



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:





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 at Avara,

an international CDMO with decades of proven, large-scale commercial results in the pharmaceutical industry.

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 at Translational Drug Development,

a cutting-edge oncology CRO focused on helping their clients cross critical development milestones.

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?

"We didn't want the risks associated with maintaining servers onsite. It's always a hot point for auditors because they want to see your security and maintenance around those systems. That's why we decided we would have everything in the cloud."

**Joel Stephens, Senior Director of Technical Operations,
Peachtree BioResearch Solutions**





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.

"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 at Precision Medicine Group,

a global CRO specializing in the development and commercialization of pharmaceutical products.

"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**





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.

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.

"We have the power to configure without assistance from ZenQMS support, allowing us to take control and rely less on external resources."

-Senior Quality Assurance Specialist at Alimentiv,
a leading global gastroenterology-focused CRO.

"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



What is configurability and why does it matter for CROs? [Find out here.](#)





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. .

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. 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."

-John Shay, VP of IT PMO at Precision Medicine Group,

a global CRO specializing in the development and commercialization of pharmaceutical products

"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**



Want to learn more?

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!

