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VISIUM I DEVIN I 2026 BENCHMARKING REPORT

Pharma quality is ready for AI.

Just not any AI.

We asked 230 quality professionals across 100+ Life Science organisations where deviation management breaks down, and what an AI solution would have to prove before they'd let it near an investigation.

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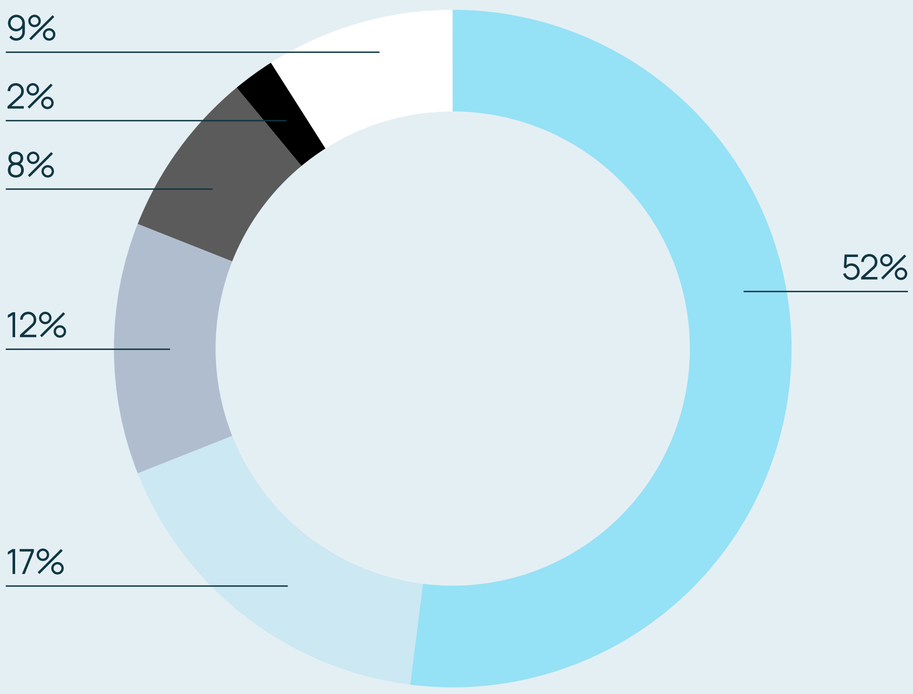
Methodology

Online survey

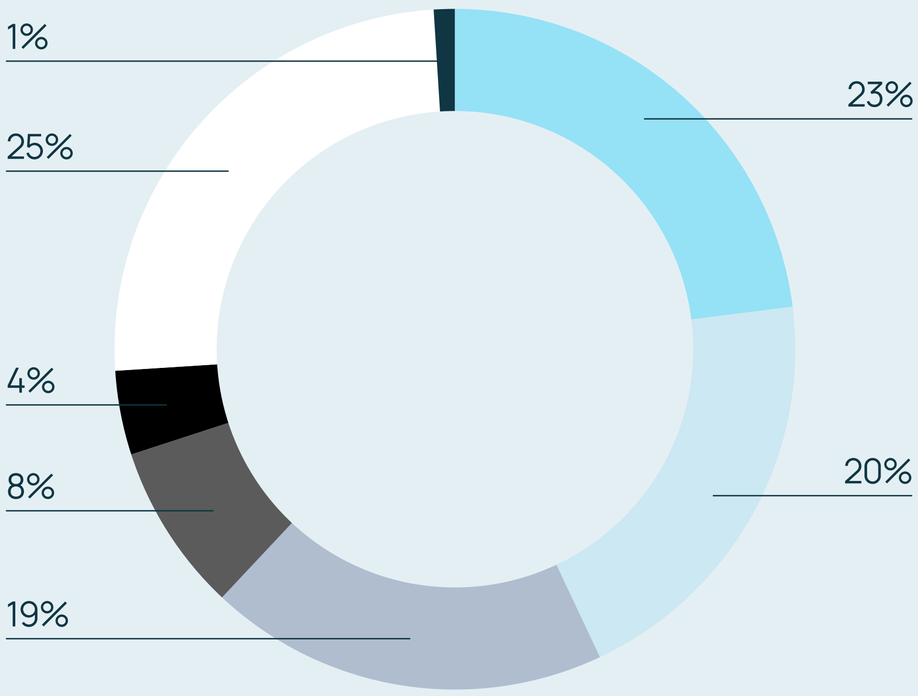
Fieldwork	Respondents	Organisations	Geography
15 February – 27 August 2026	230 completed responses	100+ distinct organisations named	40 countries; 80% Europe

Organisation type



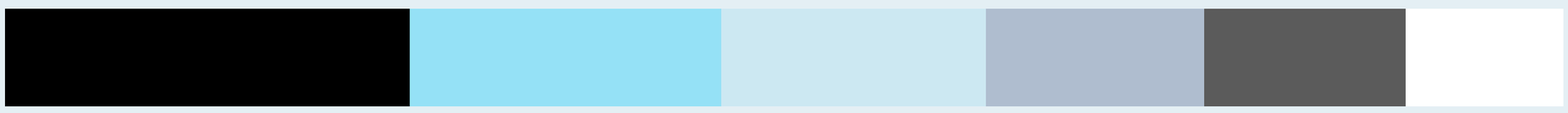
- Big Pharma
- Mid-size or specialty pharma
- Full-service CDMO
- Med-tech
- API or niche manufacturing
- Undisclosed

Roles



- QA Manager
- QA Specialist
- Global role in Quality
- Qualified Person
- Digital or IT in Quality
- Other quality and manufacturing roles
- Undisclosed

Organisation revenue



EUR 20B+ 26% · EUR 5–20B 20% · EUR 250M–1B 17% · EUR 1–5B 14% · Under EUR 250M 13% · Undisclosed 10%

Base sizes

Not all respondents answered every question. Bases range from 145 to 230. Multi-select questions show the percentage of respondents choosing each option, so totals exceed 100%. Open-text answers have been grouped into themes.

Report summary

The report in three numbers

91%

Deviations are a board-level priority for 2026 — with time to closure the metric leadership watches most.

#1

Root cause analysis is the bottleneck — the top reason work stalls, the most manual step, and the number one place teams want AI to help.

92%

are open to a validated, GxP-compliant solution.

Who we asked

A read on quality operations

230

Respondents

Quality professionals surveyed

100+

Organisations

Pharma, CDMO and med-tech

80%

Europe

40 countries represented

QA

Roles

QA Managers, QA Specialists, Qualified Persons and other roles across quality

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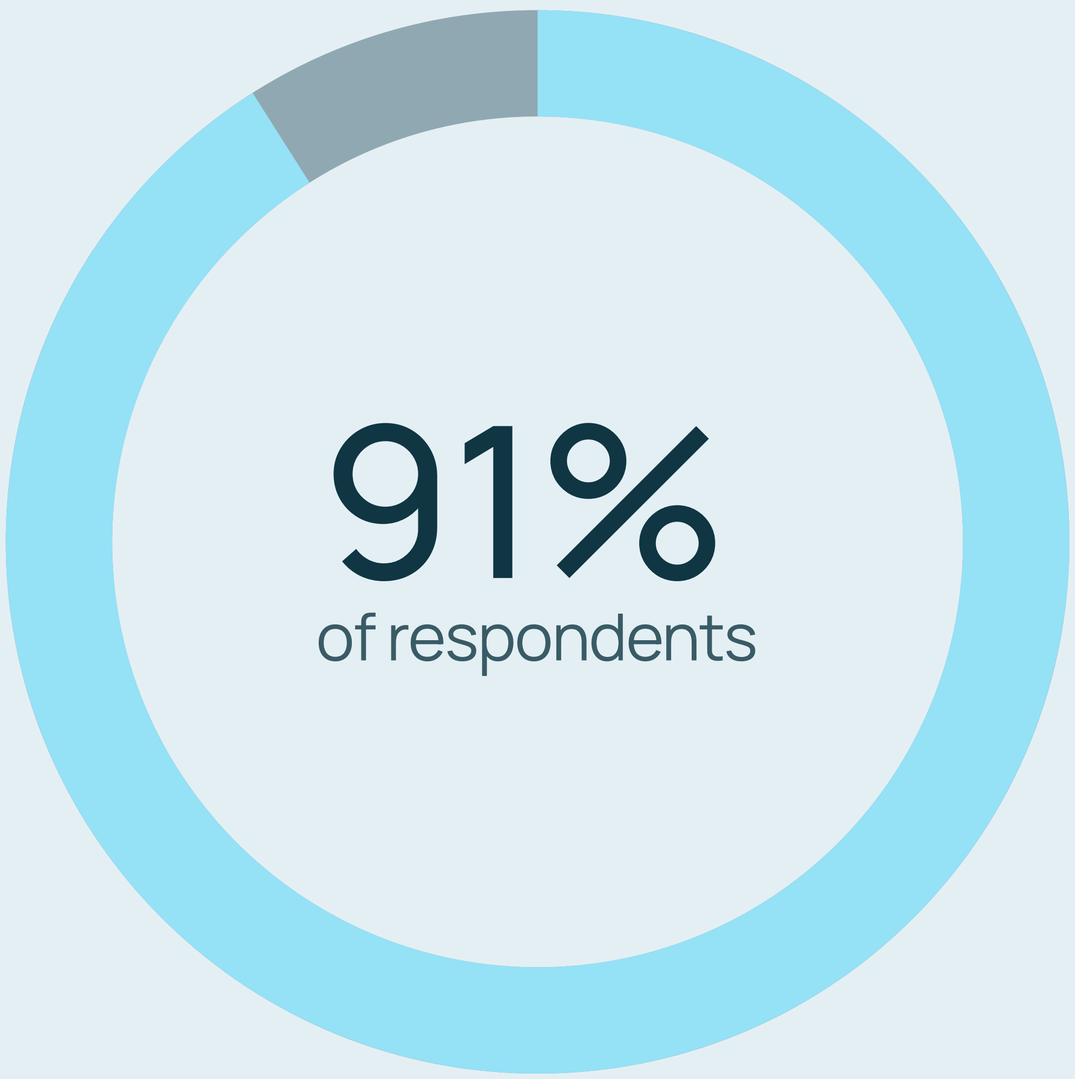
PART 01

Where the time goes

Deviation management is standardised on the surface and manual underneath. Every route through the data — stalled investigations, repeat events, backlog pressure — leads back to the same place.

Finding 01

Deviation performance is a board-level priority



More than nine in ten call improving deviations and right-first-time performance a **strategic priority for 2026** — and the metric leadership fixes on is **time to closure**.

Most-watched metric

Time to closure 39%

21%
Recurring deviations

13%
CAPA effectiveness

14%
Deviation severity & impact

13%
Total volume

KEY TAKEAWAY

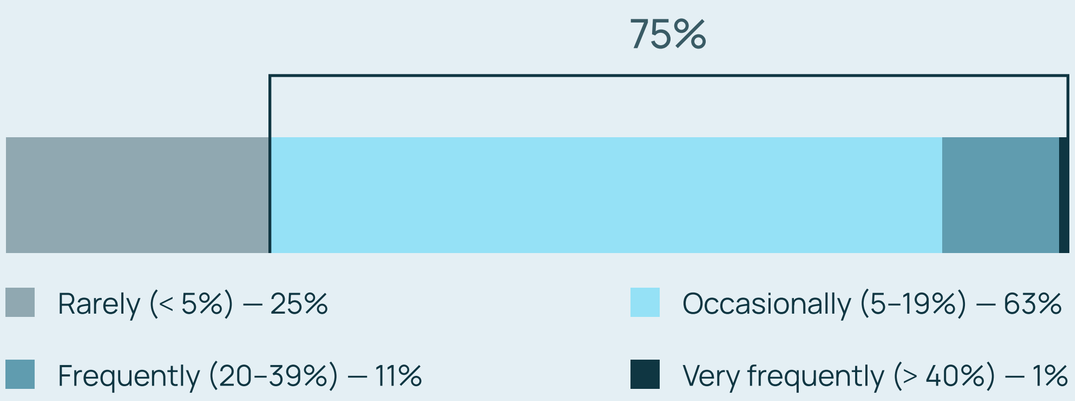
Leadership wants deviations closed faster — but not at the expense of investigation quality or compliance.

Finding 02

Recurring deviations are the persistent problem

Repeat events are common even in mature systems — and a standardised process does not prevent them.

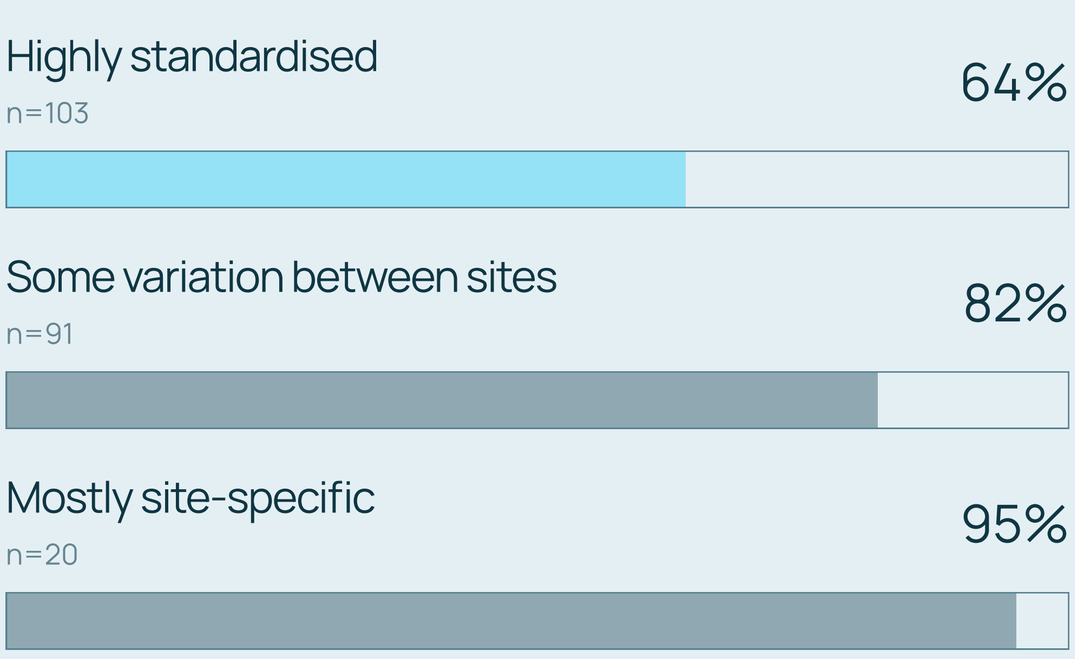
How often repeats happen



75%

see deviations repeat. Three in four teams are solving problems they have seen before.

Repeat rate by how standardised the process is



64%

of teams running a highly standardised deviation process still see repeats. Standardising the workflow has not stopped the same problems coming back.

Key Takeaway

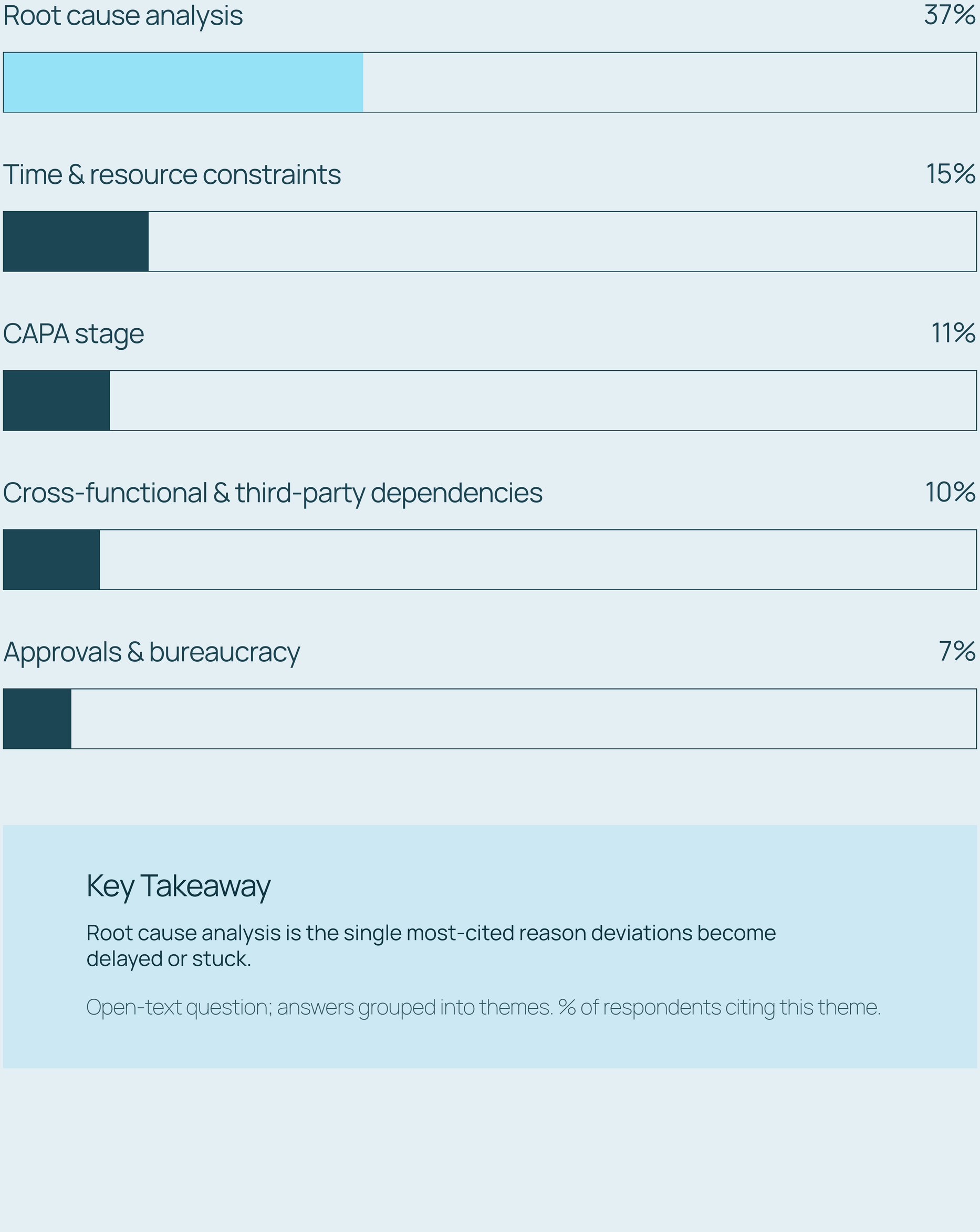
Standardisation fixed the workflow. It did not fix recurrence — and recurrence is an investigation problem, not a process one.

Base: 227 respondents for repeat frequency; 214 for standardisation. Percentages rounded to whole numbers.

Finding 03

Root cause analysis is where investigations stall

The hardest part of deviation management isn't documenting what happened.
It's determining why.



Key Takeaway

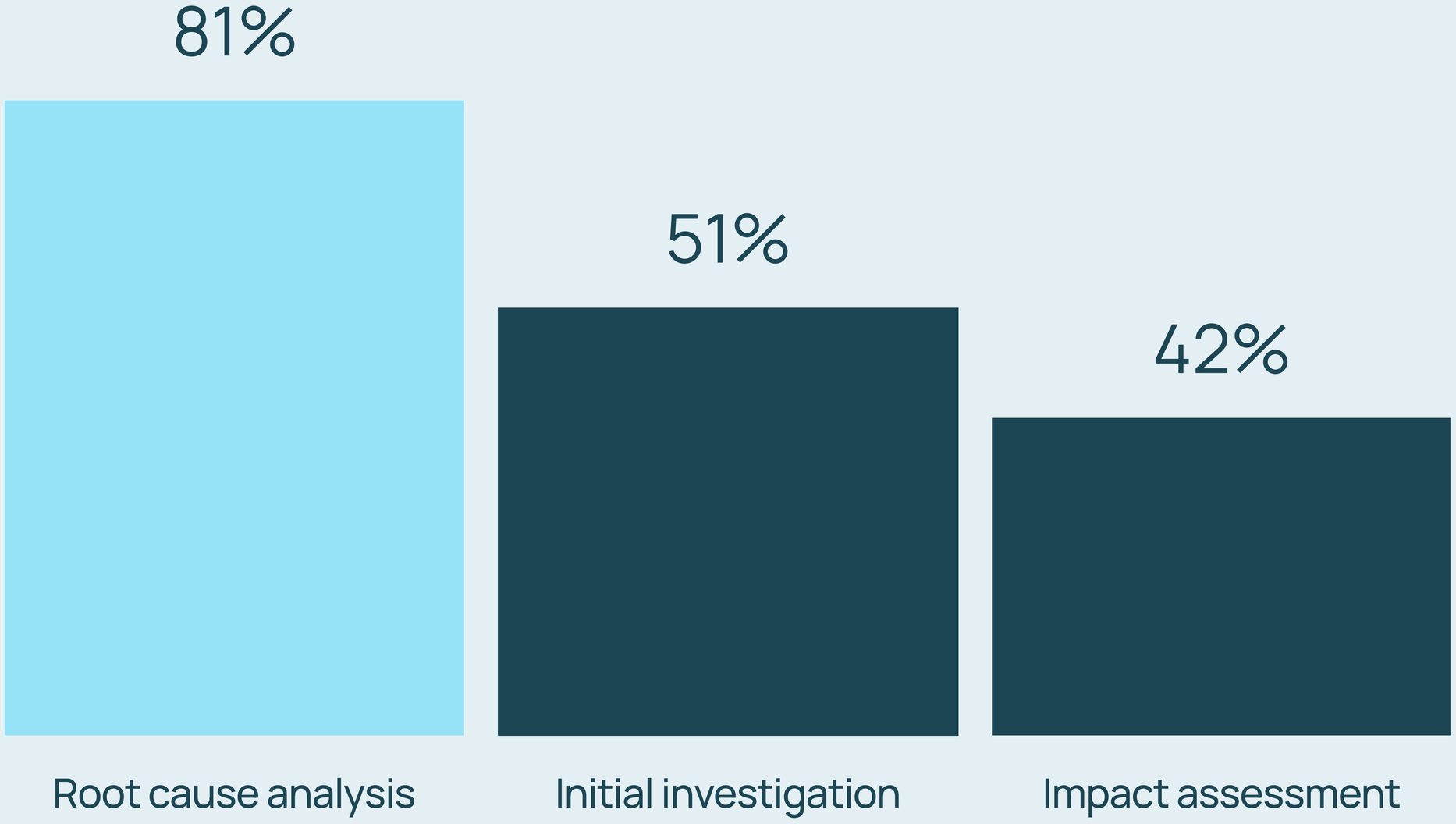
Root cause analysis is the single most-cited reason deviations become delayed or stuck.

Open-text question; answers grouped into themes. % of respondents citing this theme.

Finding 04

The most important work is still done by hand

Manual effort concentrates in exactly the stages that demand the most judgement and evidence.



Key Takeaway

The manual burden sits on the judgement-heavy steps — creating delay, inconsistency and dependence on individual experience.

Multi-choice question. % of respondents citing this answer.

Finding 05

Production takes the hardest hit

Deviations cause the most disruption at the heart of manufacturing.

Stage 1

72%

Drug production

Stage 2

40%

Packaging

Stage 3

32%

Finished goods

Key Takeaway

Faster, better investigations would flow straight through to production continuity.

Multi-choice question. % of respondents citing this answer.

Finding 06

Current systems are accepted, not loved

Biggest tool pain points

39%
Heavy form filling or repetitive data entry

32%
Too many hand-offs and approvals

34%
Poor support for root cause analysis

25%
Not connected to relevant data sources

34%
Weak cross-functional collaboration

24%
Limited collaboration with partners or CDMOs

75%
only moderately satisfied with their current tools

Key Takeaway

Existing platforms provide structure and control — but they don't remove the manual work around investigations.

Multi-choice question. % of respondents citing this answer.

Finding 07

Backlogs are draining team capacity

81%

report moderate-to-high stress caused by deviation backlogs.

If you had told me five years ago that the thing keeping me up at night would not be an OOS result but a backlog of root cause analyses, I would have laughed.

Now I just quietly refill my coffee and open another investigation. This report finally puts numbers on what every QA team already mutters to each other in the hallway — and refreshingly, the fix isn't 'hire more people,' it's 'stop making your smartest people fill out forms all day.'

If AI can take the grunt work off root cause analysis without taking the judgement out of it, sign me up. Just don't ask it to sign the deviation report — I still need someone to blame when things go sideways.

Dr Mark de Souza James
Senior Quality Specialist Lead

Key Takeaway

Persistent investigation pressure affects decision-making, productivity and the ability to focus on prevention.

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PART 02

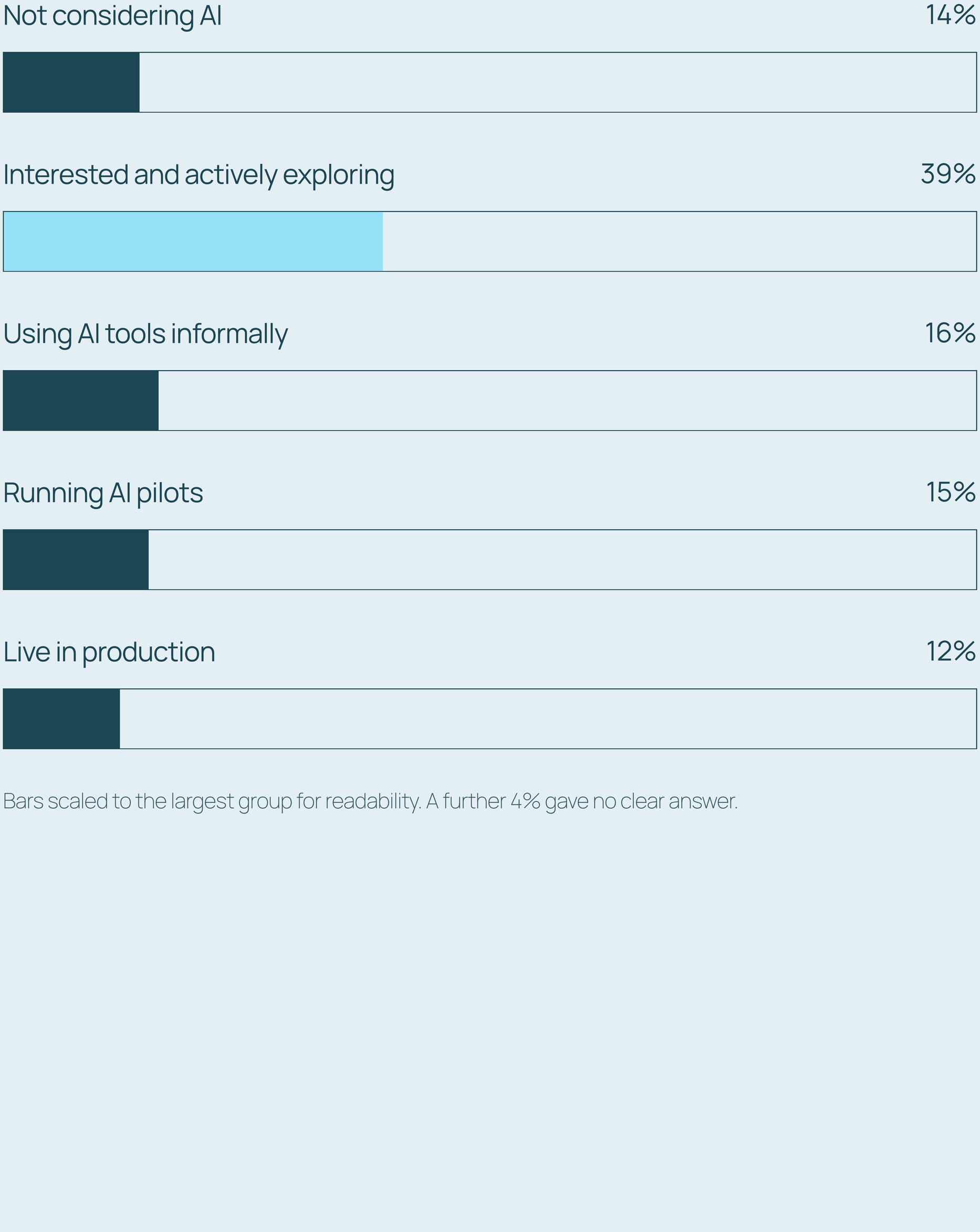
Where AI comes in

Interest is high and the use case is obvious — but adoption is early, and trust and compliance are the gates. Here's what teams are doing today, and what a solution would have to prove.

Finding 08

AI interest is high — production use isn't

Many people are already experimenting. Few have anything validated in production.

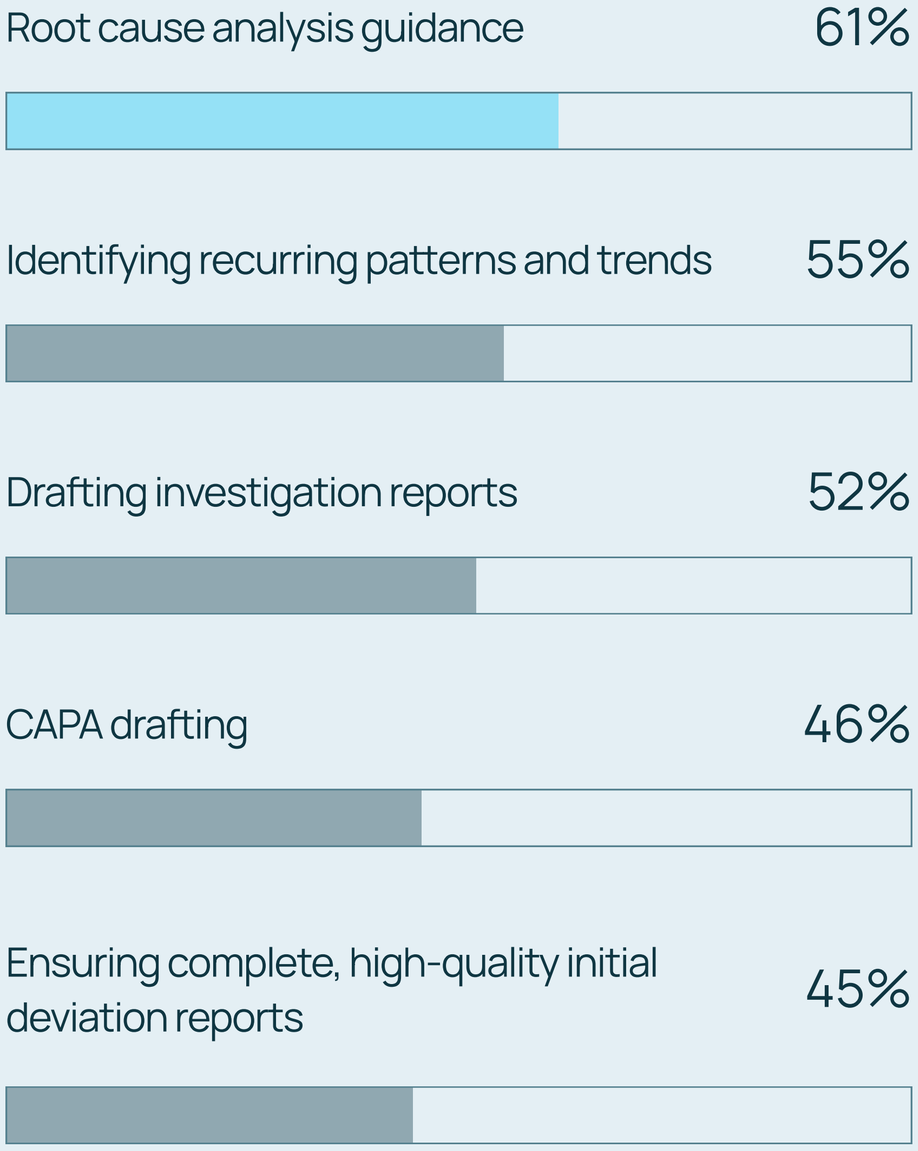


Bars scaled to the largest group for readability. A further 4% gave no clear answer.

Finding 09

Root cause analysis is the biggest AI opportunity

Respondents want AI to improve the quality of investigations — not simply automate forms.



Key Takeaway

The strongest use case is decision support — the exact place the data says teams lose the most time.

Multi-choice question. % of respondents citing this answer.

> For some, the opportunity is clear
>
> Having worked in both Operations and Quality, I concur with these findings - root cause analysis is the biggest AI opportunity.
>
> The key takeaway is that we'd want to 'rationalize' the decision-making process through an AI proposal, with a human in the loop — QA oversight — to double-check it.
>
> The real value would be narrowing down the ecosystem within the deviation management system to focus only on the most crucial potential root causes.
>
> Tilman Rock, PhD
> Head of Quality NBE

> But not everyone agrees
>
> The data and statistics are sound, but I don't fully agree with where the main value lies. Using AI for root cause analysis still requires manually inputting all the RCA data — and by the time that's done, competent investigators will already have held their root cause analysis meetings, so I'm not convinced AI meaningfully speeds that up.
>
> The real value I see is different: using consistent prompts to review written deviations in a consistent way, and confirming — before closure — that all key regulatory considerations are covered.
>
> Justin Lynch
> Head of QA Ops

Finding 10

What it has to prove

No single KPI dominates the investment decision — the value case is balanced across efficiency, quality and prevention.

23%
Less manual work

22%
Fewer recurring deviations

22%
Better right-first-time

19%
Faster time to closure

Key Takeaway

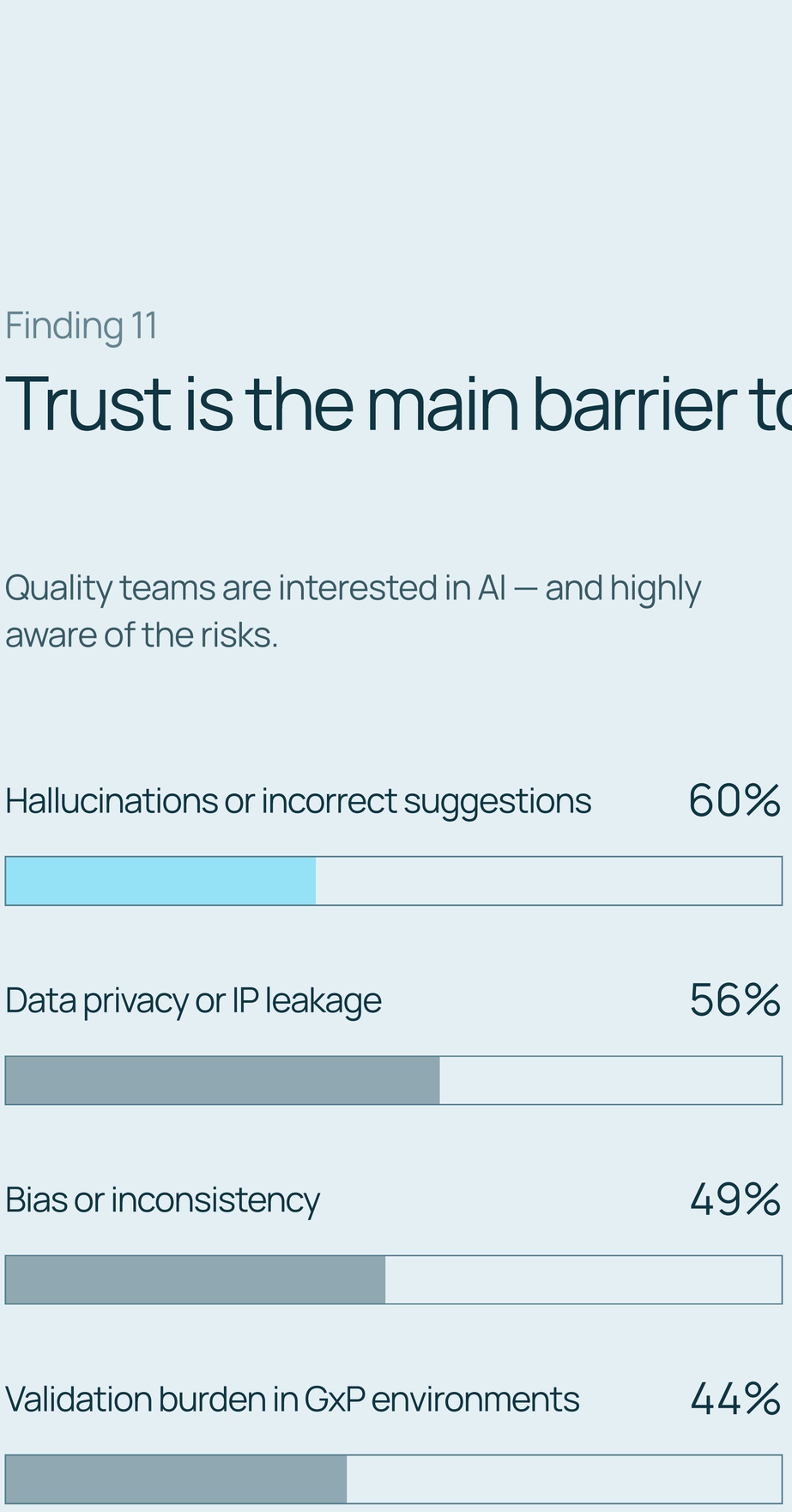
A winning solution has to show more than time saved — it must improve investigation outcomes too.

Four most-cited of seven options shown.

Finding 11

Trust is the main barrier to adoption

Quality teams are interested in AI — and highly aware of the risks.



Key Takeaway

The obstacle isn't interest. It's confidence that AI can operate safely, consistently and transparently.

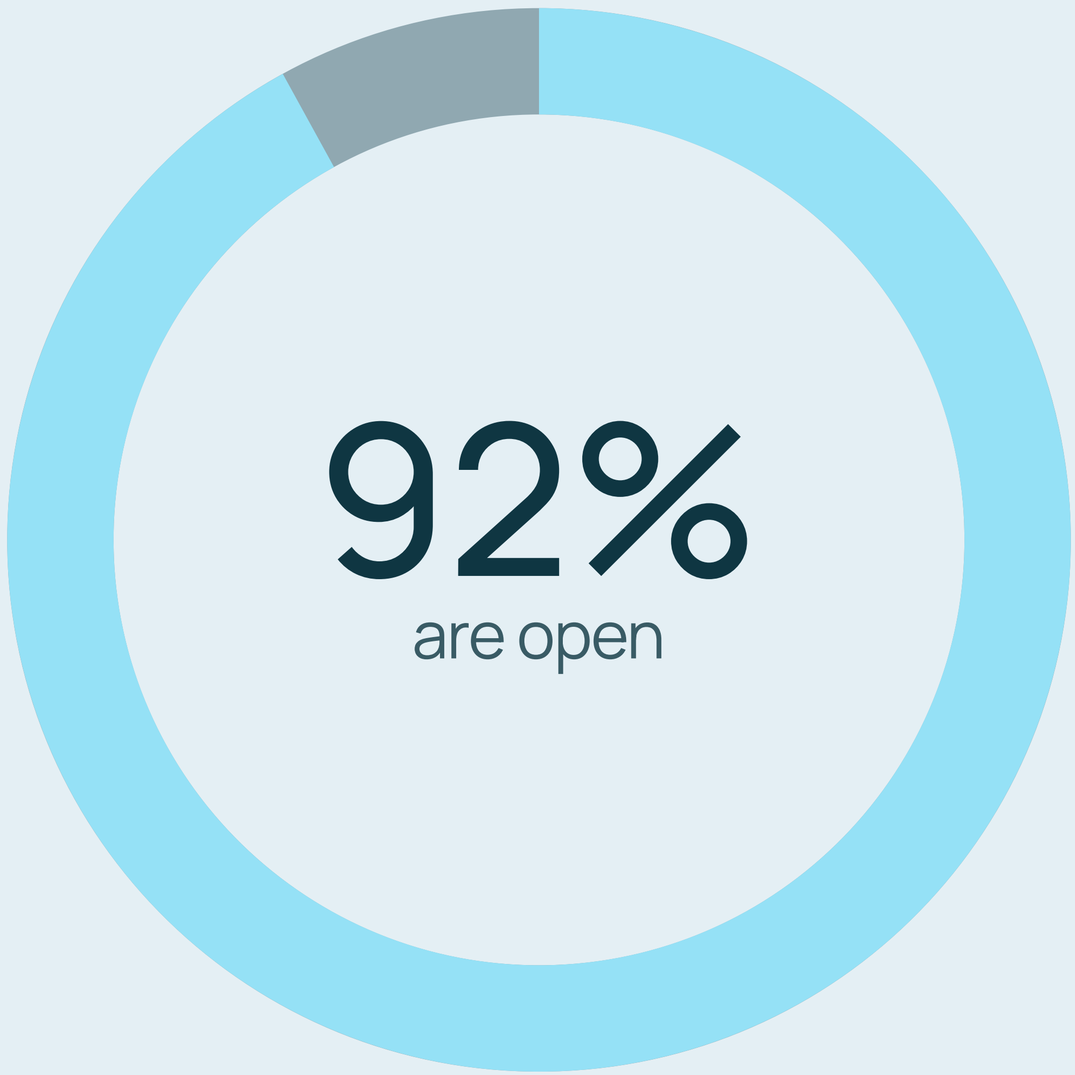
Multi-choice question. % of respondents citing this answer.

> The key to maximising the benefits of AI in GxP Quality is to trust AI to do the work AI is best at, and to trust humans to do the work humans are best at. Finding the exact sweet spot for that handoff in every system and process is essential.
>
> Stephen Parker
> Director of Quality and Qualified Person

> The challenge is not a lack of process, but the ability to consistently derive high-quality root causes and prevent recurrence. AI offers significant potential as a decision-support tool, provided it is explainable, validated, and always keeps quality professionals firmly in control of critical decisions.
>
> James Parker, PhD
> Director of Quality Assurance

Finding 12

Quality is open to a validated solution



Only 8% score their interest low. 92% are open to a validated, GxP-compliant AI that could meaningfully cut investigation time or clear deviation backlogs — and 65% are highly interested.

Key Takeaway

Compliance isn't only a barrier to AI adoption — it's the requirement that unlocks it.

THE BRIEF

Taken together, the findings point to a clear opportunity.

Root cause analysis is the central point of friction. It is where investigations become most manual, where teams experience the greatest difficulty, and where they see the greatest potential for AI to help.

The problem is not the system of record. Existing platforms are established and broadly adequate; the greater challenge lies in the work around them — bringing evidence together, collaborating across functions, and moving an investigation towards a defensible conclusion.

AI has a role to play, but the bar is high. It needs to produce useful, reliable and explainable outputs while fitting the privacy, IP, validation and GxP requirements of the environment.

This points to a solution that is:

- Focused on the investigation, particularly root cause analysis
- Designed to work alongside existing systems
- Transparent enough to support human judgement
- Built for the realities of a regulated environment

The opportunity is clear. The question is what we build to meet it.

> The findings highlight a clear opportunity for AI, but successful adoption will depend on moving beyond experimentation.
> The real value will come from embedding AI into quality processes in a controlled, risk-assessed way — with clear ownership, governance, and measurable outcomes.
>
> Ahmed M. Farag
> Global Regulatory Affairs Director

Meet Devin

An AI agent that classifies, drafts, and investigates deviations - every step reviewed and approved by QA teams.

50%

Time savings

Reported reduction in human touch time from opening to closing deviations.

85%

RCA accuracy

Reported first time quality of the AI assisted root cause analysis before HITL* verification.

100%

Improved quality

Users reported an overall improved quality versus the baseline process.

See how your quality function compares

Book a demo