? Don't forget to examine your problem log to determine additional metrics your organization should track.

  What patterns or consistent issues do you see? Are there specific actions that are frequently delayed? For example, a lengthy document approval time could mean you need to track the time between signature request and completion, or a long list of outdated documents might signal it's time for a document up-versioning project.

- **Move away from paper and spreadsheets:** Excel or Google Spreadsheets might seem good enough for tracking metrics, but they come with big drawbacks, like the potential for human error and tedious manual data entry. An eQMS can automate the tracking of key metrics and generate reports that are not only more accurate but also more timely.

- **Add context to your reports:** Data is only as valuable as the insights it provides, so don't just paste four different graphs in a presentation and press send. When you present reports to leadership, provide context by explaining the trends you're seeing, the potential future impacts, and recommendations for action. Most importantly, frame your insights in terms of business outcomes. For example, instead of just stating that the average deviation resolution time has decreased, explain how it has shortened production downtime and reduced costly market delays.



An example of the Insights module dashboard within ZenQMS.

Easy-to-read dashboards make tracking and reporting on quality data simple and impactful.

Section 2

eQMS Security

Quality Secured: Best practices for eQMS security and data confidentiality

Why Quality teams need to prioritize data privacy and confidentiality

Worldwide, regulatory bodies impose strict rules to ensure that sensitive data related to GxP operations is handled with the highest level of care. In fact, a single failure to maintain data privacy could lead to severe penalties.

This means that for Quality teams, the stakes are high. Your eQMS likely holds private records like patient data, intellectual property, employee information, and more. That makes it critical to understand, review, and regularly update your data security protocols.

By doing so, you protect not only the future viability of your organization but also the patients and customers who rely on the safety and efficacy of your products.

eQMS security best practices

It's one thing to say you take data security seriously, but protecting your data means staying alert and being proactive with data management. Take eQMS data privacy a step further with these security best practices:

- **Review access permissions regularly:** One of the weakest points of data security lies within access control, which often involves manually adding and removing user access. (Remember, all manual processes carry some risk of human error.) This is especially true for CROs, which may quickly increase or decrease their staff based on changing site volumes. Mitigate this with regular reviews or audits of eQMS access permissions checking that each role can access only the most necessary information. To make this process easier, use an eQMS that allows for user grouping by roles and access permissions.

- **Conduct intrusion detection monitoring:** Your team likely assesses any security alerts in real time, but a more thorough, regular review of all system logs provides added reassurance. On a weekly basis, comb through your logs to make sure no anomalies or threats slipped through the cracks or were miscategorized. If you do find an error, it's time to take a closer look at your security processes and permissions.

- **Ask about data storage and recovery:** While the Quality team plays a role in eQMS security, responsibility also lies with the eQMS vendor itself. Whether you're looking for a new system or are perfectly happy with your current platform, take time to ask where sensitive data such as patient information, test results, and proprietary details are stored. Also confirm which protocols are in place for business continuity and disaster recovery to prevent data loss.

- **Ask about security incident reporting:** It's never pretty, but mistakes happen – and when they do, you want to know about it. Ask your eQMS vendor about their procedures for identifying, documenting, and communicating any data security incidents. Get specific and ask about their incident response time, what level of incident requires customer notification, how they notify customers, and what steps they take to mitigate damage. Just as important as a vendor that can prevent incidents, is one that's transparent, honest, and fast acting when they occur.

- **Pay attention to certifications:** Any eQMS you choose should be as intense about data privacy as you are. Read and understand the security certifications on the next page — and confirm your eQMS actually has them.

eQMS certifications and standards to know (and require)

Data security is a complex world, and it can be difficult to navigate alone (especially if you don't have an IT background).

Thankfully, the Life Sciences industry has agreed to a set of standards that prove an eQMS is compliant with data security and privacy best practices. The following list may seem like a lot, but when you're handling sensitive patient or company data "risk averse" is the name of the game.

ISO 9001:2015

This is the internationally recognized standard for Quality Management Systems created by the International Organization for Standardization, an agency with representatives from 172 countries.

At its core, it provides guidance on how to mitigate risk, make processes more efficient, and continuously improve quality. It also ensures that a QMS is meeting regulatory requirements.

The "2015" refers to the release year of the most current version, upgraded from ISO 9001:2008. Any eQMS you choose must have an ISO 9001:2015 certification to guarantee the most secure platform.

ISO 27001:2022

eQMS platforms house a lot of sensitive data – which is why ISO 27001:2022 certification is so critical. This sets the standard for information security management and provides parameters on how to manage, store, and secure private data.

An eQMS with ISO 27001 certification has proven data risks are mitigated with procedures like risk assessments, access controls, encryption, and more.

SOC 2 Type II:

SOC 2 Type II is an audit report that details how a company – specifically one which uses cloud-based storage – handles sensitive data.

As part of the audit, the company hosts third-party inspectors who look at five main components, called the Trust Services Criteria.

These are:

- **Security** – How does the company protect sensitive information?
- **Availability** – Can customers easily access important information within the system?
- **Processing integrity** – When the company processes data, is it accurate, complete, and done in a timely manner?
- **Confidentiality** – Is sensitive information secured behind strict access controls?
- **Privacy** – Does the company's security controls actually meet its privacy commitment detailed in its published Privacy Notice?

When an eQMS completes and passes a SOC 2 Type II audit, it confirms it has the right data privacy and security controls in place to protect its GxP-regulated clients.

21 CFR Part 11

With globally dispersed teams, it's no longer efficient for companies to rely solely on physical signatures for document approval.

Electronic signatures are now the norm. However, the FDA requires GxP-regulated companies to prove the authenticity of its electronic signatures and the validity of its electronic records, and they've mapped out how to do this in the 21 CFR Part 11 requirements.

These requirements set the criteria under which electronic signatures are considered trustworthy, reliable, and equivalent to paper records.

In order for the documents and signatures you manage through an eQMS to be FDA-compliant, the eQMS must adhere to 21 CFR Part 11 guidelines.

Annex 11

Annex 11 comes into play for GxP companies with operations in the EU.

It focuses on computerized systems (like an eQMS) and

provides guidance on validation, data integrity, risk management, and system access controls.

Though it's not legally required, compliance with Annex 11 shows your eQMS takes security and risk as seriously as you do, and provides extra insurance that it meets GxP regulatory expectations.

GAMP5

GAMP5 stands for the 5th publication of the Good Automated Manufacturing Practice guidelines, developed by the International Society for Pharmaceutical Engineering (ISPE).

Its goal is to make sure that the computerized and automated systems that are used in manufacturing processes are properly validated and compliant with regulatory requirements.

Organizations that follow GAMP5 are better equipped to mitigate risk, protect data integrity, and meet GxP requirements.

GDPR

The General Data Protection Regulation (GDPR) is a data privacy law that protects the personal data of anyone who lives within the European Union.

It specifies how much data you're allowed to collect, when you can collect it, how it's stored, and what you can do with it. Any organization, no matter the location of its headquarters, must comply with GDPR if it processes the data of EU residents.

Even if your organization doesn't currently process data from individuals in the EU, you'll want to prioritize an eQMS that's GDPR compliant in case your operations ever expand.

HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) sets strict guidelines for healthcare related organizations on how they handle Protected Health Information (PHI).

To be HIPAA compliant, an eQMS platform must encrypt PHI data, control access, and ultimately, preserve patient confidentiality.

Data Privacy Framework

The Data Privacy Framework (DPF) provides an avenue for companies to transfer personal data between the European Union and the United States in a way that complies with EU privacy laws. To participate, companies must self-certify to the U.S. Department of Commerce that they follow the DPF's privacy principles, which are enforceable by US law.

Success Story

Nordic Pharma uses an eQMS to become 21 CFR Part 11 compliant

Switching from manual quality management to an eQMS may seem daunting, but it's a necessary step to improve data security, confidentiality, and compliancy. See how Nordic Pharma seamlessly made the switch and the steps they took to prioritize 21 CFR Part 11 compliance.

NORDIC PHARMA

During our first post-implementation FDA inspection, we were able to quickly and efficiently provide the requested documents. Nordic Pharma's quality of documentation control process with ZenQMS was appreciated by the FDA inspector as expressed during our Management closeout.

Marie Myers
Nordic Pharma's Quality System Manager

About Nordic Pharma

Nordic Pharma, Inc., subsidiary of Nordic Group B.V., is partnered with well-established global biopharmaceutical companies and is uniquely positioned to leverage its expertise in bringing biotechnology derived medicines, sterile manufacturing and other state-of-the-art technologies to the marketplace.

Nordic Pharma's Leap from Paper to Digital

Nordic Pharma provides high quality, safe medications, and medical devices to a global patient population. However, in order to continue their mission, they realized the quality tools they used were in need of an upgrade.

When the Vice President of the Quality Unit, Nancy Fulginiti arrived, she aimed to bring their quality management system up to modern standards to meet the dynamic needs of the company and ensure strict regulatory compliance.

Her first task? Move the company away from paper wrought with limitations around accessibility, efficiency, and organization. A move to shared cloud drives for storing documents and SOPs was a step forward, but still insufficient. As any quality professional will tell you, shared drives lack accountability and are not compliant with 21 CFR Part 11.

Thus, the decision was made to explore electronic quality management systems (eQMS) that could not only keep their operations organized, but also meet and maintain regulatory compliance requirements. In particular, they were searching for an eQMS that would allow them to build their unique workflows.

Success Highlights

- **Effortless configuration of specialized workflows**
- **Increased efficiency for smoother audits**
- **21 CFR Part 11 compliant**

"One system we looked at was an 'out-of-the-box' solution," said Marie Myers, Nordic Pharma's Quality System Manager. "That sounds good, but when you have to use it for all of your quality systems, it's not going to match every company's needs.

We have a lot of specific workflows we want to track, but that's not possible to do with other business solution software."

> **It's really user-friendly**
>
> "When we rolled out ZenQMS, it was a learning curve, but once we completed our training and understood the workflows and requirements, everybody came back and said, "Oh, this is so much better." said Marie.

With their need for strict compliance, highly configurable workflows, and improved efficiency, ZenQMS was a clear fit. After the transition to ZenQMS, Nordic Pharma immediately realized the benefits.

Compared to shared drives, ZenQMS offered better visibility and company-wide accountability, and the system's automated notifications clarified responsibilities and deadlines for the entire team.
ZenQMS wasn't just a hit with Nordic Pharma employees. Regulatory inspectors also noticed the improvement in the readily available documentation.

"During our first post-implementation FDA inspection we were able to quickly and efficiently provide the requested documents," said Marie. "Nordic Pharma's quality of documentation control process with ZenQMS was appreciated by the FDA inspector as expressed during our Management closeout."

Workflows that match your preferences

Nordic Pharma's search for an effective eQMS led them to evaluate several solutions, with ZenQMS emerging as the preferred choice due to its configurability and user-friendly interface.

Panos Boudouvas, CEO of ZenQMS, provided a compelling presentation that showcased the system's ability to manage complex quality scenarios. Additionally, the platform's ability to consolidate their quality systems in one place, coupled with its top-tier customer service, made ZenQMS stand out from the competition.

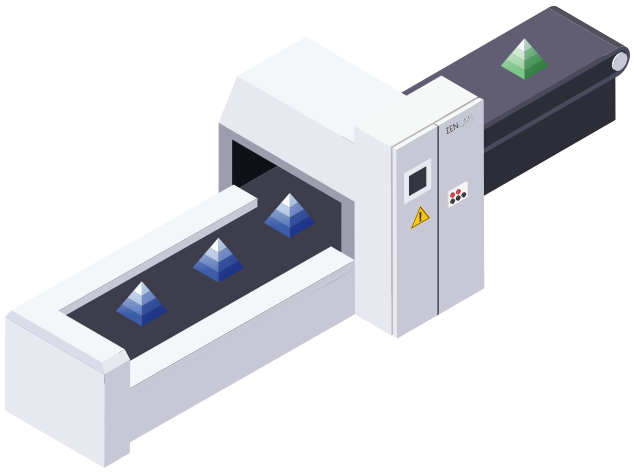
"To build these workflows, we needed little assistance from ZenQMS."

Marie immediately realized that the primary advantage of ZenQMS is its configurability. Nordic Pharma had unique, yet critical workflows they wanted to launch for Field Alerts, Investigations, and Commitments that out-of-the-box solutions simply couldn't accommodate due to their rigidity. "The forms we've created in the ZenQMS Issues module aren't anything we could've built in another system that I'm aware of," said Marie.

But perhaps the real differentiator of ZenQMS is empowerment. Sure, a configurable eQMS is helpful, but with ZenQMS, not only could Nordic Pharma design processes to address their specific operational needs, but creating new workflows was simple, bypassing the delays that come when dealing with internal and external support.

Section 3

eQMS Revalidation



When (and why) does your eQMS need revalidation?

What is validation?

At its core, validation is simply proving a piece of software does what it says it can do and that it's fit for its intended use. For example, that your eQMS training module allows you to assign, track, and report on training, and you plan to use it that way.

Regulatory bodies like the FDA want to see that you've validated any software that has an impact on your GxP operations before you start using it.

If your life sciences company is using an eQMS, you've gone through the validation process already (...hopefully), so congrats! Job well done.

What is revalidation?

Validation happens when you first bring an eQMS on board, but it's not a one-and-done task. Software platforms make updates often, and depending on the size and impact of those updates, you may need to revalidate the system.

The basic concept of revalidation is the same: after a feature has been added or changed, can you prove the system still does what you need it to do? Does it still protect patient data and support your GxP efforts? Do any of your quality processes have to adapt based on the platform update?

The tricky part is determining when revalidation is necessary and when you can requalify the eQMS without it.

Need a refresher on validation and the difference between CSV and CSA?

Check out our guide on how to validate your eQMS in our eQMS 201 eBook

Revalidation vs Requalification

There may be times when you only need to requalify your eQMS rather than do a full revalidation. But what's the difference?

When you requalify an eQMS, you carry out a series of steps that confirm the system is still fit for its intended purpose after an update. Those steps could be as simple as reading the release notes and determining the platform still has the features you need.

Or maybe you read through the eQMS vendor's revalidation documents, decide you trust their testing, and declare the system requalified.

Revalidation involves *proving* the eQMS is still fit for use by running test scripts that are specific to your company's unique configurations, and then documenting the results. Revalidation can be part of your requalification process, but it's not always a requirement.

Think of it like conducting a job interview. When you interview a candidate, you *qualify* them by making sure their experience matches the requirements for the job. You might do a background check, call a couple of references, etc. But maybe you want to go a step further and prove their experience, so you give them a test.

They mentioned they could code in a specific language, so you ask them to do a small coding test to *validate* that their qualifications actually meet your needs.

Does an eQMS need to be revalidated after every update?

True to quality's complex nature, the answer is "it depends." Some updates will require revalidation of the software... and some won't. To determine the right answer, you have to look at a few key factors:

Vendor Type
If a software vendor isn't critical to your GxP operations, you may not even need to keep track of their updates or changes. For example, maybe your Marketing team uses Word Documents to write a monthly newsletter. The software isn't storing sensitive information or patient data and isn't crucial for business continuity, and therefore isn't among your critical vendors that need to be revalidated.

On the opposite end of the scale, your eQMS likely contains a lot of sensitive information and plays a vital role in your GxP activities. It's a critical vendor and therefore every update warrants at least a readthrough of the release notes.

Impact of the Change
As you're reviewing the eQMS software changes, consider the answers to these questions:

- How will this change impact the team?
- How will it impact the way you work?
- Will it impact workflows?
- Will it impact data storage, privacy, or security?
- Will it require the team to retrain on the software?
- Will any quality processes need to be updated?
- Is the update considered high risk (a substantial change), medium risk (a minimal change), or low risk (a cosmetic change)?

The bigger the impact, the more likely the update will require a revalidation of the system.

Revalidation best practices

Have a revalidation policy in place: It may seem obvious, but one of the most important components of a good revalidation policy is... actually have a revalidation policy in place.

You'd be surprised how many organizations don't consider revalidation at all until they're asked for validation documentation during an audit years later. Whether it's a change control category, a change management procedure, or simply a checklist, your quality process needs something that reviews changes in software and provides justification for your revalidation decisions.

Consider impact now vs later: Even if you find a software change doesn't impact your operations now, consider how it might impact you later.

Your team might only use the Documents and Training modules of your eQMS, and so an update to the Issues module has no impact on your current GxP activities. But what if 6 months later your team begins to use Issues?

You need a procedure in place that triggers a reevaluation of the software, whether that's a periodic review to see if any previous software changes have now become relevant, or a workflow that launches a new risk assessment when your use changes.

Ask your eQMS vendor about their validation documentation: eQMS vendors conduct validation on their systems, and users can often utilize this documentation during their own validation and revalidation processes.

Unfortunately, a lot of eQMS vendors charge clients extra fees to access these validation documents, which forces

clients to either start validation from scratch or pay a hefty price on top of the software cost. Remember, you don't have to accept this as the norm.

While you're evaluating which eQMS platform is right for your team – or considering if it's time to switch your current eQMS provider – ask the vendors whether or not they charge for revalidation document access.

Section 4

An Evolving eQMS

It's Alive! How your eQMS should evolve as your quality needs grow (which they will!)

Your electronic Quality Management System (eQMS) is more than just a data storage box – it's a living, breathing entity that should evolve alongside your organization's needs. As your company grows, regulations change, and your quality processes mature, your eQMS has to keep pace.

Why your eQMS should never be stagnant

Does your company look the exact same as it did a year or even 3 months ago? Probably not. New hires or departures, shifting business goals, more competition in the market, new products or research findings, updated processes... in the dynamic world of life sciences, it's unlikely your organization is standing completely still.

And if your company isn't stagnant, your eQMS shouldn't be either. Quality management is the backbone of compliance, product quality, and patient safety, and it's essential that it evolves with your organization.

A stagnant eQMS is a liability, making processes inefficient, increasing the risk of non-compliance, and even jeopardizing the business as a whole.

Here's why your eQMS should always be evolving:

Regulatory Changes: Industry regulations are constantly shifting, and staying compliant with the changes is a proactive endeavor. Whether it's new data tracking guidelines, updated labeling regulations, etc., the way you approach quality within your eQMS is guaranteed to change over time.

Business Growth and Scaling: As your company grows, your quality management needs will become more complex. Whether you're expanding into new markets, increasing production, or growing your team, your eQMS must be able to scale with your business.

Process Improvements: Continuous improvement is the name of the game for successful life sciences companies, and your eQMS should reflect this. As you identify more efficient or effective ways to manage quality, your system should update to support them.

Risk Management: The risks your organization faces today may not be the same as those it faced a few years ago. Supply chain vulnerabilities, cybersecurity threats, or increasingly error-prone manual processes will all spark necessary changes to your eQMS activities.

Signs it's time to update your eQMS processes

It's easy to get into a groove (or a "rut" for the glass-half-empty folks) with your eQMS and simply do what's always been done, whether it's the most efficient method or not. However, there are clear signs that it's time to evaluate and update your eQMS processes:

- **New regulations:** Any time a new regulation is announced, set your eQMS review process into motion. What needs to be updated to stay compliant? Will approval workflows need to change? Will new data need to be added to the system? Will different reports need to be pulled?

- **Bloated workflows:** Just like a house, an eQMS gathers clutter over time as new workflows and stages are added. Are you collecting the same data across multiple stages? Is the data you're collecting actually needed? Do you have separate stages that can actually be combined into one? If quality processes are slowing down, bloated and redundant workflows could be the culprits.

- **Slow approvals:** If your team is struggling with slow approvals and missing signatures, it's a strong indicator that your eQMS isn't keeping up with your needs. Take a look at which documents have the longest delay and monitor for any trends in the signature steps that are holding approvals up.

- **Risky workarounds:** Is your team creating workarounds to bypass limitations in your eQMS? Are your processes moving to manual quality management at any point? Time to reevaluate how your eQMS is configured. These kinds of workarounds can lead to errors, data integrity issues, and overall less efficiency.

- **Difficulty scaling:** Is it getting increasingly difficult to scale your training matrix as your company grows? Your training management procedures may need an overhaul. Make sure you're taking advantage of the automations, user groupings, and training courses in your eQMS, as well as eQMS integrations like SCORM.

- **Audit Findings and Compliance Gaps:** If audits consistently reveal gaps in your eQMS, it's a clear sign that updates are needed. This could include findings related to document control, data integrity, or lack of alignment with current regulatory requirements. Addressing these gaps proactively by updating your processes can prevent future compliance issues.

Best practices for keeping your eQMS up-to-date

There are three main goals to focus on while updating your eQMS activities: successfully implement the new processes, train your users, and maintain compliance throughout the transition. Here are some best practices for managing eQMS updates:

- **Start with a configurable system:** Technically, this is a vital step during your vendor evaluation process, but prioritizing a configurable eQMS is the most important part of keeping your quality process up-to-date. A configurable system makes it easier to adjust your workflows after their initial creation without having to run to Support or IT for every change. Unfortunately, some eQMS platforms advertise themselves as configurable when they really mean they're customizable, so make sure you understand the difference before choosing a system.

- **Conduct a thorough gap analysis:** You know something needs updated about your eQMS process, but what is it? Use a gap analysis to find out. Where are quality activities falling short? Where are the most errors being generated? What's taking longer than it should? Your eQMS should have reporting or insight capabilities that provide helpful data for pinpointing opportunities for improvement.

- **Engage stakeholders early:** Involving stakeholders early in the update process is crucial for getting buy-in and ensuring a smooth adoption. Collaborate with IT, Regulatory, Operations, and other departments to learn which eQMS changes could support their own activities and to get aligned on goals and expectations.

- **Requalify new features:** Are you using new features in your eQMS as part of your process updates? Just like when you first implemented your eQMS, new features must be qualified or validated to ensure that the system continues to function as intended. Take a look at the validation section on page 14 for details on how this works.

- **Test Before Full Implementation:** The risk adverse know it's best to plan for nothing to go to plan. Before officially rolling out changes, use a sandbox environment to test new configurations. This allows you to identify and address any issues without causing disruptions or triggering potential compliance risks.

- **Think through a training plan:** Adopting new workflows or implementing new modules within your eQMS may require retraining for users. Develop a training plan that covers both the technical updates and the reasons behind the changes.

- **Monitor post-changes:** Remember, "set it and forget it" should never be in a Quality team's vocabulary. After implementing changes, monitor the system to make sure everything still functions as expected. Encourage users to provide feedback and be prepared to make adjustments if necessary.

- **Plan for continuous review:** Continuous improvement is made possible by continuous review. Make periodic reviews, internal audits, and metric tracking standard practices so your eQMS is always keeping pace with your quality needs.

About ZenQMS

ZenQMS is an eQMS platform that empowers Quality teams to control quality and keep their companies compliant from anywhere with less stress, less complexity, and more support.

From early stage to enterprise, over 100,000+ users trust ZenQMS.

Built by Quality leaders who believe Quality teams deserve better, simpler tools, ZenQMS is designed to be easier to use, quicker to validate, and more effective for companies of any size. Here are just a few things that make us different:

- **No seat licenses**. We don't charge by seat licenses, meaning pricing never holds your growth back. All members of your team can have access from day one.
- **Effortlessly configurable.** ZenQMS adapts to match your specific processes, operations, and quality needs. With our system, you get exactly what you need, when you need it, the way you're used to seeing it.
- **Validation made simple.** Validation is required... validation headaches are not. We don't charge for access to our validation materials and our support team guides you through the process from start to finish.
- **Easy to use. Really.** No need to retrain employees on how to use the system every time they sign in. Our dashboard allows everyone to see their compliance status at a glance, quickly find the docs and training they need, and easily complete assigned tasks — without needing an IT degree.
- **Implementation at your speed.** Need to get started ASAP? We can do that. You set the pace of implementation and our team moves to match it so quality never misses a beat.

Want to learn more about ZenQMS?

What makes us different, and how we can help? Reach out to contact@zenqms.com or set up a quick chat here!


ZENQMS