

QUALIO SURVEY SERIES

# Life science quality trends report 2023



# What did we learn from our 2023 global life science quality professional survey?



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Quality Operations Manager

*This is Qualio's second global life science survey, and therefore our first opportunity to make a year-on-year comparison of the state of the profession. And it's the areas of continuity from last year that stand out as the most interesting takeaways.*



Paper- and spreadsheet-based quality systems remain stubbornly widespread amid a general picture of under-supported and under-resourced quality teams.



A third of respondents have electronic quality management system investment squarely in their sights as a key 2023 objective.



As a result, unnecessary amounts of time are still being lost to manual quality admin and assurance tasks. Estimates of quality impact and realization of department potential remain middling.



And our special investigation of the impact of recent economic headwinds found quality more resilient and less affected than other professions.



But there are some positives to celebrate, too! Those able to digitize and modernize their quality systems are reaping the rewards and reporting higher levels of quality maturity.

*Although the profession shows signs of treading water, the stage is set for a more proactive and exciting future.*

# The state of play — Quality management in 2023

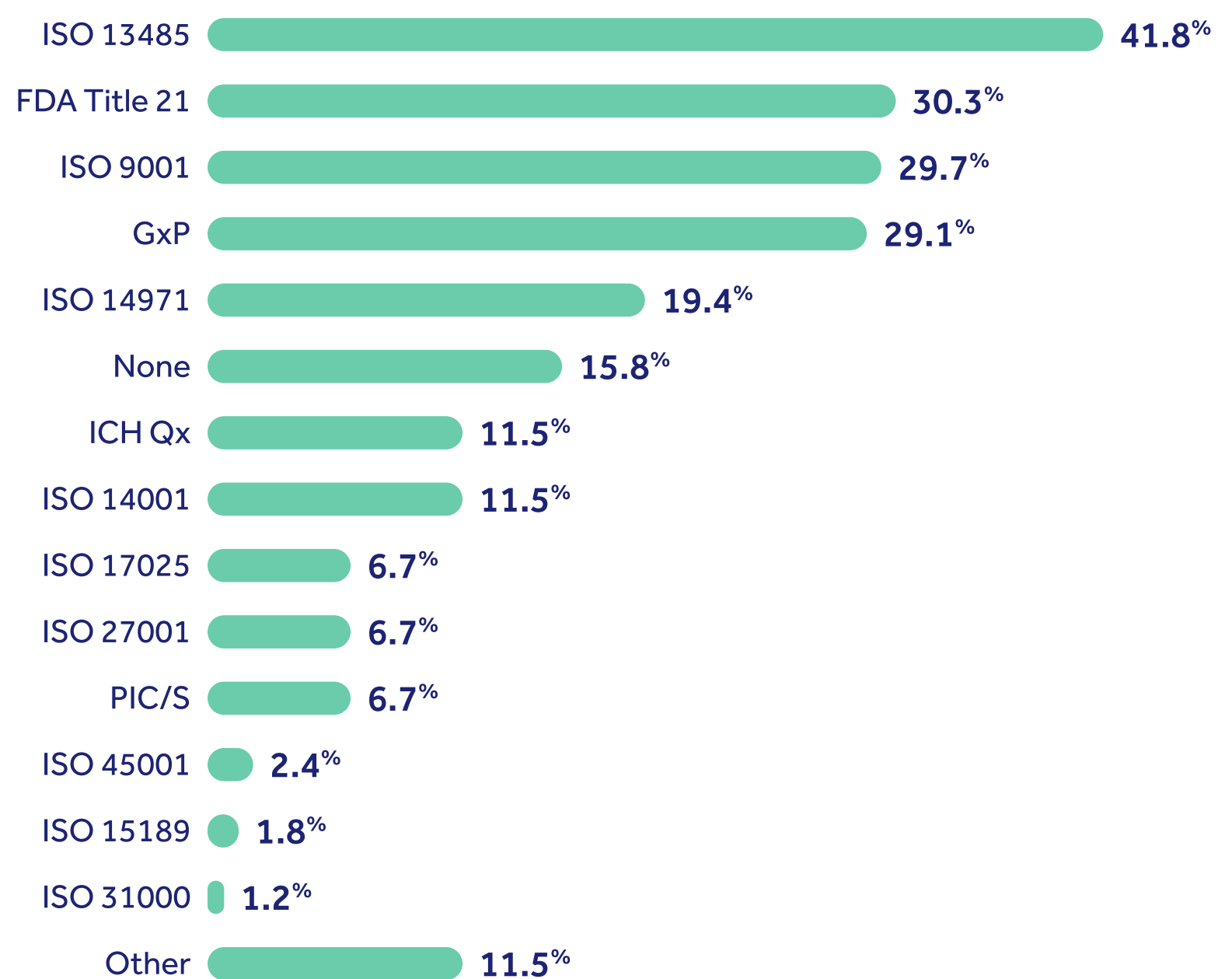


# 1 2023 objectives



## Quality standards and regulations already achieved

Just under one-sixth of our respondents were from early-stage start-ups, and therefore had no formal quality standards under their belts yet. But for the rest, ISO 13485 and FDA compliance continue to reign supreme. As in last year's report, only very small numbers of life science companies are interested in risk, environmental or health and safety standards – probably because of the disproportionate compliance burden of this sector leaving little extra quality bandwidth for areas like this.



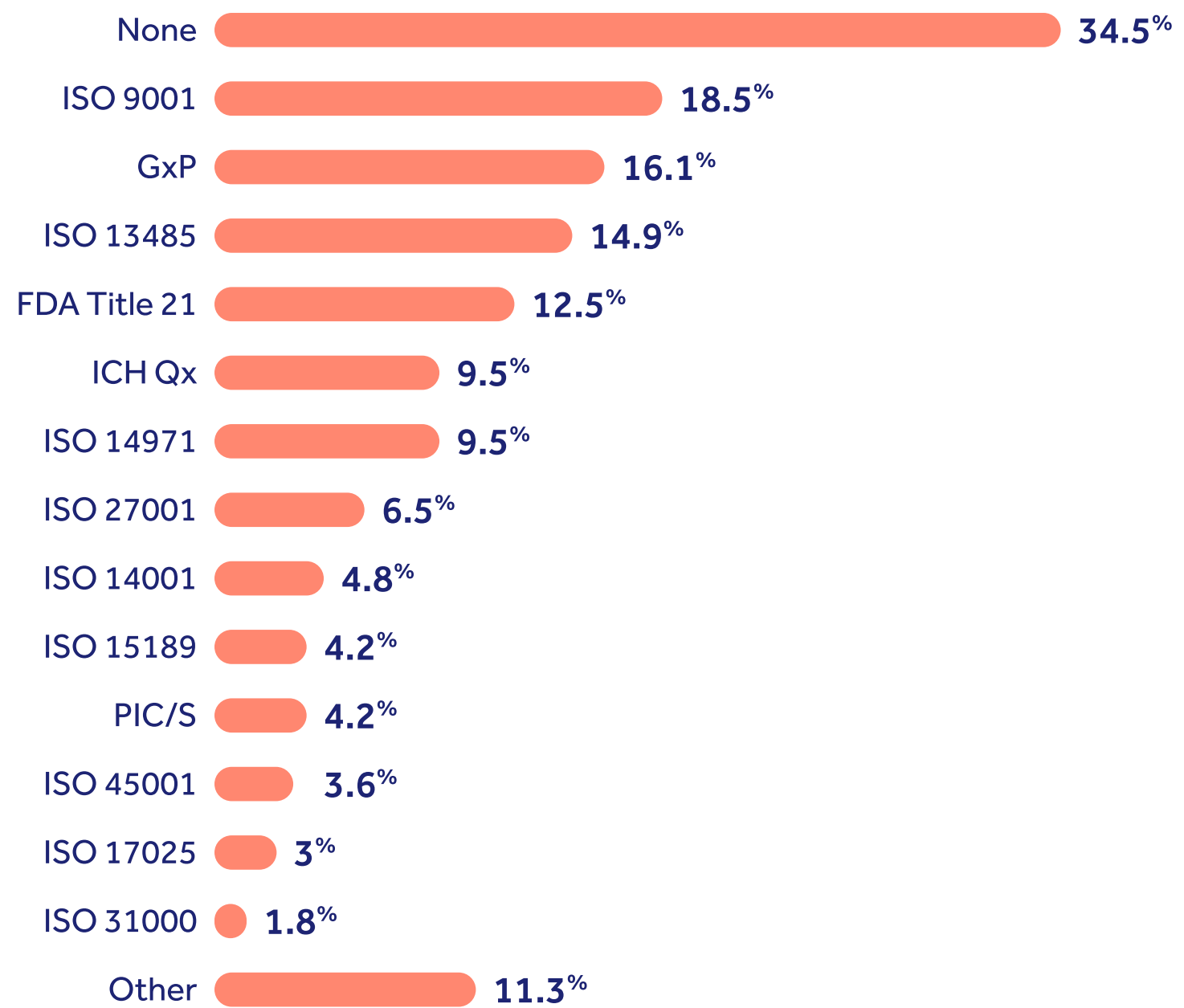


# Target quality standards and regulations for 2023

Over a third had no standards or regulations in their crosshairs for this year, 7% more than in last year's report.

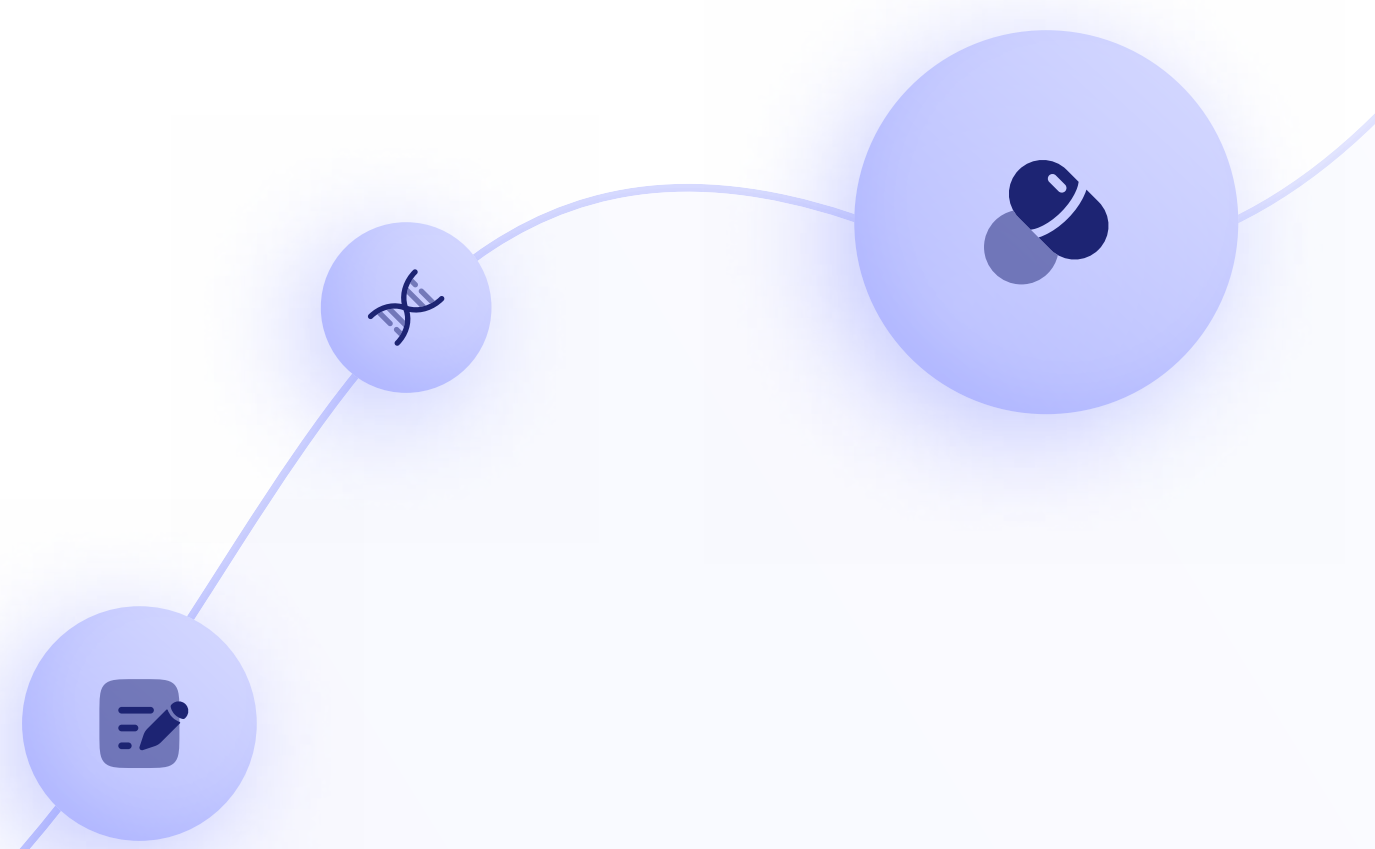
GxP and key ISO standards like 9001 and 13485 topped the priority list, while information security and risk standards continue to generate little interest among life science companies.

Among the 'other' target standards and regulations, the MDSAP, EU compliance and CE marking were key, along with a smattering of less common targets like WHO and GACP compliance.



## Analysis

- 01** — 38% of our respondents were from pharmaceutical, biotech or CRO/CMO organizations, yet ICH and PIC/S compliance are neither deeply embedded or targeted – with GxP and FDA compliance the primary consideration for these companies.
- 02** — Conversely, medical device companies were far more likely to pursue ISO 13485 and ISO 14971 compliance on top of their national regulatory requirements – perhaps demonstrating a stronger quality focus or international expansion appetite in this sector.
- 03** — ISO 9001 has grown in popularity since last year's report despite its generic nature. Life science companies appear increasingly open to adopting ISO 9001 as a baseline for expansion into other more industry-specific requirements.



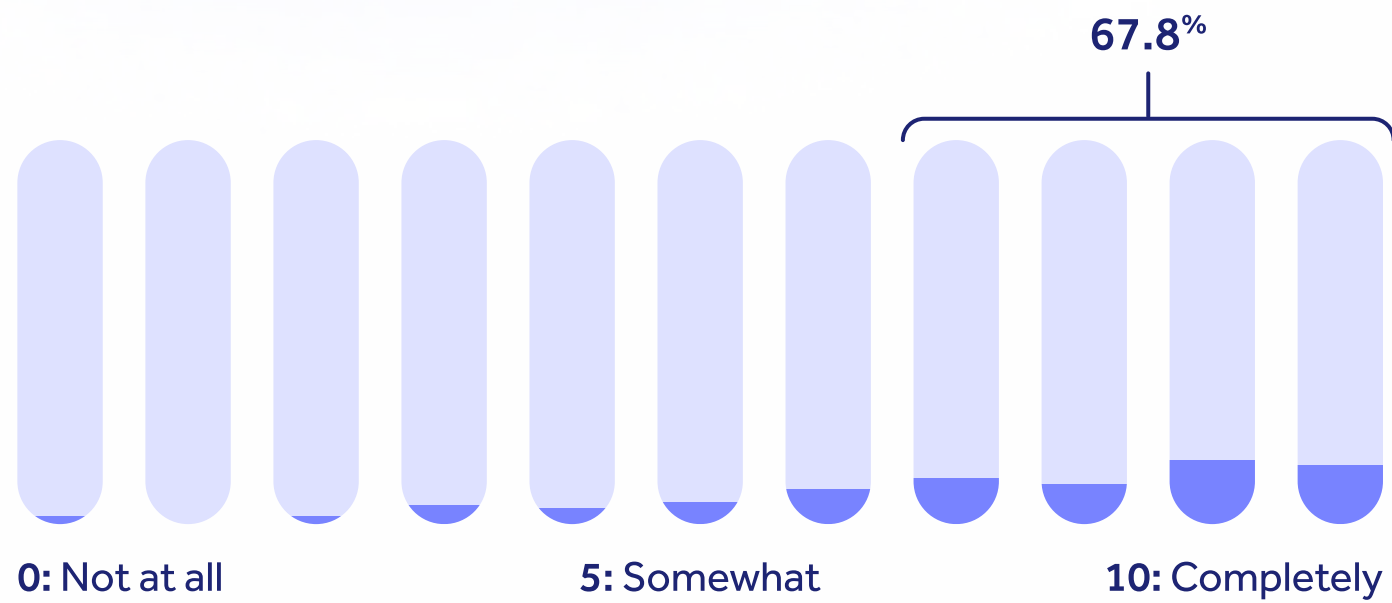
**Aiming for ISO 9001?**  
[Try our toolkit ▶](#)

**Aiming for ISO 13485?**  
[Access helpful resources ▶](#)

## 2 Quality snapshots

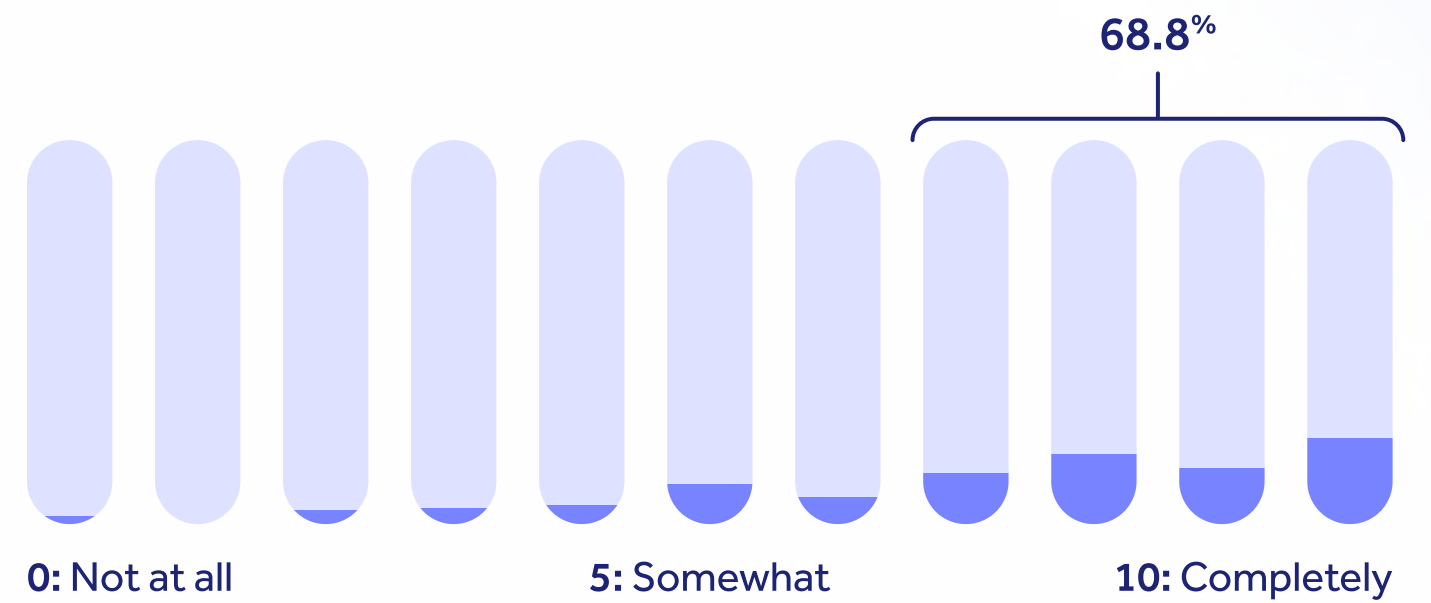
"Quality is high on your corporate agenda."

Avg. 7.3



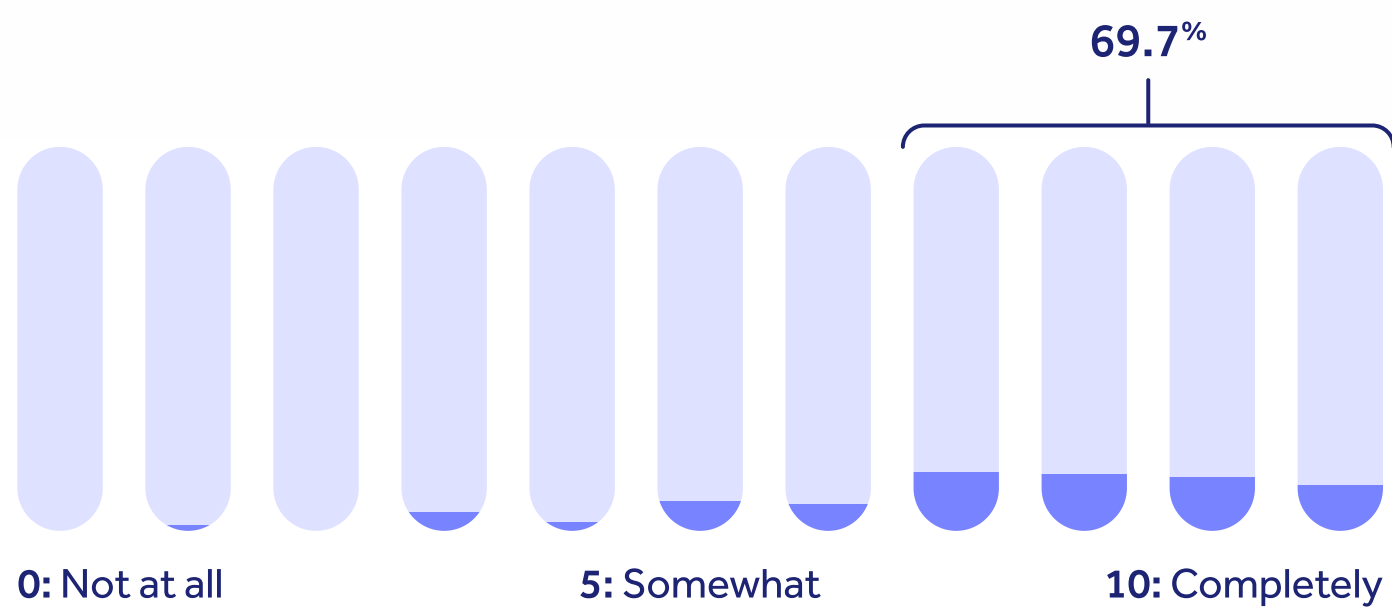
"The importance of quality is effectively communicated by your senior leadership."

Avg. 7.2



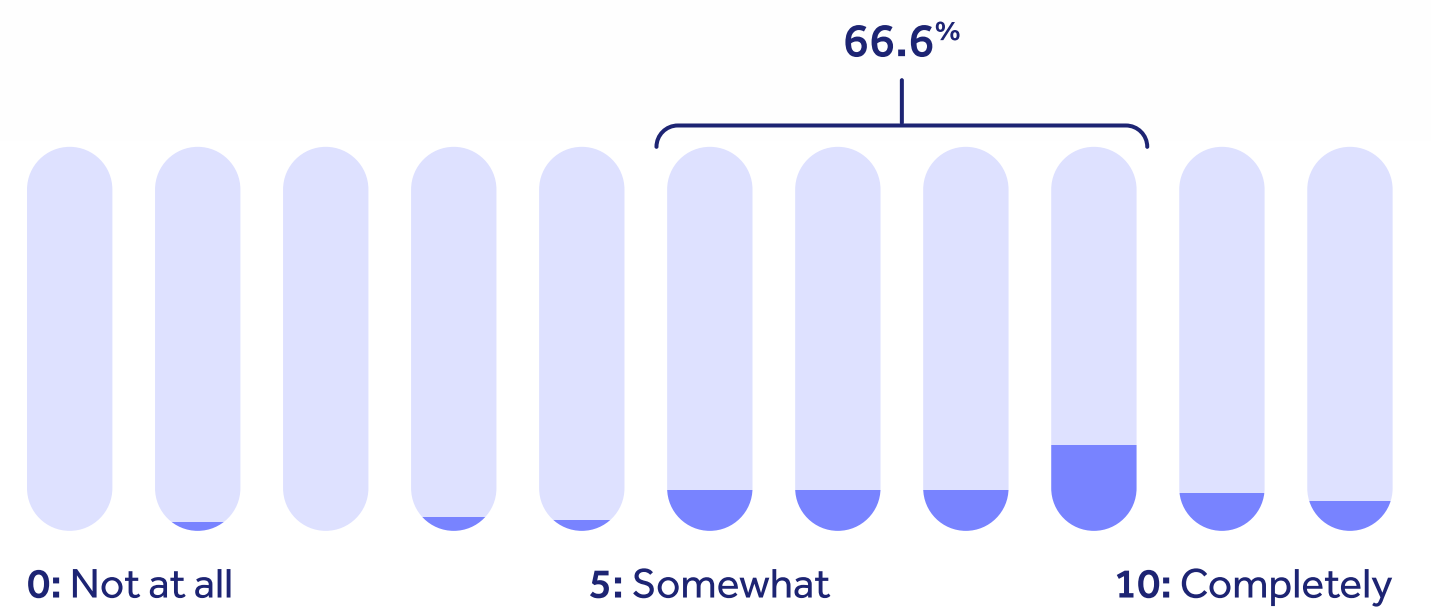
"Your internal policies and procedures are fit for purpose."

Avg. 7.2



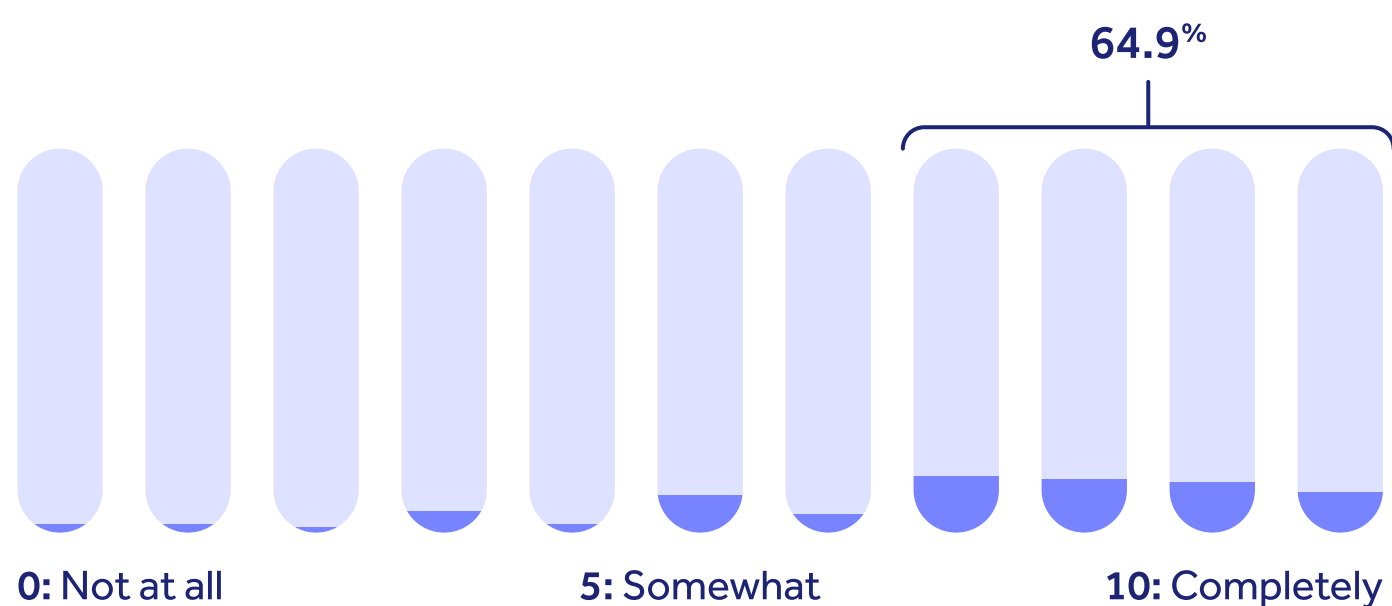
"The quality department is effectively resolving risks, opportunities and issues."

Avg. 6.9



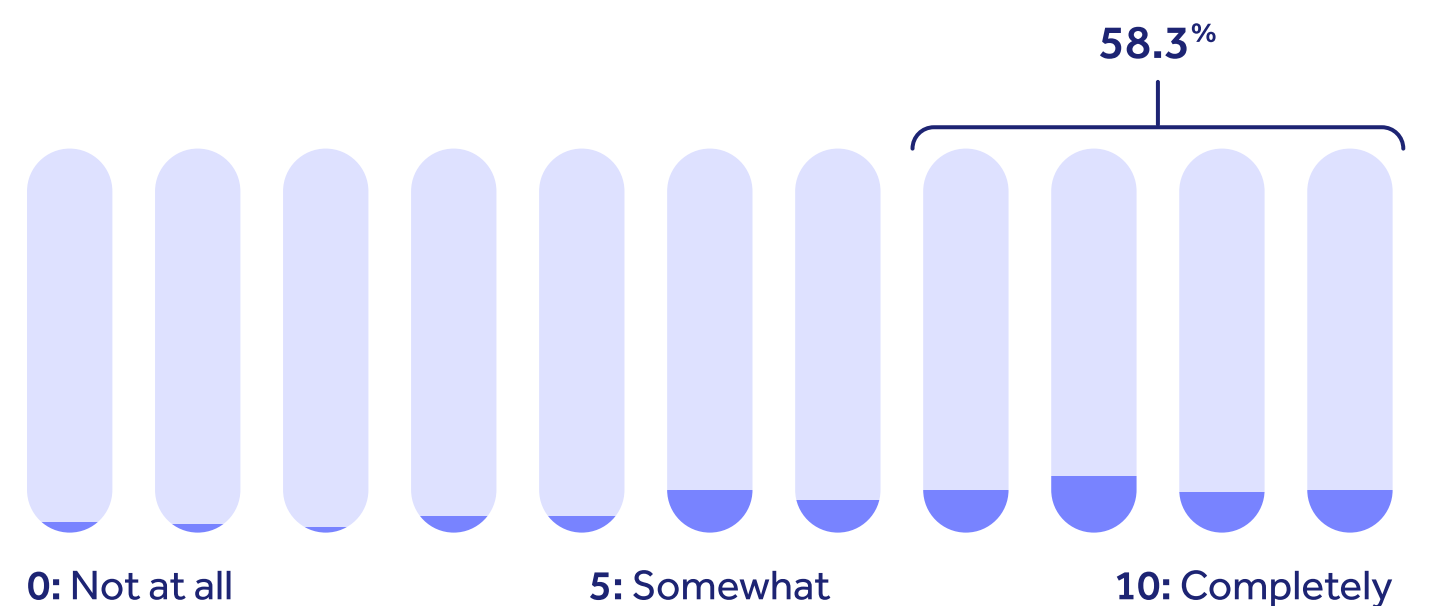
"You feel valued and have the training and support you need to be confident in your role."

Avg. 6.8



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

Avg. 6.6



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



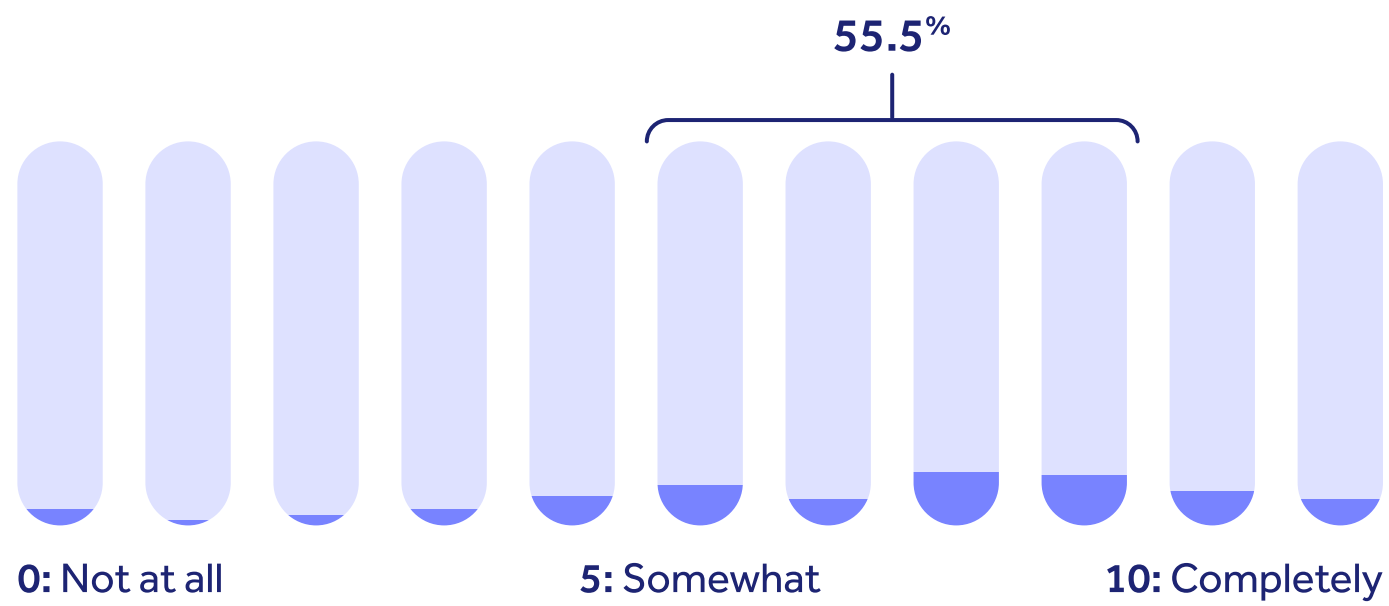
Trending up from 2022 figures



Trending down from 2022 figures

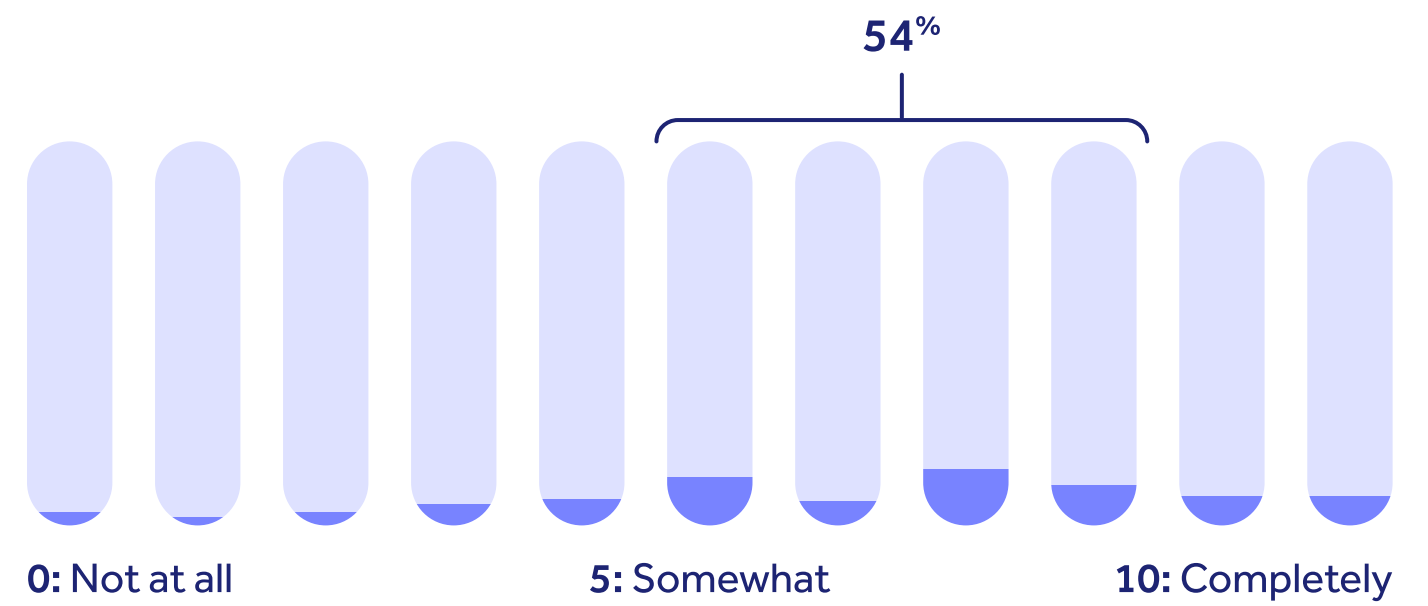
"The quality department has the resources and support it needs to function properly."

Avg. 6.2



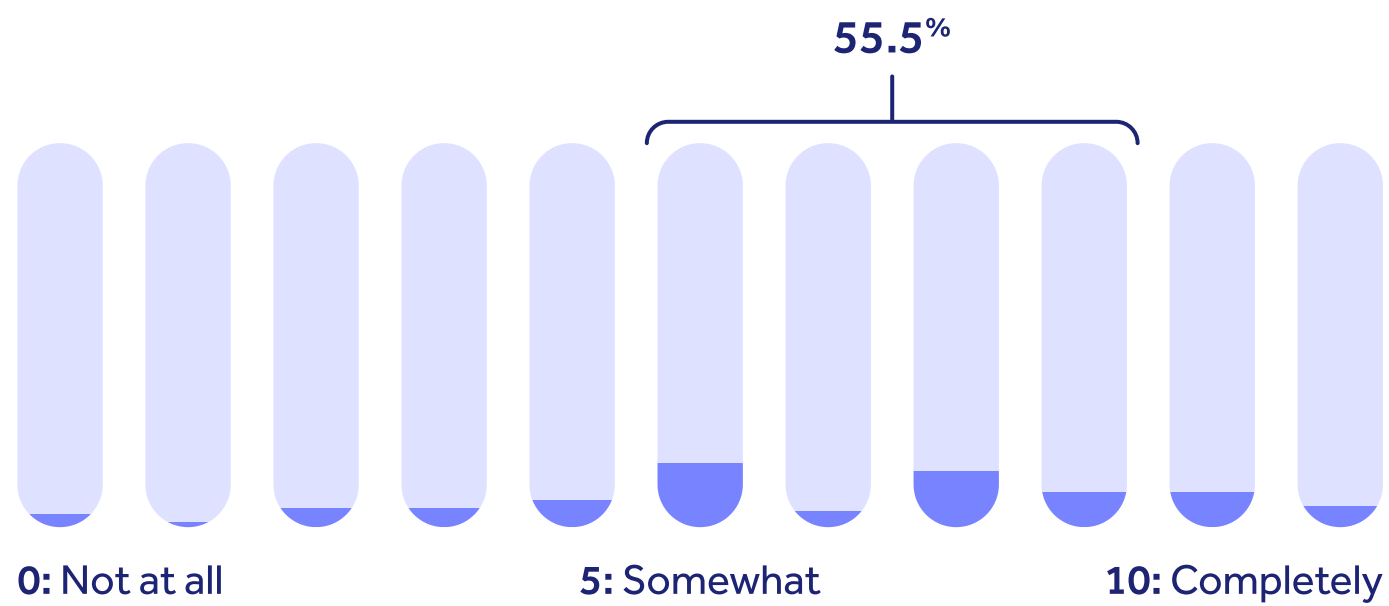
"The quality department is being used to its full potential."

Avg. 6



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

Avg. 5.9

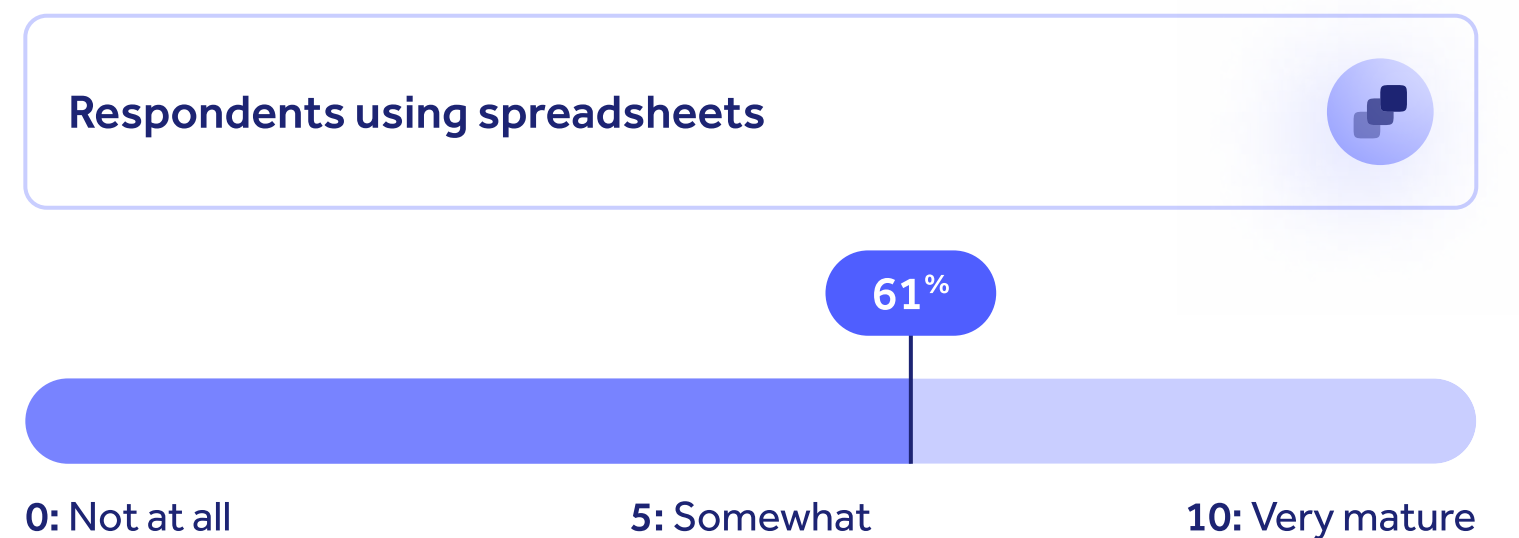
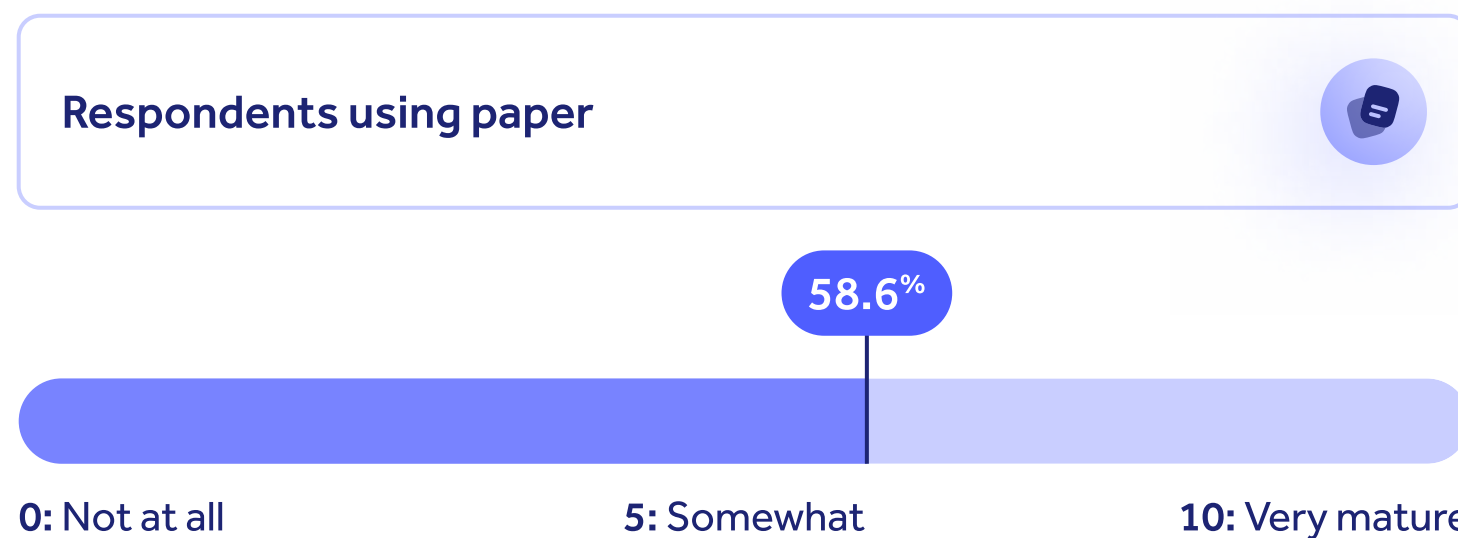


## Analysis

- 01 — Our findings align very interestingly with last year's report. Life science business leaders continue to place a theoretical premium on quality that isn't necessarily translated into concrete support, investment, spend and resources – particularly compared to other business areas.
- 02 — As such, fewer than 10% of respondents felt their quality team was reaching its complete potential. Confidence in current policies and procedures appears fairly high, while audit readiness and ability to effectively fix business issues lag behind.
- 03 — Proactive industry initiatives like the FDA's [Quality Management Maturity program](#) and new [CSA guidelines](#) therefore appear well-timed amid a general picture of middling, static quality management with limited space or support for improvement.



## “How would you rate the maturity and overall effectiveness of your quality management system?”



## Analysis

A key finding from last year is amplified this year: digitization of quality shows a clear correlation with quality maturity, confidence and ability to drive continuous improvement. As one respondent put it:

“ *An integrated **electronic QMS** brings exponential improvements in compliance and efficiency.*

— Female U.S. quality engineer



# 3 The quality role

We ran a dedicated in-depth [quality professional salary survey](#) last year, only briefly touching on the topic in this survey. Nevertheless, our findings in both surveys correlated.

A similar figure – 26% of our respondents in this survey – said they’d been promoted in 2022.

Salary satisfaction appears similarly middling and mediocre. Only 10% were completely satisfied with their pay, with the bulk of responses falling between the ‘somewhat’ and ‘completely’ satisfaction brackets.

Nevertheless, exactly half of respondents have been in their role for 1-5 years and over a third longer than that.

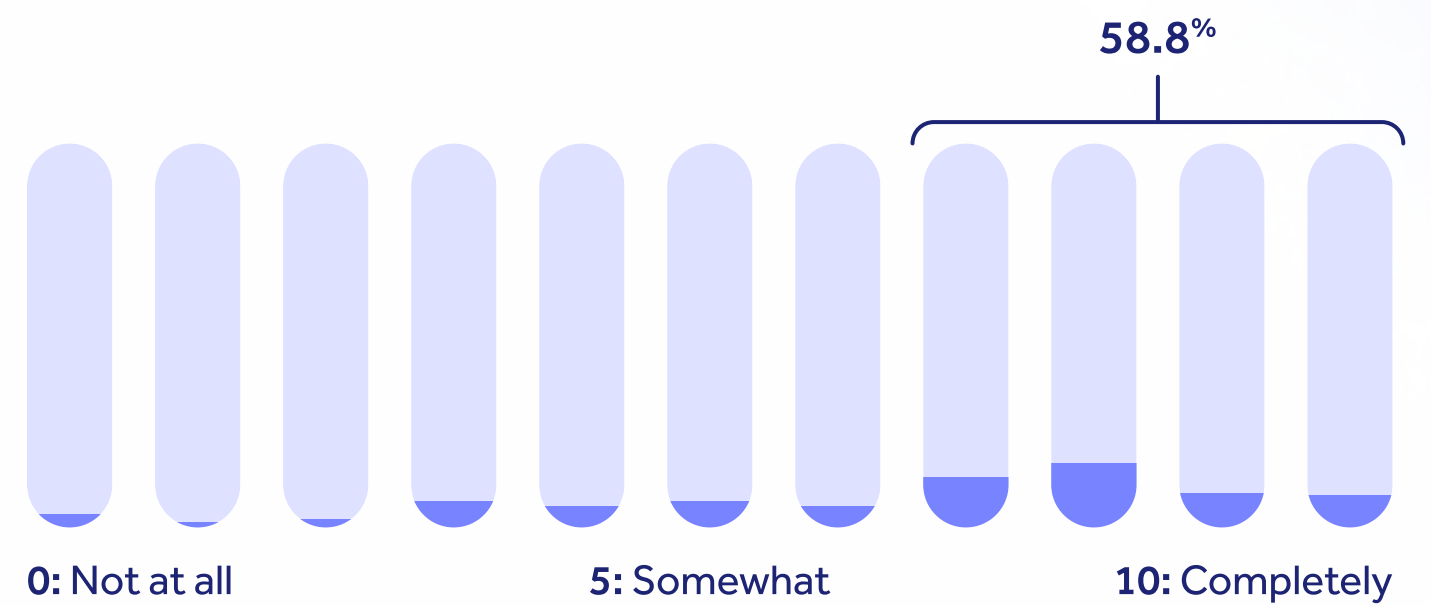
Life science quality appears to be an unusually sticky role with lower-than-average attrition, perhaps down to its highly specialized nature.

## Reporting & accountability

Exactly half of our respondents reported directly to a managing director or CEO in their day-to-day work.

24% reported to a quality director, 13% to a quality manager, 5% to a consultant, and the remainder to another job role.

How satisfied are you with your pay? Avg. 6.4



Download our detailed salary report

[View insights now](#) ▶

↗ Trending up from 2022 figures ↘ Trending down from 2022 figures

## 4 Mini-report: 2022 headwinds

*2022 was an unusually chaotic year in the business world, marked by rocketing interest rates, widespread lay-offs and a global teeter to the edge of recession.*

*We asked our respondents an extra set of questions to gauge the impact of these economic headwinds on the quality profession.*

### Headcount

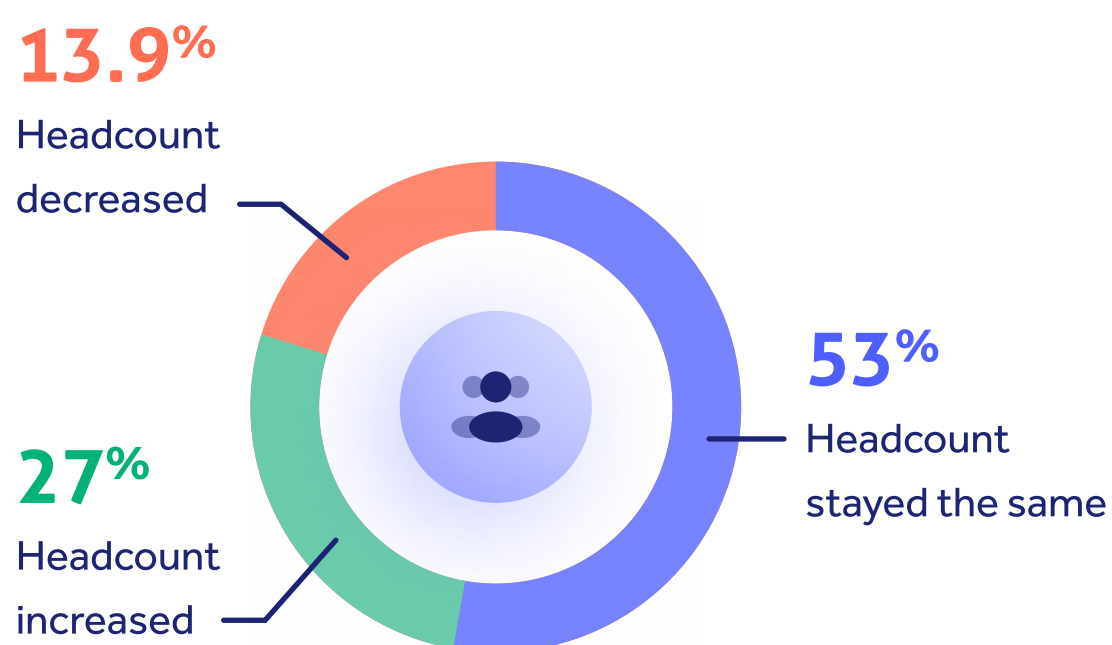
Quality headcount appears fairly stable compared to other impacted professions.

53% of respondents said their quality team had stayed the same size and that hiring hadn't been affected in 2022, while 27% even reported growth. 20% said their team had shrunk in 2022.

Of those respondents that had witnessed expansion of quality headcount, over half agreed that quality department growth had kept proportional pace with the growth of the wider business.

However, a not inconsiderable 30% felt that quality hiring was slower than in other departments, and only 16% felt the size of the quality team had grown as a proportion of the wider company.

Almost a third witnessed a hiring freeze, and only 15% saw quality hiring accelerate.



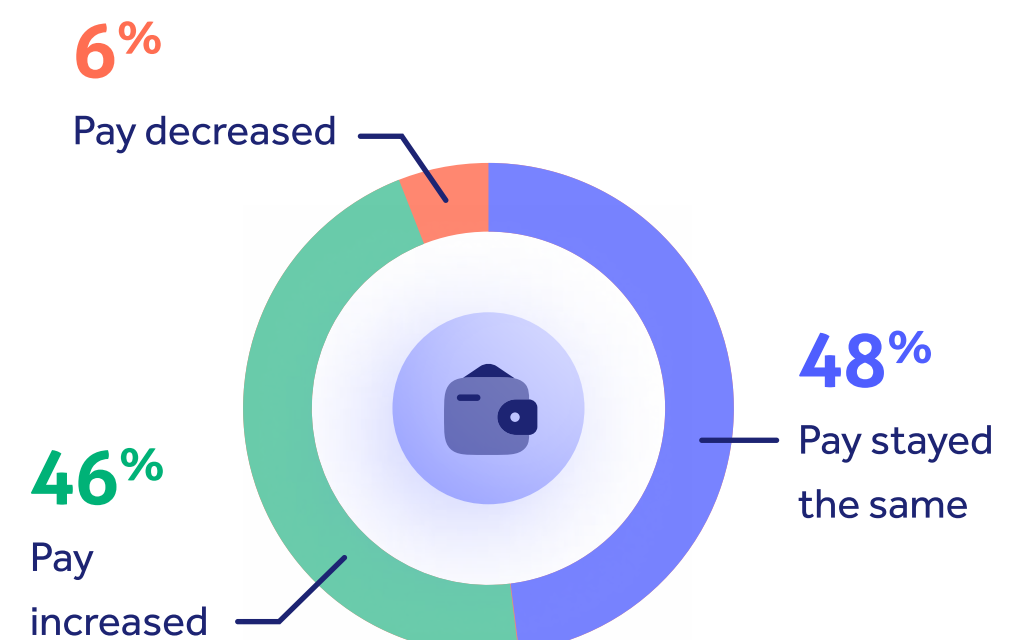
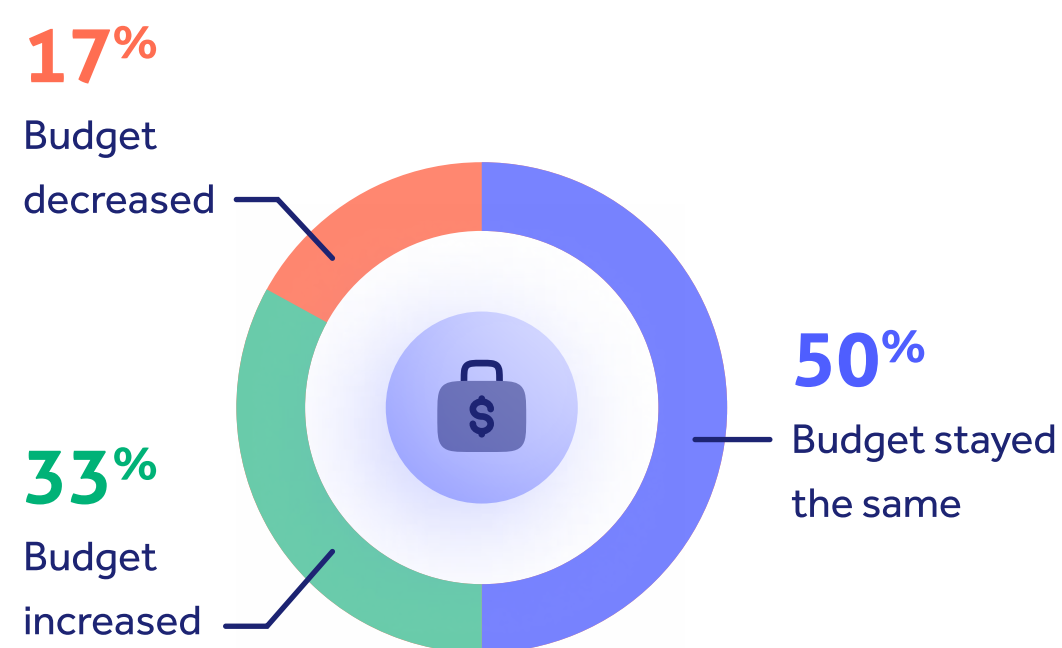
### Budget & pay

Half of respondents saw a freeze in both budget and salary.

However, few suffered any cuts: only 17% saw their budgets slashed and only 6% had their pay reduced.

A third could happily report an increase in budget in 2022, and 46% had a pay increase.

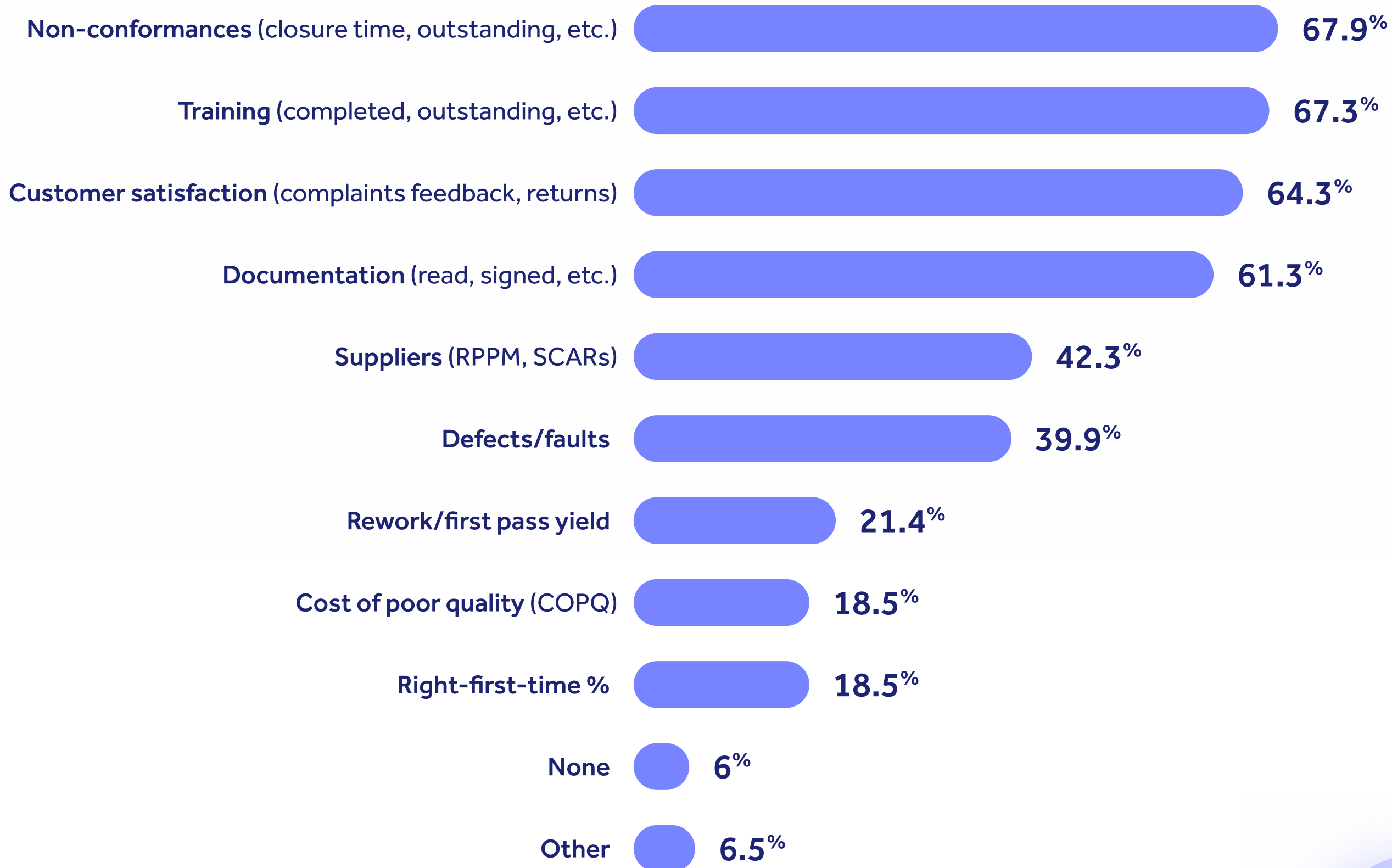
The picture is therefore intriguingly mixed: quality appears to have met the challenges of 2022 with either stagnation or continued growth, rather than any serious contraction in presence or budget.



## 5 The day-to-day

### Metrics

Most common KPIs tracked by life science quality professionals



### Analysis

- 01 — Non-conformance metrics narrowly replaced training at the top of the most commonly tracked quality metrics this year.
- 02 — Customer satisfaction and the cost of poor quality, vital metrics which appeared undermeasured last year, both increased this year, but at the expense of supply chain metrics.
- 03 — Careful balance of metrics, including financial and supply chain impact of quality, is the key to an optimized QMS – so quality professionals should be conscious of the handful of key data points they prioritize.

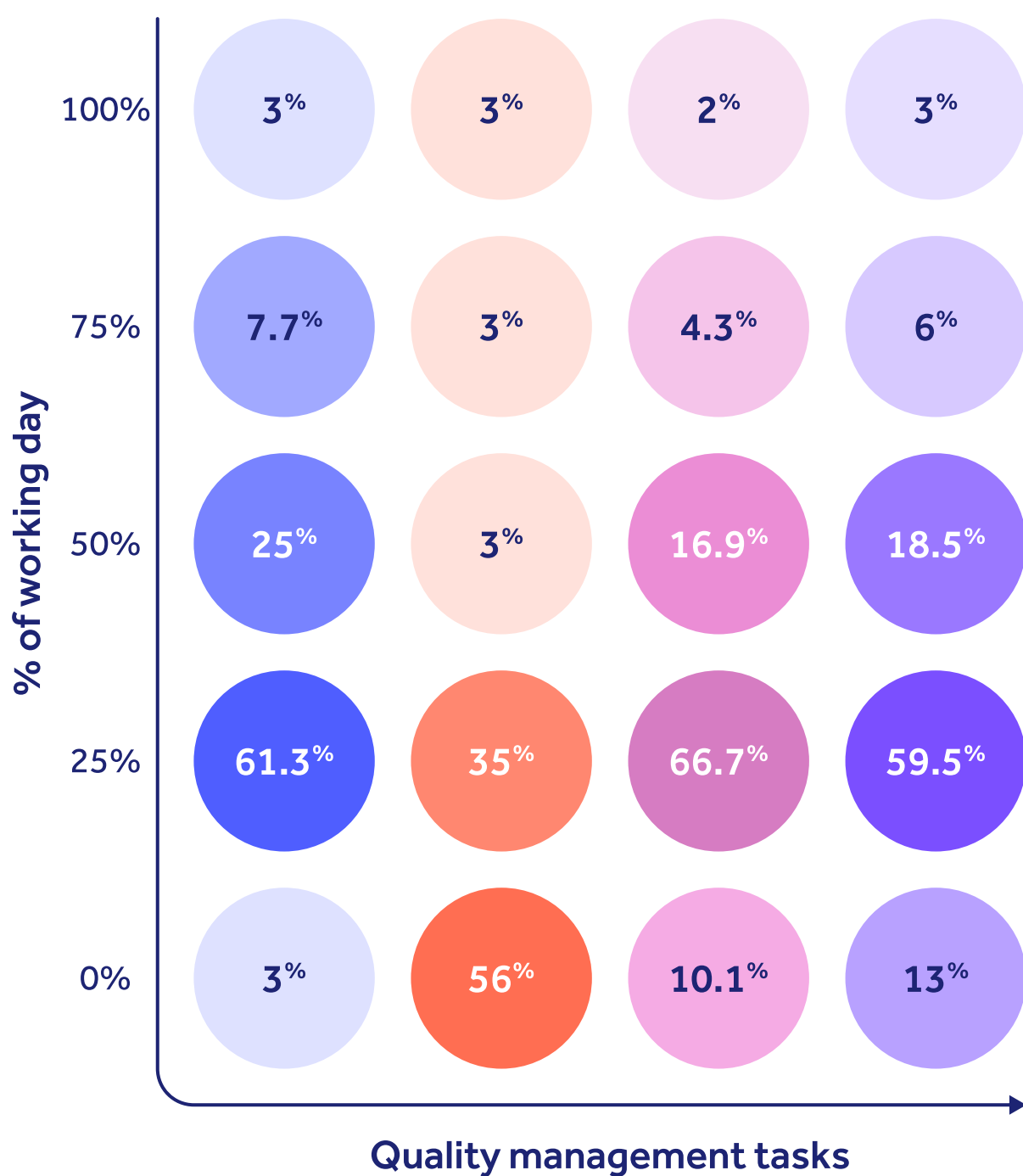


## Key tasks

In keeping with the general feedback of underinvestment in quality management, quality professionals are spending large chunks of time on manual admin and upkeep tasks, rather than value-add activity like assurance and improvement.

Over 60% of quality professionals lose a quarter of their day to admin, while 25% lose a whopping half of their time to spreadsheets, reports and data-finding.

Over half of life science quality professionals now spend no time at all on quality control activity, while three-quarters of respondents could allocate no more than 25% of their time to proactive quality improvement.



- **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 last year’s report, the majority of life science quality professionals seem to be attempting a somewhat equal balance of time allocation between the four task groups.

**02 —** But in keeping with the stubbornly high adoption of paper and spreadsheets, unnecessary amounts of time are still being lost to basic quality tasks. The largest percentage group, 66.7%, fell to those who spent a quarter of their time on quality assurance tasks like managing documentation and training — processes which naturally demand more time expenditure in manual, paper-based quality systems.

**03 —** There are some positive trends to cheer: in the main, less time is being spent on admin than in last year’s study. But the number of life science quality professionals with no time at all for quality improvement has increased, while quality control time allocation has slumped.

**04 —** Maximizing time spent on quality improvement and QMS optimization by minimizing time spent in the other areas continues to be the primary focus for both professionals and regulators. As an FDA report puts it...

“ *Standards for material systems, equipment and facilities, production, laboratory, packaging and labeling, and a quality system... are foundational and set a minimum threshold that companies must achieve... they do not include more advanced levels of quality management...*

— FDA drug shortages 2019 report



## Professional membership

39% 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](#))
- Research Quality Association ([RQA](#))

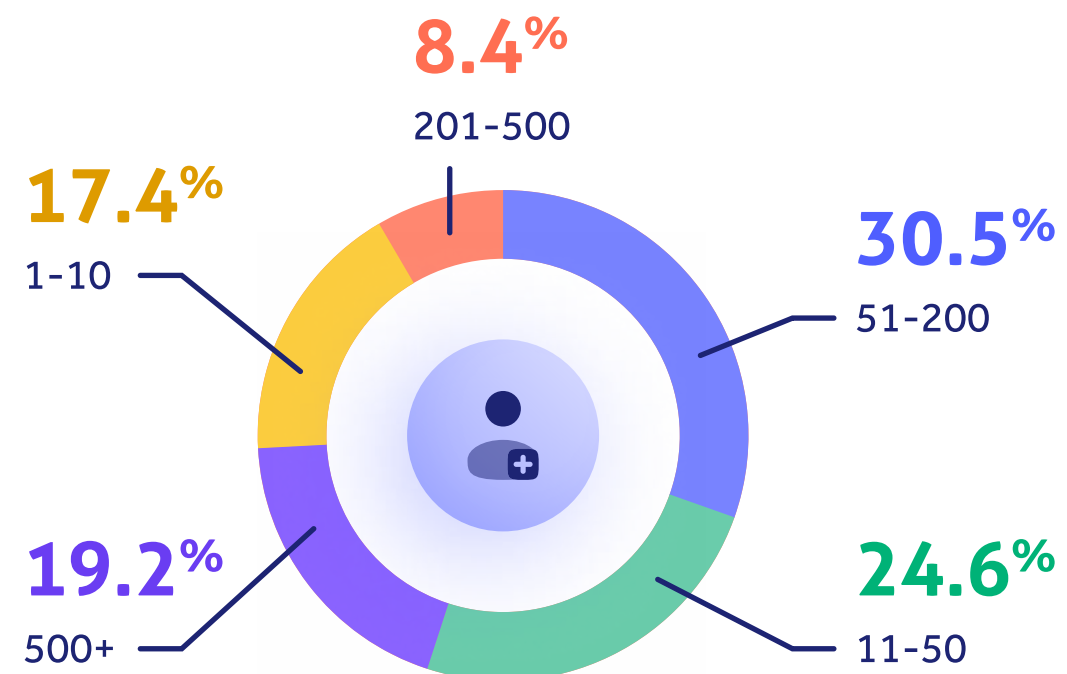
## Finger on the pulse

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

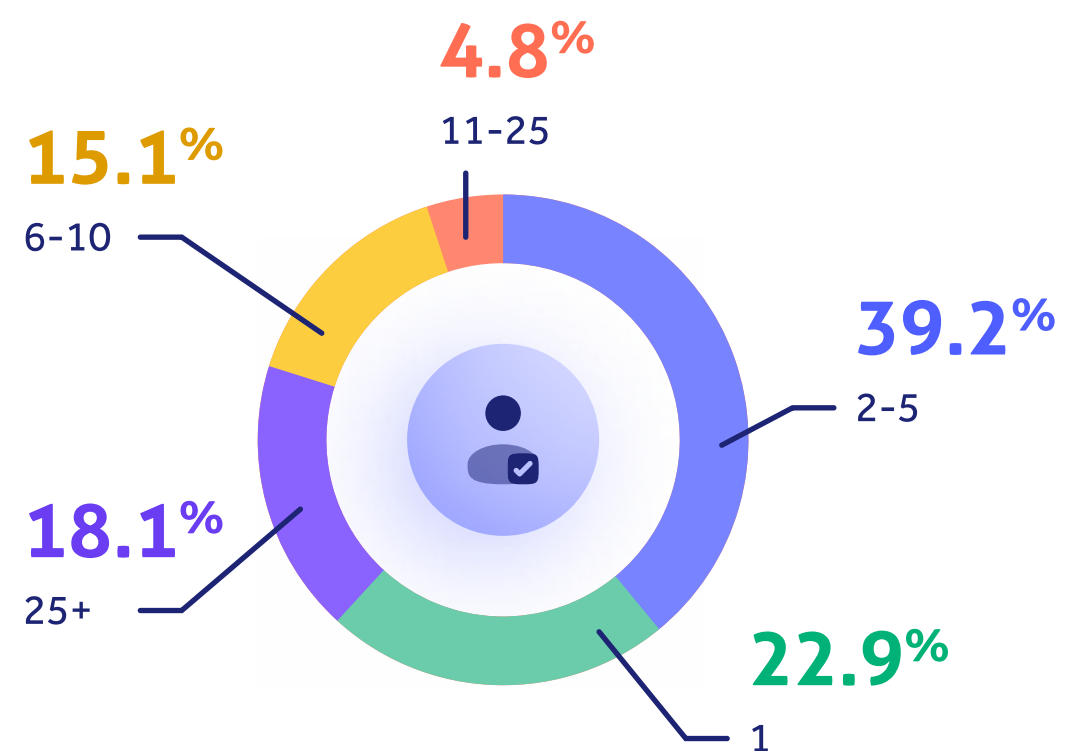
-  Newsletters: FDA, RAPS
-  Websites: LinkedIn, ISO
-  Webinars: FDA, BSI, Qualio
-  Third-party consultancy

## 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:

Getting people to buy into an eQMS and its time/money saving effects

### Quality processes only implemented in the quality department

Keeping up with compliance in a volatile, changing world

Internal regulatory/compliance experience

Internal training

Working remotely

### Company-wide quality culture

Making SOPs people follow

Aligning product development with regulatory demands

Having sufficient time to investigate and adequately understand quality issues

### Convincing executive management of the importance of quality

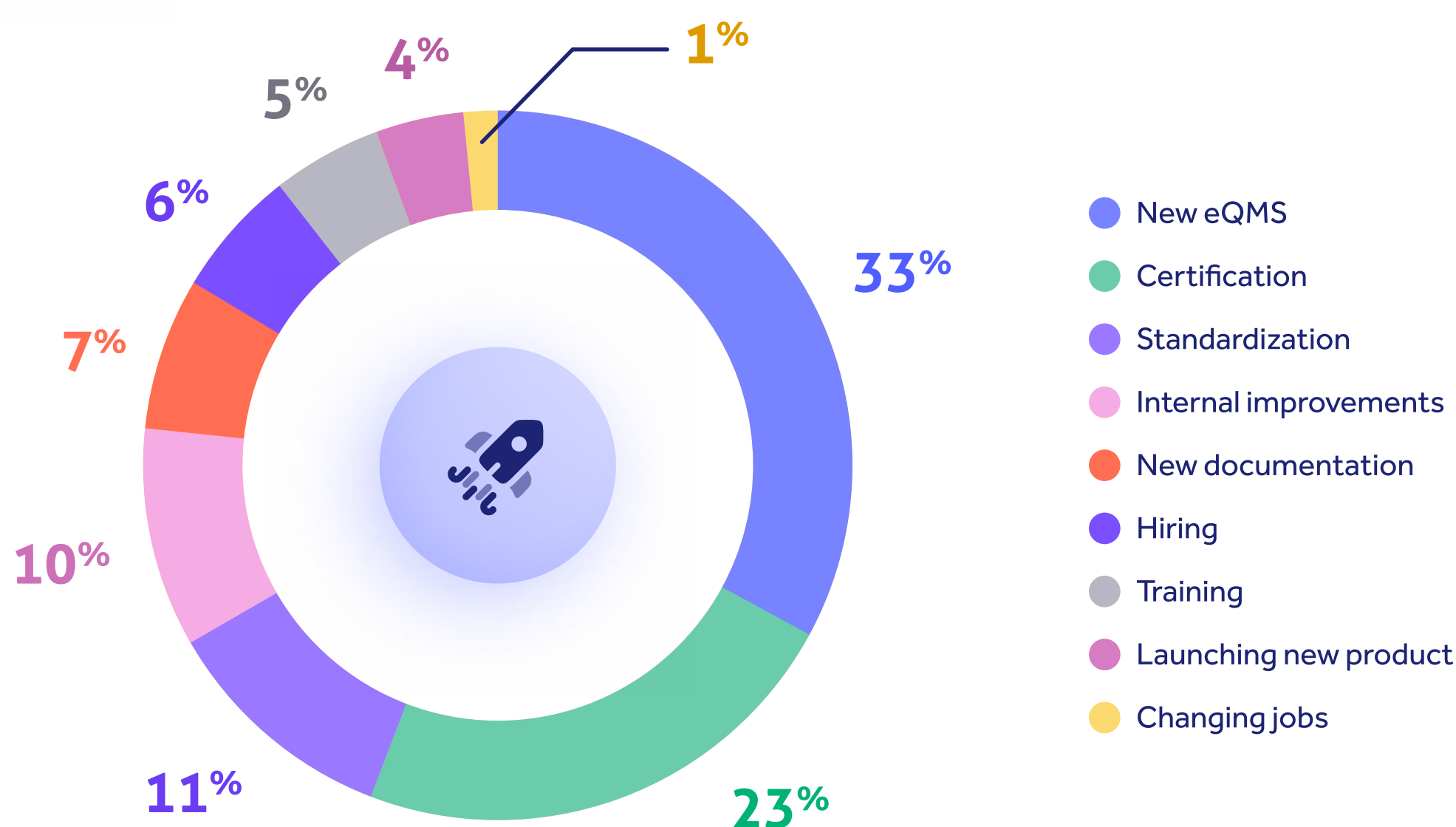
## When asked what they'd change in their role if they could, the most common answers were...

-  *Get everyone to take quality and compliance seriously in a regulated industry*
-  *Make quality everyone's responsibility*
-  *Get more technological support*
-  *My director!*
-  *Try and get into the management team to make changes*
-  *More tools, training and resources*
-  *More automation of entered data*
-  *Reduce admin*

## 6 Some lessons learned in 2022

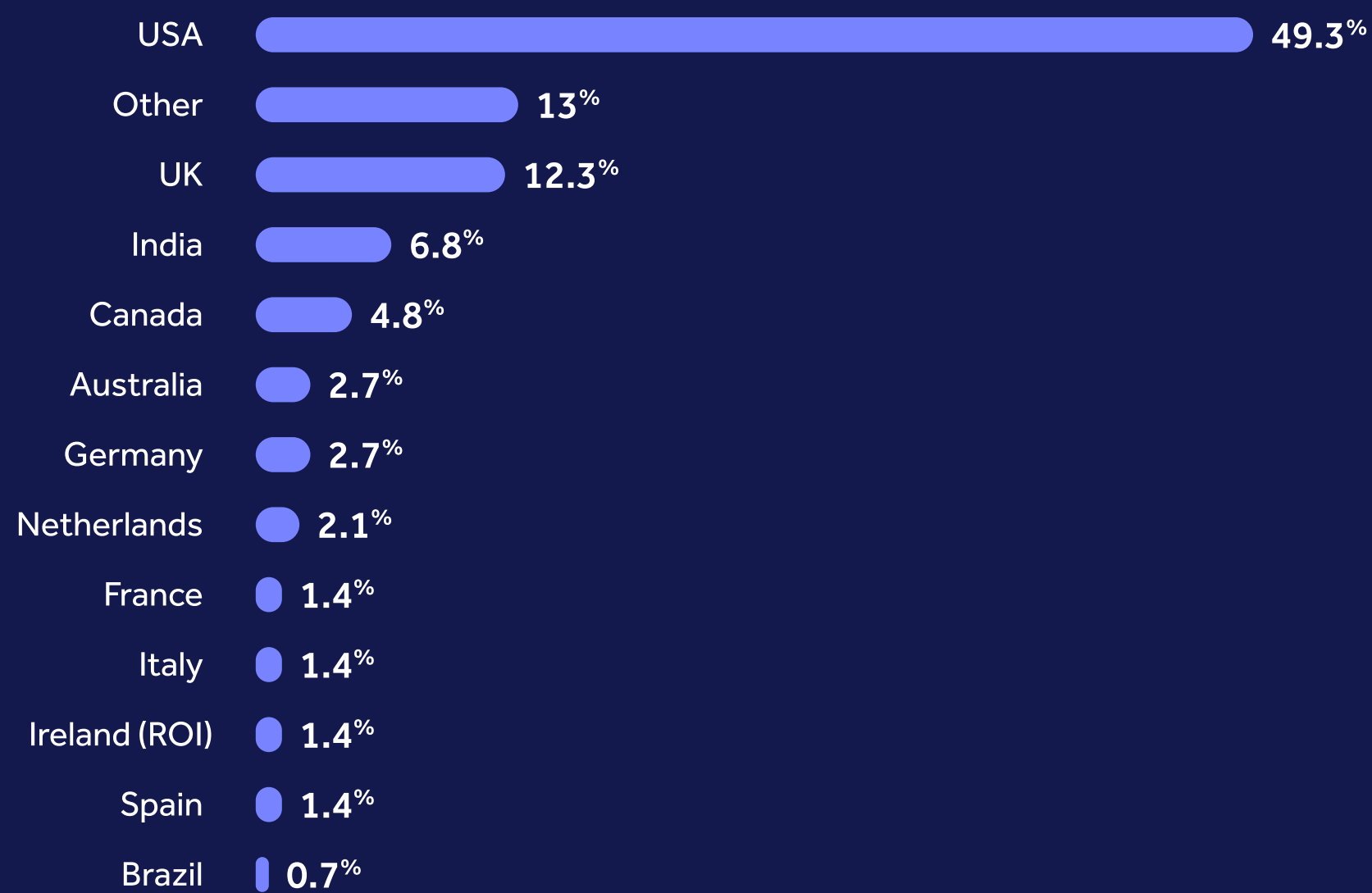
- 01 — “Don't put the cart (product) before the horse (QMS processes)”
- 02 — “Collaboration between engineering, R&D and quality is 90% of the company. Compliance is *very* difficult without it”
- 03 — “Perseverance! Quality is important so keep pressing the message”
- 04 — “Regulatory strategy can make or break a business”
- 04 — “Feelings of ownership of the QMS by key management and department leaders are essential”
- 06 — “The EU MDR is a monstrous piece of legislation. Anti-small business, anti-innovation, stifling”
- 07 — “The cost of an eQMS is less than the cost of manual labor spent on performing tasks”
- 08 — “Having a dedicated quality person and digital technology is make-or-break for small life science companies”
- 09 — “Quality by tickbox is as prevalent as it ever was in corporate pharma & medical device sectors!”
- 10 — “How amazing a cloud-based eQMS is”
- 11 — “Having outstanding, compliant vendors will minimize time lost to fixing QA issues with products”
- 12 — “Timeliness in closing out investigations is important and working too slowly can be costly”

## 7 Plans for 2023

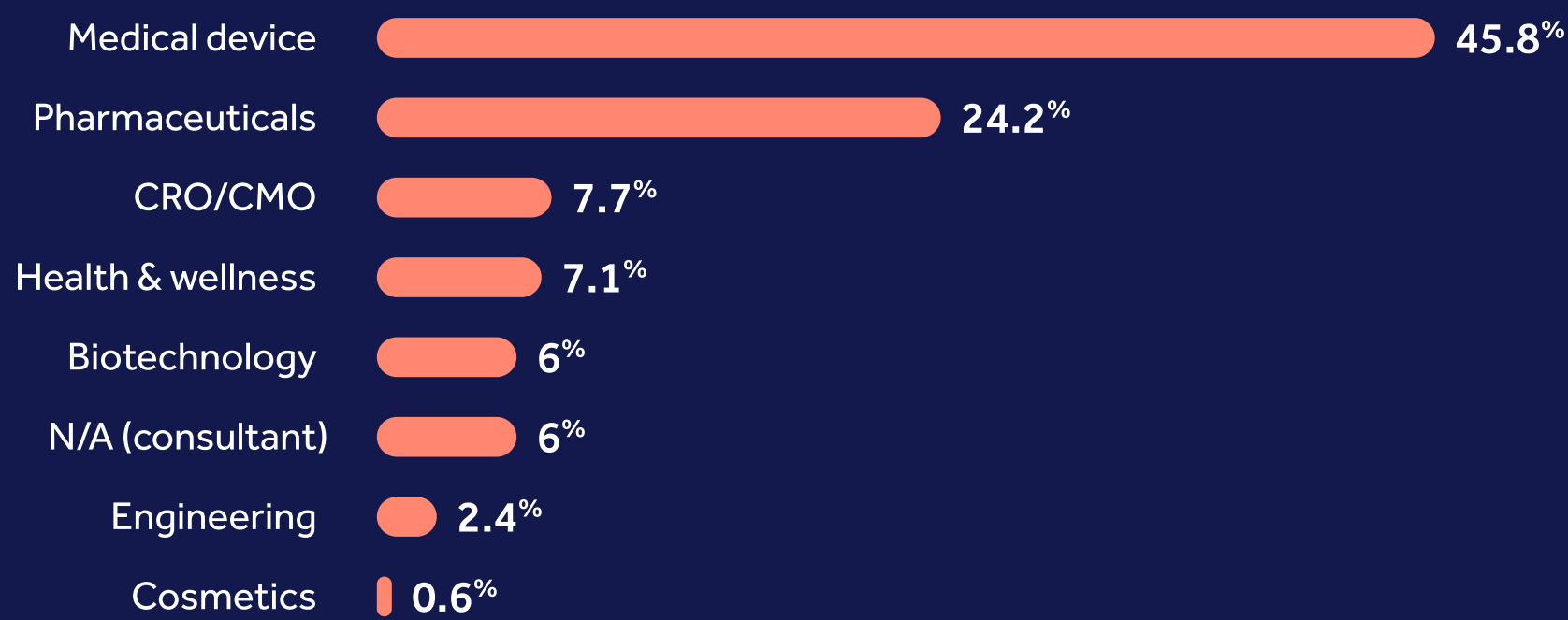


# Methodology

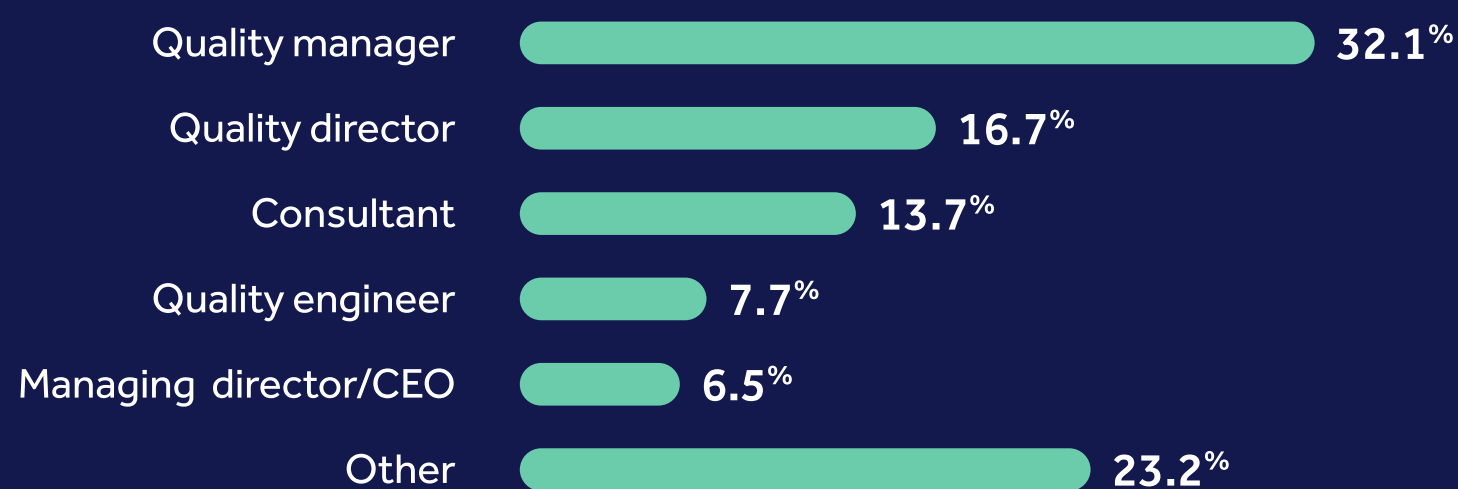
## Location of respondents



## Respondent company sectors



## Profession of respondents



The survey was distributed by Qualio to 2000 life science quality professionals in March-April 2023.



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