ZENQMS

The Less Stress eQMS for Life Sciences

eQMS 201 eBook

A Complete Guide to Validating, Implementing, and Configuring Your Electronic Quality Management System

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A Note from Panos Boudouvas, CEO ZenQMS

The need for life sciences companies to operate with an electronic Quality Management System (eQMS) has never been clearer. Whether you're ready to move away from paper/manual systems or are looking to upgrade your existing processes, the right eQMS – one that meets you where you're at today and scales with you in the future – can be a game-changer.

In our previous guide, eQMS 101, we covered the basics. This guide, eQMS 201, goes deeper into outlining the steps necessary to efficiently transition to a more sophisticated eQMS framework.

Many of us at ZenQMS have stood in your shoes. We understand the challenges and decisions you face in selecting, implementing, and operating an eQMS. It's not just about adopting new software; it's about finding a system that aligns with your unique quality needs. We hope this eBook can serve as a valuable tool, helping to guide you towards more informed decisions and successful implementations.

-Panos

Section 1:
How to Validate Your eQMS

Now that you've done your research, secured budget approval, and found the electronic quality management system (eQMS) that's right for you, the real work begins. The good news is that we're here to help. The whole point of this eBook is to clear up the processes you might not be familiar with if you've only ever worked with a manual quality system before. The first step is software validation, or in other words, determining if the system you chose can fulfill the necessary operations of your life sciences company

Validating your eQMS can feel overwhelming; like navigating uncharted waters without knowing if you'll ever reach the shore. But fear not! In this section, we'll outline the process and discuss the FDA's recent move to Computer Software Assurance (CSA) to help relieve the stress from over-burdened quality teams.

All about validation: CSA is not a four letter word

We'll cut to the chase: you have to qualify and validate your eQMS software. There's no way around it, especially if you care about patient data safety (and, of course, FDA regulations). Unfortunately, the thought of validating software makes most quality teams cringe. Even the FDA has acknowledged that their former guidance, Computer Systems Validation (CSV), made the process more difficult than necessary.

That said, once the process is complete, proper qualification and validation will give you peace of mind about your data and the integrity of your electronic signatures. And that's really the point, isn't it? Plus, the long-term consequences of a failed or inadequate validation are not fun.

Thankfully, the FDA has replaced CSV with new validation guidelines called Computer System Assurance (CSA) that lighten the load without losing the impact. Let's cover the basics.

What is software validation?

Validation is the process of confirming that a piece of software does what it says it can do, meets your requirements as a user, and protects both your organization's and your consumers' data. In the life sciences industry, companies are required by the FDA to carry out validation on all software that could impact quality, safety, or effectiveness. That includes your eQMS.

When the FDA auditor arrives, you'll need to prove the eQMS you chose is fit for your needs and that you followed your SOPs to qualify it.

"Prove" is the key word here. It means you must have:

- A documented set of requirements for your needs
- Documentation of how your selected eQMS meets those core requirements and how you confirmed it
- These documents will help you when the auditor asks questions like:
- Did you follow your own SOPs?
- Where's the audit and risk assessment?
- Is your qualification based on your risk assessment?
- Can you explain/ defend it easily?

Old vs New: Software validation guidelines

You'll notice a few of the auditor questions above focus on a "risk assessment." That's a result of new software validation guidelines from the FDA.

The old CSV approach was all about checking the validation boxes without considering different levels of risk associated with the software you're qualifying. That created a lot more work and documentation than necessary.

But the FDA's recent move to CSA and the new GAMP5 guidelines call for a mindset switch. This approach is risk-based and focuses on the software's intended use, its level of customization, the phase of your product, and each feature's level of impact on your operation and safety as a whole.

Depending on where the software falls on the risk-based scale, the complexity of validation goes up or down.

For example, an eQMS built in-house at your organization or a heavily customized system will naturally lead to a more stringent validation process. Whereas an eQMS that was developed in accordance with all relevant standards, has a defined quality manual, and has its own validation documentation will be a much lighter lift for your organization. In fact, the new CSA guidance encourages companies to leverage the validation efforts of service providers to reduce the burden – something many were hesitant to do under the old guidelines.

With this new school of thought, patient safety and product quality are still prioritized while workload and documentation are drastically reduced.

Key Takeaway:

The FDA says format and structure aren't as important as information. Instead of restrictive templates, focus on proving the best fit-for-purpose, contextualize the risk, and recognize that not all feature failures are fatal.

How to validate a cloud-based eQMS

SaaS platforms should already have core validation documents in place and ready for review. That means you'll just need a memo or qualification document that:

- Describes the need for an eQMS, including a basic list of your requirements
- Describes your vendor selection decision, including mitigation for any critical missing requirements
- References your audit/risk assessment of the selected vendor and vendor documentation
- Justifies your qualification on a risk-based approach. (This should link back to your audit/risk assessment above and document your expected approach to acceptance testing and any re-qualifications for updates.)
- Documents your User Acceptance Testing (or Mini-PQ) that proves your specific configuration of the software is "fit for your purpose." (In this case, you aren't verifying the system functionality – the vendor did that! – you're verifying the categories, workflows, user groups etc. are all set based on your specifications.)

Should you pay for validation?

Software validation is non-negotiable, and it has a big impact on consumer safety as well as on the stress levels of your quality team. In other words, validation is table stakes and it is our opinion that it should come as a standard part of implementation.

However, some eQMS vendors charge extra fees to access their validation documents. This forces clients to either start validation from scratch (a time-intensive process with a lot of room for error) or to fork up more money on top of the core software cost. Plus, every time a client has to revalidate the system (like after a software update), they're hit with the validation fee all over again.

When talking to your eQMS vendor, make sure that you understand any costs associated with validation and validation support.

Section 2:
eQMS Implementation Tips

Implementing an eQMS is a delicate balancing act. Take too long and you risk losing out on the ROI an eQMS is meant to provide. But move too fast and your team could spend years fighting inefficient processes that could have been prevented. To avoid setbacks, we've outlined some necessary steps that will set everyone up for success, making the implementation process enjoyable and rewarding for all.

How to setup your eQMS implementation plan for success

Because an eQMS is a serious investment, the implementation you begin today will have major repercussions for years to come. Poor implementations lead to lots of wasted time and money, and can slow your time to market, so it's best to have a plan in place and know what you're getting into before beginning the journey. Here's how to stay on track:

Above all, communication between Quality, the eQMS vendor, and the rest of your company is the biggest determining factor when it comes to predicting implementation success. Keep that in mind when you're staying organized around:

- Preparation
- Timeline
- Configuration
- Support
- Adoption

Preparation

Before beginning your implementation, you'll want to document the objectives of the eQMS and the company as a whole. Not only is this required by FDA inspectors, being clear on your goals will help define what success means, especially when demonstrating the ROI of the eQMS to your C-suite later on.

Next, you'll want to have your quality team in place, and involve the IT department if necessary. Knowing who you can rely on will keep things running smoothly during the process.

Finally, you'll want to communicate this software change to the rest of the company and determine how they'll access the system once it goes live. You may have to buy additional equipment for workers at remote sites, labs, etc. in order for them to log in and stay compliant.

Timeline

Now that it's time to begin the actual implementation, you'll have to set a realistic target date to go live in the system. Consider your team's own deadlines and commitments, because more likely than not, this work will be done on top of daily responsibilities. If you're hiring an experienced consultant to help, it will add to the cost, but it will also speed up the process.

There are a few things to think about when estimating a timeline that covers the scope of an implementation:

- Type and quantity of documents migrating into the new system
- Availability of previous training histories or training records
- Assigning correct permissions to staff based on their expected usage and role
- Complexity of your training matrix (how will training be assigned/who's responsible to train on what?)
- Complexity of existing processes and how seamlessly they transfer into the new system

Additionally, it's important to know if there are fees/penalties associated with delaying or deviating from the agreed-upon proposal. For example, adding documents after the initial migration plan may come at a cost, so it's best to know that information up front.

Implementation is a delicate balance. You'll want to give yourself time to migrate the documents you want (and archive the ones you don't), and build out processes in a thoughtful, organized manner, but you'll also want to get the most bang for your buck and start using your new system as quickly as possible. Your vendor's project manager can help you set a timeline that works.

Configuration

Often, the vendor will provide a sandbox environment that allows you to test-drive the system. This is critical because some eQMS solutions are more flexible than others. You'll find out how much of your process (if any) needs to be reconfigured to adapt to their system.

Ideally, you'll be able to transfer your existing workflows into the new eQMS without a problem, as consistency will lead to better adoption from your co-workers. However, if building a custom configuration to match an existing process requires extra work from the vendor's IT team, it may affect your budget and timeline.

Support

Once you've kicked off the implementation process, the vendor's project manager and support team will be in contact to make sure you're trained on the system, staying on schedule, and managing resources properly.

Still, you never want to feel like you're on your own. That's why it's important to know how much help is available, where to find it, and how much it will cost. You'll also want to know what you can expect in terms of response time from the support team. As long as both sides are clear about what's included and what's extra, you'll be in good shape.

Adoption

Even the best eQMS is worthless if no one uses it. That's why the best implementations have a roll-out plan to ensure successful adoption. This plan can include:

- A company-wide email stating the reasons for moving to an electronic system, the short- and long-term benefits, and why employees should be excited about how the system will make their workday easier.
- Executive-level support that reiterates the importance of maintaining compliance to align with company goals.
- An invitation to attend a general user training led by the Quality team, the consultant, or a training specialist on the vendor's side.
- Supplemental materials like FAQs, articles, videos, and a link to the eQMS' knowledge base. These will help general users find answers quickly on their own.
- Internal support from the quality team - another line of defense for users to get help before resorting to submitting a ticket.
- Clear instructions on how to submit a ticket for the vendor's customer support team.

Along with a roll-out plan, it's recommended that you add a course or curriculum within the eQMS on proper usage. These instructions can be tailored and assigned to specific groups, depending on their role (General User, Document Manager, System Administrator, etc.)

Providing your co-workers with lots of information before the system goes live will keep questions and complaints to a minimum and increase buy-in for a successful transition.

Section 3:
All about eQMS Configuration

Designing an eQMS that keeps your company's quality processes in a state of control is a goal that can be reached in a few different ways. Some life sciences companies opt for customized solutions while others prefer theirs to be configurable. In this section, we'll define what goes into each process and explain why we feel one option is superior to the other.

Configurability vs. Customization: How much flexibility do you need?

Configurability: The Agile Approach to Quality Management

The words “configuration” and “customization” can often be used interchangeably, but in eQMS, they have wildly different definitions. A customized eQMS is one built from scratch to meet the specific needs of an organization. It’ll do exactly what you want it to do, but at a cost.

Customized solutions require a lot of work from the eQMS vendor, your internal IT team, and often, an outside consultant. You’ll need to know exactly what you want at the outset because you’ll be writing your own requirements, and once they’re established, making changes can be difficult and costly. Additionally, a customized eQMS takes longer to design, test, and implement, and it requires a hefty validation effort.

A configurable eQMS is a little more straight-forward. Think of it like your smartphone. Just as you personalize the home screen with your favorite, most used apps, a configurable eQMS allows you to build out your workflows to match your preferences, without being locked into that process forever. When needs change, not only is the process flexible, but you can do it yourself, without having to wait for the consultant, IT team, or vendor. Add, delete, and move things around, just like your apps.

As far as validation goes, the effort required on the customer’s end is much less than that of a customized solution. It’s limited to testing specific high-risk configurations while the core functionality is maintained. The customer can leverage the eQMS vendor for design, requirements-gathering, and the majority of the validation (which the FDA encourages). This is a huge advantage because the vendor has already built the system and is familiar with the market requirements. The heavy lifting has already been done.

Configurability Reigns Supreme

While a customized eQMS might seem appealing at first blush, it introduces complexity, delays, and costs. Custom-built features can trap you in a cycle of dependency, where each minor change adds additional time and expense. Customization might offer a wide range of flashy, exciting options when you’re first prospecting, but in the long run, it's a rigid approach.

Configurability, on the other hand, is about sustained adaptability. It's about aligning your eQMS with the specific demands of your environment – from document control to training to CAPA management – and allowing for change when the need arises. This flexible approach significantly reduces the learning curve for quality admins and general users alike, fostering faster adoption and empowering your team with intuitive tools and actionable insights. Here's what sets it apart:

- **Rapid Deployment**: Configurable systems can be deployed in approximately 90 days, a stark contrast to the 6+ months often required for fully-customized solutions.
- **Cost-Efficiency**: Avoid the hidden costs of customization, from initial development to long-term maintenance.
- **Less Work**: Smaller validation projects, as they are maintained by the vendor, not the customer. (Confirm that your eQMS vendor shares their validation data ahead of time.)
- **User Empowerment**: Place control in the hands of those who use the system daily, ensuring changes can be made swiftly and efficiently, aligning with evolving needs without dependency on IT or vendor support.

Imagine if an internal audit raised some red flags. Do you really want to wait for your IT team or the eQMS vendor to fit those changes into their schedule before a regulator shows up, or would you prefer the ability to immediately make changes yourself? We know which option we'd choose.

Opt for Ongoing Flexibility

Flexibility shouldn't be a one-time feature but rather an ongoing capability. A customized eQMS, built from the ground up, might offer you 100% customization from the start, but unless that flexibility remains embedded and accessible to stakeholders who actually use your eQMS, that promise of flexibility is an empty one.

Our advice? Ask about continued flexibility that gives your team autonomy to adapt to new regulations, organizational changes, or operational shifts without the constraints of custom-coded systems.

By choosing configurability over customization, you invest in a solution that grows with you, ensuring your quality management system remains a robust, responsive ally in your quest for excellence and compliance.

Why does eQMS configurability matter to life sciences organizations?

To put it simply, it's a game changer.

If you couldn't already tell, configurability is close to our hearts. It might sound like jargon, but it's the best way to describe how to make sure your eQMS feels like it was made for you without having to over-invest in the time and resources it takes to actually build it yourself.

Adapting to Change

Let's be honest, keeping up with the pace of the life sciences industry can feel like chasing a moving target. There's always a new competitor on the horizon. Meeting the specific demands of clients and sponsors is not always easy. And time-to-market looms over everything. Changes can also occur due to internal forces: new leadership, a merger/acquisition, or other strategic decisions; pursuing an ISO certification for example. Regardless of the reason, having a configurable eQMS allows you to adapt on the fly, which means less sweating over new requirements and more focus on what matters—innovation and safety.

Growing Without the Growing Pains

Whether you're a startup ready to conquer the world or an established player expanding your horizons, a configurable eQMS seamlessly grows with you. Adding modules and introducing new training courses are a breeze. And so are adding or changing approval workflows, and building new Change Control processes and Issue management processes. Tasks like activating/deactivating employees and assigning permissions can be done in minutes. No, it might not be quite as simple as 'just add water!' but for a quality management system that is critical to supporting your processes and team growth, it's pretty close.

Making Things Click

Integrating a new system shouldn't feel like fitting a square peg into a round hole. Configurability means your eQMS slots into your existing processes like a missing puzzle piece, making everyone's life a bit easier.

Avoiding the Money Pit

Custom workflows built from the ground up sound cool until you see the price tag and understand the timeline. Endless rounds of validation and revisions from your vendor, your internal IT team, or an external consultant that doesn't want to leave can also put a strain on your resources (and your patience!) Configurability offers the personal touch you want without emptying your pockets or dragging things out.

Data That Talks to You

In a world driven by data, a configurable eQMS lets you dial into the metrics that matter most in a way that makes the most sense. Better visibility leads to smarter decisions and sharper strategies.

Everyone's on Board

Configurability leads to a painless eQMS experience, encouraging everyone to hop on board the quality train. Sure, no one loves reviewing SOPs or completing training assignments, but when those processes can be set-up simply and intuitively, it leads to higher compliance rates and happier teams (and happier Quality Directors!)

Navigating Risks Like a Pro

In the high-stakes world of life sciences, managing risk is everything. Some eQMS modules allow you to manage issues based on their risk level, and link their associated tasks to ensure a timely resolution. They also provide full visibility to stakeholders and management in a single view.

So, why does configurability matter? Because in the fast-paced, ever-changing world of life sciences, having a system that adapts to you—not the other way around—makes all the difference. It's about making your life easier, your processes smoother, and your products safer. And that's something we can all get behind.

3 eQMS configuration best practices you can begin immediately

Improving the flexibility, or more accurately, the configurability of your eQMS should be a key goal for your quality team. That's because a configurable system allows you to modify settings, templates, and workflows to better align with your company's QMS and compliance requirements, all without needing a PhD in Computer Science.

An eQMS should make quality management easier, but if you're not taking full advantage of configuration within the platform, or your configurations are outdated, you might actually be making it harder. Here are three best practices to make sure your eQMS is an asset, not an obstacle.

1. Keep it Simple

The right eQMS isn't necessarily the one with the most bells and whistles. It's the one that can maintain the flexibility that best supports your company, even as you scale up.

As you're configuring workflows and processes into your eQMS, it's tempting to add every potential role, document category, stage, etc. you could ever dream of needing, especially if you're used to dealing with a rigid system. But overcomplicating your configuration could actually cause more stress – the exact opposite of what your eQMS should do.

Remember, you can always add in configurations in the future. Don't over complicate your system up front. This is why it's so important to choose an eQMS that makes configuration easy

2. Look for Redundancies

When you switch from paper and/or spreadsheets to an eQMS, a truly configurable platform allows you to translate your current quality processes into the system almost exactly. But just because you can doesn't mean you should. If you didn't scrutinize your QMS workflows while moving them into your eQMS, it's likely a few redundant stages or signature steps made it into your configuration. Employee turnover, process changes, and company growth can all lead to configurations that no longer serve your team, too.

At least once a year, you should clean out the eQMS clutter. To judge whether a configuration might actually be slowing down your processes, look for things like:

- Repetitive signature steps
- Unnecessary data fields
- Workflows with too many stages

3. Think outside the box, not out-of-the-box

Though an "out-of-the-box" (aka one-size-fits-all) eQMS usually means you can get up-and-running pretty quickly, this type of system is pretty rigid. What you gain in speed, you give up in flexibility. Plus, you lose the familiarity of your tried-and-true quality workflows.

That's why a lot of life sciences companies prioritize a robust, configurable eQMS over an out-of-the-box solution. The ability to transform it into exactly what you need it to be is a powerful feature. But while you may already know how a configurable system benefits your quality team, a truly configurable eQMS can be used across different departments. For example, with the right data-fill customizations and categories, HR documents like employee onboarding forms can easily be created and automated in the system. Encourage your team to think creatively. By thinking outside the traditional confines, you can take full advantage of everything a configurable eQMS has to offer.

Section 4:
Audit Preparedness for your eQMS

Your eQMS shouldn't just be a repository of quality documents. Ideally, it should serve as a dynamic tool that fosters an always-audit-ready culture. From understanding the regulatory landscape to implementing best practices for continuous improvement as it relates to compliance, we've laid out some helpful strategies to help prepare your organization for audits.

eQMS Best Practices for Simpler Audits

Deciding on your company's approach to audits can seem like a giant task, but tackling necessary updates sooner rather than later can make all the difference. We're sharing some steps you can take to get your company in shape for a smoother year of audits.

Step 1: Perform an honest assessment of your operation

To get fit, you wouldn't run into a new gym, jump on the closest weight machine, and hope for the best, would you? Instead, you'd likely identify what you'd like to work on ahead of time and then set actionabe, achievable goals.

The same is true with audit prep. Performing regularly-scheduled risk-assessments is a low-stakes way to find out where you're deficient before having to answer to an auditor. By setting (and meeting) benchmarks and holding people accountable before a regulatory audit takes place, when the time comes, you've already taken steps towards proving how you're keeping quality processes in a state of control.

Step 2: Train your team on good audit etiquette

Every great team needs a great coach. So before the regulator knocks on your door (or visits your company remotely) you should set aside time to instruct colleagues on proper audit etiquette. It's a tall order to keep emotions in check when an inspector is firing direct questions at you and demanding to see specific SOPs, but it's important to remember that they're auditing the process, not the individual. So try not to take it personally.

The more you practice remaining calm and acknowledging that they're performing an inspection, not a witch hunt, the better the chances are of a shorter audit that allows everyone to get back to business as usual.

That includes having all staff (not just QA) up-to-date on their training, familiar with potential issues and scenarios related to their job (workstation cleaning, equipment use, etc.), and informed about where to find relevant documents. They won't be answering the majority of the inspector's questions (nor should they!), but if they are asked a direct question, they should be prepared to answer honestly and succinctly.

Step 3: Keep an open mind

A perfect physique doesn't happen overnight, and neither does a perfect quality process. For real results, you keep at it. Going into an audit, you should feel confident about the steps you've taken to make your company's processes safer and be ready to defend them. But when you're in an audit, you're given the chance to see different perspectives that allow you to learn. An audit can reveal pathways to decrease risk and identify strategies for further improvement.

Success Story: ZenQMS Keeps Precision Medicine Group, LLC Audit-Ready Across Their 40+ Global Sites

About Precision Medicine Group

Vanguard Clinical Inc. (Vanguard) is a boutique CRO and FSP based in San Diego, CA. Vanguard's mission is to provide white glove service to clinical trial execution by combining passion, transparency, and fully customized solutions to elevate and advance patient care.

Business Need

Getting a company of 3,000+ global employees trained, compliant, and audit-ready is no easy task, but that's exactly what VP of IT PMO John Shay and Project Manager Nicole Klee accomplish every day at Precision. The company has been growing exponentially for the past 12 years to include clinical trial organizations (CROs), labs, and specimen storage facilities, among others.

Maintaining such a broad footprint across the clinical pharma development spectrum means Precision hosts multiple coordinated audits across the network annually. But doing so was becoming increasingly difficult without a way to absorb documents from business units and aggregate and manage those documents and SOPs centrally for the entire company. It was equally challenging to manage and report on training compliance across the organization. Adding to that, many of the business units within Precision were leveraging paper-based/manual systems.

With an increasing GxP audit and compliance burden and looking to simplify their training and document management process, Precision searched for a scalable electronic QMS with the functionality and features they needed at a reasonable price.

"A lot of the quality systems we looked at had a slick interface, slick workflows, and all the bells and whistles we're never going to use," said John Shay. "We didn't need the kitchen sink. We needed function over fashion."

Staying audit-ready was the key. Precision was looking for a central document management system, applicable at scale, that could satisfy industry requirements for producing training dossiers and provide evidence that their documents were being held in a controlled system with proper access and security. They also needed to be able to easily digitize imported SOPs from business units across the organization with a secure, scalable, and economical solution.

“We completed our analysis and landed on ZenQMS,” said John. “The features, functionality, and price point were perfect for what we wanted.”

Business Impact

As a Project Manager at Precision, Nicole Klee works closely with the QA team and has seen the positive changes ZenQMS has made to her day-to-day operations.

“The time it takes to prepare for an audit and execute audit requests has decreased exponentially,” said Nicole. “We’re no longer chasing down wet-ink signatures or going through training binders to see who’s out of date. That’s where I see the ROI. Because of the scrutiny of the audits we go through, it’s very significant.”

Moving to an electronic system has helped bring harmonization to Precision’s sites by putting all of their quality documents in one place and increasing training visibility.

“ZenQMS has made the lives of our managers and QA folks so much easier because the training matrix is intuitive and we can see exactly which groups everyone is in and what courses they’re assigned to,” added Nicole. “And it drives up compliance. Paper doesn’t turn red when you’re overdue.”

And Nicole isn’t shy about her appreciation for the ZenQMS support team, specifically when it comes to helping Precision’s new employees get trained and compliant once they’ve come onboard. “The ZenQMS help desk is fantastic, cordial, and prompt. We’ve had some tough one-off questions, and we powered through them together, so I always like to throw them some praise when I can.”

A topic that Quality Leaders can agree on (and one that often gets overshadowed), is the importance of Quality’s role in the financial health of an organization, and how a robust eQMS can help provide security and stability. John stressed how Quality should be viewed as the revenue protection engine, and that, in terms of budget priority, they deserve a seat at the table.

“People say, ‘You guys don’t generate revenue.’ ‘No, we protect revenue!’ said John. “When we’re looking to sign a customer deal worth millions and they audit us, we have the evidence to show that we’re following proper processes, we have training procedures in place, and our documents are in a state-of-control. It’s how we measure and manage our business and ensure outsiders that we’re following good business practices.’ We protect the company’s revenue and ZenQMS is a critical component of that.”

“There’s no question ZenQMS has been worth it, not only as an audit preparedness, readiness, and evidence production tool, but as a platform as a whole. It’s stood the test of time against all the audits that we’ve had, and it’s a part of every one of them.”

Regulated organizations of any size don’t have to struggle to find the features and functionality they’re looking for in a quality management system. Schedule a consultation with a ZenQMS sales representative and we’ll help find the best solution for you.

Section 5:
About ZenQMS

ZenQMS is an eQMS platform that empowers QA 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 QA 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 for 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 hostage. All members of your team can have access from day one.
- **Effortlessly configurable.** ZenQMS is fully configurable and easily adapts to match your specific processes, operations, and quality needs. And as your company grows, our system keeps pace – without added cost.
- **Simple validation.** We don't charge for access to our validation materials and our support team will guide 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 your QA 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
The Less Stress eQMS for Life Sciences