Qualio

QUALIO SURVEY SERIES

Life science quality trends report 2024

What's new this year?

Meg Sinclair
Quality & Customer Support Manager

We're excited to share the results of our third annual life science quality professional survey. We asked 2000 quality pros from across the globe to share their lessons, headaches, working styles and plans with us. Here's what stood out.

As an eQMS provider, we're always keen to see the tools and systems that quality professionals are using. **42%** of our respondents reported **using paper**, down from 49% last year.

Coincidentally, another 42% said they'd digitized their quality approach with an eQMS at some point in the past 2 years. That's more than double the 20% who reported this last year!

Almost **half of respondents felt quality and compliance gets more difficult each year**, and recurring frustrations around leadership support, quality culture and inability to drive change surfaced throughout.

Despite these difficulties, the industry retains lower-than-average attrition figures with long average tenures. Process optimization stood out as the key 2024 objective, followed by almost half aiming to bring a new product to market this year. Life science quality professionals are a resilient bunch!

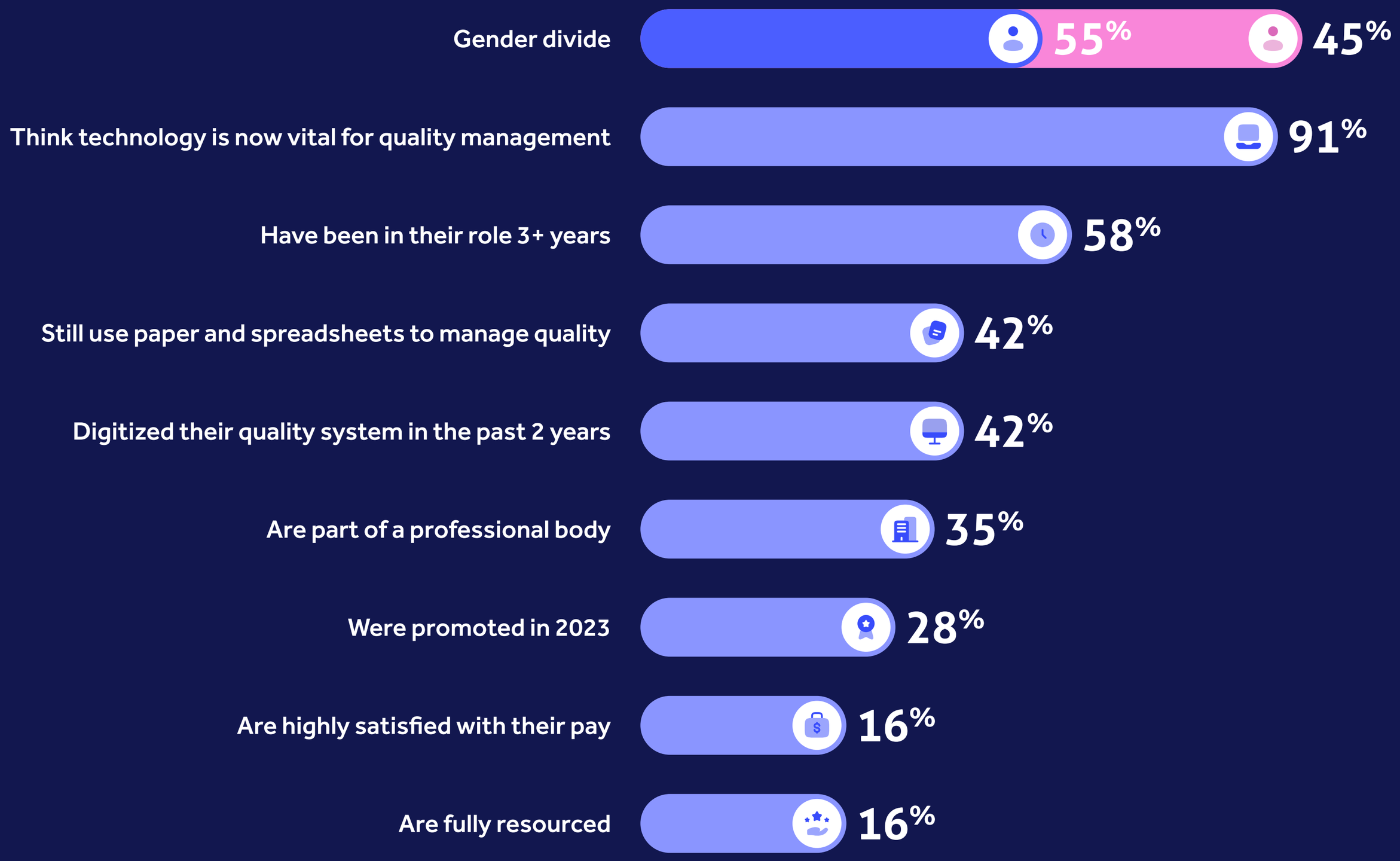
Life science business leaders still don't quite match their promotion of the quality agenda with concrete support and resources, but the overall picture looks better than last year – with our **respondents** more likely to agree that they feel **properly trained, equipped and supported in their vital work.**

Despite this positive swing towards digitization, paper, spreadsheets and SharePoint remain widely in use. Those using them reported lower operational and quality maturity, and a more difficult day-to-day.

A key theme of last year's report – disproportionate time spent on quality admin – persists this year, with upkeep and non-value-add tasks continuing to occupy quality professionals and minimizing time spent on the proactive continuous improvement activity encouraged by regulators.

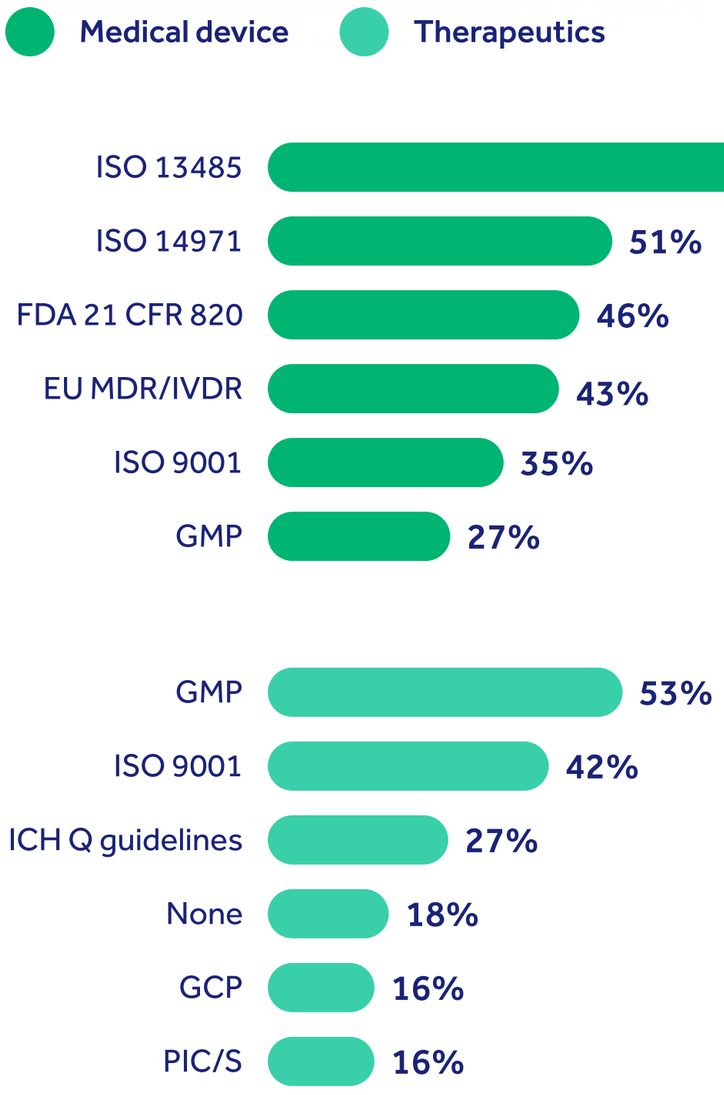
The life science quality profession has weathered the storms of 2020-23, emerging with stronger management backing and a new focus on optimizing processes, applying digital tools and bringing fresh devices and drugs to patients.

The state of play: our quality survey respondents in 2024

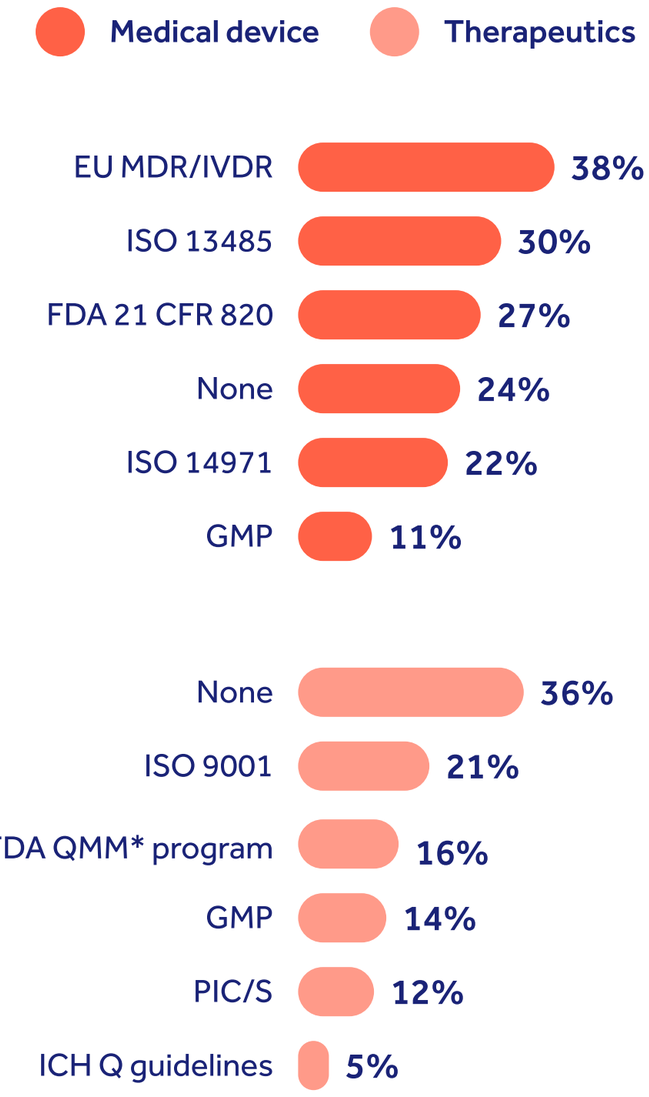


1 2024 quality & compliance: key standards & regulations

Already achieved



Targets for 2024



Quality Management Maturity

Analysis

The international quality and risk management standards of ISO 13485 and 14971 continue to dominate the medical device regulatory landscape.

Pharma and biotech companies continue to operate in a looser, less tightly defined regulatory environment. General national good manufacturing practices continue to form the main focus of quality efforts, followed by the generic, industry-agnostic quality framework of ISO 9001.

With over a third having no new regulatory or standard plans for the year, only 16% interested in aligning with the FDA QMM program, and only 5% planning to meet ICH Q best practice in 2024, the therapeutic world seems to be missing an opportunity to move beyond the bare-minimum industry baseline of GMP.

How this clear difference in quality focus affects the trajectory of these two key life science subsectors in the long term remains to be seen.

2 Quality snapshots

"Quality is high on your corporate agenda."

Avg. 7.5

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

Avg. 7.5

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

Avg. 7.1

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

Avg. 7

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

Avg. 6.8

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

Avg. 6.7

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

Avg. 6.4

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

Avg. 6.3

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

Avg. 6.2

"You're satisfied with your salary as a quality professional."

Avg. 6

Analysis

01 — As in previous years, a gap remains between theoretical and actual support of the life science quality department. Our respondents were more likely to report good corporate communication of quality than actual resources, support and investment.

02 — There's good news too. Compared to last year, our respondents were more likely to feel trained and supported on both an individual and departmental level.

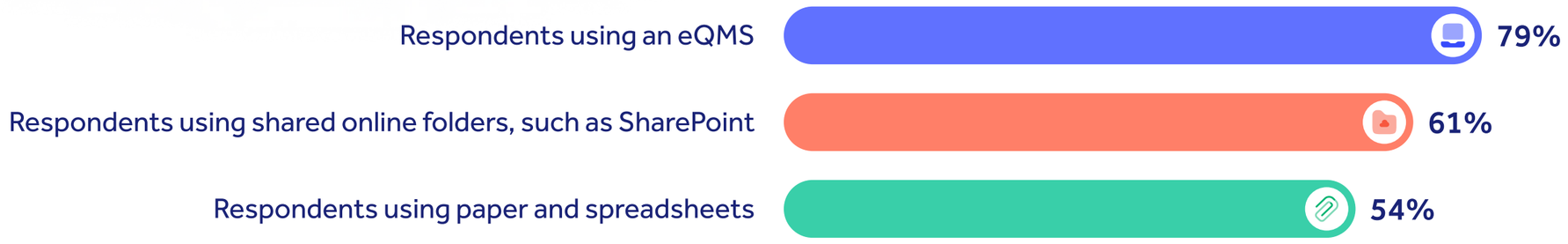
03 — There's still work to do. Only 14% felt their quality department was reaching its full potential. 46% felt that quality and compliance was getting more difficult every year - and in the US, only 7% completely agreed that new FDA initiatives were making good quality management easier to achieve.

We asked our respondents to what extent they agreed with these statements.

Trending up from 2023 *Trending down from 2023*

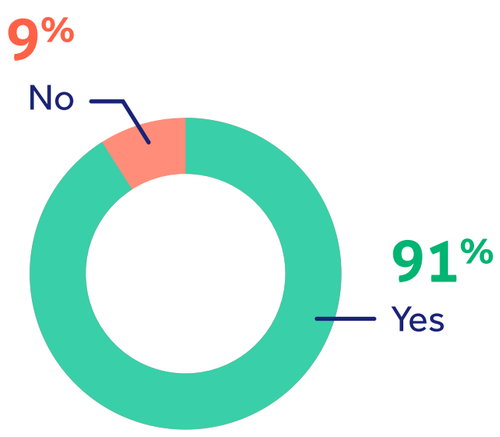
3 Tools and digitization

"On a scale of 1-100, how would you rate the maturity and overall effectiveness of your quality management system?"

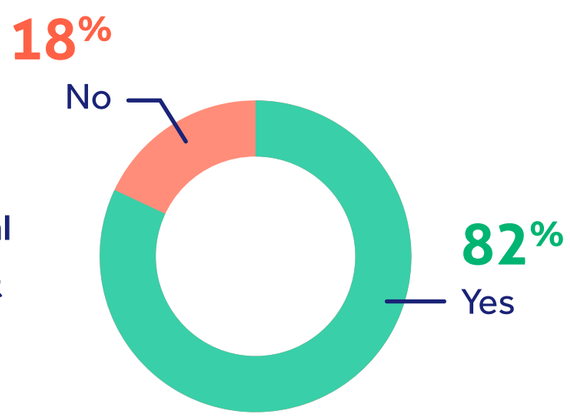


Impact of an eQMS

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

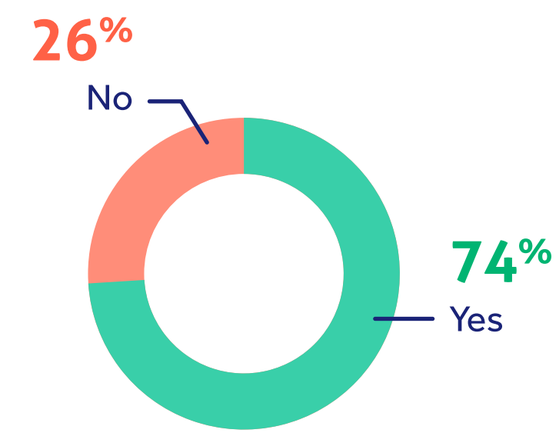


"Did implementing an eQMS have a beneficial effect on your product and process quality?"

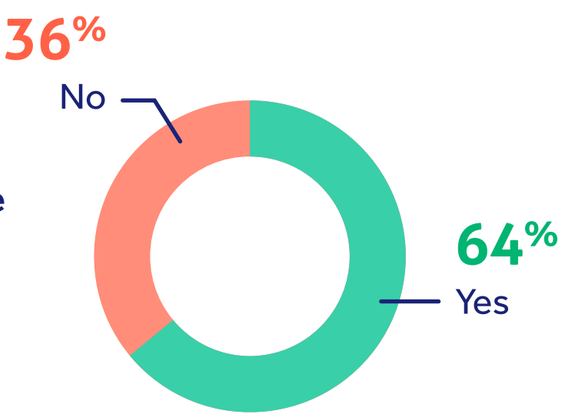


Using paper, spreadsheets & OneDrive

"Does your current quality approach make your day-to-day work more difficult?



"Does your current approach make it more difficult to optimize your product and process quality?"



4 The quality role

28% of our respondents had a promotion in 2023, slightly higher than in previous years.

Though 29% had only been in their role for 1-2 years – the largest individual group – twice that number had been in their role for over 3 years.

19% had enjoyed an incredible decade or more in their current role, reflecting the specialized and generally low-attrition nature of the life science quality role.

Reporting & accountability

Just under half of our respondents reported directly to a CEO or managing director.

A third reported to another quality professional, whether a director, manager or consultant.

And the remainder reported to a range of other roles, from COOs to operations and lab managers.

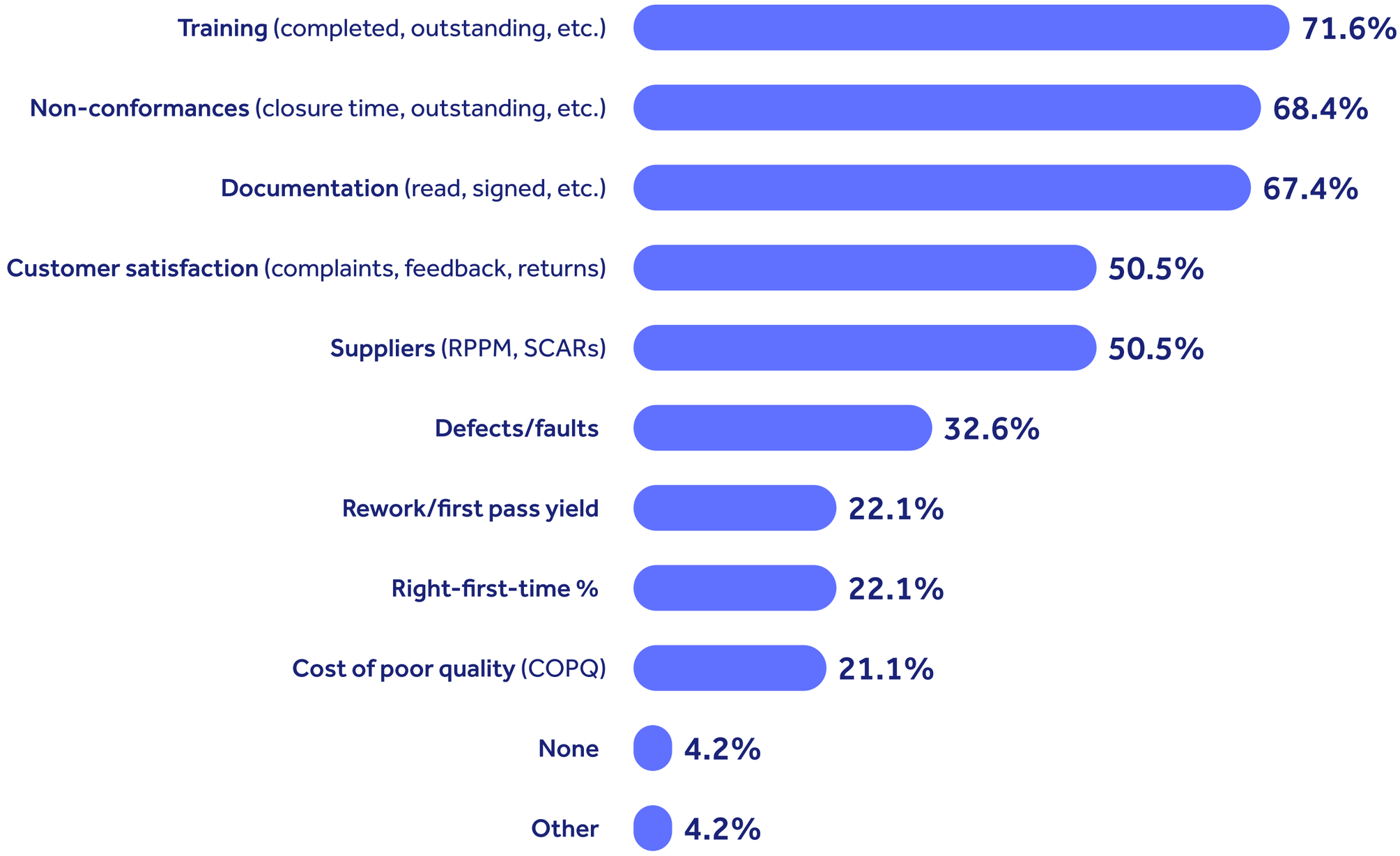
Why your business doesn't care about quality – and how to change that

Watch the webinar recording ▸

5 The day-to-day

Metrics

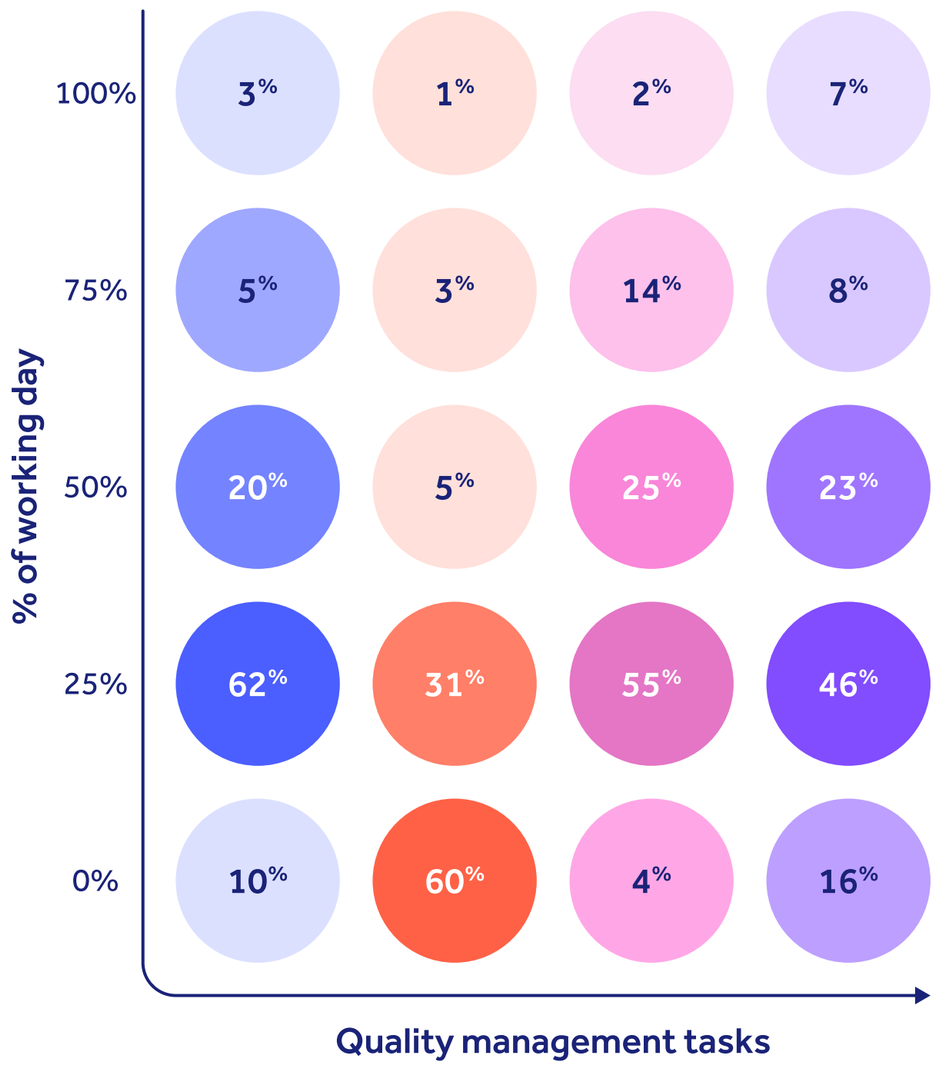
Most common KPIs tracked by life science quality professionals



Key tasks

A recurring theme from recent industry initiatives is the push for life science quality professionals to maximize proactive continuous improvement opportunities as a remedy to device faults and drug shortages.

But less proactive ‘negative work’, such as quality admin tasks, continue to block this push. 62% of respondents lost a quarter of their working days to automatable tasks like spreadsheet population, report creation and information-gathering.



- **Administrative tasks**
  (populating spreadsheets, producing reports, searching for information...)
- **Quality control**
  (batch inspections, sampling, testing...)
- **Quality assurance**
  (auditing, training, documenting...)
- **Quality improvement**
  (process changes, feedback actioning, CAPA execution...)

Analysis

01 — As in previous years, life science quality professionals are attempting to juggle admin, control, assurance and improvement tasks fairly evenly.

02 — But quality improvement tasks continue to be given less priority than they should. Only 38% could allocate more than a quarter of their time to improvement activity.

03 — 60% of respondents did no quality control activity whatsoever, like batch inspections, sampling and testing. This could be explained by increased automation of activity in these areas, with tools like process analytical technology increasingly seen on drug manufacturing lines.

04 — Minimizing and automating admin tasks in a similar manner should allow quality professionals to refocus on other task groups, with beneficial results. This could explain why almost 30% of respondents plan to ‘definitely’ adopt an eQMS in the next 12 months.

> ***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.***
>
> — Sion Wyn
>
> *GAMP SIG expert*
> *Managing Director of Conformity*

Professional membership

35% of respondents were members of a professional, statutory or regulatory quality body. The most common memberships were:

- The Regulatory Affairs Professional Society (RAPS)
- Parenteral Drug Association (PDA)
- The American Society for Quality (ASQ)
- The International Society for Pharmaceutical Engineering (ISPE)
- Chartered Quality Institute (CQI)
- Food & Drug Law Institute (FDLI)

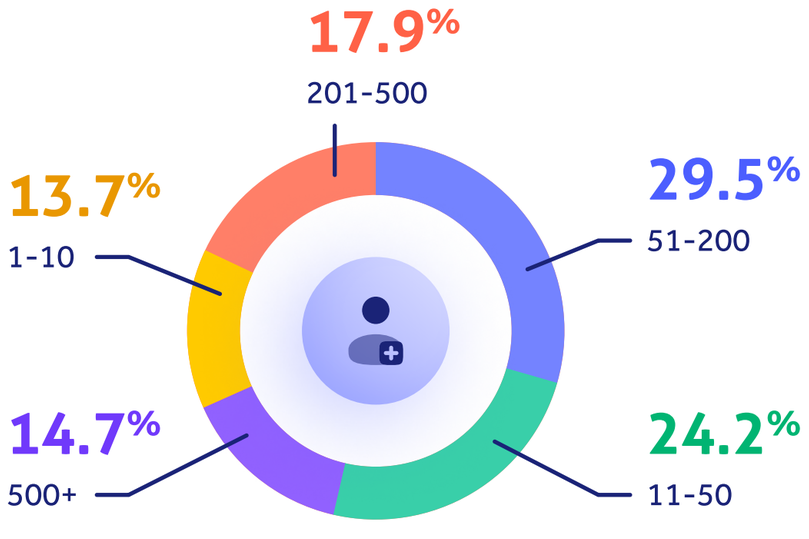
Finger on the pulse

The most common information sources for our surveyed life science quality professionals were:

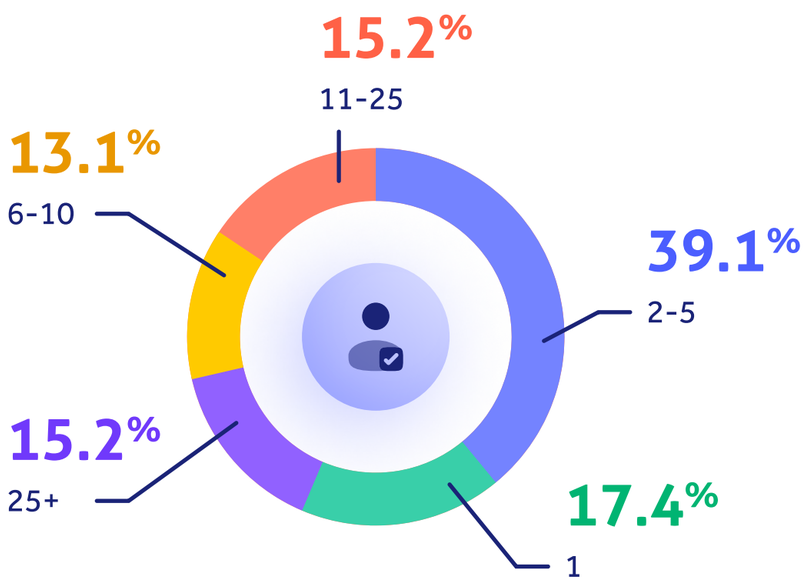
- Newsletters: FDA, RAPS, other national regulatory and notified bodies
- Websites: LinkedIn, ISO, Qualio blog
- Webinars: FDA, BSI, Qualio
- Third-party consultancy
- General Internet search

Headcount

How many people work in your organization?



How many people work in your organization's quality department?



Daily challenges

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

Dealing with the lack of quality and compliance culture in the company

Harmonization across multiple business units

Keeping up with document reviews **Knowledge transfer** **Root cause analysis**

Being the lone quality person

Keeping all the plates spinning! Manual/analog quality processes

Convincing other departments of the benefits of quality recommendations

Lack of management leadership

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

Having more time for improving processes and less time doing things that could be delegated

Get more visibility into quality/business metrics in real time

Give quality a louder voice

More time with senior leadership

More decision-making authority

Get an eQMS

Build a quality culture

Get your culture of quality in place

Download the culture of quality toolkit ▸

6 Some lessons learned in 2023

01 — "QA shouldn't be the company police, but can become it if you aren't careful"

02 — "Upfront investments in quality pay dividends later in the product lifecycle"

03 — "All regulatory bodies audit differently"

04 — "If it doesn't start at the top, it doesn't start at all!"

05 — "Maintaining a QMS is way more difficult than building one"

06 — "The merits of an eQMS vs. paper"

07 — "Always tell it like it is"

08 — "Quality isn't always appreciated, but we're all necessary"

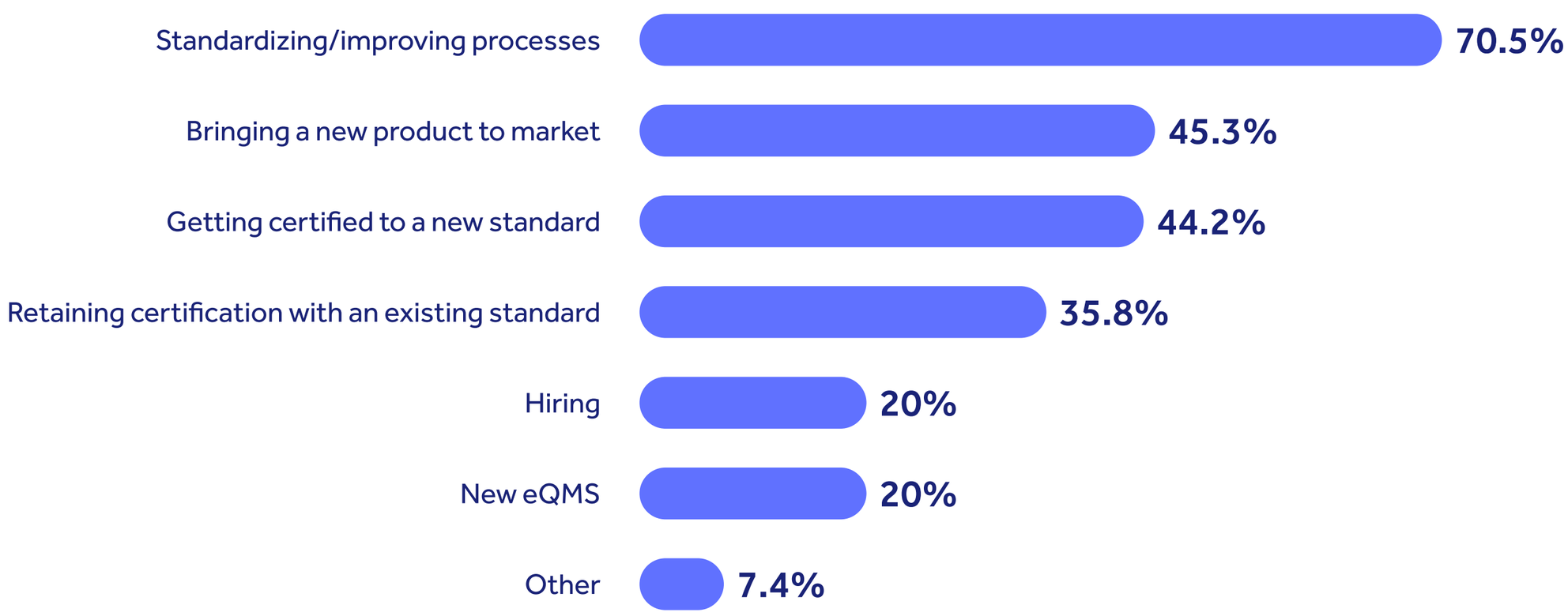
09 — "The maximum attention span during quality training is 15 minutes. Not everyone is as excited by quality as we are. Plan accordingly."

10 — "Expect the unexpected"

11 — "Tailor the message to the audience"

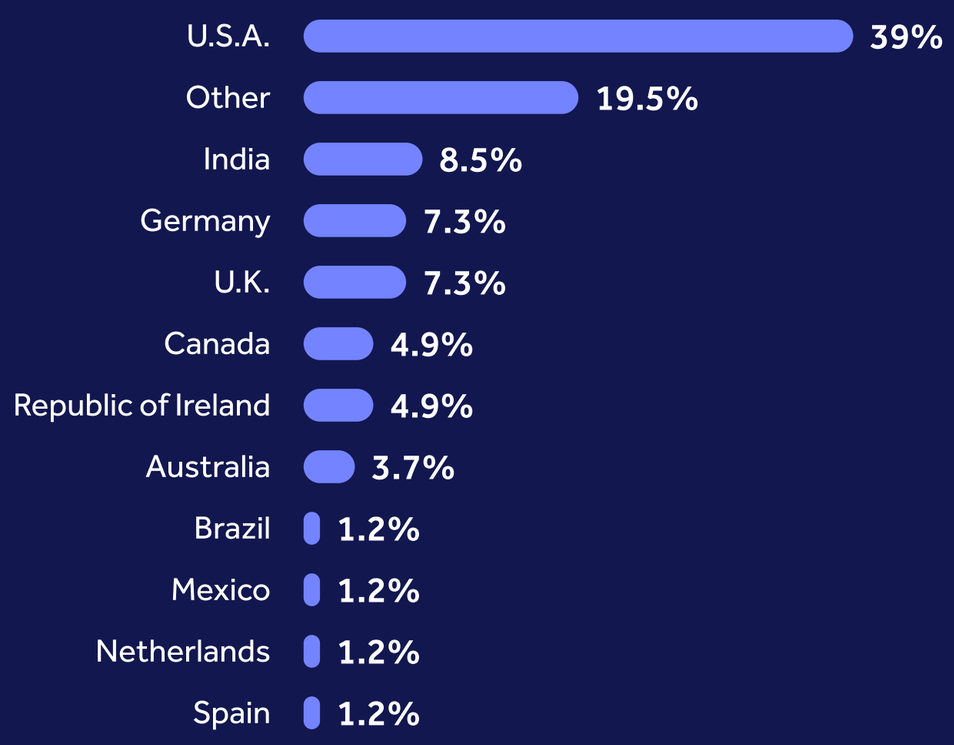
12 — "Simplicity is hard to recover once things get complicated - fight complication!"

7 Plans for 2024

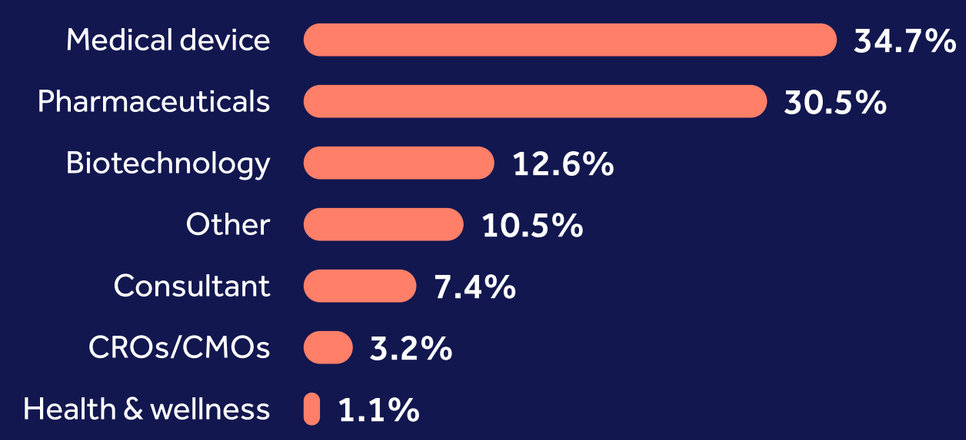


Methodology

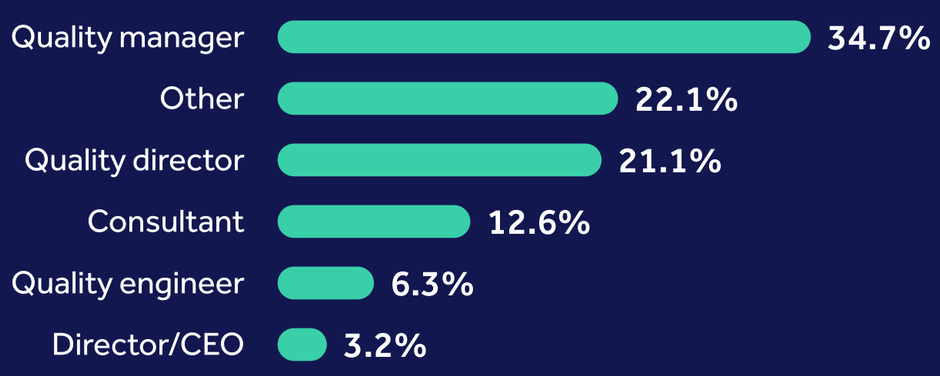
Location of respondents



Respondent company sectors



Profession of respondents



The survey was distributed by Qualio to 2000 life science quality professionals in March-April 2024.

Get more life science quality resources!

qualio.com/resources

Qualio