Qualio

12 questions to ask before buying an eQMS

Make the right choice for the next chapter of your business

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Picking the right electronic quality management system (eQMS) is critical to the success of your organization.

Pick wrong, and you frustrate your team, weaken your compliance and waste money. You might experience a painful implementation journey and blunted results as you bring the new system online. You could even hand your competitors a crucial advantage by slowing your time to market.

Pick right, and you unlock an integrated, quality-first approach that lifts the lid on your business growth and maturity. Compliance and 24/7 audit readiness become automatic. Employees engage and a real culture of quality comes to life.

But how do you make the right choice? With careful planning and by asking the right questions.

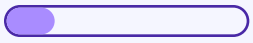
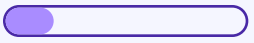
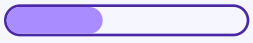
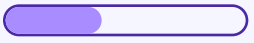
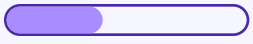
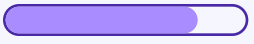
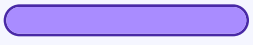
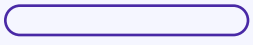
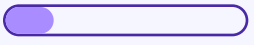
At Qualio, we've helped hundreds of organizations select the right quality tool for their business. Our greatest hope is that you'll use the information within this e-book to make an empowered and impactful decision for your business.

And even if you don't buy from us, we hope that each stage of the process, from building your user requirements specification to vendor shortlisting and implementation, will be a positive and rewarding experience for you.

Meg Sinclair

Senior Manager, Quality and Support

1. What do I want to achieve?

Requirements	eQMS	Manual	SharePoint
Visibility			
Audit trail			
Scalable			
Lifetime cost of ownership			
Efficiency			
Accessibility			
Functionality			
Reporting capabilities			
Configurable			
Low initial cost			
Maintenance cost			
Speed of implementation			
Ownership			
Ability to manage change			
Compliance			

Finding the right eQMS software vendor starts by establishing what you need and what your long-term business objectives are.

Here are some common drivers for an eQMS procurement project:

- No visibility on why decisions have been made
- Reactive culture
- Mistakes which led to high expense or damaged reputation
- High cost of poor quality (COPQ)
- Failed audit(s)
- No formal management system
- High growth
- Bringing a new product to market
- Compliance silos
- Lack of engagement with the management system
- Outdated legacy systems

Defining your needs is very important. If you have lots of compliance requirements, we recommend assembling a User Requirements Specification (URS) to help centralize and document your operational needs.

This can be sent to a future shortlist of vendors to ensure you get the best possible solution for your business.

> *Qualio is easy to work with, and makes life much easier in the quality sector.*
>
> **— Sara Viguera**
> Quality Manager, Leaseir Technologies

2. Does it meet my industry needs?

Starting your search for a QMS software can be nothing short of overwhelming.

There are hundreds of vendors listed in the quality management category on popular third-party review websites. So a sensible first step is to narrow your search by focusing on systems which can provide the fastest time to value for your organization.

Your organization has two main options when it comes to selecting a QMS software and narrowing down vendors:

01. Pick an eQMS designed for your specific industry needs, such as the exacting quality demands of the life science sector

02. Pick a generic eQMS system and attempt to retrofit your GxP and regulatory requirements

Industry-specific QMS software offers an advantage for most use cases in highly regulated verticals like life science. Naturally, a QMS built specifically in accordance with FDA, ISO and other regulatory requirements can generate extra value for life science organizations by providing built-in compliance and streamlined validation processes.

An FDA-compliant quality system is necessary to manufacture and sell devices, drugs, or biologics in the US, and ISO-compliant certified systems are necessary for approval in non-US markets. Your organization can face significant regulatory penalties, fines and recalls if your QMS fails to meet regulatory standards.

While your organization has the option to modify generic QMS software to meet FDA or ISO requirements, this will require significant resources and could increase your regulatory risks. The QMS will require

revalidation each time a significant update is made to the system. And if your configurations require custom code, there may be significant, long-term hidden costs required to maintain this code plus any custom integrations over the long term.

The path of least resistance is therefore a QMS built specifically for organizations in the life sciences industry.

It should offer automated quality workflows for monitoring quality, complaints and CAPAs to meet FDA and ISO requirements.

It should slice your regulatory risks by providing built-in tools for compliance. And it should help your organization exceed compliance requirements and become genuinely quality-driven by delivering real value and enabling your organization to operate in a constantly audit-ready state.

> *Qualio has allowed me to develop a complete medical device quality system for a small company in a way that is Part 11-compliant and provides custom formatting, easy navigability, flexible assignments for roles and training, metrics and specialty tools — without breaking the budget.*
>
> **— Barbara Young**
> Senior Quality Manager, Proscia

3. Does it meet my organization's size and scaling needs?

> *We chose Qualio as we needed our system to be scalable to support our rapid growth and facilitate quick employee onboarding. Qualio's simple-to-use interface and automated workflows ensure high employee engagement, supporting full compliance and audit readiness. We couldn't do it without them.*
>
> **— Deb Glancy**
> Director of Quality, Ultragenyx

The best eQMS for your organization depends on your company's size and growth trajectory. Start-ups and scale-up companies have very different needs to Big Pharma companies and global enterprises.

A QMS for a life science enterprise body will need to accommodate and maintain a large, well-established global portfolio of products which are approved for market. An army of administrators and IT teams can work behind the scenes to drive any monster complex implementation project. Agility isn't required, and not everyone needs to use it.

But if you're a start-up or scale-up, fixed complexity is anathema. You need to avoid systems which are so complicated they require a dedicated administrator. Agility, baked-in compliance, the capacity to grow, and early buy-in from as many members of the business as possible are vital.

In this case, an eQMS should help you build scalable, compliant processes that match where your business is on its size and maturity journey.

The best way to evaluate software based on company size is according to the number of employees — organizational size can be a better gauge than software characteristics.

For example, a well-known enterprise eQMS product is tailored to organizations with 1,000-5,000 employees.

Qualio's functionality, on the other hand, is best suited to life science organizations with 5-500 employees. Software in this 'SME sweet spot' can offer greater ease of use and scalability to help start-ups grow through their research and product approval phases and beyond.

Even so, you shouldn't take this for granted. Some software vendors targeting smaller life science businesses offer rigid, templated quality systems with the aim of selling quick and easy fixed compliance. This may sound a good idea in practice, but in reality may not afford your business the flexibility to map your eQMS onto your real and ever-evolving business processes. In the long run, this can cause shoehorning and, eventually, outgrowing your software altogether.

Closely linked to this, you should therefore consider how any eQMS will serve your business in the coming years as well as now. Your QMS should scale and expand as your organization's processes and compliance requirements mature. While you may not need CAPA features now, for instance, you will as you approach pre-market approval.

And if your organization is in the research and development phase of creating a new product, you could meet your needs by adopting a system which only offers, say, document management and employee training functionality. But a wiser approach would be to consider your quality needs 6, 12, 24 and 36 months down the line, then to adopt software which will help you manage these processes at scale.

Which brings us to...

4. How customizable and flexible is it?

Believe it or not, customization, flexibility and configuration are three different things:

Customization is the potential for a system to be modified to fit your current processes and requirements

Configuration can mean a system's potential to be modified at the technical level, generally using custom code

Flexibility refers to non-technical capacities to scale, grow and add new users and processes

As we've seen, your eQMS should be ***customizable*** enough to fit your existing processes and scale as your organization grows.

It should have enough ***flexibility*** for your organization to quickly modify processes when you discover opportunities for quality improvement.

But unless your organization is an enterprise or has a strong use case to perform extensive configurations on a system for a custom implementation, you probably don't want a highly ***configurable*** system. Too much custom code can result in an expensive implementation and long-term system maintenance requirements.

Evaluate flexibility to understand how much value your company can get with an out-of-the-box system.

How quickly can you begin using a new eQMS once you sign a contract with a vendor?

If your start-up grows to need audit capabilities, can you add these modules

seamlessly — or will you need to wait a length of time and pay for costly system integration? Is there a cost to scaling features according to need?

The best QMS for your organization should meet your current and future requirements and offer few barriers to real-time growth.

Most smaller life science organizations have a use case for customizable systems which don't require writing code, contacting the vendor, or going through extensive system revalidation.

Customization features which generally matter to these smaller organizations include the ability for non-technical users to change quality workflows, create forms, create templates, and add users.

And your quality unit should be able to make all of these changes to your eQMS without having to rely on the software developer.

> *The customization that Qualio offered was a huge differentiator from other solution we looked into prior to choosing Qualio as our eQMS.*
>
> **— Gene Vought**
> Quality Manager, Cirris

5. What should I budget?

> *The price point is great for a small start-up biotech company, and Qualio also has the ability to scale as needed. If you are looking for an affordable cloud-based QMS system that incorporates all required features then I personally recommend you take a look at Qualio.*
>
> **— Drew Mateya**
> Director of Quality, ECM Therapeutics

It's true: investing in an eQMS is going to initially cost more than using manual processes. So careful budgeting and cost planning is crucial.

To set your budget, we would recommend calculating the total cost of ownership of your existing business processes.

Consider:

- How much waste is there?
- How long does it take to process?
- What is the cost of the wasted time?

Most leadership teams are surprised when they realize how much manual quality and compliance processes are really costing in time, money and lost opportunity.

The right cost for your organization naturally depends on what you find here, as well as your size and maturity. A QMS which is affordable for a start-up is likely to have very different pricing tiers to software for the enterprise. In addition to the cost of the software itself, consider whether the vendor offers any services that can help your organization maximize growth, such as:

- Quality assurance support
- Templated regulatory content to feed into your eQMS
- Strategy sessions, gap assessments and audits

It's important to evaluate the software's pricing listed on a vendor's website to determine whether there are any hidden fees.

One common fee charged by QMS vendors is overage fees for data storage: some vendor's listed pricing may offer very limited data storage and a sharp increase in costs for clients who exceed these data limits.

Other vendors require clients to "bring their own database," or manage the costs of secure data storage separately from the subscription or licensing fees. Secure, compliant data storage isn't cheap, so it's important to understand these costs fully or fast-track vendors who offer free, unlimited data storage.

And the cost benefits of a cloud-based eQMS (hosted remotely) versus an on-premise system (hosted on your on-site physical servers) shouldn't be ignored either: cloud-based systems typically cost more in the first instance, but pay for themselves in months by allowing you to eliminate the upkeep, capital and overhead costs of an on-premise platform.

Cloud-based platforms also offer more flexible billing, as well as faster set-up. Which leads us to...

6. How long will it take to get up and running?

Depending on the trustworthiness and effectiveness of your vendor, software implementation projects can sometimes run well over their time and cost estimates.

So before you select a new QMS, it's important to ensure that you aren't signing up for a long, costly implementation. There are several factors which can determine the cost of your implementation. These are:

- Your organization's size, structure and maturity stage
- The vendor's timelines and requirements
- Cloud vs. on-premise software

Cloud-based software is significantly faster and cheaper to implement than on-premise alternatives. If you choose a legacy solution which is hosted on-site, your organization will be responsible for implementing the infrastructure, customizing the software, and maintaining the product over the system lifetime. A premises-based choice is more likely to have a delayed implementation, too, especially if you heavily customize the software before your launch date.

Organizations across industries report their companies are going live faster by choosing SaaS. If your organization opts for an industry-specific SaaS solution, you're likely to experience a fast implementation with minimal customization requirements. Speed to market can be an enormous competitive advantage in highly regulated industries such as life sciences.

Small organizations with fewer than 50 employees can generally make a technological change in a period of weeks. Medium and large organizations can experience initiatives which range from

months to years. Factors which can prolong your initiative include:

- A globally distributed workforce
- The need to transition employees from existing systems
- The complexity of your processes
- The volume and complexity of your existing quality data

And of course, your vendor will play a significant role in the length and timeline of your progress too.

Ask how quickly your vendor has gotten clients to go-live at similar organizations to your own.

Ask about an implementation queue, and how quickly they can begin actively working on your project as soon as you sign the contract.

And see whether you will be assigned a dedicated account manager and project manager for your implementation to boost communication and transparency during your transition.

At Qualio, we've applied years of extensive client feedback and recommendation to sharpen our eQMS implementation to an industry-leading 60-day timeframe.

> *We knew Qualio was going to take care of us better than the bigger guys.*
>
> **— Adolfo Ramirez**
> Director of Information Systems and Data Compliance, Irisys

7. Will it support my compliance needs?

An eQMS can fast-track and streamline your compliance if it's built in accordance with the correct regulatory standards.

Generally, life sciences organizations should focus on systems which are built to accommodate:

- FDA 21 CFR Part 820
- FDA 21 CFR Part 11
- ISO 13485:2016
- ISO 14971:2019
- GxP

Your eQMS should reduce the risk that your organization falls out of compliance with FDA or ISO demands. While your organization may not yet be considering global approval for the sale of your products, a system which is built for global compliance can create a strong baseline for future compliance. Evaluate regulatory readiness by asking the following questions:

- Does the software offer templates which are built to collect all required quality data?
- Does it offer automated reminders to streamline compliant operations?
- Does the QMS group and link compliance documents?
- Is it simple and easy to use for all members of the workforce?
- Can I prove my colleagues are appropriately trained and competent for their roles?

Compliance is complex, but meeting your regulatory requirements shouldn't be difficult with the right eQMS.

> *My favorite thing is how Qualio keeps us in a constant state of audit readiness. We chose Qualio as we needed our system to be scalable to support our rapid growth and facilitate quick employee onboarding.*
>
> **— Deb Glancy**
> Director of Quality, Ultragenyx

8. Are onboarding services included?

Some vendors require new clients to purchase onboarding services.

Others offer onboarding services as an optional, value-added service for clients.

Others offer very limited support to new customers.

Generally, onboarding services are an extremely valuable service for new adopters of eQMS software. Expert onboarding services can provide support throughout the entire adoption process, including software set-up, migration and training.

Onboarding services will streamline the amount of time it takes for your organization to go live with your new software, and ensure that your company is ready to succeed as soon as you make the transition. Expert guidance and support will help you mitigate risks throughout the implementation process.

Remember, the quality of vendor onboarding services can vary significantly. It's important to evaluate their services by more than just cost. Determine the expertise of their onboarding staff, and whether you'll have a dedicated account representative.

It's important to partner with an organization whose staff have plenty of field experience helping companies similar to your own go live quickly with a new eQMS.

Qualio offers clients a 60-day go-live promise with concierge onboarding services and a full set of success tools from set-up to data migration.

> *Qualio makes a great first impression. People don't have the same reaction that I've seen with larger, more complex solutions that tend to seem overwhelming.*
>
> **— Tyler Cochran**
> Exec. Director of Quality, Linical Americas

9. What's the support like?

The quality and availability of a prospective vendor's customer support services can be a huge factor in determining your long-term satisfaction with an eQMS.

After you go live, what happens if your organization faces an issue?

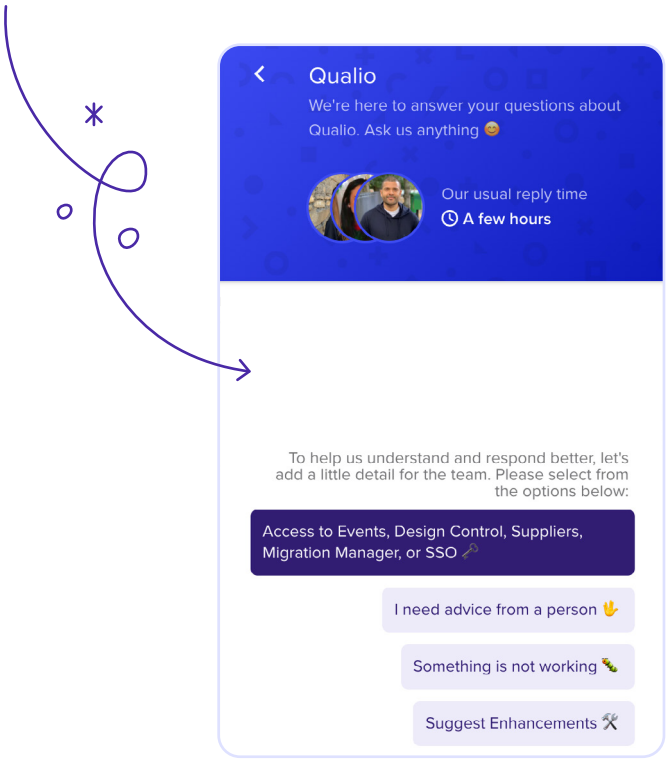
Are your calls to support going to be answered with a voicemail — or silence?

Will you have to wait 48 hours for a response on mission-critical support tickets? Even worse, does the vendor offer limited support to customers unless you're willing to shell out for monthly support packages?

Some software vendors are interested only in increasing their annual recurring revenue by getting you to sign on the dotted line.

Others, like Qualio, will commit to a full relationship with you. Qualio's strategy to 'grow by case study' means we value the satisfaction of each and every customer and commit to high-touch support to keep you and your team happy.

> *I really like the in-app support chat function. It is easy to get in touch with the Qualio team with questions or concerns and the team responds quickly.*
>
> **— Soni Mikkilineni**
> QA/RA Director, NovoSource



10. Will my quality data be secure?

Expecting your data to be secure, confidential and available is a given. All three of these criteria are important to your company's success as an organization. So before you select a vendor, it's important to thoroughly evaluate their data policies to understand whether they are in compliance with industry best practices for data security.

A cloud vendor will be managing your data storage and handling for you, so they should staff data security experts with significant industry experience, and be committed to evolving their business practices as requirements and threats evolve.

In addition to knowledge, consider data availability. If you're partnering with a cloud-based vendor, you need a highly reliable service that your organization can trust. The software should be highly redundant and based on best practices to keep running even if servers fail or there's a natural disaster.

An important metric of data availability is uptime: a vendor should offer 99.999% uptime or better.

Evaluate your vendor's data backups and business continuity policies. Ideally, any cloud vendor should perform multiple system backups each day and store backups in a remote location.

As a final measure of data security, inquire about your vendor's encryption practices. Prioritize vendors who offer 128-bit SSL encryption in transit, and 256-bit AES at rest to protect your data from prying eyes and hackers.

> *With Qualio we were able to get SOC 2 Type II-certified in about a year and a half, which is very impressive. This has led to increased trust with our customers and helped us grow faster.*
>
> **— Colin R.**
> CTO/CIO

11. Will it help us go paperless?

Companies in highly regulated life sciences industries are subject to specific requirements for electronic data handling.

This includes, but isn't limited to, FDA 21 CFR Part 11, which has strict standards for audits, system validation, e-signatures and software documentation.

Effectively managing data isn't simple when your organization is subject to HIPAA, Part 11, ISO 13485 or other requirements.

Start-ups and scale-ups sometimes assume the easiest approach is to skip regulatory requirements for electronic systems by using paper. While this can work for a period of time, paper simply doesn't scale.

Over the long term, paper-based systems bring much higher risk than electronic eQMS platforms.

They're more time consuming and resource-intensive.

They can become lost or damaged due to natural disasters, theft, tampering or human error.

And they can become a barrier to communication and collaboration as your team expands globally.

So the 'e' in 'eQMS' is key.

The right time to switch to an eQMS is before paper becomes a barrier to productivity and compliance. You don't want to wait until your analog systems are clogging communications and putting your organization at risk of a failed audit.

It's important to consider software features here. An eQMS with robust document management capabilities will support a faster, simpler transition into the cloud. If you have a high volume of

paper documents, home in on software which offers support for multiple document types, metadata tagging and fast search features to help your users retrieve the information they need after you go live.

Transitioning from paper can seem overwhelming, but the right vendor should be able to help you make a painless transition into electronic quality management.

Ask your vendor if they provide targeted support for organizations transitioning from paper to electronic QMS. Verify their experience by determining whether they've supported other companies successfully through this process. Ask how long the transition took and how they supported continuous operations during the changeover.

Finally, ask about cost. Qualio believes only fully integrated electronic quality management can embed lasting compliance — so we help our customers transition from paper to eQMS free of charge as part of our concierge onboarding services.

> *We needed an eQMS for the company's activities and paper was becoming unmanageable.*
>
> **— Karen Hue**
> Head of Quality & GxP Compliance, 30 Technology

12. Is it easy to use?

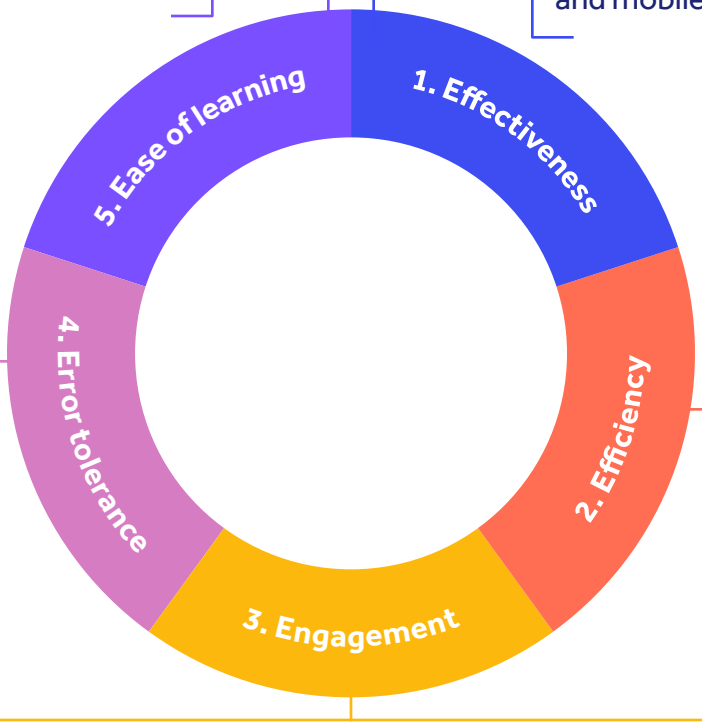
None of this matters if you choose an eQMS your colleagues hate and ignore. Ease of use is absolutely critical if your eQMS is to drive a collaborative, business-wide culture of quality engagement.

But what does 'easy' mean? 'Easy' for an IT professional may not be easy to a lab researcher or an administrative assistant. The most effective way to determine ease of use is by completing a demo or product trial with a cross-functional team which represents your entire workforce.

Unless the software is intuitive for *every* member of your organization, you could face resistance on the road to adoption. User experience expert Mericarmen Teran defines five criteria which contribute to ease-of-use:

How quickly can your users succeed within the software? Does the vendor support fast adoption with training and free resources for learning?

How simple is it for users to complete tasks on desktops, tablets and mobiles at the point of work?



Does the eQMS have zero error tolerance and enable real-time process monitoring and visibility into operations?

Does the product make it simple to pursue quality management with guided workflows, automated reminders, templates, and other factors that streamline processes?

Does the product keep team members engaged by integrating all of your quality processes to minimize the amount of software you need to use?

Qualio deserves praise for its simplistic and user-friendly interface. We made the right choice by introducing Qualio to our organization. Highly recommended. Welcome Qualio!

— **Dragan Velickovski**
Software Engineer, Axiom

Qualio

Evaluating vendors now? Got some understanding of your eQMS requirements?

Schedule a demo with us

We don't do 20-minute sales pitches. Instead, we'll walk you through a custom demo that covers:

1. Our approach to quality. Learn how quality management is changing, and what quality-driven means to companies that are using quality to drive growth.

2. How to streamline your critical quality functions. See how Qualio can help you transition your existing and future quality processes into simple, streamlined steps with real-time collaboration.

3. How to track and stamp out your quality issues. Learn how to capture quality events like non-conformances, deviations, complaints and bring them through to resolution with CAPA and detailed reporting.

4. How to become audit-ready. Learn how closed-loop quality management in Qualio gives you 24/7/365 audit readiness.

5. How to become a quality-driven organization. Learn how Qualios help our customers become fitter, quality-centric businesses with boosted customer satisfaction, product quality, employee engagement and growth.