Qualio

QUALIO SURVEY SERIES

Life science quality trends report 2022

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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.

Read G2 reviews

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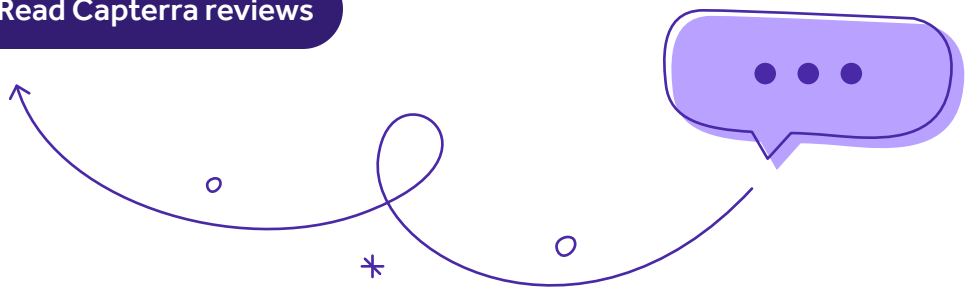

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THE RARE DISEASE COMPANY

Lunaphore
technologies

AVECTAS

Biofidelity.

Cardiaccs

PROSCIA

What did we learn from our first ever global life science quality professional survey?

There are plenty of positives to take away. Survey respondents voiced a general confidence in the position of quality on the corporate agenda, in the suitability of their policies and procedures, and in the ability of senior leadership to articulate and communicate the value of quality internally. Two thirds reported directly to a managing director, CEO or quality director, demonstrating the perceived value of the QMS at the directorial level. But this confidence is as middling as it is broad.

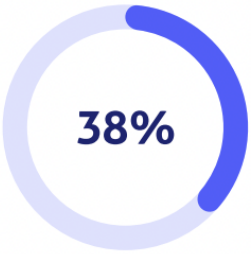
Only 18% completely agreed that the quality department received its fair share of investment compared to other departments. And only a quarter felt their quality department had all the resources and internal support it needed to function properly, and that the full potential of the quality department was being applied.

Manual quality management methods continue to dominate to a surprising degree. 38% of respondents still rely entirely on paper and spreadsheets to manage their QMS. Half still use adapted legacy tools, including shared online folders such as SharePoint. And, closely connected to this, 54% still dedicate an entire quarter of their working days to performing administrative tasks like data entry.

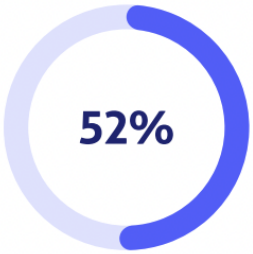
Improving access to resources, maximizing quality improvement time and unlocking the full potential of the quality department therefore stands out as the key challenge for the industry this year.

Kelly Stanton
Director of Quality, Qualio

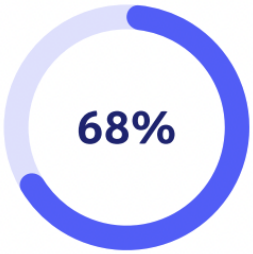
The state of play: quality management in 2022



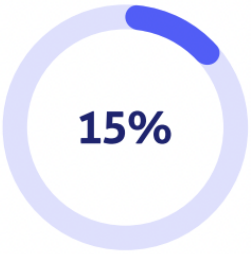
still use only paper and spreadsheets



are male

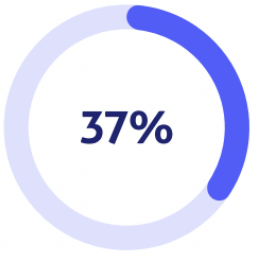


think technology is important for the modern quality role

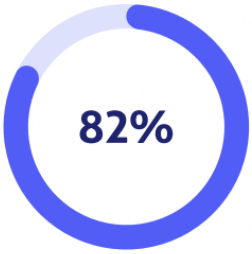


implemented an eQMS in the past 2 years

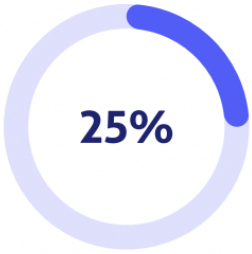
have been in their role 3+ years



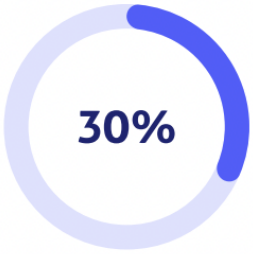
are part of a professional body



are satisfied with their pay



have all the resources they need



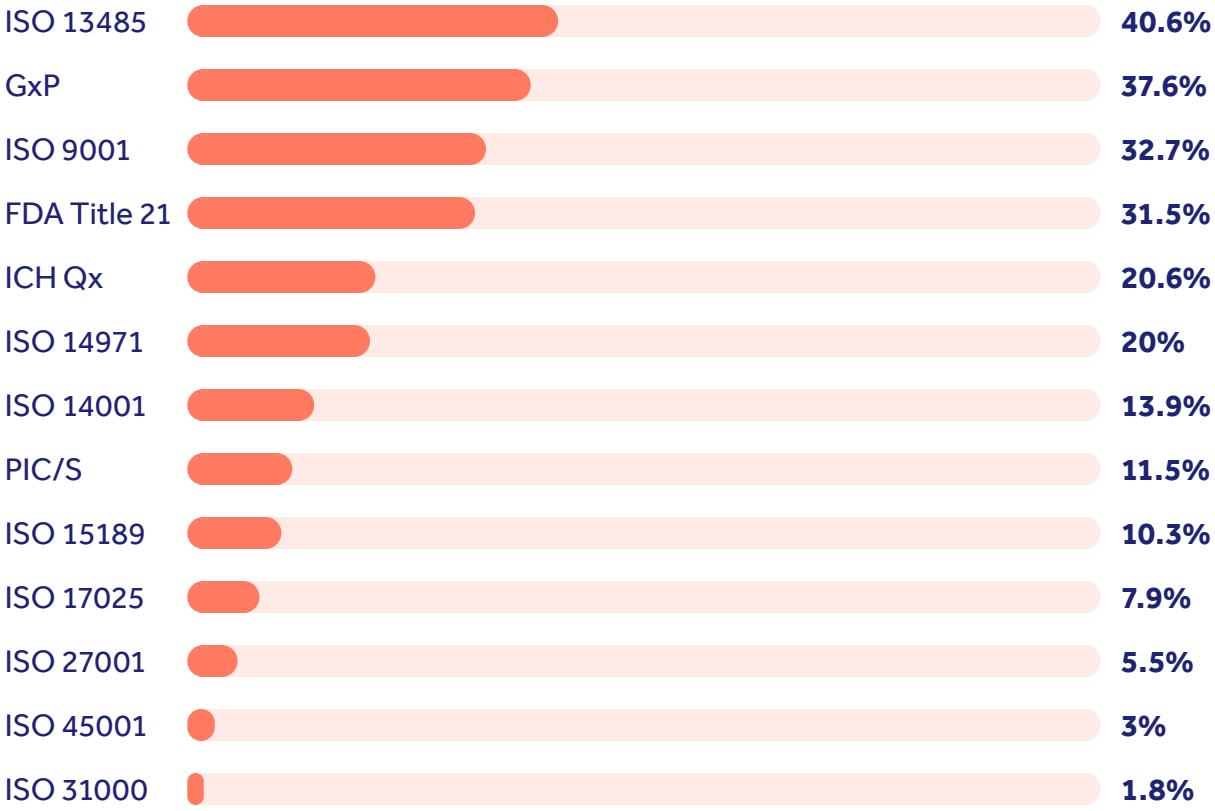
were promoted in the past year

2022 objectives

Our respondents were evenly split between medical device and pharmaceutical companies.

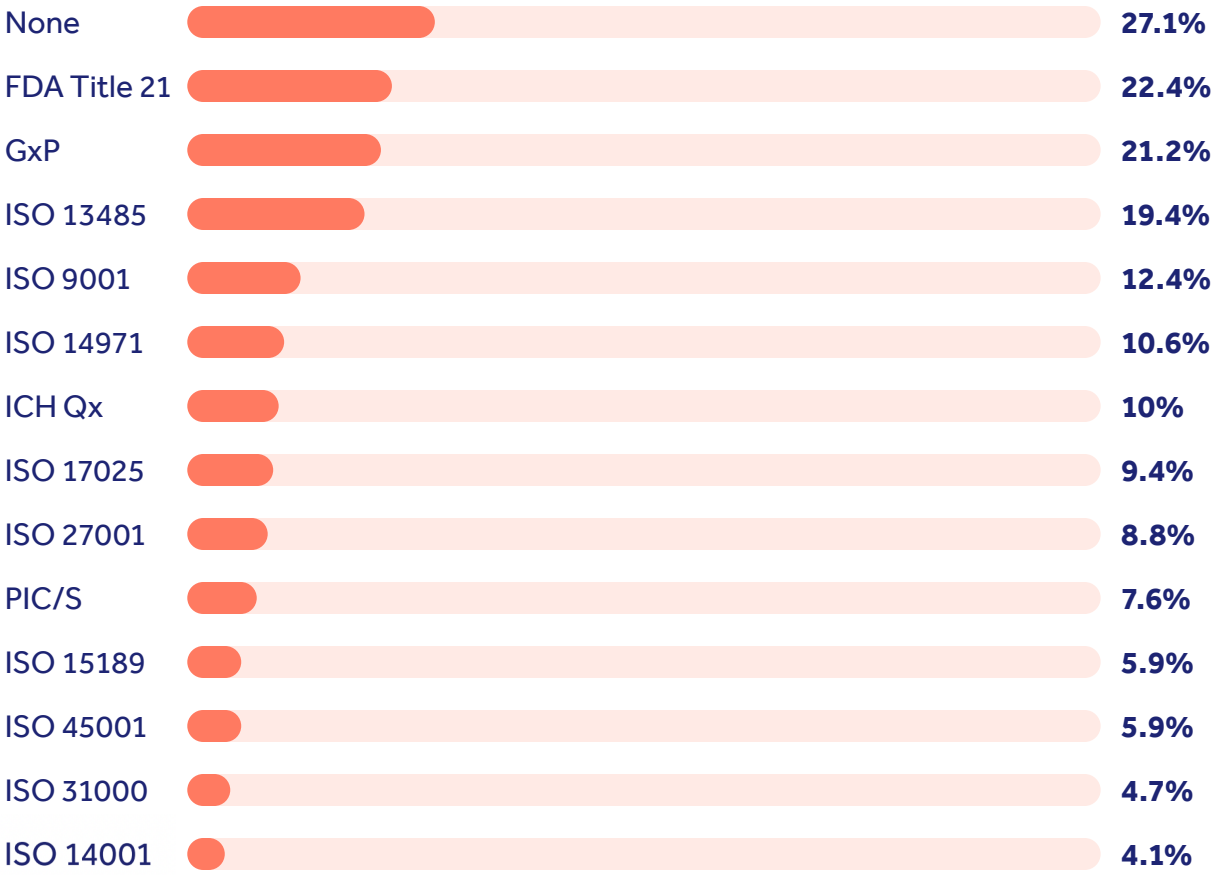
So it wasn't surprising to see ISO 13485 and GxP dominate the quality standards they had already embedded and were meeting the requirements of, followed by FDA requirements and general QMS compliance in the form of ISO 9001.

Quality standards and regulations already achieved



The quality objectives for 2022 were revealing:

Target quality standards and regulations for 2022



27% had achieved all the standards they required and had no accreditation objectives for 2022. FDA, GxP and medical device quality requirements loomed large for those who did have 2022 plans, while broader quality standards like environmental, health and safety (ISO 14001/45001) and information security (ISO 27001) had only low levels of interest.

GxP plans for 2022? Try our toolkit ›

Aiming for ISO 13485 accreditation? Access helpful resources ›

Analysis

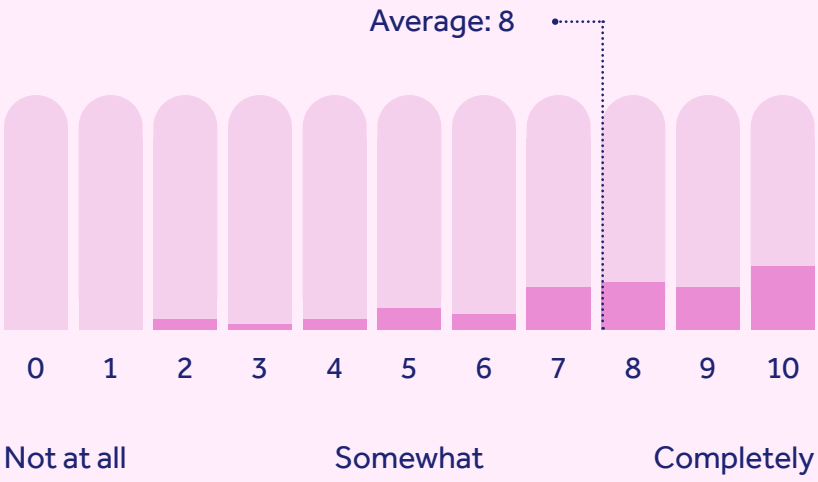
This tight focus on a handful of key standards is perhaps unsurprising: with the burden and effort of ISO accreditation journeys in mind, life science companies are taking a measured and appropriate approach to compliance and focusing effort only on those standards which directly impact the path to market.

Nevertheless, with only 5.5% of respondents currently accredited to ISO 27001 and only another 8.8% planning to be in the next year, the dominance of uncontrolled paper- and spreadsheet-led quality systems does look like a potential long-term risk to the integrity and security of the data flowing through these organizations.

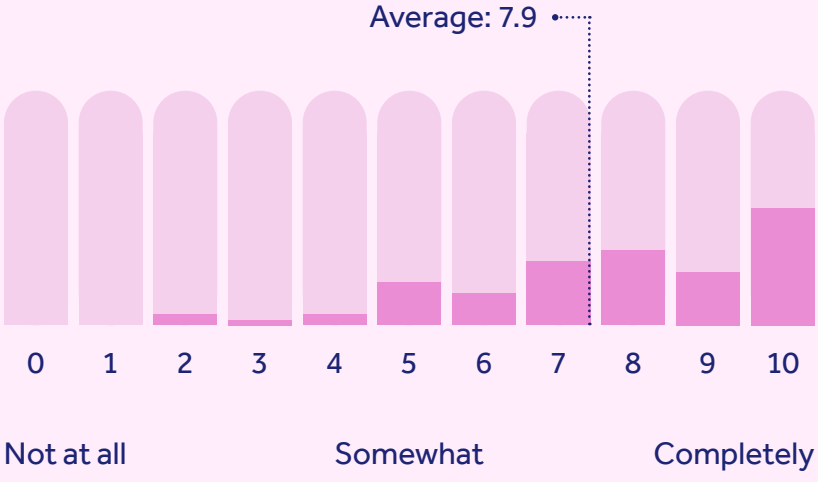
Quality snapshots

When asked to provide their response to a series of qualitative statements, our surveyed quality professionals had this to say.

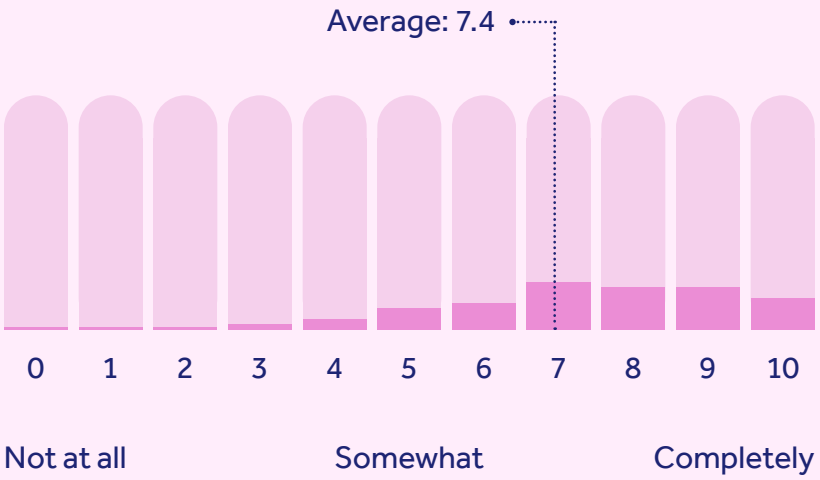
"The importance of quality is effectively communicated by your senior leadership."



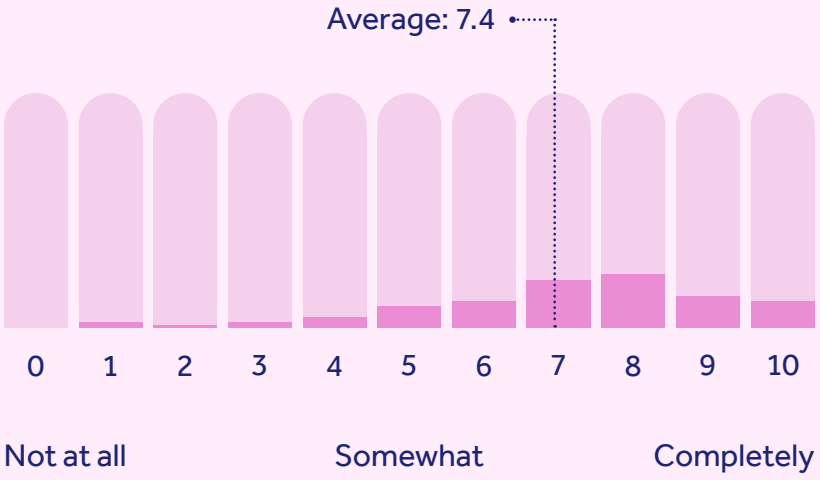
"Quality is high on your corporate agenda."



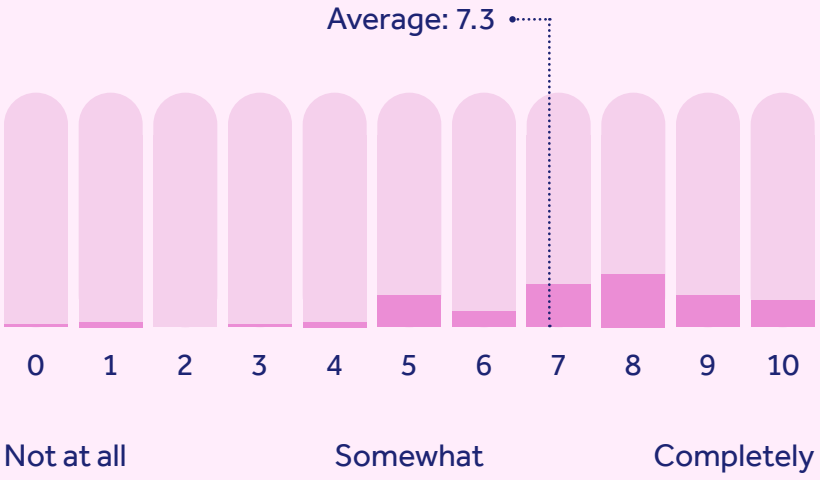
"You feel valued and have the training and support you need to be confident in your role."



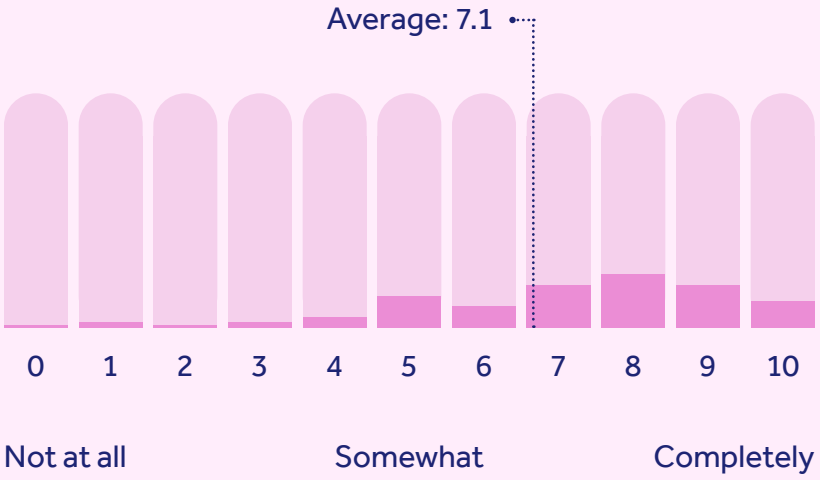
"The quality department is effectively resolving risks, opportunities and issues."



"Your internal policies and procedures are fit for purpose."



"You are confident that everything is there and ready when your auditor arrives."

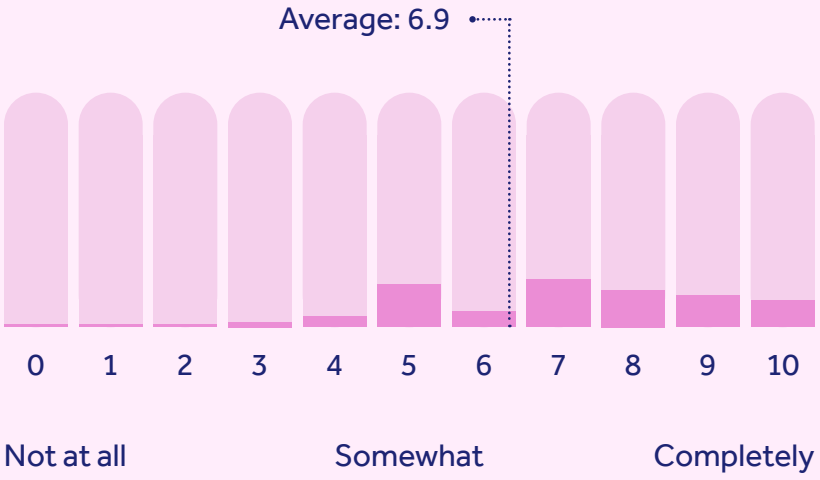


Most quality professionals agreed that the value of quality was adequately voiced internally, was properly supported with training and occupied a high position on the corporate agenda - meeting the requirements of Annex SL Clause 5.

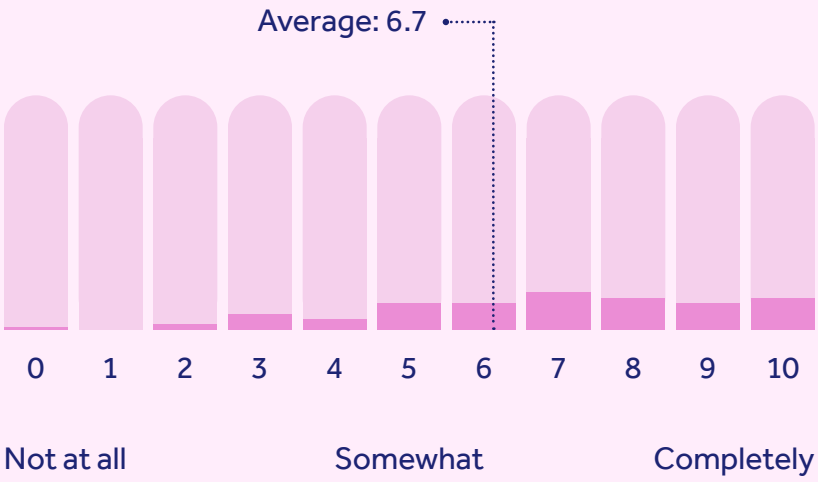
And most were generally happy, if not thrilled, with their ability to prepare for an audit and resolve risks, opportunities and issues as they arose, with only 8% believing they weren't at least somewhat effective at doing so.

But the picture evolves with deeper questioning about the resourcing, support and overall potential of the quality department:

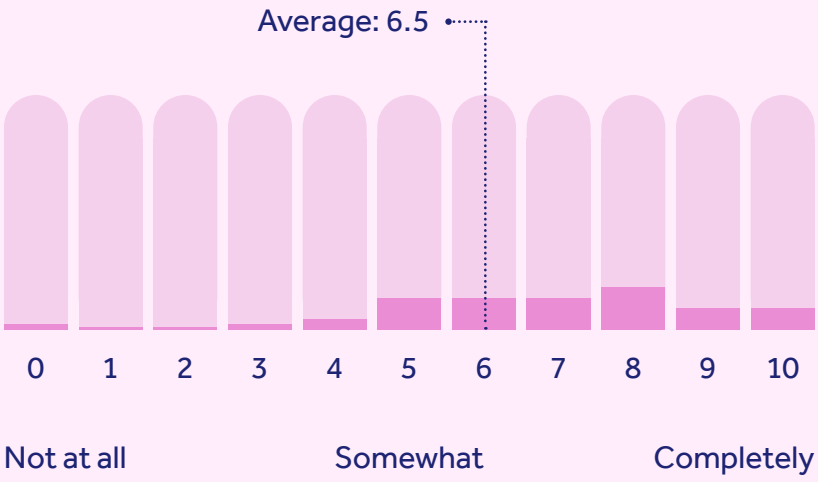
"The quality department has the resources and support it needs to function properly."



"The quality department is being used to its full potential."



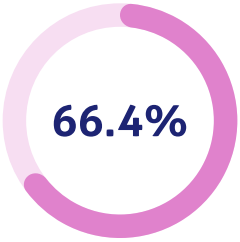
"The quality department receives a fair share of investment and spend compared to other areas of the business."



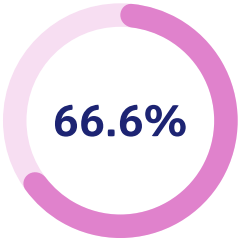
Analysis

Are management talking the talk but failing to walk the walk in terms of investing in quality? It may be that business leaders are sincerely invested in the significance of quality, but are misunderstanding the function or are unaware of the transformational impacts of further investment. The positive impact of investing in quality tools and technology, such as an electronic quality management system (eQMS) for instance, is plain to see from our respondents below.

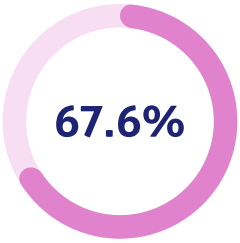
"How would you rate the maturity and overall effectiveness of your quality management system?"



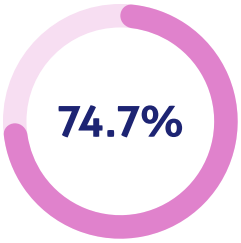
Respondents using paper



Respondents using spreadsheets



Respondents using shared online folders



Respondents using an eQMS

Analysis

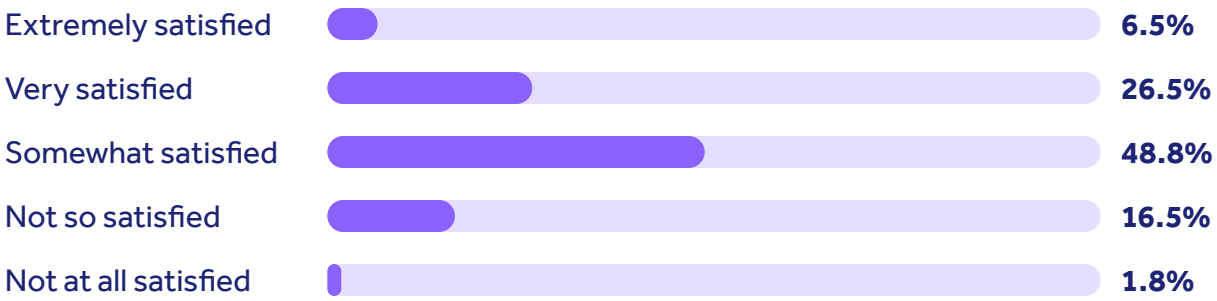
It's clear that quality professionals recognize the potential value of an eQMS for their business, and there may be some encouraging signs of recognition from budget-holders too - with 43% of those not already using one highly likely or certain to implement one in 2022.

At the same time, it's crucial that quality professionals learn how to articulate the full potential of the quality department internally: low potential realization probably stems from top management failing to understand the underlying potential that exists, rather than not trusting quality to do more.

> *"As a profession, we are appalling at marketing ourselves. We need to get better at that."*
>
> **— Vincent D.**
> CEO, Chartered Quality Institute

The quality role

How satisfied are you with your pay?



The quality profession ranks highly for upward mobility, remuneration and tenure time compared to other industries.

About half of respondents felt their pay as a life science quality professional was about right and somewhat satisfying, well above the U.S. national average of 39%. A third were 'very' or 'extremely' satisfied with their compensation.

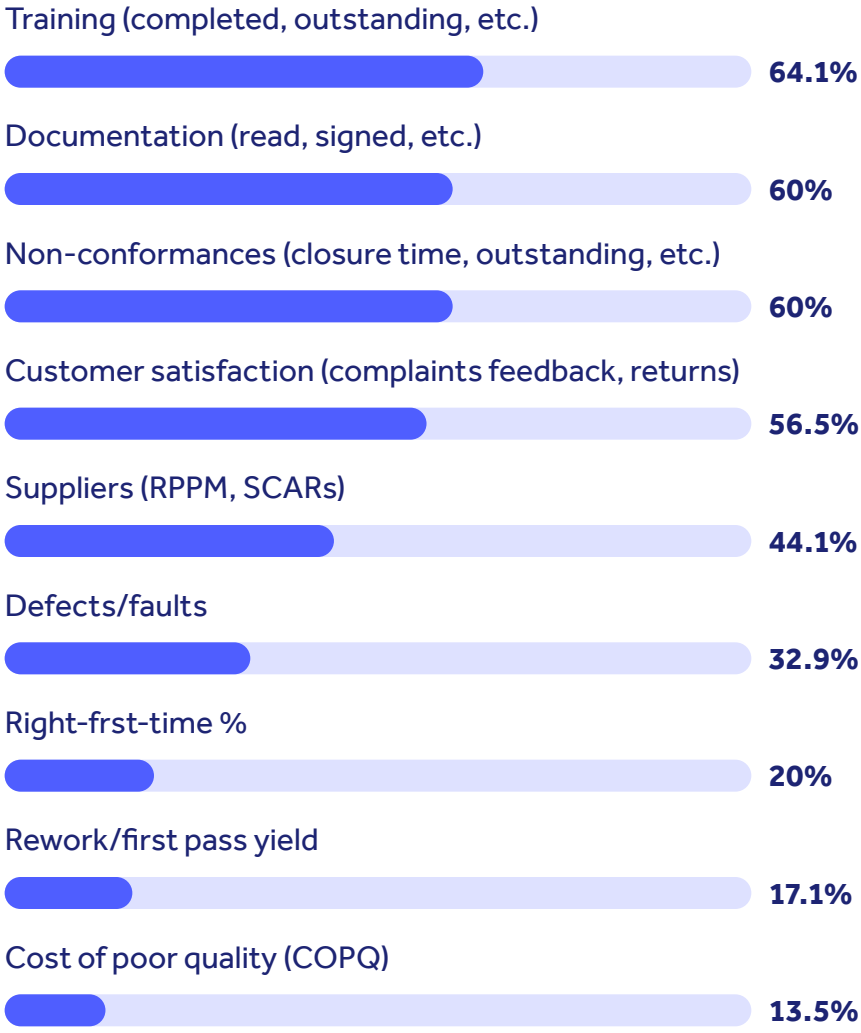
30% were promoted in the past year, a relatively high figure which might reflect an increase of responsibilities triggered by the COVID-19 pandemic.

And although the industry has not been immune to the 'Great Resignation' of 2021, with 18% being in their roles for less than a year and 27% for 1-2 years, it still appears fairly steady: almost a third have been in their role for 3-5 years (reflecting the median American employee tenure time of 4 years), while a quarter have been in their role for 6 years or more.

The day-to-day

Metrics

The most common KPIs tracked by life science quality professionals were:



Analysis

Only 13.5% of respondents measuring the cost of poor quality is pretty low, and this could be connected to the need discussed above to further demonstrate the potential of the quality department.

Putting a financial figure on the impact of quality, and how operational changes can alter that figure, is a great way to get the attention of senior management.

Key tasks

Quality management tasks	% of working day				
	0%	25%	50%	75%	100%
Administrative tasks (populating spreadsheets, producing reports, searching for information, etc.)	6.4%	54.1%	27.1%	11.8%	0.6%
Quality control (batch inspections, sampling, testing, etc.)	46.5%	34.7%	12.3%	5.3%	1.2%
Quality assurance (auditing, training, documenting, etc.)	10%	52.9%	23%	10.6%	3.5%
Quality improvement (process changes, feedback actioning, CAPA execution, etc.)	10%	55.3%	21.2%	10.6%	2.9%

Quality managers are struggling to dedicate their time to value-add quality improvement tasks, with a whopping 54% losing a quarter of their time to administrative tasks like entering and searching for information and producing reports.

Only 13% could spend more than half their time refining processes, actioning feedback and completing CAPA tasks to improve their levels of quality - and 10% did no quality improvement work at all.

And although almost half didn't complete any quality control tasks themselves day-to-day (reflecting the heavy management focus of our survey), a broad 4-way split between admin and quality control, assurance and improvement across the working day can be identified for the other half.

Analysis

The 54% of respondents bogged down by admin aligns almost perfectly with the 55% of respondents not using an electronic quality system, which would typically automate these activities.

It's good news that about half of the respondents are managing to find a general balance between the four task groups – but those quality professionals who can ditch admin tasks and fill the resulting time with quality improvement activity will be much better-placed in the long run. Quality improvement and assurance should never replace good quality control, but maximizing the value added (rather than maintained) by the quality department goes hand-in-hand with making your company fitter, faster, stronger and more profitable – and increasing your internal profile at the same time.

> *"The regulators are realizing there has been, historically, too much of a focus on compliance and manual quality control activities. Although this is important and essential, the real focus should be on quality improvement.*
>
> *Where there aren't the tools and systems in place, there aren't enough resources or energy to put into quality improvement. 80% of the effort should be there, but currently it's where only about 20% of time is spent.*
>
> *This means we're not focusing on the bigger picture, which is patient safety. Instead of line-by-line compliance, our focus should be on critical thinking and risk-based agile approaches to streamline assurance activity and evidence capture."*
>
> **— Sion W.**
> GAMP SIG expert, Managing Director of Conformity

Headcount

The average headcount of surveyed companies was **238**.

The average headcount of their quality departments was **10**.

44% said the size of their quality department had stayed the same in the past year. 42% reported growth, and 14% said their quality team had shrunk.

Of the quality professionals who'd seen their quality team grow, 78% were satisfied that the growth had kept pace with the broader headcount growth of their business.

Professional membership

36% of respondents were members of a professional, statutory or regulatory quality body. The most common memberships were:

- The American Society for Quality (ASQ)
- The Regulatory Affairs Professional Society (RAPS)
- The International Society for Pharmaceutical Engineering (ISPE)
- The Chartered Quality Institute (CQI)/ International Register of Certificated Auditors (IRCA)

Finger on the pulse

Our surveyed quality professionals drew on a wide range of sources to keep on top of the latest quality and compliance developments. The most common sources were:

- FDA
- BSI Compliance Navigator
- ISO
- U.S. Pharmacopeia
- Qualio blog
- Consultant support

Challenges & frustrations

We asked our respondents to share the most challenging part of their day-to-day role. The most common answers were as follows:

When asked what they'd change in their role if they could, the most common answers were:

"Try an all-in-one quality application"

"Get more senior management involvement"

"Secure more resources"

"Employ additional QA/RA resources"

"Get an eQMS in place"

"Get more autonomy to try new quality strategies"

"Less paper, more automation"

"Attend more webinars that explain new regulations and how I can improve my QMS"

"Make the role more varied. It can be boring just doing administrative work all day"

"Get more headcount in the department"

Some lessons learned in 2021

01. "Consider the risks in every single process and document everything"

02. "Don't try to retrofit quality. Get it right the first time"

03. "When quality ranks highly in a company culture, employee satisfaction follows"

04. "The digitization of quality operations is the future of quality"

05. "Lean Six Sigma is great!"

06. "Don't just audit once a year. More frequent reviews are crucial"

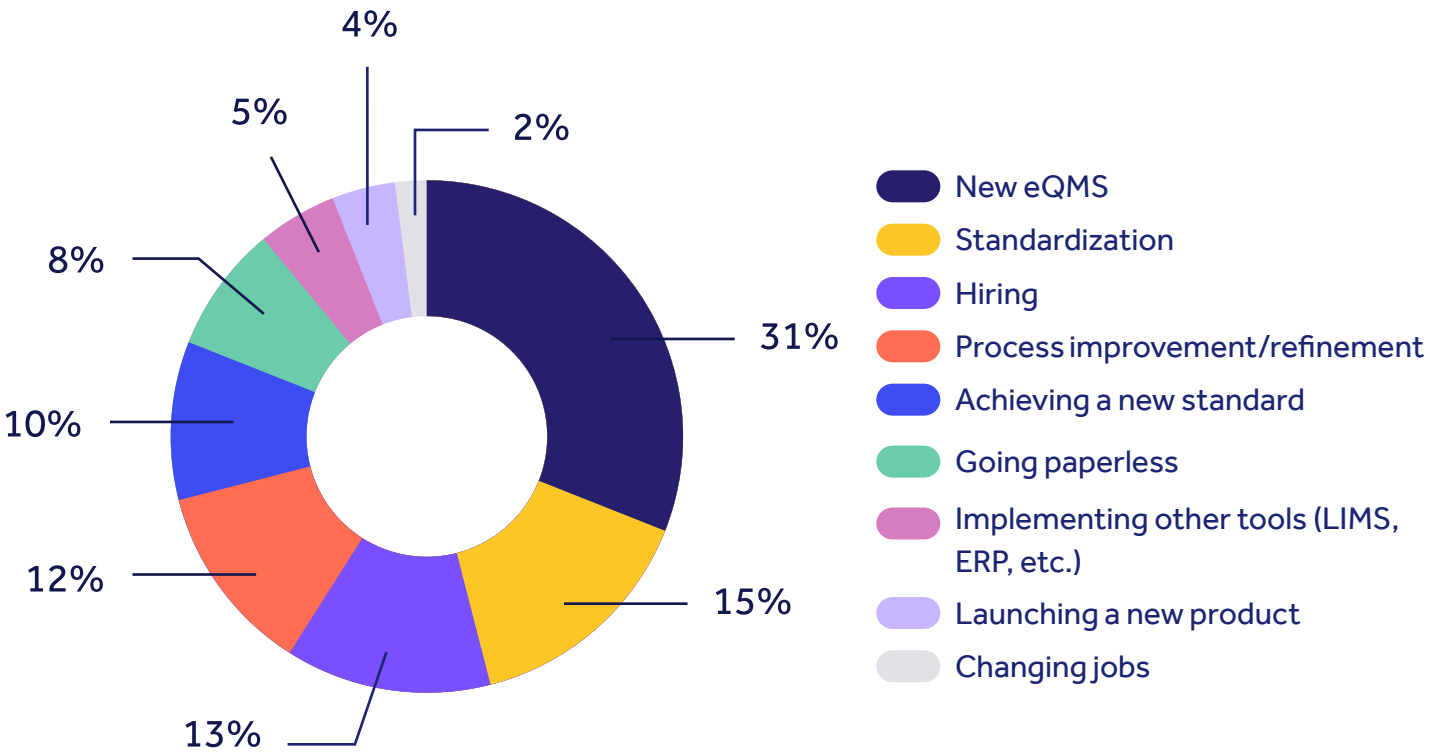
07. "Keeping quality awareness alive in the business is a constant struggle that's never over"

08. "An eQMS is the best way to go"

09. "Work smarter, not harder!"

10. "Be on your guard against too many documents that don't link to systems and processes"

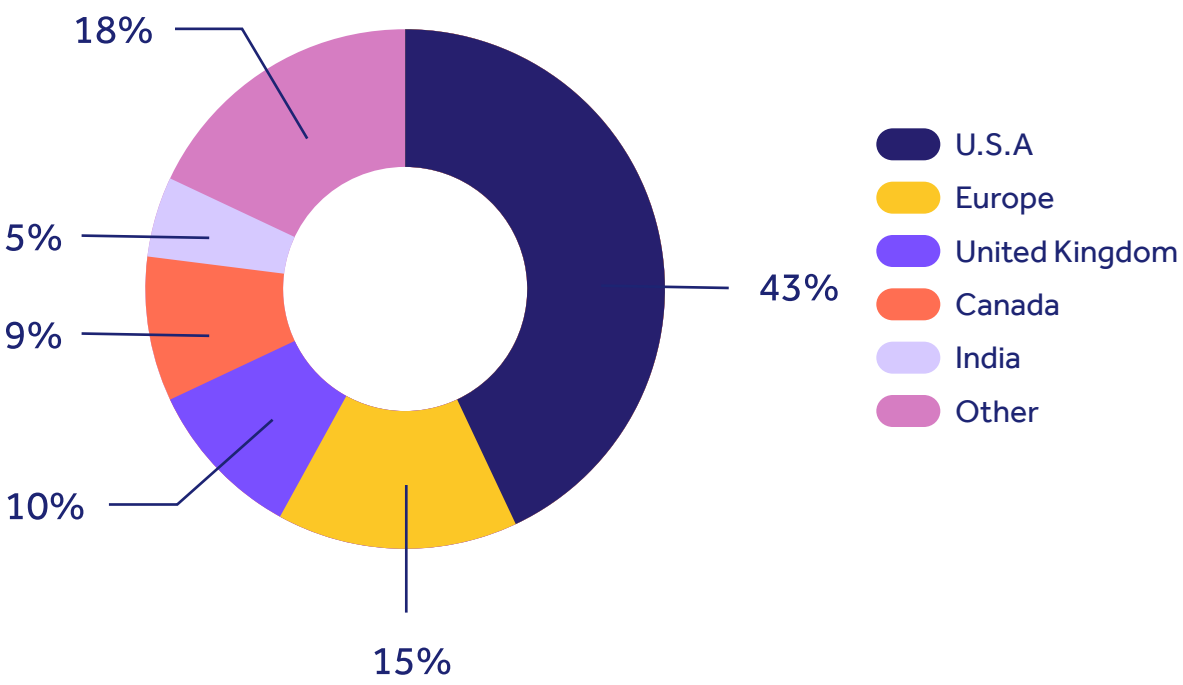
Plans for 2022



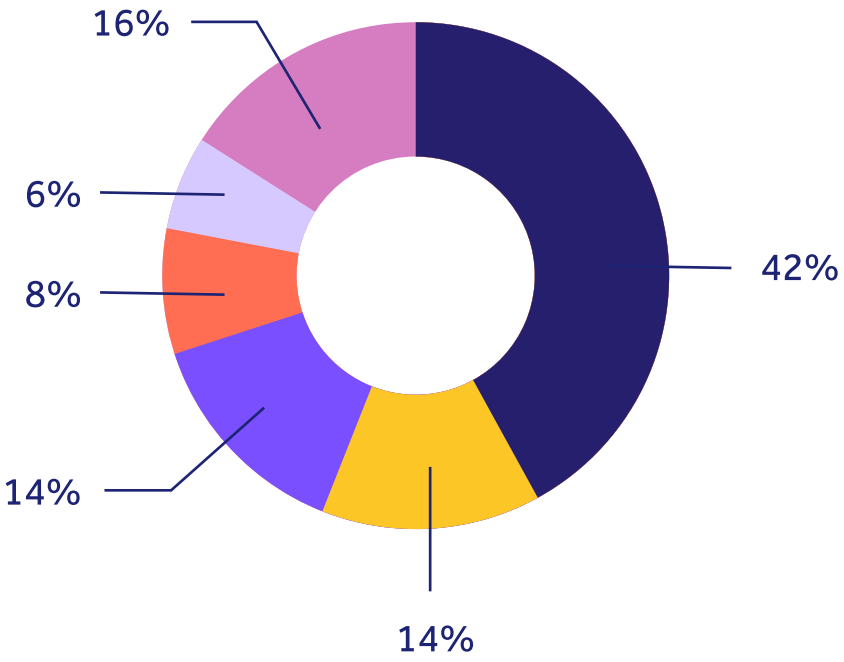
Methodology

The life science quality trends survey was distributed by Qualio to thousands of life science quality professionals in January 2022. The survey was open for 3 weeks.

Location of respondents:

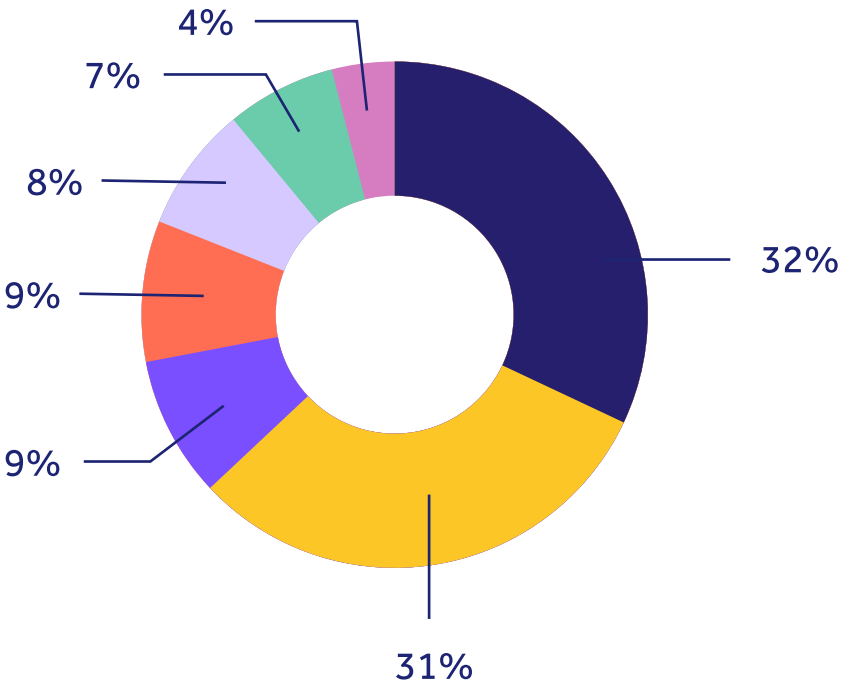


Profession of respondents:



- Quality managers
- Quality directors
- Quality and regulatory consultants
- Managing directors, CEOs and business leaders
- Quality engineers
- Other: quality analysts, auditors, validation leads, clinical development scientists, VPs of operations, quality trainers, etc.

Respondent company sectors:



- Medical device
- Pharmaceutical
- Health & wellness
- Life science engineering
- CRO/CMO
- Biotechnology
- Other: cosmetics, etc.

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