



Validation in Transition

2025's Top Trends, Tools, and Takeaways

Presented by:

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For Discussion Purposes Only

Today's Moderator



Art Gehring

VP of Marketing, Kneat

About Kneat

- Global organization with operations in **Ireland, USA, France, Germany, Switzerland, Denmark, and Canada.**
- Public company, listed on the Toronto Stock Exchange (TSX), **held to high governance standards.**
- Validation platform to **8 of the top 10 global Life Science companies**
- **100+** customers across **350+** locations.
- **40+** certified global partners.
- **All in-house development**, no outsourcing for maximum quality.
- **ISO 9001:2015, ISO 27001 certified**



65,000+

users globally

8/10

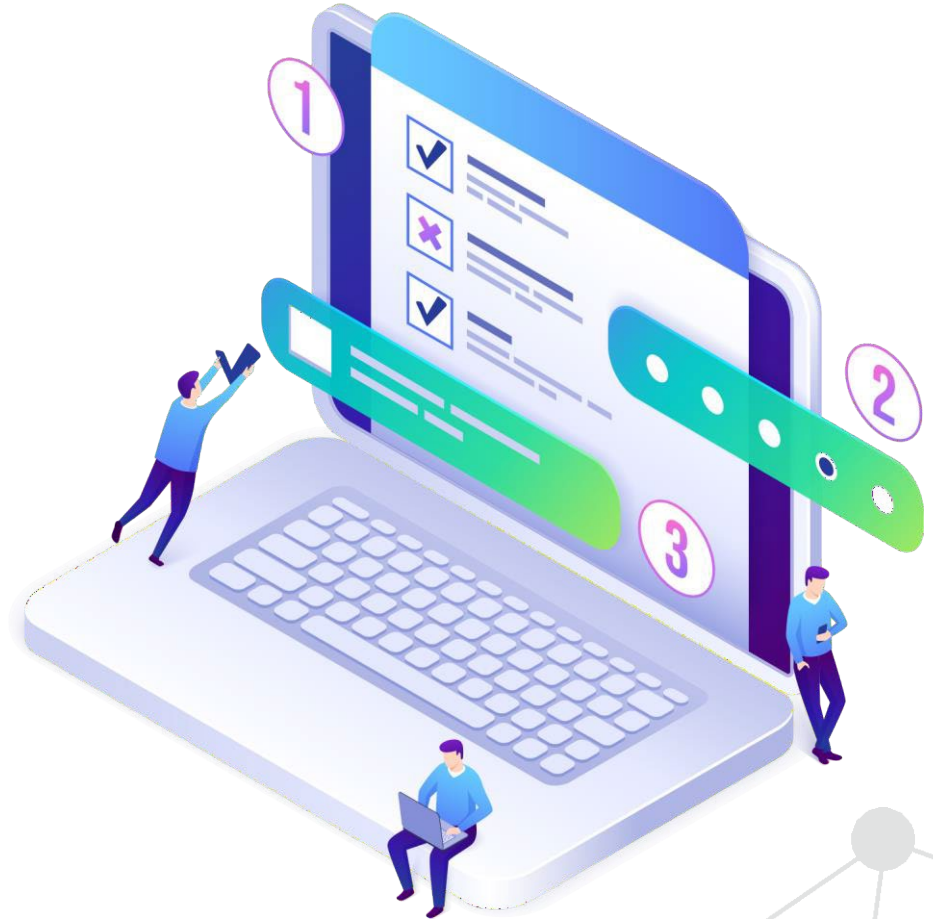
of the world's top 10
pharma companies

1st

to fully digitize facility, utility, and
equipment C&Q for a new large
facility build

Agenda

- Introductions
- Background
- Question Set and Demographics
- Key Findings
 - People and Organizations
 - Current Validation Practices
 - Digital Transformation and Technology
- Conclusion
- Q&A



Your Speakers



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State of Validation Report 2025 Background



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Kneat



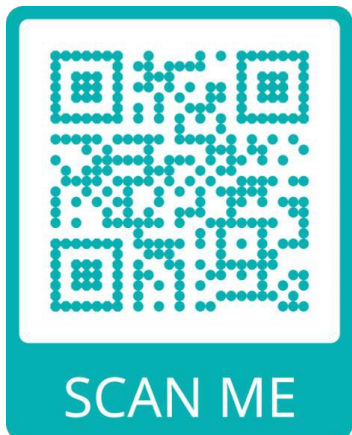
MMR
CONSULTING

Kneat

State of Validation - Overview

- Fourth year with **75% survey response growth** from 2024.
- Initiated in 2022 by Kneat, an annual global validation study — **the first and only of its kind in the validation industry**.
- Includes **qualitative research insights and showcases trends** to highlight the evolving dynamics in the validation industry.
- Enables regulated companies to reference, benchmark, and enhance their validation programs, teams, and technologies.
- Enables a **deeper longitudinal analysis** of broader trends impacting the validation industry.

Author and Contributors



- The 2025 report is authored by life sciences industry expert **Jonathan Kay**, Harvard University alumnus and co-founder of one of the first online medical market research firms.
- With oversight from **validation subject matter experts** at Kneat Solutions, Körber Pharma, and MMR Consulting.
- Thank you to all **contributors, survey respondents, and interviewees** whose insights contributed to the report.
- Register your interest in participating in the 2026 State of Validation survey now at **stateofvalidation.com/survey**

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Question Set and Demographics



Question Set Overview: Four Sections

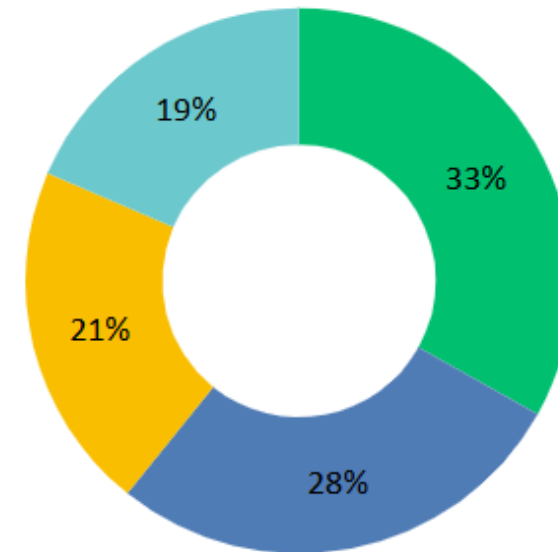
1. **People & Organizations:** Organization size, type, industry, geographic distribution, seniority, experience, job function, team challenges, workload, and size, and outsourcing.
2. **Validation Programs:** Structure, management, goals, budget allocations, CSA adoption, regulatory audit practices, and work processes.
3. **Digital Transformation & Technology:** Digital validation adoption, key barriers, implementation challenges, benefits, ROI, functions, and integration with other systems.
4. **AI Integration in Validation:** Adoption of AI and use cases, industry impact, primary concerns, and evolution in validation practices.

A **dedicated whitepaper, published later this year**, will explore Section Four — AI in Integration in Validation — in greater depth, with expanded insights and practical guidance.

Participants: Broad Representation

Q: What Is the Size of Your Organization?

- Participants included validation professionals varying in **company size, years of experience, seniority, job function, location, and team size — 61% in Life Sciences** — others in consumer healthcare, healthcare packaging, food & beverage, and equipment manufacturer.



■ Medium (between 100–1,000 employees) ■ Enterprise (5,000+ employees)
■ Small (up to 100 employees) ■ Large (between 1,000–5,000 employees)

Poll #1

What Is the Biggest Validation-Related Challenge Facing Your Organization Today?

Please select one:

- A. Audit Readiness
- B. Efficiency
- C. Compliance Burden
- D. Data Integrity



Validation Challenges

Q: What Are the Primary Challenges Your Validation Team Faces?

- Survey respondents cited **audit readiness** as the paramount challenge, followed very closely by **compliance burden**.
- Efficiency** and **data integrity** have consistently ranked among the top 5 validation challenges every year since 2022.



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Discussion #1: Validation-Related Challenges



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Key Findings



Section 1 | People & Organizations: Key Findings

- **Workloads continue to 4 year rise in 2025**, with 66% of respondents reporting increased demands over the previous 12 months, up from 61% in 2024. While the percentage has dipped slightly from a peak of 80% in 2022, **the majority of respondents across all four years continue to report growing workloads**, confirming this as a persistent and dominant trend.
- **Organizations are not investing in validation staff.** Teams with 1–3 members remain the most common, hovering around 25–35% across all years.
- **Validation is increasingly being outsourced to managed services providers**, with 70% of respondents outsourcing some validation work.
- **There is significant depth of experience within the validation sector**, with most (42%) holding between 6 to 15 years total validation experience — highlighting a strong mid-career presence and a deep bench of seasoned professionals.

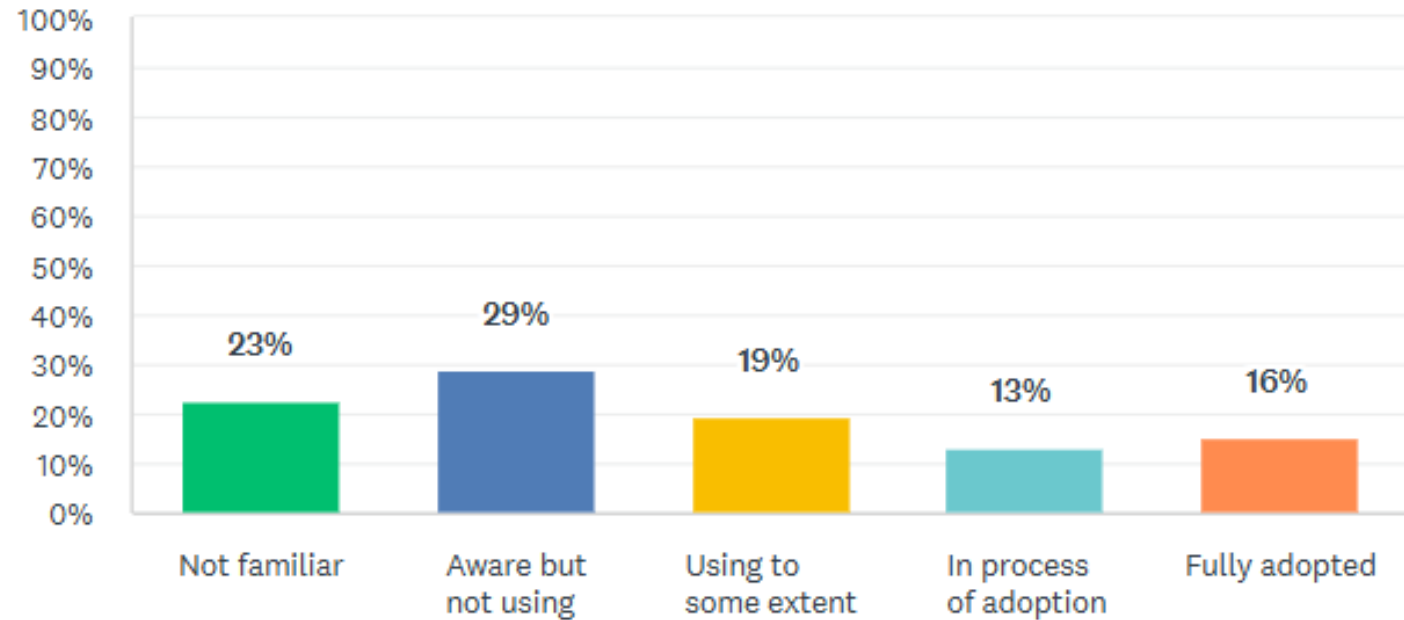
Section 2 | Current Validation Practices: Key Findings

- **Validation costs remain a significant challenge to control**, and one in four say validation consumes more than 10% of total project budget — a notable share that may **reflect high regulatory complexity, extensive documentation requirements, or inefficient processes** that still rely heavily on manual effort.
- The survey reveals **varying levels of adoption of CSA processes**, with half not using CSA and half somewhat along the adoption curve.
- **Audit readiness** was identified as the top goal in 2025 as organizations aim for continuous compliance and inspection preparedness.
- Sizeable adoption of remote regulatory audits, with **two-thirds reporting some level of remote auditing** over the past year.

Computer Software Assurance Processes: Adoption Rate

Q: How Familiar Are You with Computer Software Assurance (CSA)?

- 52% of respondents are not using CSA, while the other half are somewhere along the adoption curve.
- 23% are **not familiar with CSA**, highlighting a continued **need for education and industry-wide communication**.



Top Goals of Validation: Trends

Q: What Are the Primary Goals of Your Organization's Validation Program?

- **Being more audit ready/audit success** highlighting the industry's shift toward proactive compliance strategies amid growing regulatory scrutiny.
- **Creating process efficiencies** continues to be a dominant goal year-over-year — as organizations strive to manage increased workloads with lean teams.

Top Goals	2022	2023	2024	2025
1	Create process efficiencies	Create process efficiencies	Create process efficiencies	Being More Audit Ready / Audit Success
2	Right First Time / Minimizing Deviations	Right First Time / Minimizing Deviations	Being More Audit Ready / Audit Success	Create process efficiencies
3	Upskilling the Validation Team	Robust Data Integrity	Harmonizing Processes Across Sites	Introducing New Technologies to Improve Validation

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Discussion #2: CSA Engagement & Top Goals



Section 3 | Digital Transformation & Technology: Key Findings

- Results show a **sizeable shift towards digital validation** in the industry. Only 7% "not interested".
- **Education and training gaps** account for the largest share of cited obstacles to digital validation adoption, highlighting a strategic opportunity for upskilling and external support to drive adoption.
- **Data integrity remains the highest-ranked benefit** of digitalizing validation — as it was in 2024.
- Of those who indicate they have already adopted or are currently adopting a digital validation system, only 9% reported that **ROI fell short of expectations**.
- Respondents ranked **safe and secure storage of validation records** as the most important function of a digital validation system, underscoring the critical role of data integrity, audit readiness, and regulatory trust.
- While adoption of digital validation is growing, **integration with key systems** like project management, analytics, and tech transfer tools **remains limited**.

Poll #2

Where Are You on Your Journey to Digitalization?

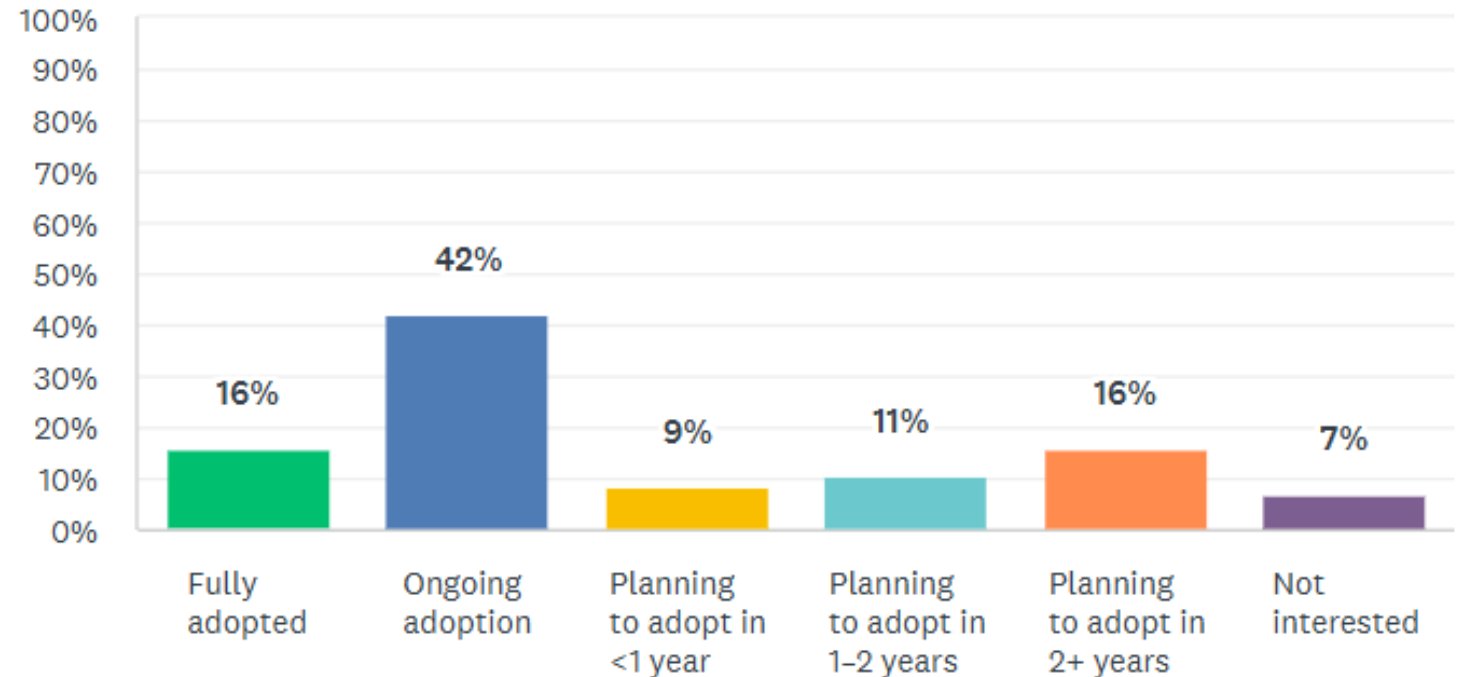
Please select one:

- A. It starts with this webinar today
- B. Initial discovery, some preparatory work & discussions done
- C. About to launch our first digital validation project
- D. Some projects delivered



Digital Validation: Adoption Rate

- 58% currently use a digital validation system — a **28-percentage point increase from 2024**, when only 30% reported using a digital validation system.
- Only 7% of organizations are not pursuing digital validation — but their **reasons differ based on scale**:
 - Cost concerns dominate for smaller companies
 - Larger companies face cultural or strategic friction

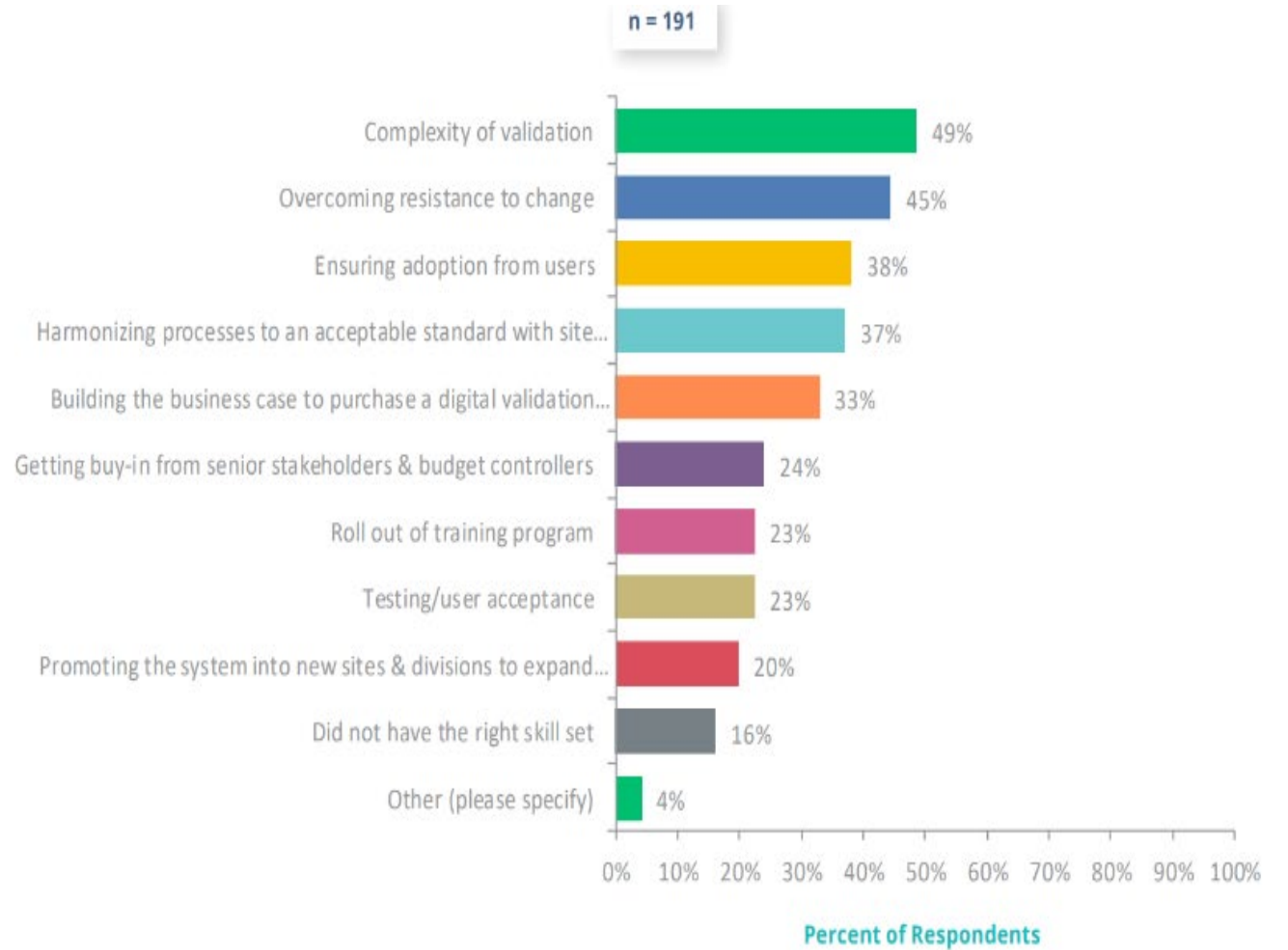


Implementation Challenges

Q: What Were the Biggest Challenges Your Organization Faced When Managing an Implementation Project for a Digital Validation System?

- Nearly half said **complexity of validation itself** as the top challenge.
- **Overcoming resistance to change** was the second most common challenge.
- Close to 40% struggled with **ensuring adoption from users**.

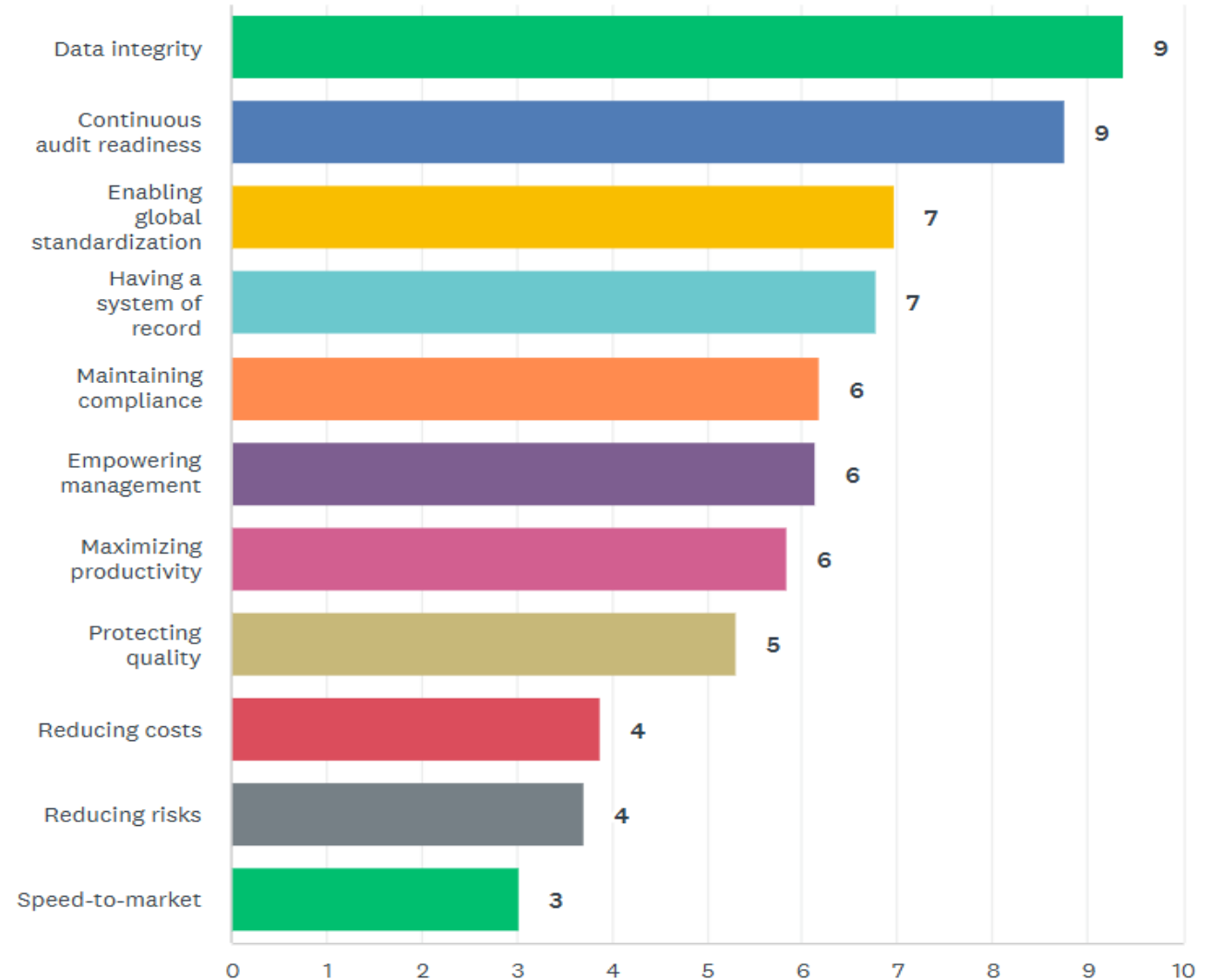
Implementation Challenges



Digital Validation: Benefits

Q: In Your Opinion, What Are the Leading Benefits of Digitalizing Validation?

- **No change** in top 3 from 2024 results.
- **Continuous audit readiness** ranked just behind data integrity.
- With **audit readiness now ranked as the #1 validation challenge**, digital validation systems are proving essential.



Voice of the Industry: Benefits of Digitalization

Q: How has the increasing regulatory focus on data integrity affected your validation practices in recent years?

"When things are paper-based, weird things can happen there. From a validation perspective, when everything is digital, there's this kind of data integrity that comes with a digital system."

- **Validation Director, Global Biotechnology Company, North America**

Poll #3

Does Your Organization Currently Use AI in Validation Activities?

Please select one:

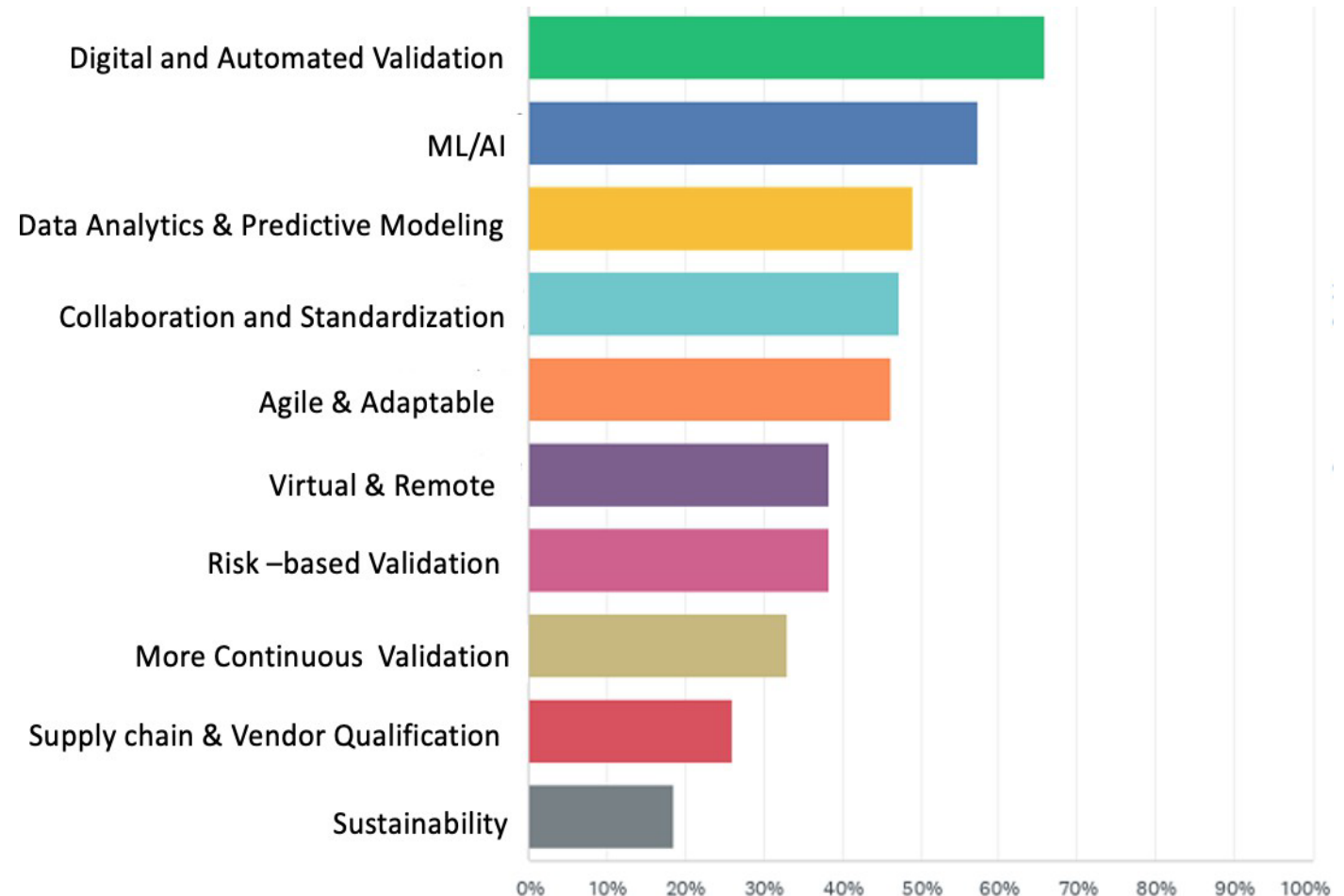
- A. Yes
- B. No, but planning to implement
- C. No, not considering



Validation Leaders Saw it Coming: 2024 Predictions

Q: How Do You See the Validation Industry Evolving Over the Next Five Years?

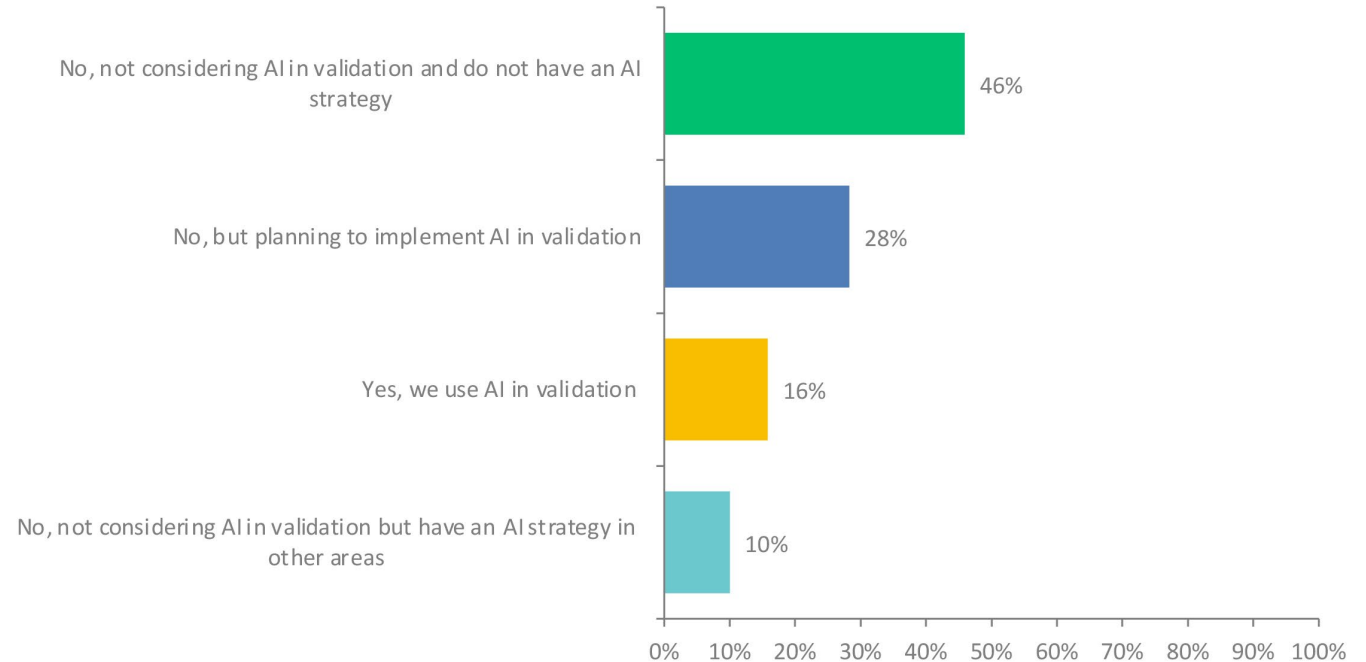
- In the 2024 State of Validation survey, **digital and automated validation** was seen as the clearest path forward.
- In 2025, **93% currently use or plan to adopt a digital validation system.**
- But look at what ranked second: **Machine Learning and AI.**
- This shows that the industry already recognized AI's potential.



In 2025, We're Starting to See AI's Use Come to Life

Q: Does Your Organization Currently Use AI in Your Validation Activities?

- 28% of respondents are in the **planning phase**.
- Only 16% have begun **actively using** AI in their validation processes.
- 46% of organizations are **not currently considering** AI for validation activities.
- Highlighting a **significant opportunity for innovation and competitive advantage**.



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Discussion #3: Digital Validation & Technology



Conclusion: Recap of Key Findings

- **Workforce under pressure:** Teams face increasing workloads and limited resources, making strategic resourcing, upskilling, and retention essential. Audit readiness is now the top challenge.
- **Digital validation goes mainstream:** Adoption jumped to 58% in 2025. To maximize ROI, organizations must prioritize implementation planning, user adoption, and system integration.
- **AI on the horizon:** Although still in early use, AI is gaining traction. Now is the time to build internal capability and monitor regulatory developments.

Thank You

Learn more at
stateofvalidation.com

Tell us what you
thought of the webinar



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