EBOOK

Sponsor-Ready Quality Management for CROs

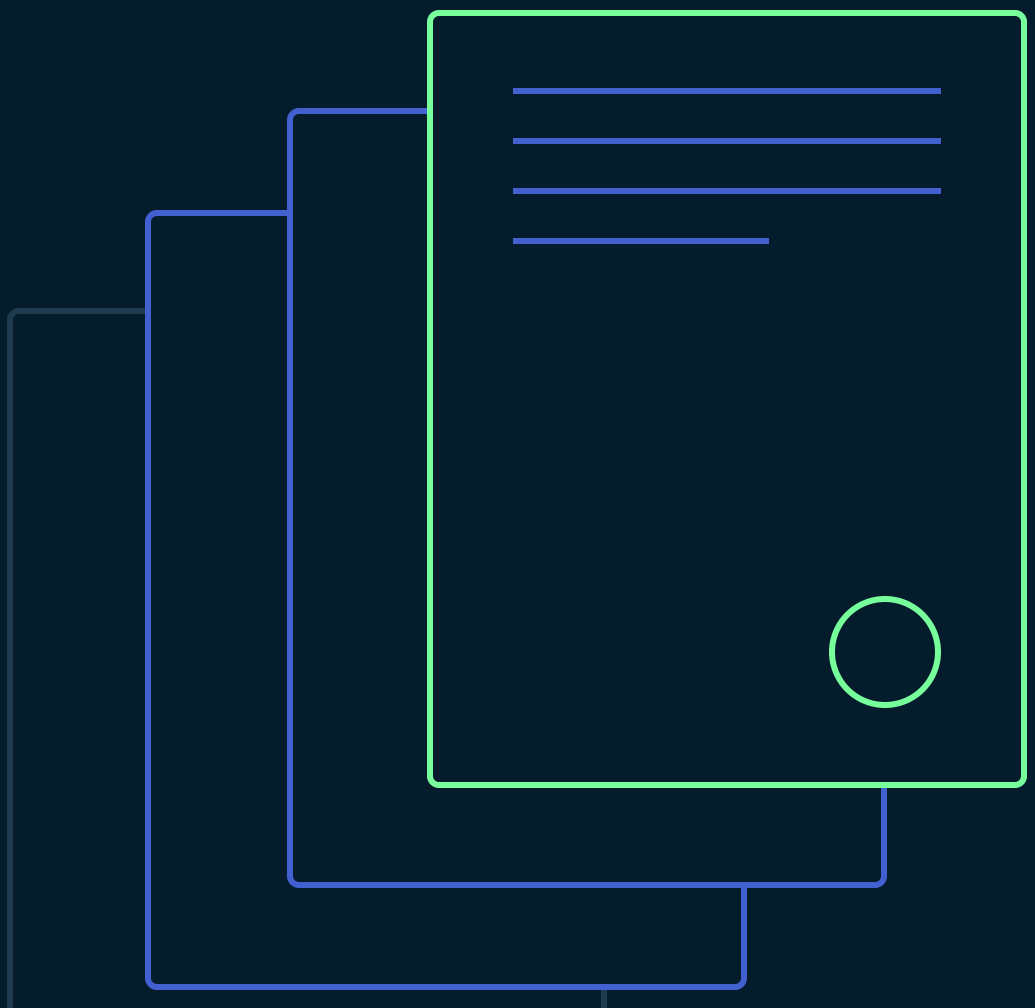


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SECTION 01

01

5 Quality Signs Sponsors Look For During CRO Vendor Evaluation

5 Quality Signs Sponsors Look For During CRO Vendor Evaluation

When Sponsors evaluate **contract research organizations (CROs)**, scientific expertise, therapeutic experience, timelines, and pricing all matter. But once an organization has shown it can perform the work, another question takes center stage: Can we trust this organization with our program?

The answer relies on the quality operation behind the work.

During vendor qualification, sponsors are looking for evidence that quality processes are well controlled, scalable, and consistently followed. They want confidence that if their program grows, regulations change, or an unexpected issue arises, your organization has the processes to respond effectively.

In essence, they're looking for signs of quality maturity, and the organizations that can prove it will get a leg up on the competition.

Every Sponsor has its own qualification process, but there are several characteristics that consistently signal a mature quality operation. If you're hoping to expand your Sponsor network, here are the five quality maturity signs you'll want to showcase:

1. Audits are thorough, but not complex

Sponsors have a responsibility to ensure every vendor they work with is qualified, compliant, and capable of managing potential issues before risks emerge. (In fact, this Sponsor expectation was recently enforced with the **updated ICH E6(R3) guidance**.)

For CROs, this means handling frequent audits. And the organizations that make those audits easy for Sponsors will likely make the shortlist of preferred vendors.

For example, imagine a Sponsor asks to see the current version of an SOP, the associated employee training records, and every change that has been made to the procedure over the last two years. Which CRO would you work with again based on their response?

Option 1

The Quality team searches through multiple folders, emails another department for training records and waits an hour for a response, and then spends the next twenty minutes confirming they have the correct document version.

Option 2

The quality team retrieves everything within minutes. The document history, approvals, training records, and audit trail are all connected, complete, and easy to follow.

Both teams may ultimately provide the same information, but the experience leaves a vastly different impression of the organization's state of control.

That's why mature organizations don't think about audit readiness as something they do a few weeks before an inspection. It's simply the byproduct of well-managed quality processes.

Pro Tip: Look for an **eQMS that includes audit sharing capabilities**. This is a feature that allows Quality teams to create a secure, read-only workspace containing only the documents, records, and quality events relevant to a specific audit. Instead of navigating an entire system, Sponsors get only what they need when they need it.

But be careful – streamlined audits don't mean sparse audits. Make sure your system of record tells a complete story:

YOUR SYSTEM OF RECORD SHOULD ANSWER

- Who approved this document?
- When was it revised?
- Is it attached to a CAPA?
- Which employees completed training on the new version?
- If AI was used to help generate content or perform an action within the quality system, can that activity also be traced?

Pay special attention to that last bullet. As organizations incorporate AI into regulated quality processes, **audit trails must capture AI-assisted activities** alongside human actions.

Get audit management tips & more

- Check out **QMS University** to learn more audit management best practices, plus get templates and step-by-step guides across all facets of quality management.

2. Your quality system flexes to fit sponsor needs

Each Sponsor comes with a different set of expectations for workflows, approval processes, documentation requirements, etc. and they expect their vendors to adapt to their preferences... not the other way around.

The problem is that some eQMS platforms are actually pretty rigid, forcing specific naming conventions or workflows (or charging serious fees to customize the system). For the CROs that use these systems, that means potential red flags like:

- Approval workflows that are significantly different than Sponsor requirements.
- Employees maintain information outside the system because of its inflexibility.
- Manual workarounds that create inconsistencies from one study or client to the next.
- Time-consuming or costly system customizations every time a new Sponsor or region introduces different requirements.

That's why flexibility – a.k.a. **configurability** – is the name of the game for CROs hoping to build stronger Sponsor relationships.

Here's the catch: Some vendors say they're "configurable" when they really mean "customizable." To find the truth, ask questions like:

- **Can workflows be modified without custom development?** As Sponsors request different approval paths or quality processes, your team should be able to make adjustments without IT intervention.
- **Can forms and fields be updated as requirements change?** Your eQMS should make it easy to add, remove, or modify fields as needed.
- **Can permissions and roles be configured for different studies or clients?** As your organization grows, you'll need to ensure the right people have access to the right information – and only that information – at all times.
- **Can the system scale without extensive reconfiguration?** Supporting a new Sponsor, expanding into another region, or taking on additional studies shouldn't require starting from scratch.

3. Your training program works – and you can prove it

Sponsors want more than a list of completed training assignments. They want confidence that the right employees are trained on the right procedures, that they understand those procedures, and that training is contributing to better quality outcomes. Here are a few signs of a **mature training program**:

You measure competency, not just completion.

"Read and understood" may satisfy a training requirement, but it doesn't confirm employees retained the information. Competency tests, assessments, or other knowledge checks can help demonstrate that training is actually effective.

You can quickly demonstrate training compliance.

During a Sponsor audit, Quality teams should be able to report on who has completed required training, when they completed it, and which version of the procedure they were trained on. At-a-glance dashboards and real-time reporting make it much easier.

You connect training to quality outcomes.

Mature organizations look for trends, like whether a revised SOP or targeted training initiative led to fewer deviations, recurring issues, or other quality events. That data helps demonstrate that training is reducing risk, not just checking a box.

4. Issues are traced in detail from discovery to resolution

The fewer deviations that happen, the better – but deviations will happen. Sponsors don't expect CROs to be perfect, but they do expect them to respond quickly and effectively when quality events occur.

The organizations that can clearly demonstrate the full lifecycle of every quality event (and do it quickly) will protect their reputations among Sponsors. This means being able to prove:

- How and when the issue was identified.
- Who investigated the event and what the root cause was.
- What corrective and preventive actions (CAPAs) were implemented.
- Whether those actions were effective at preventing recurrence.

That level of traceability gives Sponsors confidence that issues are managed through a consistent, controlled process designed to reduce future risk.

It's why it's important for your eQMS to **connect quality events** rather than treating them as separate records. Deviations, investigations, CAPAs, change controls, supporting documents, and approvals should all be linked together, creating a complete history that's easy to follow during audits and Sponsor reviews.

KEY DATA POINTS TO HAVE ON HAND

- Average days to complete an issue or change control
- Percentage of issues closed by the established deadline
- Average recurrence of issues

The easier it is to tell the story of a quality event from beginning to end, the easier it becomes to demonstrate that your organization has a mature approach to continuous improvement. (See more **key data points**.)

5. Quality data is actionable

You can collect all of the data in the world, but if you can't act on it, you don't have "insights," you just have numbers in a spreadsheet.

Sponsors want confidence that you're monitoring for trends, identifying potential risks early, and making improvements before risks become problems. In other words, they want evidence that quality management is proactive, not reactive. Start by making sure your quality reporting tool can track things like:

- **Deviation trends.** Are issues increasing, decreasing, or recurring in certain areas?
- **CAPA effectiveness.** Are corrective actions preventing similar issues from happening again?
- **Training effectiveness.** Have targeted training initiatives led to measurable improvements in quality outcomes?
- **Audit findings.** Are the same observations appearing audit after audit, or is the organization learning from previous inspections?
- **Process performance.** How long does it take to close deviations, complete change controls, or approve critical documents?

Then, make sure your tool helps you take action. A couple of nice features to look out for are:

Features that turn data into action

- **Automatic alerts based on custom-set data triggers:** Set the threshold for alerts on any dashboard metric or period-over-period changes and get notified automatically when it's hit.
- **Scheduled report exports:** Set automatic, recurring dashboard and data exports and have them delivered to the exact stakeholders who need them to make informed decisions.

When quality data is easy to access and understand, teams spend less time building reports and more time acting on what the data is telling them.

Quality maturity is the competitive advantage

Every CRO has talented scientists and experienced teams. What separates one organization from another is how confidently it can demonstrate the quality systems supporting that work.

Remember the phrase "show, don't tell." The more CROs can make their quality maturity visible, the more they can strengthen Sponsor confidence, simplify vendor qualification, and create a competitive advantage that extends beyond a single study.

Want to see how ZenQMS can support a quality program that impresses Sponsors? Our team is ready to chat!

SECTION 02

02

3 Ways an eQMS Keeps CROs and CDMOs Audit-Ready

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It's the night before an audit. Is your team: A) frantically searching for training records, double checking SOPs across multiple sites, and tracking down last minute signatures; or B) sleeping soundly knowing everything is where it needs to be?

For CROs and CDMOs that face frequent audits from sponsors, clients, and regulatory bodies, anything other than Option B means a lot of sleepless nights for your Quality team.

What is audit-readiness?

"Audit-ready" means an organization is fully prepared to host an external inspection or audit at any time with very little notice, and is confident that it will meet or exceed the auditors standards.

That makes staying audit-ready priority number one for these life sciences contractors. When dealing with teams and sites spread around the globe, "audit-ready" can seem like an impossible standard... unless your Quality team has the right tools. Here's how an eQMS makes it easy for CROs and CDMOs to embrace audit-readiness.

1. Maintain version control across all sites

It's common for CROs and CDMOs to have sites in multiple locations, sometimes spanning across several countries, each with its own regulatory requirements and Sponsor/client needs. It's also common for a rogue, outdated SOP to be floating around one of those locations if the organization is still using paper or spreadsheets to manage Quality. Manual systems like these might require someone on the Quality team to drive from site to site to collect old documents and replace with updated versions, or put the responsibility (and risk for error) on site teams to toss out retired documents.

An auditor wants to see that every site has access to only the most current, approved versions of documents, whether those are clinical trial protocols, SOPs, quality manuals, manufacturing procedures, or anything in between. That's where an eQMS shines. With an eQMS, all documents are stored in one location and can be updated or retired with a few clicks, making sure everyone has access to the most accurate version. Plus, it's easily searchable, which means every document is exactly where you need it, when you need it.

2. Manage – and prove – training compliance for a dispersed team

A quickly growing team spread across global sites is nightmare fuel for Quality teams tasked with training management on a manual Quality system. When you have to assign, track, and most importantly, prove every person is trained on Sponsor protocols across all sites with nothing but pen, paper, and Excel, staying audit-ready can feel like a pipedream.

An eQMS takes this herculean task and automates it. Training can be assigned by group and reminders are sent automatically, empowering Quality leaders to keep teams compliant at all times, not just in preparation for an inspection. And when a Sponsor or client asks to see all training records on a specific SOP, an eQMS means real-time reports can be pulled at an audit's notice.

3. Make change actionable and trackable

Whether it's a product's design, a clinical protocol, or a manufacturing process, change happens. And auditors want to know all about it.

An eQMS makes it easy to document who made the change, when it happened, and why – all answers you'll appreciate having at the tip of your fingers when the inspector arrives. As an added bonus, managing change controls in an eQMS ensures users follow your defined workflow for documenting and approving changes. With a controlled system, nobody can skip a necessary step, so you always have clear evidence of compliance and proper change management.

And it's not just the Quality team that will appreciate the perks of an audit-ready eQMS. It's also a breath of fresh air for inspectors who vastly prefer looking at easy-to-read reports and audit trails over sifting through stacks of paper or mind-melting spreadsheets.

The bottom line

- Audit readiness isn't only about passing inspections – it's about establishing a culture of trust, efficiency, and compliance that spans the entire organization.

SECTION 03

03

How to Prepare for a Sponsor Inspection: 5 Tips for CRO Quality Teams

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Sponsor inspections aren't exactly a rare occurrence for Contract Research Organizations (CROs). In fact, in our 2026 Quality Management Industry Report, CRO respondents told us they host upwards of 12 external audits a year.

But while frequent audits are simply a fact of life for CROs, an impending inspection can put even experienced Quality teams on edge. The good news is that inspection readiness doesn't require perfection.

What actually matters is your ability to demonstrate control: that you know what's happening within your quality system, your people are following established processes, your records tell a consistent story, and when something isn't going according to plan, you know what to do about it.

Of course, inspection readiness should be built into your everyday Quality operations... but it's still a smart move to double check your processes in the weeks before a Sponsor arrives. Here are the five areas to prioritize:

1. Review your documentation – and make sure you can actually retrieve it

Documentation is an obvious place to start, but it's not enough to confirm the required documents exist. Before the inspection, review your documentation to confirm:

- Required periodic reviews are completed.
- Employees have access to the most current approved SOPs.
- Obsolete or uncontrolled SOPs aren't circulating in the lab.
- Required signatures, approvals, and other documentation are complete.
- Raw data and supporting records are appropriately documented.
- Documents and records can be quickly retrieved.

That last point is key. It doesn't matter how controlled your documents are if you can't find them when the inspector arrives.

Sometimes, Sponsors will give you a heads up on which records they'd like to check. Maybe they want to see a list of employees working on their trial, which will signal they're interested in training histories, CVs, job descriptions, NDAs, or other documentation demonstrating that those employees are qualified to perform their assigned work.

Or maybe they won't, in which case you'll be extra thankful for a system that makes finding documents quick and easy rather than shared drives or disconnected spreadsheets.

Prepare with a document retrieval drill

- Pick several records and ask the appropriate employees to retrieve them as though an inspector were waiting. Track not just whether they find the records, but how long it takes and whether there's any confusion about which version is active.

2. Follow your own trails before the inspector does

There's one question inspectors love to ask when they first arrive: "So, what's new?" It points them in the direction of change, which then gives them a clear trail to follow in order to prove control.

For example, let's say your CRO recently installed a new piece of equipment. That one change may spark an inspector to ask for the equipment's validation records, the change control attached to the equipment switch, the new user manual, an updated SOP, the risk assessment, updated work instructions, the training records of employees who use it… you get the idea.

Before your next Sponsor inspection, get ahead of the question. Make a list of what's changed since your last inspection. Depending on your organization and the trial, that could include:

- New equipment
- New protocols
- New suppliers or subcontractors
- New technology or software
- Significant personnel or process changes
- New applications of emerging technology such as AI

Then follow the evidence for each significant change.

Failed control

→ issue → investigation → CAPA → effectiveness

New equipment

→ change control → risk assessment → validation → SOP → training

New supplier

→ qualification → supplier documentation → received material → trial use

This shifts inspection preparation away from, "Do we have everything?" toward a more telling question: "Can our records demonstrate that our processes worked the way we say they did?"

3. Don't hide gaps. Demonstrate control over them.

If you could wave a magic wand, you'd enter an inspection with your documentation current, training completed, all CAPAs on schedule, suppliers qualified, not one signature overdue and quality metrics exactly where you want them. Unfortunately, quality teams are usually short of magic wands.

It's not unlikely something will be amiss when the inspector arrives, whether that's an overdue CAPA, training compliance under your internal benchmark, a late signature, or anything in between. Of course, some issues are bigger red flags than others, but in most instances, the inspector cares about your state of control more than your state of perfection.

FOR A KNOWN GAP, BE ABLE TO EXPLAIN (AND HAVE DOCUMENTED)

- **1.** What happened?
- **2.** Why did it happen?
- **3.** What risk does it create?
- **4.** What are you doing about it?
- **5.** Who owns the remediation?
- **6.** When will it be resolved?

Before the inspection, review your **key quality metrics** and look closely at anything outside your CRO's established acceptable range, including:

- Training compliance
- Overdue CAPAs
- Open deviations or other quality issues
- Periodic review compliance
- Supplier qualification status
- Change control status

4. Inspect the operation, not just the QMS

A sponsor inspector won't spend the entire visit sitting in a conference room reviewing SOPs. They may walk through the lab, open a freezer, inspect your bench, reagents, equipment, and/or records associated with the sponsor's trial.

Before inspection day, conduct your own walkthrough and look at the environment through an inspector's eyes. Again, these things should always be true, but before inspection, take a moment to confirm your quality processes are working and that:

- Refrigerators, freezers, incubators, and other applicable equipment are maintained.
- Required temperature or equipment logs are complete.
- Reagents and chemicals haven't expired and are properly labeled.
- Opening and expiration dates are documented where required.
- Materials and chemicals are stored appropriately.
- Equipment has appropriate qualification, validation, maintenance, and supporting documentation.
- Employees are following PPE requirements and appropriate laboratory practices.
- Work areas meet applicable procedural and safety requirements.

And don't forget about the underlying trial evidence. For example, an inspector might select a particular sample run and ask to see the associated control results. Can you demonstrate that the controls passed? If they didn't, can you demonstrate that the failure was handled according to your procedures?

Make sure you know where to find lab notebooks, raw data, instrument outputs, QC results, control results, and other trial-specific records.

5. Prepare your people

An inspector doesn't necessarily have to direct every question to your Head of Quality. They may walk through the facility and strike up a conversation with an employee, which adds another layer of unpredictability to the inspection.

Even the most experienced employees can get nervous when the person asking the questions is carrying a clipboard. It's critical to prepare your staff before the inspector arrives. That's where a mock inspection comes in handy. Designate an "inspector" and have them:

RUN A MOCK INSPECTION

- Request specific documents.
- Select a deviation, issue, or CAPA and follow its history.
- Ask for training records for specific employees working on a trial.
- Walk through the laboratory or facility and examine equipment or storage areas.
- Speak spontaneously with employees.
- Ask about significant changes since the previous inspection.
- Time how long it takes to retrieve requested records.

This helps your employees understand what to expect while also uncovering the gaps that aren't immediately obvious. You can then use the results to strengthen your actual inspection preparation.

Bonus tip: Remind employees that they don't need to know everything. If someone doesn't know the answer to an inspector's question, guessing isn't the solution. Instead, encourage them to explain that they don't know and direct the inspector to the appropriate supervisor.

SECTION 04

04

3 Ways CROs and CDMOs Can Improve Site Training

3 Ways CROs and CDMOs Can Improve Site Training

Whether it's a client, a sponsor, a regulatory body, or your own team performing a mock audit, sooner or later, somebody is going to look at your training records. That means it's important for quality teams to constantly keep them up-to-date and in a state of control.

For life sciences contractors like CROs and CMOs/CDMOs that have sites and employees spread out across the globe, that's not always easy. But there are steps these organizations can take to help keep training organized wherever they're located. Here are three that CROs and CDMOs should consider:

1. Add more robust testing

You're probably familiar with the "Read and Understood" method of training verification. After reading (and understanding) an assigned document, users check a box, sign it, and as far as everyone is concerned, they're trained. For some documents, surface-level accountability like this might be acceptable. However, plenty of quality professionals and their supervisors will tell you they'd prefer a bit more oversight and a better way to confirm employees are properly trained, especially on critical SOPs.

That's where SCORM training can help. SCORM is a file type that is the technical standard for eLearning programs across industries. Where Quality is concerned, the format allows creators to design and build interactive training programs that are a cut above basic "Read and Understood" methods. SCORM files add more depth to training by pairing quiz questions with audio and visual components that can more accurately test a user's grasp of the material. SCORM also allows admins to quickly check the results of each users' score to determine if retraining needs to take place.

For CROs and CDMOs in particular, SCORM-based programs are a more robust way to prove to sponsors, clients, and inspectors that employees are properly trained on their relevant materials. To add this level of reassurance, make sure you have an electronic quality management system (eQMS) that can **host SCORM files**.

2. Focus on traceability

The auditor is waiting… do you know where your effective SOPs are? For CROs and CDMOs with remote testing facilities and manufacturing sites, it's tough enough enforcing compliance, let alone making sure everyone is training on the most up-to-date documents. Paper-based QMS solutions make it difficult to get timely signatures from site to site and increase the chances of documents getting lost in the shuffle. And with every facility acquired and employee added, a company's **training matrix** can quickly spiral out of control. The reality is, if additional complexity affects your ability to locate the right document quickly, training compliance is now at risk. This isn't the look you want to present to an inspector or potential client.

Here's the thing – moving to the cloud is only half the battle. Sure, an Excel file might be easier to find on a server compared to a filing cabinet (provided there aren't multiple drives with different naming conventions), but just because it's in the cloud doesn't automatically mean it's 21 CFR Part 11 compliant for electronic signatures. An auditor or potential client will expect some proof.

The solution to keeping quality documents and SOPs traceable and in a state of control is to **migrate them into a validated eQMS**, where they can be stored securely and immediately accessed by everyone (with proper permission, of course). Even better, once inside the system, training documents can be automatically updated to the latest version, giving quality leaders one less thing to worry about. No more walking around a facility with a stack of SOPs, swapping out the old ones for the latest versions!

"The training features were superior to other solutions, our entire company could access the system, and ZenQMS was more affordable. It was almost night and day."

Neil Sharma, General Manager
Boston BioProducts, a CDMO providing custom buffers to thousands of labs worldwide

3. Utilize a training dashboard

With many CROs and CDMOs spread across multiple sites, staying audit-ready at all times can be a challenge. That's why having instant visibility into company-wide training status is so important. The faster you can see who's overdue on their training, the faster you can alert them and get them back on track. The same is true for regulatory, sponsor, or client audits; the faster you can provide them with the information they're looking for, the better.

That's where a training dashboard comes in. The dashboard is essentially a snapshot of who's compliant, who's overdue, and what training courses they've been assigned to. For a quality administrator at a CRO or CDMO, it's ideal because they can have the data at their fingertips in seconds, and can quickly pass it along during a remote or on-site audit. The training dashboard is a useful tool for employees as well, because a quick glance tells them exactly what's expected as far as training is concerned.

An eQMS, especially one that's intuitive and easy-to-use, will come standard with a training dashboard. So instead of sifting through binders, filing cabinets, and multiple cloud drives just to get a compliance report, CROs and CDMOs can have training status information delivered in just a few seconds, with just a few clicks, down to the individual, course, or group. And intuitive infographics allow quality leaders to dig into details more efficiently without the fear of anything falling through the cracks.

"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. And it drives up compliance. Paper doesn't turn red when you're overdue."

Quality Administrator
Precision Medicine Group, a global CRO

With that kind of visibility into company-wide training status, combined with automatic notifications from the eQMS about upcoming training for all employees, imagine how much easier it will be to keep everyone compliant. And for remote audits, the same control applies. An eQMS makes it easy to provide inspectors with view-only access into an audit account with exactly the documents they've requested, while protecting everything else.

If you're looking to improve compliance at your CRO or CDMO, ZenQMS offers the configurability and capability necessary to strengthen and organize existing training while providing near-instant company-wide visibility in an easy-to-use, validated platform. For more information, **talk to us** and find out how we take the stress out of eQMS.

SECTION 05

05

4 Ways an eQMS Transformed Operations for CROs and CMOs

4 Ways an eQMS Transformed Operations for CROs and CMOs

In recent years, regulated life science companies have transitioned away from traditional paper and spreadsheet-based quality systems to take advantage of the benefits of their electronic counterparts. This makes sense – electronic quality management systems (eQMS) are more efficient than manual solutions and significantly better at keeping critical documents and data safe and accessible.

For contract research organizations (CROs) and contract manufacturing organizations (CMOs) in particular, eQMS solutions offer additional advantages. Here are 4 ways that ZenQMS' CRO and CMO customers have transformed their quality operations for the better since going digital:

1. Audit confidence

For CROs and CMOs, the ability to host simultaneous, remote audits across multiple sites is a powerful tool that can positively affect growth and success. An eQMS offers near-instantaneous training visibility, allowing Quality leaders to know exactly who owes what, when it's due, and exactly where to find it. When you're in the middle of an audit, every second counts.

"Thanks to ZenQMS, my team is now able to quickly and accurately respond to audit inquiries and our error rate is significantly lower than with our prior quality management system."

Heather Faber, Regulatory Compliance Analyst
Avara, an international CDMO

When you're walking into an audit, there's no substitute for the assurance you feel knowing your eQMS has the stamps of approval regulators are looking for. These include CFR 21 Part 11/Annex 11, ISO 9001/ISO 27001, a SOC II Type 2 report, and USDM Cloud Assurance certification.

"Being audit-ready at all times is a critical component of our business and our ability to effectively support the work our team does in support of our clients' projects. ZenQMS has facilitated that for us in a way that exceeded my expectations." – Tara Franks, COO, Translational Drug Development

Having on-premises file cabinets or servers invites more risk into the auditing process and gives inspectors the opportunity to ask additional questions. Why add more stress to an already stressful situation?

2. Training compliance for ALL users

If you're a quality professional spending all day in an eQMS, chances are you can figure out how to find what you're looking for. (Although for TD2, that wasn't the case. Read their customer story here.) But for those without a Quality background, or for users who only sign in a few times a year to complete training, an easy-to-use eQMS can make a significant difference.

Members of Quality teams often wear multiple hats and have better things to do than chase down those who aren't compliant, especially if they're working at remote sites. An eQMS automates the training compliance process, giving that time back to Quality teams so they can focus on more important tasks.

> **"Every other week, I train 10-20 people on the system and I don't get a lot of them coming back with questions. I'm not an IT person, I'm a microbiologist. So for me to be able to do this should tell you all you need to know about the user-friendliness of the system."**
>
> **Jenn Voisine, Quality Engineer**
> **BioAgilytix**, a GxP CRO

3. Simplified configuration

For efficiency and data security purposes, an eQMS has so many advantages over manual and spreadsheet alternatives. However, not every eQMS is created equal. Take a system's configurability for example. With the right system, contractors don't have to feel trapped working within rigid processes that can't adapt to their preferences or their clients' unique requests. There are configurable eQMS solutions available that work around your process, not the vendor's.

> **"I love that I have the ability to add custom fields in ZenQMS. I can populate them with what's important to us and use them throughout our different workflows, whether it's a non-conformance, a corrective action, or a continual improvement report." – Michelle Merwin, Director of Quality Assurance, Formlogic**

A configurable eQMS like ZenQMS gives Quality leaders the freedom to build their processes exactly as they want them. Together with the benefit of not having to wait for internal IT or external support to do so is a huge competitive advantage. This flexibility and efficiency can help companies attract a larger client base for specialized clinical trials, or in the case of manufacturers, bring products to market faster.

4. Improved quality culture

Perhaps even more important than individual tools or features is the powerful effect the right eQMS can have on an entire enterprise. It's a true case of how the whole is greater than the sum of its parts, where Quality directly contributes to company growth and success.

> **"ZenQMS has helped build our quality culture. Our Quality department has seen astronomical changes within the past 3 years. If someone saw us years ago versus today, they'd be shocked to see how much improvement there's been." – Neil Sharma, General Manager, Boston BioProducts**

A fit-for-purpose eQMS has the ability to change the negative connotation of Quality being a reactive department focused solely on checking-the-boxes, into **a proactive, unifying force** that is aligned with the same goals as the rest of the company.

> **"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. We protect the company's revenue and ZenQMS is a critical component of that."**
>
> **John Shay, VP of IT PMO**
> Precision Medicine Group, a global CRO

For more information about how ZenQMS has helped transform the organizations in this article, visit our **Customer Success Stories** page. Better yet, request a **free demo** and find out how we can help you!

SUCCESS STORY

BIOQUAL: How a Fast-Growing CRO Eliminated Paper, Strengthened GLP Compliance, and Saved Months of Administrative Time

BIOQUAL is a contract research organization (CRO) based in Rockville, Maryland, providing in vivo and in vitro preclinical research services to commercial sponsors and U.S. government agencies. The company specializes in infectious and human disease research and supports studies across well-established small and large animal models.

Success highlights

Months saved

Saved months of annual training reconciliation by automating assignments and tracking for 200+ employees.

Modern SOP management

Role-based, version-accurate acknowledgments that eliminated manual routing.

Digital deviations

Digitized deviation workflows, improving visibility and accelerating quality event resolution across the organization.

A growing CRO confronts the limits of manual quality management

When Emily Love joined BIOQUAL as Corporate Training Manager, she inherited workflows held together by paper, spreadsheets, and interoffice routing. Training sign-ins were handwritten. SOP acknowledgments required printing, initialing, and circulating through physical mail. Deviations moved slowly from person to person. As BIOQUAL continued to grow, these processes strained under the increasing volume of studies and documentation.

> **"It was very, very manual, lots of paper-based systems, and really inefficient Excel spreadsheets that weren't meeting our needs."**

Nowhere was this more evident than during year-end training reconciliation. For a GLP-aligned operation, confidently confirming training completion is essential, yet the process had become overwhelming.

> **"At the end of the year, it took a solid two months to determine who still had training left to do."**

The need for a modern **electronic quality management system (eQMS)** that could unify training, documents, deviations, and compliance became undeniable.

Choosing an eQMS built for GLP workflows

BIOQUAL's selection criteria reflected the realities of working in a regulated CRO environment. The team needed a system that supported:

- Document control
- Training and role-based assignment
- Deviations and quality events
- 21 CFR Part 11-compliant electronic signatures
- A validated, audit-ready foundation

ZenQMS met every requirement. The platform connected all core quality workflows in a single system, and BIOQUAL could configure each module to match existing processes rather than rebuild them from scratch.

Validation was a major factor. As a GLP-aligned organization, BIOQUAL needed to ensure the system was compliant and defensible from day one. ZenQMS provided the complete validation package upfront – including **qualification checklists, UAT templates**, and GAMP 5–aligned documentation – without extra fees or outsourced services. The validation path was straightforward and removed a major barrier to implementation.

ZenQMS also stood out for its functional completeness.

> **"We looked for a system that did document control, training, and deviations. Some programs would do one or two, but not all three."**

With validation support, unified workflows, and a life-sciences-specific design, BIOQUAL had confidence that ZenQMS would support both current and future needs.

A smooth, phased implementation for nearly 200 employees

ZenQMS guided BIOQUAL through a **phased implementation** designed for regulated teams. The structured approach helped BIOQUAL prepare thoroughly, test intentionally, and introduce each module at a manageable pace.

> **"The way implementation was structured in phases was very, very helpful."**

BIOQUAL went live in mid-April. Throughout May, Emily trained nearly 200 employees to use the system. She developed a full training presentation using screen recordings from both the sandbox and production environments, ensuring every user learned the system in a consistent way.

By the end of the rollout, the entire organization had transitioned to ZenQMS with shared clarity around how to access tasks, complete training, and navigate their dashboards.

Training, SOPs, and deviations: A real shift in daily work

Once ZenQMS was fully implemented, BIOQUAL saw meaningful improvements across its quality workflows, particularly in training, SOP acknowledgment, and deviation management. Each area benefited from clearer visibility and streamlined execution.

Training becomes clear, fast, and fully visible

Employees could now see exactly what training was required the moment they logged in. Supervisors gained real-time oversight, reducing the need for manual check-ins or reminders. The dashboard visuals even changed employee behavior, encouraging earlier completion.

> **"People really do like the color pie chart on their training dashboard. They always tell me, 'I'm in the green, Emily!'"**

The administrative payoff was substantial. Tasks that once required months of sorting, reconciling, and re-checking could now be completed with a few simple reports.

> **"For as big a company as we are – 200 employees – it used to take two months. I feel like now it will take about a day or two."**

SOP acknowledgments without the paper chase

SOP management saw one of the biggest shifts after BIOQUAL implemented ZenQMS. Under the old system, acknowledgments required printing a form, initialing and dating it, sending it through interoffice mail, and filing it manually. That process slowed down revisions, complicated version control, and made it difficult to ensure employees were trained on the correct SOPs – a critical expectation for any GLP-regulated CRO.

> **"It was asking far too much to print out a piece of paper and date and initial it and send it through office mail... just to acknowledge one document."**

With ZenQMS, that friction disappeared. SOP updates now trigger automated assignments tied directly to each employee's role, ensuring people only receive the SOPs and training that apply to their work. Emily explained that this shift has made users more engaged because the content is finally relevant to what they do. Managers can also easily confirm that staff are trained on the correct version of each SOP, something that was nearly impossible in the previous system.

> **"Now that I can make everybody have their own role... people are much more willing to do their work because it is relevant to them."**

Today, BIOQUAL stays fully aligned with the right SOP versions, and Emily says going back to the old process wouldn't be feasible.

Deviations move at a much quicker pace

The Issues module also brought much-needed clarity. After an additional round of supervisor training, deviations began flowing through digital workflows instead of physical mail. Quality gained visibility, and employees gained a more intuitive process.

> **"People really appreciate the ease and simplicity of not having to do interoffice mail for these paper forms."**

Together, these improvements brought cohesion, consistency, and transparency to BIOQUAL's quality operations – supporting the GLP rigor their research demands.

A quality system that scales with BIOQUAL's research

Reflecting on the cumulative impact across training, SOP management, and deviations, Emily emphasized the measurable time and resource savings for both the quality team and the broader organization.

> **"ZenQMS is essentially worth a full person or two of administrative effort just in the training and quality departments – plus a huge incremental time savings for every single employee who can now find, complete, and track their training and quality tasks quickly in one place."**
>
> **Emily Love**
> Corporate Training Manager, BIOQUAL

For BIOQUAL, ZenQMS was more than a move away from paper. It delivered a quality system that finally matched the sophistication, pace, and regulatory expectations of their scientific work.

Want to see how ZenQMS can work for you? Watch our 3-minute demo for a quick look at simple and compliant quality management software.

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 per-user seat licenses.** We don't charge by individual seat license, meaning you can reasonably grow without constantly adding new costs.
- **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?

Find out what makes us different and how we can help. Reach out to sales@zenqms.com or set up a quick chat here!

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