Boosting your competitive advantage with an eQMS

How a digital quality framework wins and keeps customers, clients and partners

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1. Meeting standards

The first advantage of an eQMS is the most simple.

By uniting your people, processes and data in a controlled digital framework, an eQMS makes it far easier and quicker to meet your regulatory requirements and receive approval, accreditation and certification in return. This, in turn, unlocks new business far more quickly.

Some life science standards are completely unavoidable: if you want to bring a medical device to the US market, for instance, you'll *need* to fulfill the requirements of Part 820 of Title 21 of the FDA's Code of Federal Regulations. For the EU market, the Medical Device Regulation's pathway is mandatory. As such, potential customers and partners in these territories will look for evidence of compliance with these standards by default.

But going beyond these core requirements and meeting additional international standards (like ISO) not only arms your business against future regulatory change – it opens fresh markets for expansion and advertises your status as a trusted, optimized and quality-centric organization which new clients and partners will gravitate towards.

Quality standards prove to potential partners that your business:

- Has a consistent repeatable framework for satisfying their demands

- Is following internationally recognized blueprints of what a compliant, quality-conscious life science business looks like

Has embedded risk-based thinking (a core requirement of the Annex SL High-Level Structure around which all modern ISO standards are built)

Has understood and applied complex industry and regulatory requirements

Lowers, rather than raises, their operational risk if they work with you

[Dive into Annex SL and start your ISO journey with our guide ›](#)

An eQMS centralizes your key quality data in a single source of truth, allowing operational weaknesses to be pinpointed and resolved with closed-loop processes and automatic day-to-day compliance to be instilled. This, in turn, positions your business to more easily meet the requirements of standards like:

- **ISO 9001**
- **ISO 13485**
- **ISO 14971**
- **ISO 27001**
- **GxP**
- **ICH Q10**

The impact of an eQMS for this journey can be dramatic. AI healthcare business Empatica used Qualio to slice its regulatory process time by 90%, while Karen Hue, Head of Quality & GxP at medical device and pharmaceutical manufacturer 30 Technology, had this to say about her eQMS-powered ISO accreditation journey:

> *I joined in November. I contacted Qualio 2 weeks later. We went live in December. We had all our users in the system by January. And we had our ISO 13485 certification by July. Without Qualio, we'd never have done that.*

Standards, in turn, become gold dust for your sales and marketing teams, and your shiny new badges can adorn your website and collateral. Independent verification of your quality and compliance by an accredited body could be the difference between winning and losing that next contract.

Top Tip!

Never forget: in the complex regulatory world of life science, your customers have their own audits and inspections to worry about. It makes their own lives easier if they can show their auditors that they work only with suppliers and partners certified to certain quality and regulatory standards – rather than having to explain why they work with you, prove your compliance at length, and audit you more frequently. Unlocking standards makes you more attractive purely on a risk- *and* effort-aversion basis!

Key eQMS impact stats*:

30% faster quality processes

90% reduction in quality admin time

140% increase in product release speed

5x faster external audits

1-3 quality FTE equivalent

*Based on Qualio customer feedback

2. Boosting retention

It's not enough to win new business with an attractive quality façade only to buckle under the new demands, slip up when it comes to meeting your new customers' requirements, then watch them leave for a competitor.

Here, too, an eQMS is invaluable. To understand why, we need to go beyond the benefits of purely 'collecting' standards to *win* new business, and delve into the real operational impact of digitizing your QMS for *retaining* business.

Modern electronic quality systems typically offer digital control and centralization of key QMS elements like:

- **Documents**
- **Training**
- **Reporting and data**
- **CAPAs, investigations, event responses**
- **Design controls (for medical devices)**
- **Suppliers**

A single source of cloud-based digital truth connecting these elements allows your business to work in a consistent, repeatable and structured way no matter where you and your colleagues are physically based. Ditching cumbersome paper and spreadsheets sharpens, controls and accelerates access to information. Eliminating admin headaches and freeing up the quality department's headspace allows careful long-term planning to continuously improve the services offered to customers.

And when things do go wrong – as they inevitably will at some frequency, no matter what system you use – digital workflows allow customer feedback, complaints and improvement suggestions to be actioned and resolved much more quickly to get things back on track.

Taken together, then, an eQMS doesn't only give you an attractive certificate on the wall. It empowers your business with the ingredients to do what the best quality-centric organizations do: to use your new quality standards as drivers of genuine, continuous improvement instead of simply as peacock feathers, and to delight and retain your customers at scale.

> **Top Tip!**
>
> Manual quality systems, and even suboptimal eQMS platforms, can clutter, complicate and sour day-to-day working relationships between life science companies, such as contract manufacturers and their clients.
>
> One Qualio customer, Heather Underwood, CEO of medical device manufacturer EvoEndo, moved away from her old contract manufacturing partner and began to hunt for a new CMO and cloud-based system purely because of the clunky on-premise quality system they relied on for their shared quality activities.
>
> Read Heather's story to see this effect in action.

You can pass audits and achieve quality standard accreditations without an eQMS. But manual quality systems will creak as new customers and tighter regulations arrive, until a ceiling and tipping point is reached. Freeing up time and resource with an agile digital system ensures your new customers get the products and services they signed up for, and stick around for the long haul.

Why is customer retention with an eQMS so important for your competitive advantage? We can see the powerful compounding, weakening effect that uncontrolled customer churn has on your company's growth trajectory when we compare a company losing 5% of its customers each year to one losing 20%:
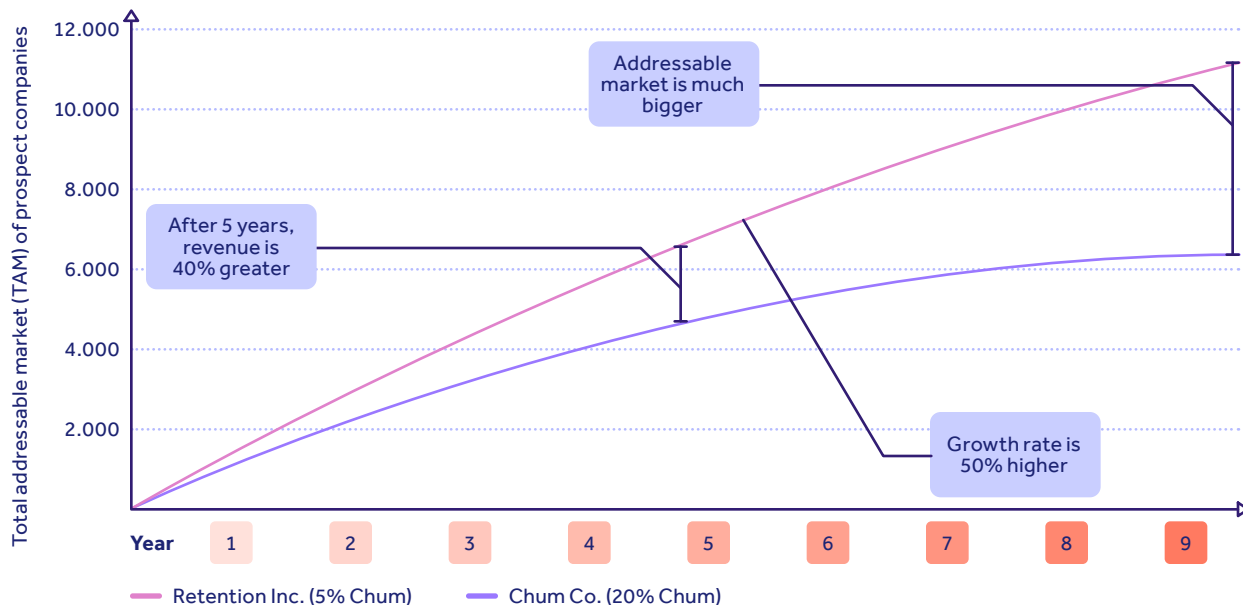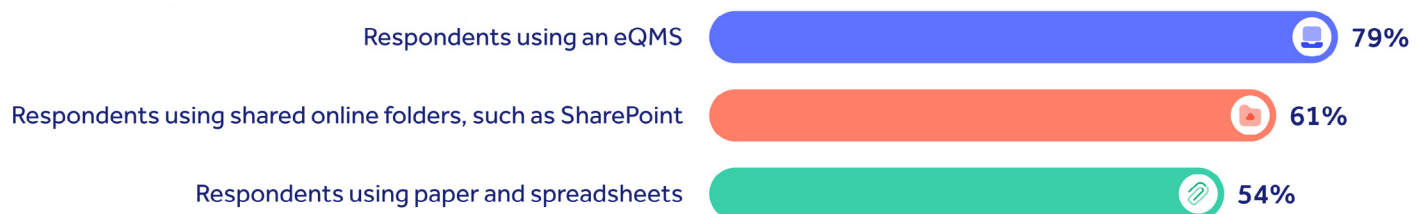

> *We've been able to show certain clients what we've accomplished with Qualio, and they were very impressed. The VP of Quality for a client company said, "If I could build from the bottom up, I'd do it exactly the way you guys did it".*

Stephana Petrino, VP of Quality, Alphazyme

3. Standing out

Above all, an eQMS investment is a clear signal of intent to clients and partners that your business intends to make your operational quality as strong as possible with the latest industry tools.

This effect is compounded by the fact that, as Qualio's 2024 global quality trends survey discovered, 42% of life science businesses still rely entirely on manual paper- and spreadsheet-driven quality systems. When asked to identify the maturity and effectiveness of their own quality systems, our respondents answered on average as follows:

Respondents using an eQMS	79%
Respondents using shared online folders, such as SharePoint	61%
Respondents using paper and spreadsheets	54%

Closely connected to this, 91% of quality professionals now believe that digital technology is vital for the quality role, and 20% of respondents not already using an eQMS said they would implement one in 2025.

What does all this mean? Digital quality management remains a stand-out USP and differentiator for life science businesses. But the growing appetite for eQMS platforms means it won't always be like this, and those companies making the early adoption will be best-placed to snap up market share before their competitors catch up and digitize.

Consider the due diligence activities any potential customer will have to perform as you and your competitors go for their business.
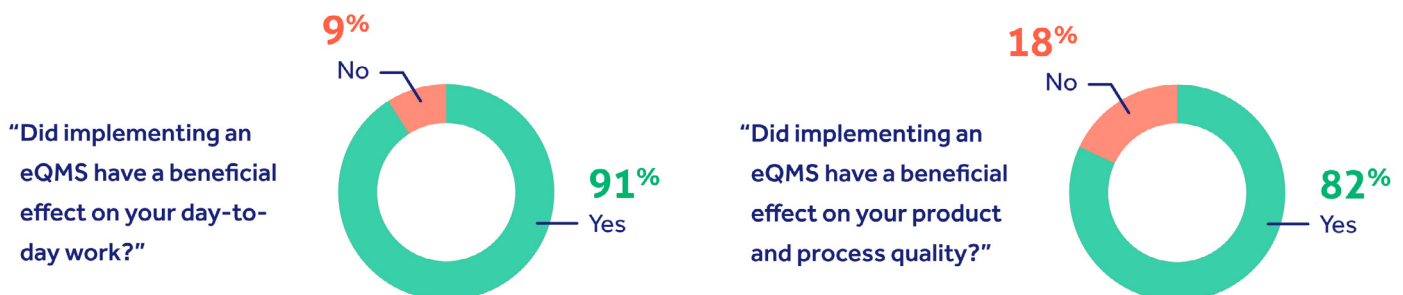
If they're a mature, compliant company themselves, they could be following a framework like ISO 31000 or ICH Q9, applying techniques like HAZOP, and performing close assessment of your operation as part of an interlocking structure of risk appetite statements, risk registers and risk management policies and procedures.

In the complex web of risk management activity which comes as two life science companies pursue a contractual agreement, those who can show a properly implemented and fully validated eQMS to a prospect, all else being equal, will realistically beat a company with a legacy QMS every time.

Qualio shows we're taking quality seriously and investing in quality improvement initiatives. We plan to keep growing with Qualio, offering visibility, continuous improvement and knowledge management to our current and potential customers.

Edgar Gimenez, Quality Assurance Specialist, The Dot

Impact of an eQMS

9%
No

"Did implementing an eQMS have a beneficial effect on your day-to-day work?"

91%
Yes

18%
No

"Did implementing an eQMS have a beneficial effect on your product and process quality?"

82%
Yes

Qualio

See Qualio in action

Qualio is the highest rated eQMS on the market and ranked as the easiest to use.

Want to learn why leading life sciences companies rely on Qualio for a quality-centric route to market?

Request a demo today

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