LDI GROUP

QUALITY

2025

BI-Annual
Quality
Survey

"...LONGER LASTING PARTNERSHIPS, ENHANCING LIVES....."

www.ldisearch.com

Welcome Message

Welcome to LDI 's Bi-Annual Quality Survey.

For the last 20 years LDI Group has worked with Quality professionals from across to globe, helping them to take strides towards achieving their career goals, whilst in parallel working with organisations to provide market intelligence and guidance upon locating the right individual for their quality needs.

"...LONGER LASTING PARTNERSHIPS, ENHACING LIVES......

2025 SURVEY

Introduction

Since LDI's creation in 2005 it has been part of our philosophy to give back to the market. One tool we use to achieve this goal has been the collation and distribution of market intelligence. For this survey we asked Quality Professionals various confidential questions to ascertain the TRENDS they see and critical Issues they face.

It is important to note that when going out to market, NO particular Seniority Level, Geographical Region or Skillset was targeted so that true and fair results were obtained.

Conclusion

Whilst there was a wide range of responses received it was clear that there were certain trends being highlighted and similar issues being faced by many professionals who participated. Growth of AI being one and the return to ONSITE working being another.

2025 SURVEY SUMMARY

Summary of KEY findings received throughout the survey

Over 45% of respondents said that the recent Regulatory Changes have had a Significant or Moderate impact on their business.

Over 85% of Respondents have said that they have either implemented or are reviewing ways they can utilise AI or Automation to improve Quality Processes and Systems.

60% of Respondents have said that their organisation have planned or are Utilising AI to improve their product portfolio

Design Assurance was seen as the most critical skills shortage in the market so far this year, with Software Quality & Regulatory Compliance skills quickly following

One of the biggest challenges facing line managers in hiring the right talent in 2025 has been candidates lack of willingness to go back ONSITE and their desire for REMOTE or HYBRID working.
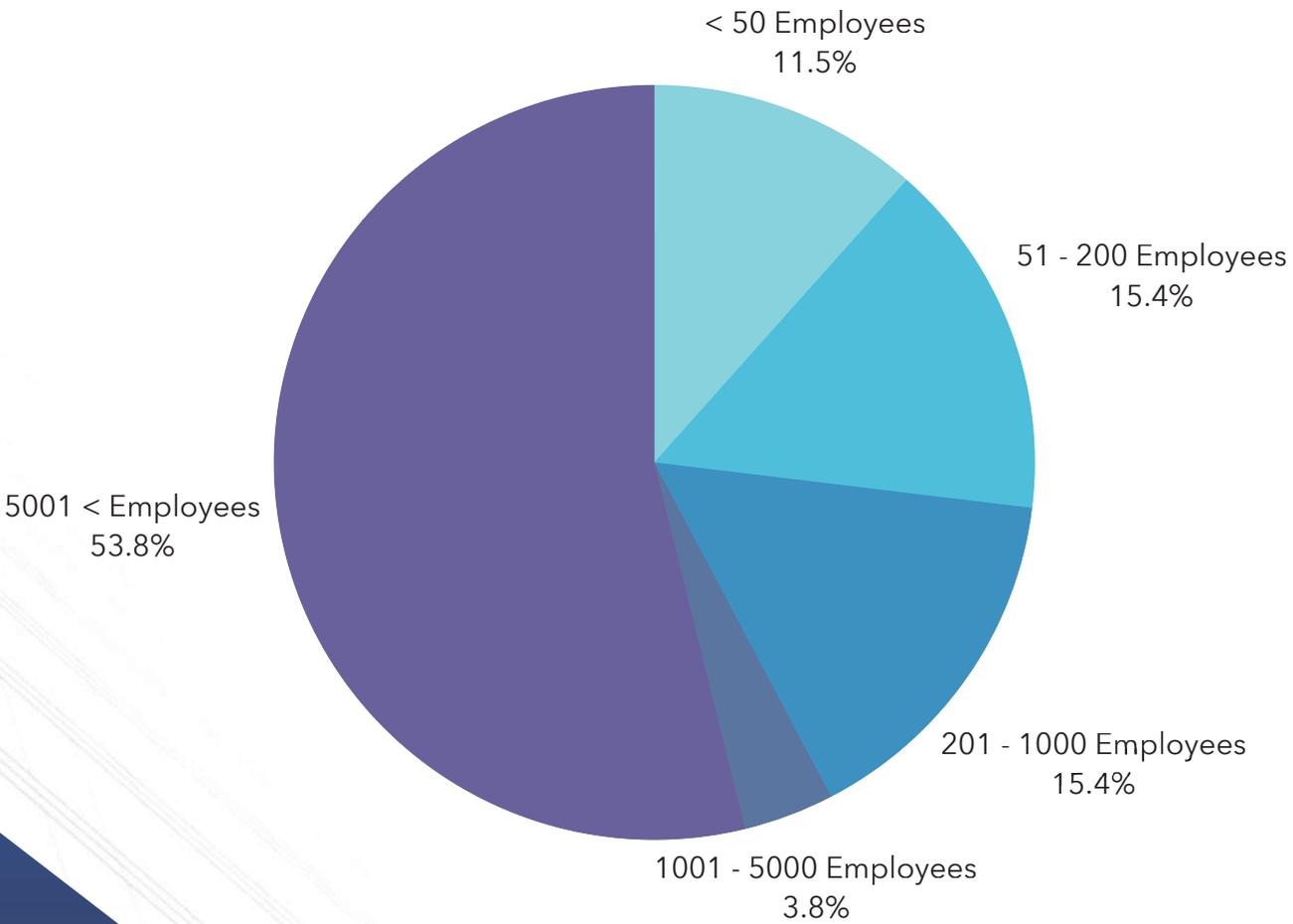
Quality Professionals knowledge and experience with AI was one of the biggest desired skillsets in the next 12-18 Months

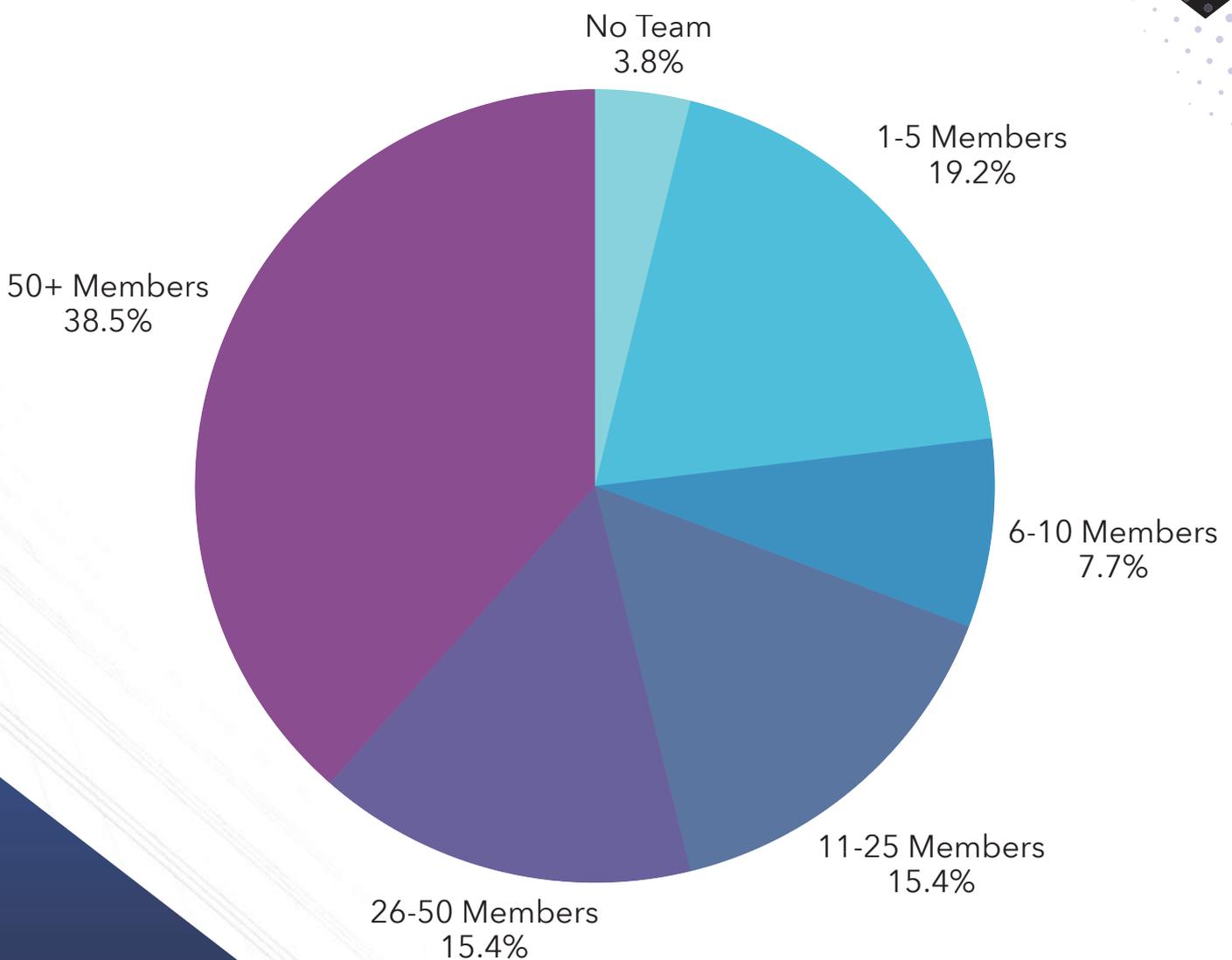Over 70% of respondents whilst happy in their role, would consider a move if approached

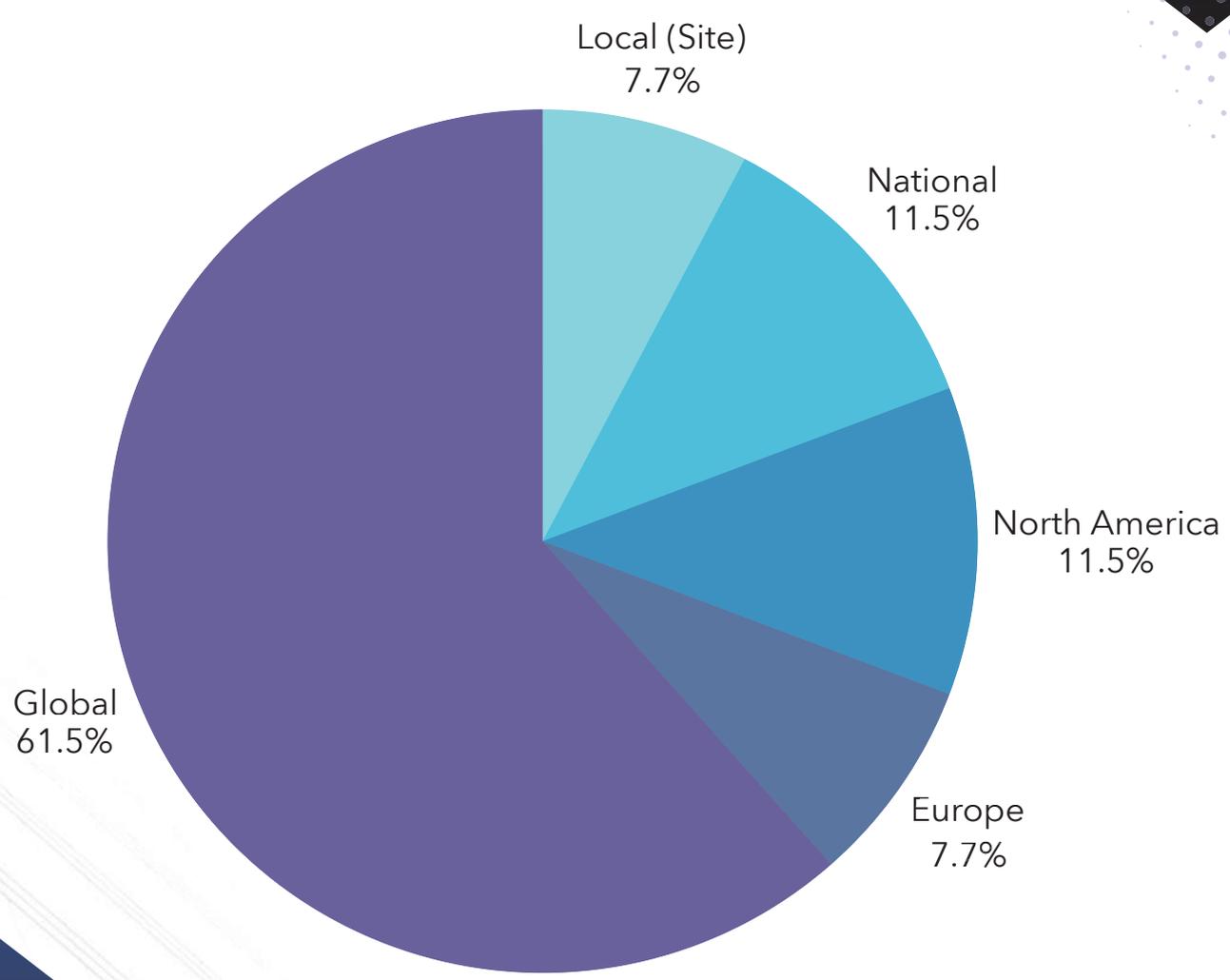**LDI GROUP**

Question 1

What is the Size of your organisation?

< 50 Employees
11.5%

51 - 200 Employees
15.4%

5001 < Employees
53.8%

201 - 1000 Employees
15.4%

1001 - 5000 Employees
3.8%

Question 2

What is the size of YOUR team?

No Team
3.8%

1-5 Members
19.2%

6-10 Members
7.7%

11-25 Members
15.4%

26-50 Members
15.4%

50+ Members
38.5%

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Question 3

What is your Geographical scope?

Pie chart:
- Local (Site): 7.7%
- National: 11.5%
- North America: 11.5%
- Europe: 7.7%
- Global: 61.5%

Question 4

Top Challenges being face in your organisation in 2025

Getting expert QA/RA/DA contractors as needed on ad-hoc basis

Poorly managed global digitalisation affecting compliance and QMS

KPI development, Root Cause Analysis, Regulatory Compliance

Uncertainty from FDA changes

Software Investment, management engagement, colleagues short cutting processes

Improving revenues and efficiencies

Procedures are not visually rich. There are plenty of opportunities for better standard work. Faster problem solving supported by try-stormings

Obsolescence, Service quality and FDA scrutiny

Continuing delays with notified bodies, increased audit activity, supplier cost increases driving business to look for alternativess

Maintaining & developing the professional training and competencies of Quality functional staff (AI), proliferation of global regulatory requirements, remediation of legacy products that have not kept apace with global regulatory changes

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Question 4

Top Challenges being face in your organisation in 2025   Continued.......

Retention of headcount, Priortisation of projects and changing regulatory landscape

QMSR, Data Analysis, Master Data Management

SaMD, CAPA, Design Transfer, EUMDR

Geopolitics, economic uncertainty, hiring of specialized roles.

Major regulatory changes impacting the daily operations such as IVDR compliance and AI Act. 2) Staff competency, below average; 3) Company transformation projects changing all the time

Keeping talent and motivating them In a stagnant organization

Inspection readiness, CCS, getting right people for right jobs

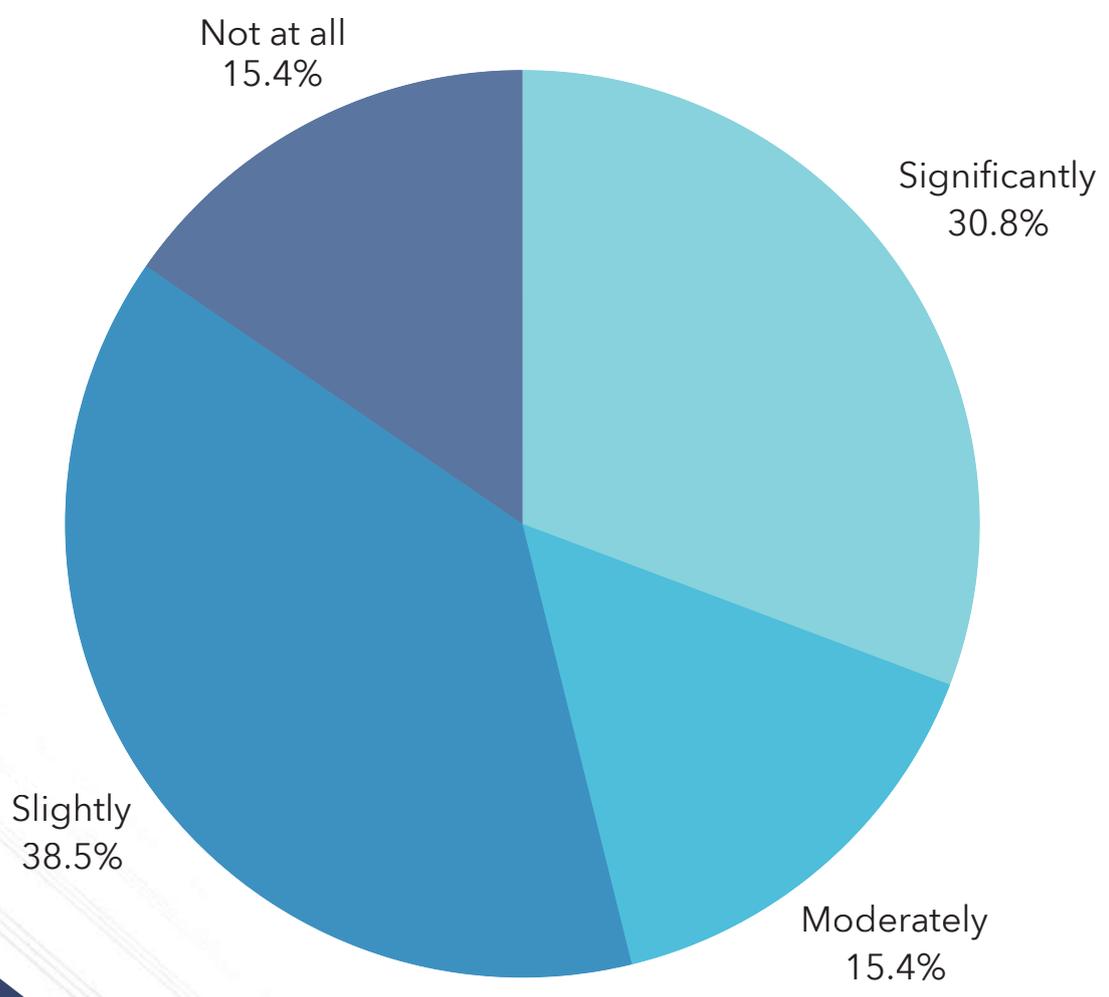Quality Culture, sufficient QA staffing, quality manufacturing

MDR Certification

Digitalisation, IVDR Implementation, Legacy Compliance Gaps, Ongoing Product Technical Issues
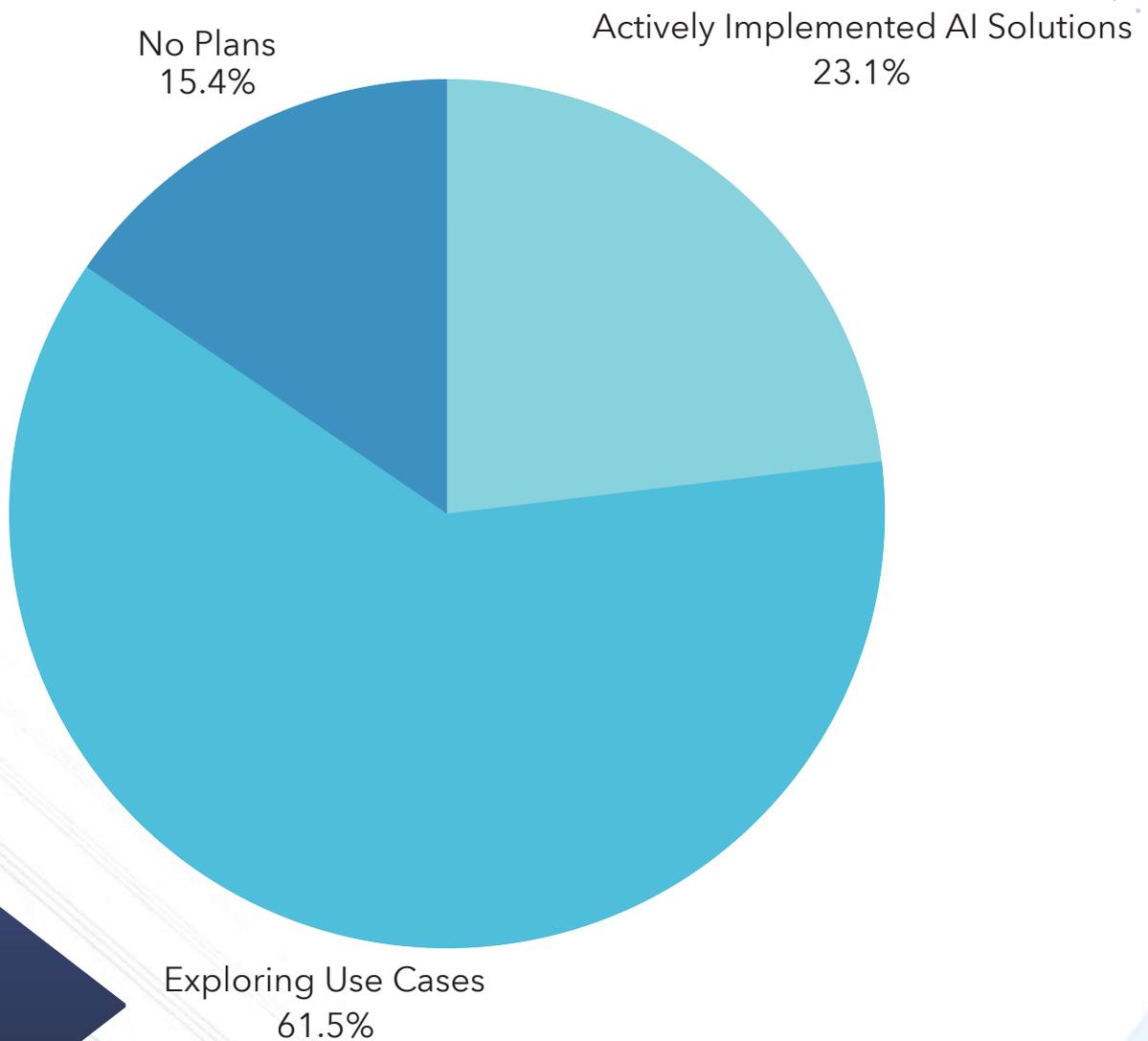
Question 5

**Have Regulatory changes in 2025 (eg FDA, MDR, ISO) Impacted your QA Strategy?**

Not at all
15.4%

Significantly
30.8%

Moderately
15.4%

Slightly
38.5%

Question 6

How has your QA team adapted to advanced in AI or Automation in quality processes this year?

No Plans
15.4%

Actively Implemented AI Solutions
23.1%

Exploring Use Cases
61.5%

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Question 7

Is your Company Already or are they Planning to utilise AI within the Product Portfolio?

Don't Know
4%

No
36%

Yes
60%

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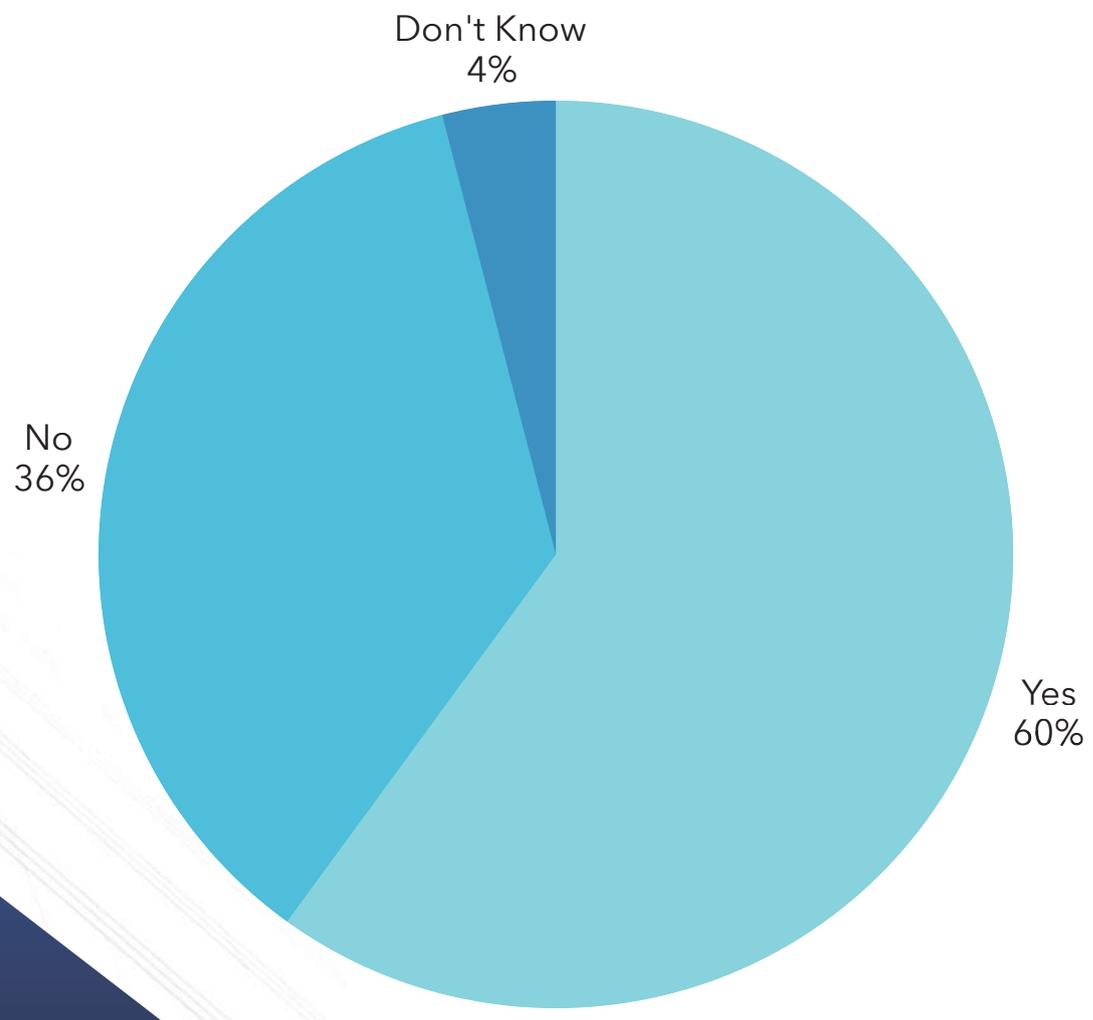
Question 8

Has your company been through any organisational restructuring in 2025?

No
28%

Yes
72%

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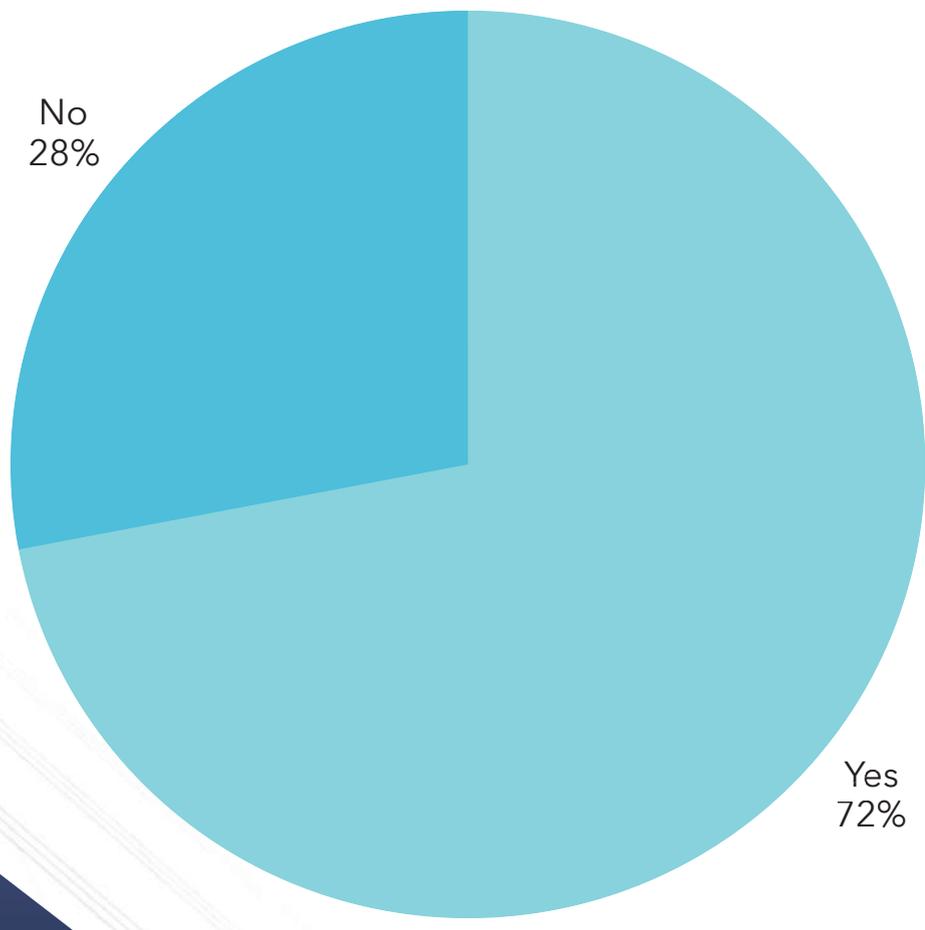
Question 9

What impact on staffing levels has this restructuring had?

Positive
23.1%

Negative
34.6%

N/A
42.3%

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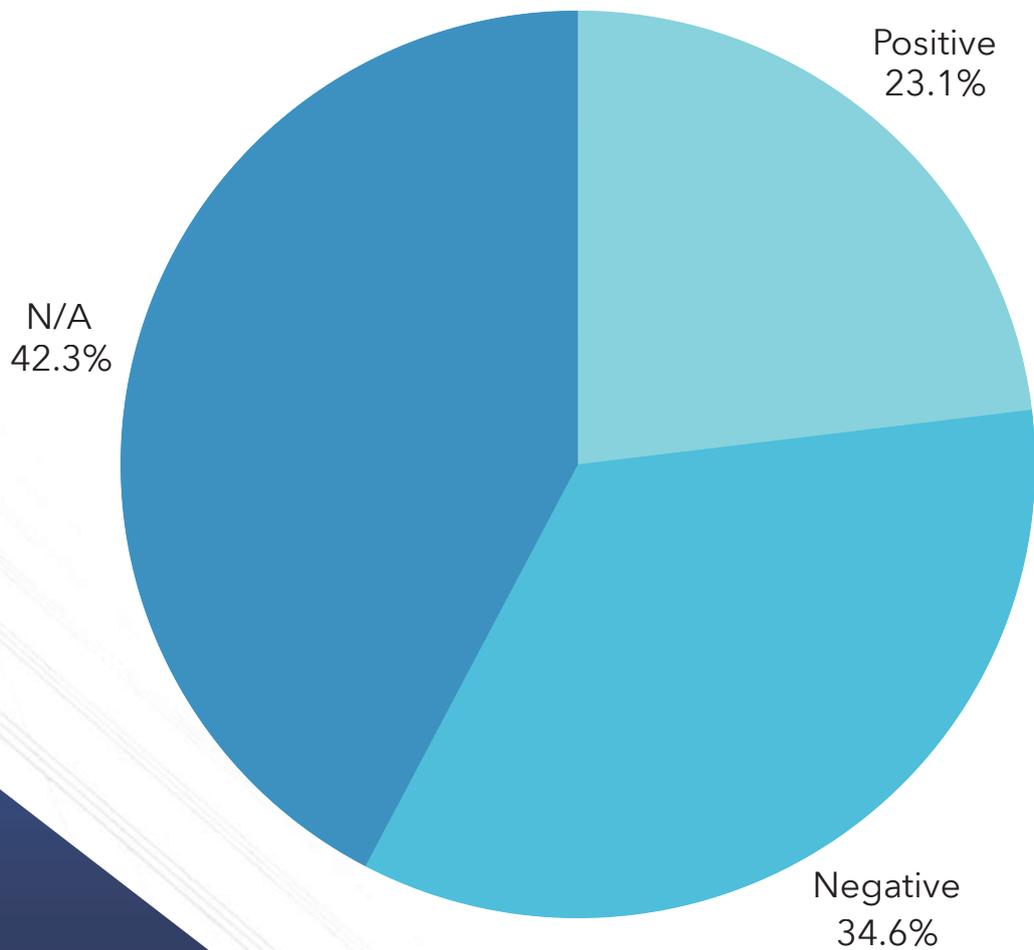
Question 10

Have you experienced any difficulties hiring for your team in 2025?

No
48.1%

Yes
51.9%

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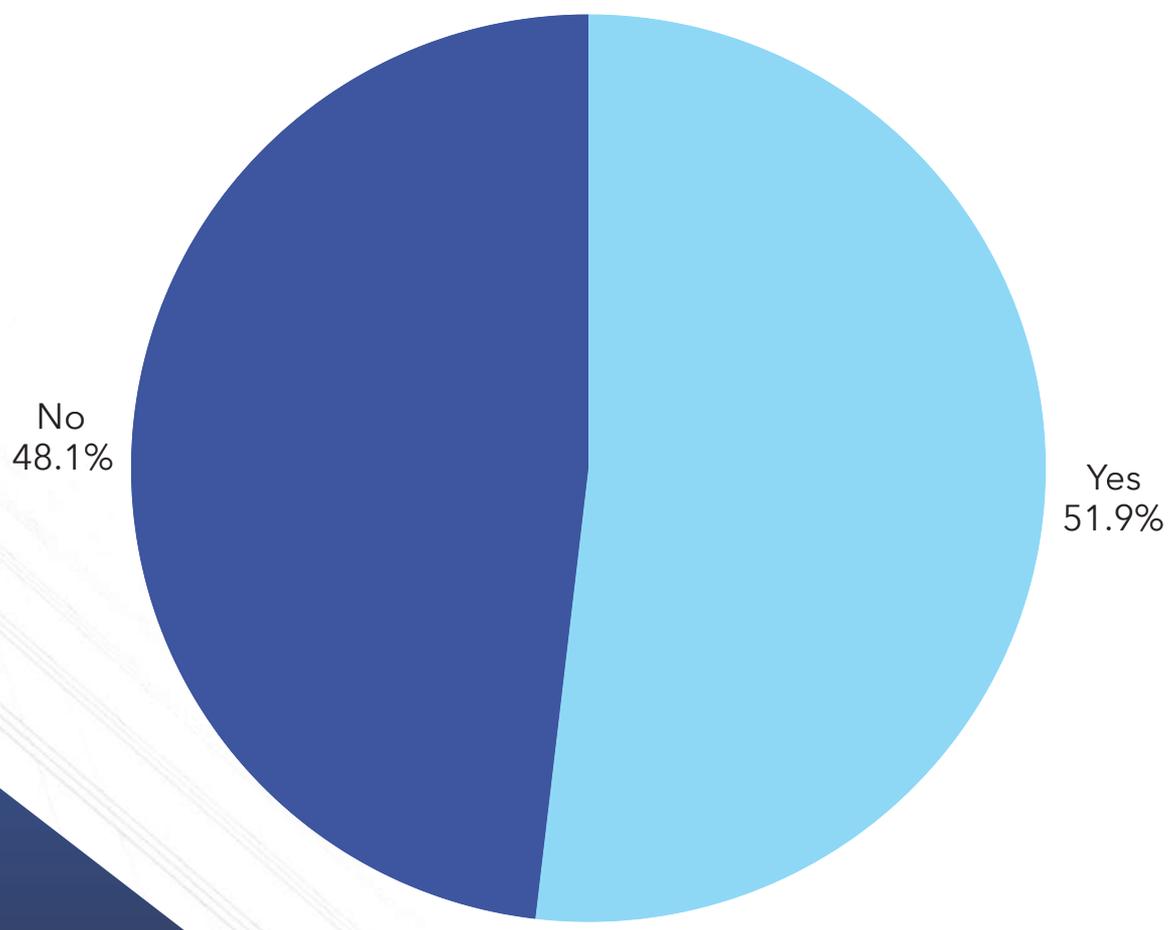
Question 11

Where do you see the most critical Talent Shortages in the Market i

Quality Systems
9.8%

SAP in QMS
2%

Operations Quality
7.8%

Post Market Surveillance
9.8%

Design Assurance
21.6%

Regulaoty Compliance
17.6%

Software Quality
19.6%

Supplier Quality
5.9%

Question 12

What has been your biggest barrier to HIRING in 2025 so far?

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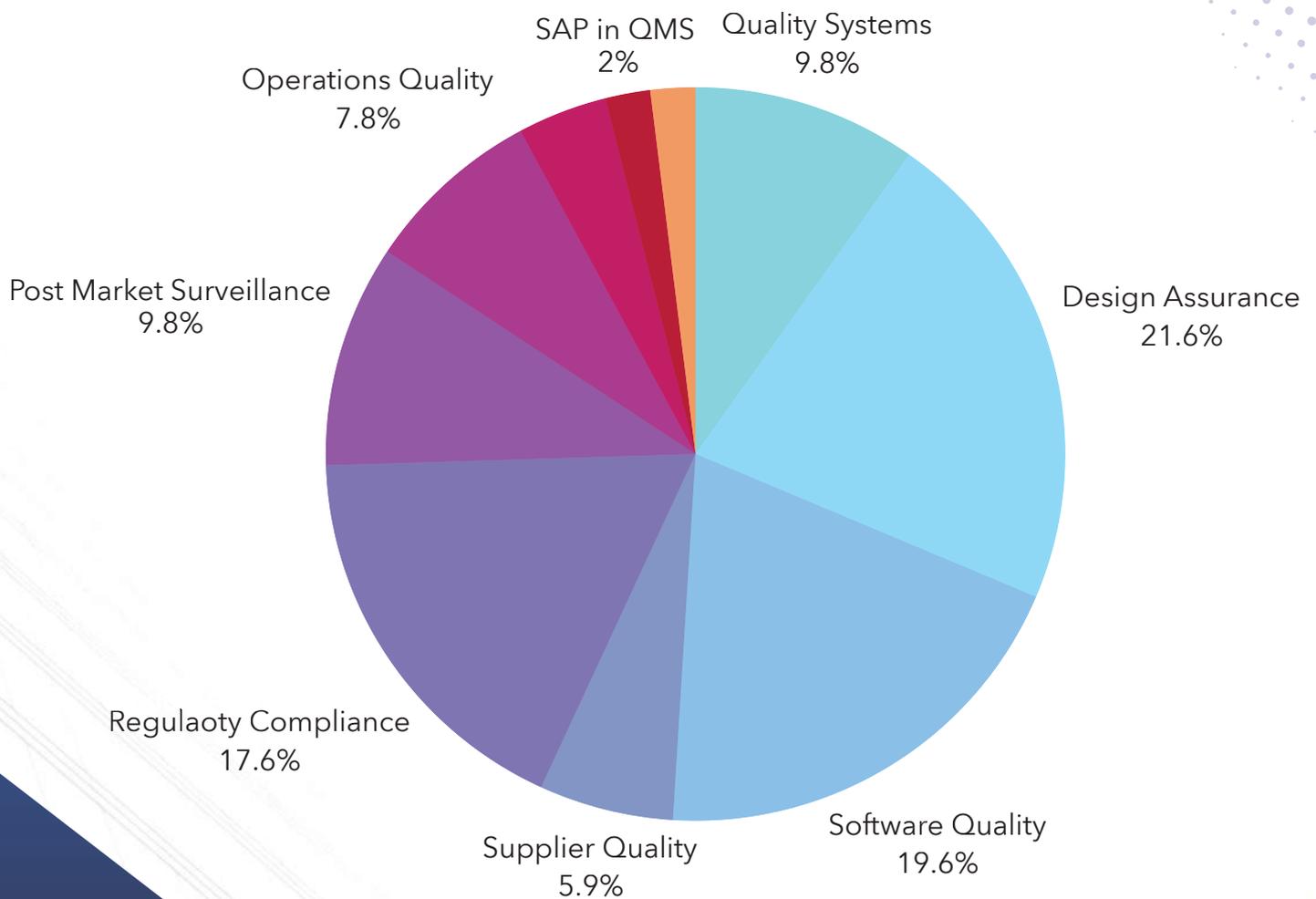
Getting high quality candidates - Only want the best

Rarely end to end experience in the full product lifecycle (design and development, manufacturing and after-sales)

Digital skills, especially advanced SAP knowledge in QM

Lack of high skillset and experience in the industry

Everyone wants to work from home

To find a multidisciplinary quality professional with global mindset and strategic thinking

Calibre of available talent

Increasing reluctance to relocate to work at our centres of excellence post-Covid , even for hybrid roles

Geographical location

Increase in Competition for talent

Funding (Budget) to search externally

Question 12

What has been your biggest barrier to HIRING in 2025 so far? Continued........

Availability of qualified professionals

As limited capacity to hire looking for super stars not just someone that fits the spec..

Moving internal talent from REMOTE to ONSITE

Lack of talent within the Software Quality Area

Talent being delivered by Internal Sources

Lack of talent with commercial acumen

Lack of Talent who can communicate cross functionally as well as managing up and down

Question 13

What **SKILLS** do you see as being important within the Quality function in the next 12-18months?

- Digital skills
- Understanding of AI
- Good understanding of regulatory
- Critical thinking
- People skills (communication), problem-solving skills, process mindset
- Global mindset
- E2E process approach
- AI regulatory compliance
- Can do attitude.
- Willingness to work outside prescribed job description.
- Flexibility to embrace quick changes.
- Kaizen mindset
- Quality Engineering
- Leadership and quality engineering
- Design assurance (risk management)
- Supplier QA (risk management)
- Ability to see the full product value stream and indirect influence of functional peer groups.
- AI, ML, SAmD, CAPA, acquisition and integration, qmsr

Question 13

What SKILLS do you see as being important within the Quality function in the next 12-18months? Continued......

Understanding changes in global regulatory requirements and impact to the QS, as well as adapting to AI and understanding limitations

Digital & Data Competence, Risk-Based & Strategic Thinking

Problem solving and critical thinking
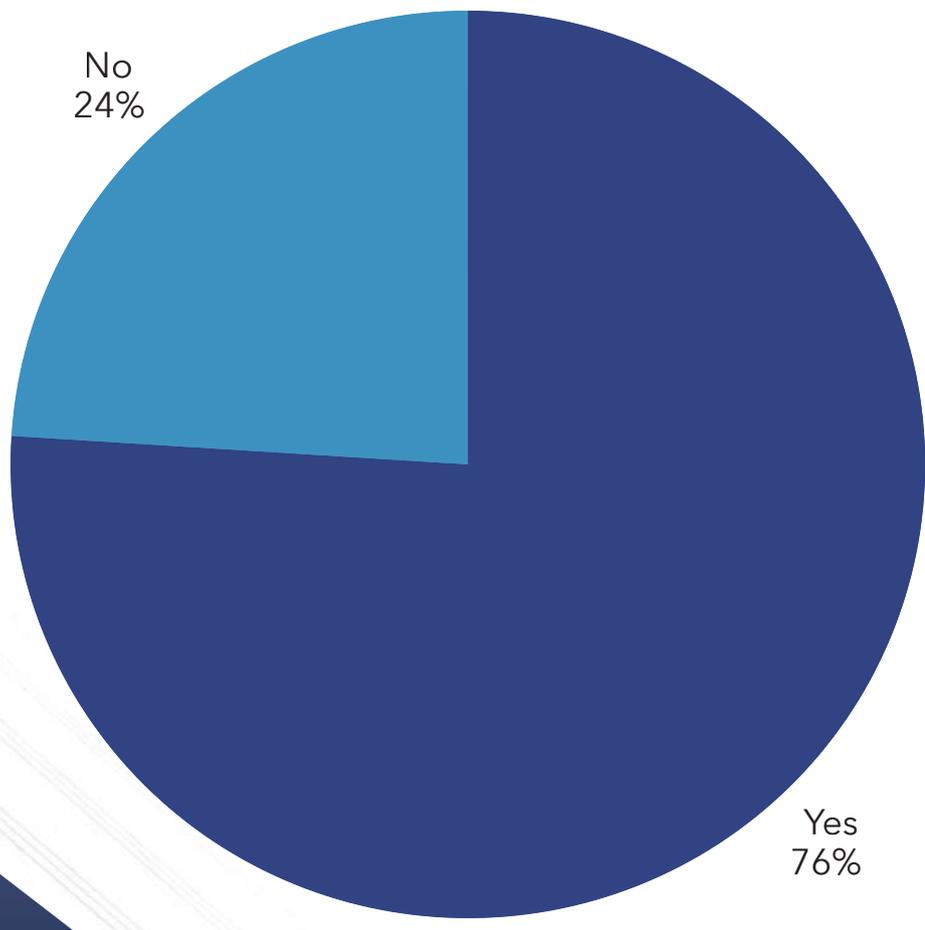
CSV, digitalisation, AI

Using AI and software tools for quality assurance

IVDR/MDR QMS expectations, risk management, QMSR

Question 14

Would you consider a Job move in 2025?

No
24%

Yes
76%

Thank You

To Everyone who Participated

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Get In Touch

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