

Why cloud-powered quality management is the future

Cut costs, save time, secure
your data and more

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Qualio was founded in 2012 with a simple but important mission: to help life science organizations bring their vital products to market with a faster, stronger, more quality-centric approach.

Over 500 life science and healthcare businesses across the globe use Qualio to centralize, optimize and automate their quality management systems.

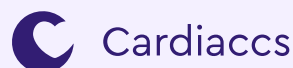
Qualio is a scalable and flexible cloud-based system that grows with your business and makes meeting your quality requirements truly simple, from ISO 13485 and ISO 17025 accreditation to FDA and GxP compliance.



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I hear from quality professionals every week who are simultaneously excited about the possibilities of the cloud and nervous about embracing it.

And that's totally natural. Us quality professionals are cautious, diligent people. The idea of moving your vital quality and compliance data from a cabinet or server in the same building as you to a remote software-as-a-service (SaaS) server managed by another company should trigger careful consideration and investigation. That's why the Qualio quality team has assembled this whitepaper.

Despite the misconceptions, myths and assumptions about the cloud, it's unlocked the most powerful quality management possibilities the profession has ever seen.

More and more organizations, particularly in highly regulated sectors like life science, are understanding that applying the powerful benefits of a cloud-based eQMS no longer means inviting extra risk — and actually strengthens, rather than weakens, their quality, compliance and competitiveness.

So if you're dipping your toes into the exciting world of cloud-powered quality management for the first time, or just want to build on your existing knowledge of what the cloud means for modern quality professionals, this guide is for you.



Kelly Stanton
Director of Quality, Qualio

1. Security

Let's start with the most common apprehension about the cloud: is it safe? At first glance, it certainly seems safer to keep your quality and compliance data under lock and key in a physical paper or server system you can control. But consider the time, effort and finances needed to maintain any decent level of long-term security in such a system. If you have any desire at all to keep your on-premise information secure and resilient in case of disaster, you'll need to think about working towards ISO 27001 (information security) and ISO 22301 (business continuity) accreditation, with all the months of preparation and planning that comes with it.

You'll need to plan and deliver in-depth disaster recovery training for your IT teams. You'll need to constantly assess and reassess the security and integrity of your servers, taking into account technology refreshes every few years and how you'll cope if your server room gets flooded, loses power, or gets hacked.

And if you still use paper, you'll need to consider how to guarantee the security of your hard documents. (We'll come to that in more detail later.)

Are SaaS cloud-based systems really safer? In a word, yes. And they require much less effort from you.

"It's the bread and butter of cloud-based software vendors to ensure the service is available and they don't damage their reputation. And if you ask me, 'Who is going to be better at disaster recovery? The company specializing in this activity day-in, day-out, or my local IT man who may have to do it once in their lifetime if they are unlucky?', I know where I would want to place my money."

— **Graham P.**

Director, Compliant
Management

Cloud eQMS vendors like Qualio, unlike their customers, can dedicate huge amounts of time, money and resources to maximizing the security and integrity of the systems they offer — freeing their customers from these obligations in doing so and letting them focus on their own integral business objectives.

As part of its ISO 27001 and SOC Type 2 compliance project, for instance, Qualio invested in a subscription to the Tugboat Logic Virtual CISO platform, a cloud-based security and compliance system for building a robust, holistic data security framework. Investment like this can stretch into the tens of thousands of dollars, but partnering with a cloud vendor gives you access to the end product — a secure, compliant eQMS — without these initial overhead costs.

The Qualio system itself is hosted on Amazon AWS, with a guaranteed uptime of 99.95% and 128-bit SSL data encryption. And with customer satisfaction and product quality in mind, cloud eQMS vendors like Qualio can commit to continuous review and improvement of their products' information security processes in a way that a pharmaceutical or medical device company battling to get to market simply cannot.

If you were to discover a bug on an on-premise platform, or a vulnerability in your paper-based system, for example, you'd have to log it with your internal IT or quality team, then wait until it's your turn in the queue for them to take a look and fix it. Depending on the size of your business, this could take precious days and weeks – and in the meantime, data could be leaked or lost.

In contrast, cloud-based software systems run on their own servers maintained and hosted by the vendor, not you. And any reputable vendor with a functioning QMS of their own will be entirely dedicated to keeping that system secure and bug-free at all times. Small problems and weaknesses therefore don't get the chance to snowball and threaten your information security as they would in an in-house system.

And when it's time for an upgrade to make your security even stronger, it's rolled out instantaneously across your entire organization. No more trawling between on-premise servers at different sites!

In the early days of the cloud, you'd be forgiven for being apprehensive about mixing SaaS with regulated GxP environments. The great steps taken in the industry over the past 15 years mean this fear has been alleviated, and there are plenty of useful reference documents, such as the [GAMP Good Practice Guide: IT Infrastructure Control and Compliance](#) (Section 18) and the work done by the [GAMP Cloud Special Interest Group](#) to demonstrate that SaaS is now very much part of the mainstream for life science quality management.

When we consider the other valuable security advantages of a SaaS quality platform over an on-premise or paper-based system, the case gets even stronger:

Contract, SLA and quality agreement documents should underpin any relationship with a cloud vendor. Your internal IT and support teams are not typically governed in this way, and may not be sufficiently trained and resourced either

Physically separate data centers eliminate the risk of disaster and disruption

FDA- and EU-compliant e-signature functionality add an extra layer of security and compliance while supporting ALCOA+ principles

Back-up and recovery processes are offered as standard by any reputable cloud vendor, eliminating the risk of data loss

Next, let's take a look at a closely connected point: the dramatic benefits of a cloud-based system compared to a legacy QMS.

2. Stronger, paperless compliance

The security risks inherent to a manual QMS driven by paper, email and Dropbox can be considerable, especially when you consider that:

7.5% of paper documents get lost and 3% get misfiled every year

The average document gets copied 19 times, with each copy reducing data accuracy and integrity

Hard documents and uncontrolled Dropbox and email documents are up to 5 times more likely to be lost or stolen than documents in a controlled digital repository

But security isn't the only concern: innovative and technology-friendly life science businesses are learning that cloud-powered eQMS platforms ease and simplify compliance, turning external audits from nerve-wracking interrogations into routine and stress-free events.

Because of the siloed nature of legacy or on-premise quality systems, they're often underpinned by manual and paper-based processes to tie things together. Running to the filing cabinet or an on-premise device to answer an auditor's questions is never ideal, and coordinating your quality management efforts to maintain compliance becomes much more difficult with disparate and disconnected systems.

Cloud-based quality platforms, on the other hand, can be rolled out quickly and easily across your entire organization, making it much easier to standardize and go paperless than it would be with an on-premise system.

The modern life science professional, from the perambulant CEO to the quality director managing a dispersed team, can now be plugged into an identical cloud-based eQMS accessible from anywhere in the world with a secure log-in.

Not only that, cloud-based systems like Qualio are constantly updated and refreshed by vendors to keep pace with industry change. System functionality provides instant automatic compliance with a range of quality best practices and benchmarks, including:

- ALCOA+
- FDA 21 CFR Part 11 e-signature requirements
- GDocP

The system notifications and touch-of-a-button reporting of modern cloud quality platforms allow quality professionals to identify slippages and potential threats to compliance as they occur, in turn giving them the opportunity to take smart and data-driven action to safeguard and tighten up compliance.



[Learn more about why a dedicated electronic document management tool beats manual paper-based systems ›](#)

The operational benefits of this digital approach are very real: at a 2020 GAMP industry event, an AstraZeneca delegate revealed their transition to paperless batch records triggered a jump in right-first-time batch manufacturing from 74% to 95%.

On top of that, validation offerings from reputable vendors make cloud systems suitable for even the most tightly regulated markets. GAMP 5 validation is no longer the headache it once was, either. Qualio offers a validation pack to customers to simplify and accelerate the validation process as part of an industry-leading 60-day onboarding timeframe.

Top Tip!

"In the post-COVID age, it's also worth considering how your business can cope with an increasingly remote regulatory structure. Cloud-based quality systems allow you to share access to your eQMS quickly and easily with an auditor, wherever they are."

Kelly Stanton,
Director of Quality, Qualio

3. \$\$\$

Cloud-based SaaS subscription services have given quality professionals an unprecedented choice of how they invest in cloud technology. eQMS users can tweak user and package selections to match their exact operational needs and budgets, safe in the knowledge that they're no longer tied to perpetual ownership as they would be with a legacy on-premise QMS platform.

But more importantly, cloud-based quality systems save money compared to an on-premise system. Consider the cost savings that come from replacing your physical on-premise upkeep, capital and overhead costs with a flat SaaS subscription fee.

Your cloud vendor carries 100% of the cost and effort of maintaining your system, including:

01. Upgrades

03. Security

02. Hosting

04. Patches & repairs

This frees you to eliminate the costs and headaches of an on-premise platform: network infrastructures, data centers, tiers of servers, expensive internal IT expenditure and so on.

In turn, you can then refocus the time and resources you've saved for what you should be doing: scaling the maturity curve to a mature, continuously improving, world class quality management system.

Typically, the total cost of ownership for a cloud system is [30% lower than on-premise](#). And crucially, there are no hidden 'backend' costs sneaking into your cloud expenditure either. Your upfront SaaS costs represent a clear and countable total investment.

On top of this, handling your quality and compliance processes in the cloud offers dramatic time and effort savings which augment these financial benefits. The improved agility and speed of cloud-powered quality can be transformational (see point #5!), and annual savings of \$100,000 or more are possible once key factors such as mitigating headcount, reducing process time and minimizing your cost of poor quality (COPQ) are executed. This tightening up of the bottom line in turn enhances the growth potential of your business and makes you dramatically more likely to reach the market and flourish in it.

For start-ups and scale-ups in the life science space, the choice is clear: expensive and cumbersome physical on-premise infrastructures taking up valuable manufacturing and laboratory space, or dramatically more cost-effective, agile cloud setups in the capable hands of a remote vendor.

4. Getting to market (and staying there!)

Applied properly, your quality management system isn't just a reactive repository for maintaining compliance. It's a competitive weapon that allows you to bring your life-saving products to market, satisfy your customers and beat your competition.

The scalability and agility of cloud systems ensures your QMS is flexible and malleable enough to keep pace with your organization and help it grow, from seed stage to full-on market expansion.

Need to share an SOP or process, train a new department, or centralize your design control data without forcing your product engineering team to duplicate work?

Whatever your quality strategy demands, cloud systems can be quickly shaped, updated and integrated with your other business tools. Unlike the stubborn ceiling of an on-premise server setup, adding new users, roles and responsibilities takes a matter of minutes, while [API integrations offer intuitive time-saving connections](#) with your broader software stack to put quality front and center of your operation.

At the same time, it's crucial that a modern life science QMS is familiar, intuitive and simple enough that all employees feel a sense of ownership and encouragement to contribute. This is another area of significant advantage for cloud-powered eQMS platforms.

Typical cloud-based quality systems support this collective buy-in with features such as:

- Single Sign-On
- Accessibility from anywhere with an Internet connection
- Configurability of system structures to match your existing ways of working, such as customizable workflow steps
- Clean, flat, modern user experiences to make complex quality tasks simple
- Built-in help and support features such as live chat

And as we've already seen, none of this requires extra IT investment. Simply onboard your users, log them in, and go. For a fast-moving life science company with strong market goals, the speed at which you leave the starting line and establish a robust quality baseline can be the difference between success and failure.

5. Culture of quality

Lastly, let's look at the unique ability for a digitized cloud-powered eQMS to act as the building block of a real, collaborative culture of quality. Employees without the benefit of a central cloud-based system typically spend half an hour a day just searching for the information they need to do their jobs. That's the equivalent of 1 in 16 of your colleagues doing no work at all!

Information silos, manual document processes and lax version control all clutter and complicate your QMS, making uniform processes much more difficult to instill and adding an unwanted layer of complexity to your compliance. This, in turn, makes a business culture that puts quality and compliance at the center impossible.

A cloud-based eQMS removes this hindrance by offering a single source of quality and compliance truth accessible from anywhere. Built-in version control allows only up-to-date and approved information to circulate. And by accessing and acting on controlled SOPs and

following structured digital system workflows, your colleagues don't need to waste valuable time searching for information or context and can act quickly, consistently and compliantly.

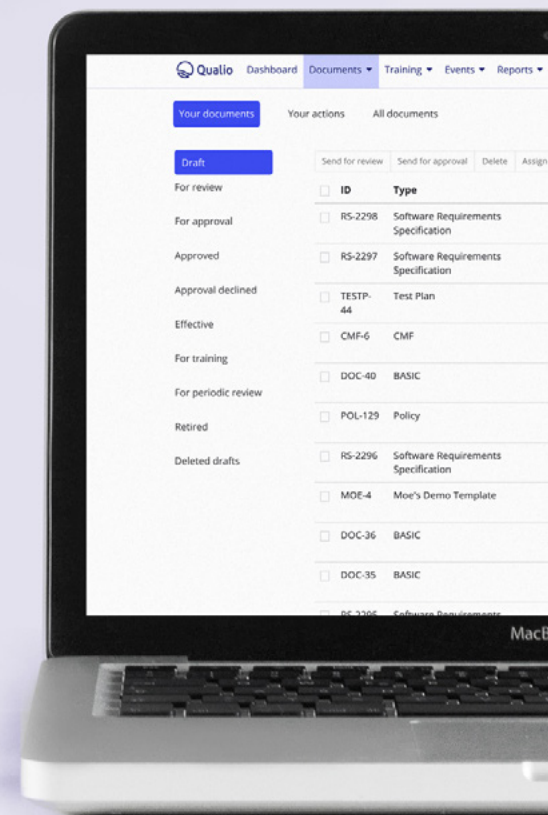
And for quality professionals themselves, a single source of truth can be invaluable. Cloud-based QMS platforms allow quality managers to, among other things:

- Access the real-time status of document approvals, training pathways, quality events, product development and more
- View and report on business-wide quality metrics
- Pinpoint risks and opportunities at a glance

For time-strapped quality professionals, distilling your entire QMS into a single cloud-based eQMS can be the most significant advantage of all.

See our cloud-based eQMS in action

Schedule a demo with us



Call us today

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