

Session 11.1

The State of Validation 2026:

Accelerating Digital
Maturity in the Age of AI



Agenda

- Introductions
- About the State of Validation
- Pressure & Practice
- Digital Maturity
- AI — Arrival & Accountability
- The State of Validation 2026 Report Launch
- Audience Q&A



Introductions

- The 2026 State of Validation report is authored by validation industry expert **Donncadh Nagle**, senior CQV consultant at Jacobs Engineering and lecturer at Technological University Dublin.
- With oversight from **validation subject matter experts** at Kneat, IPS-Integrated Project Services, PM Group, and Telstar (A Syntegon Company).



Session Panelist

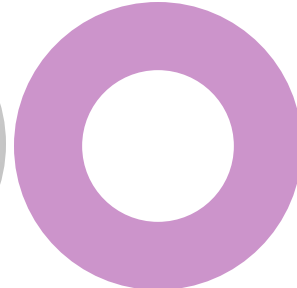


Donncadh Nagle

Moderator, Jacobs / TU Dublin



Session Panelists



Michael Sweeney

CQV Electronic Validation
Lead, PM Group



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Validation & Compliance
Manager, IPS EMEA



Ruairi McGarry

Senior Product Manager,
Kneat Solutions



About State of Validation



Background & Purpose

- Fifth year with **87% survey response growth** from 2025.
- Initiated in 2022 by Kneat, an annual global validation industry study — **the first of its kind in the validation industry.**
- State of Validation 2026 includes **qualitative research insights and showcases trends** to illustrate the evolving dynamics in the validation industry.
- The **only available and actionable industry dataset** that 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.

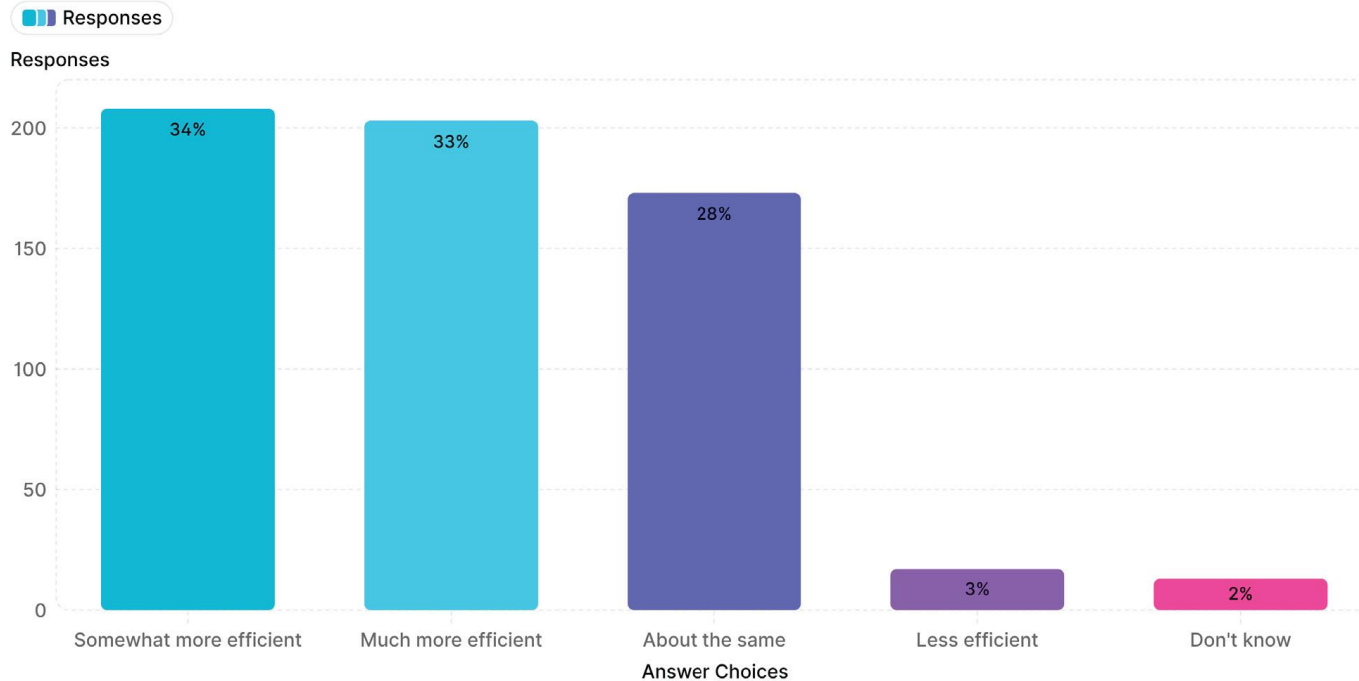
Pressure & Practice

WORKLOAD | CHALLENGES | EFFICIENCY PARADOX



Workload at a Five-Year High

- 80% report increased workload in 2026.
- 45% say workload increased significantly — the highest in 5 years of the study.



Challenge + Efficiency Paradox

- Top 3 challenges — 3rd consecutive year.
- 67% report greater efficiency than a year ago:
 - 33% much more efficient
 - 34% somewhat more efficient
 - 3% less efficient

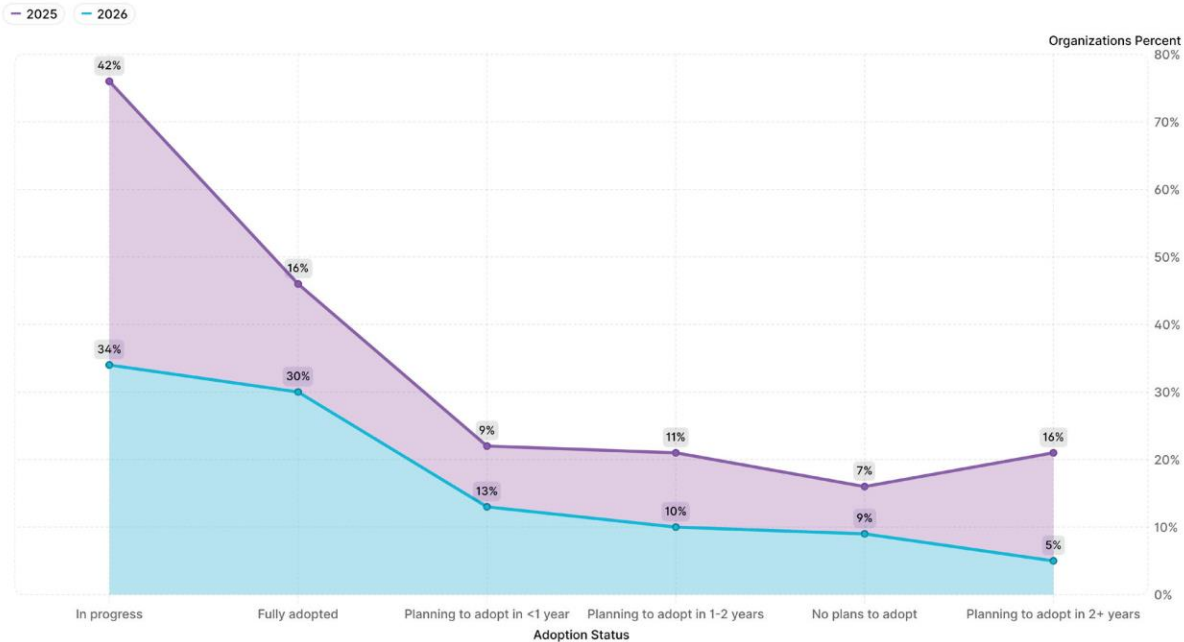
Rank	2026	2025	2024	2023	2022
#1	Audit readiness	Audit readiness	Compliance burden	Shortage of human resources	Shortage of human resources
#2	Compliance burden	Compliance burden	Audit readiness	Efficiency	Efficiency
#3	Data integrity	Data integrity	Data integrity	Lack of tech resources	Lack of tech resources

Digital Maturity

DIGITAL VALIDATION ADOPTION | THE PAPER GAP



Digital Tool Adoption — The Tipping Point



- 64% using or implementing a digital validation tool:
 - 30% fully adopted
 - 34% in progress
 - Full adoption nearly doubled year-over-year (16% to 30%)

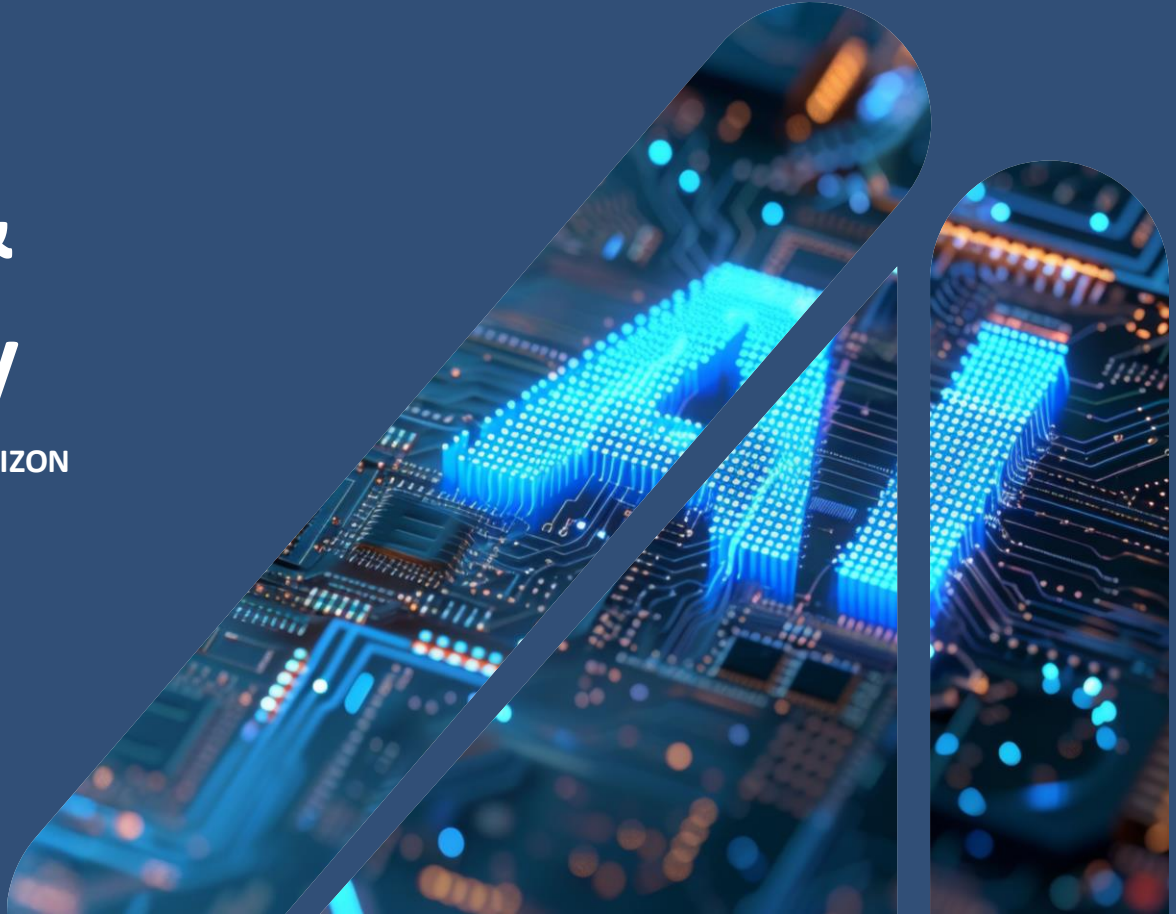
Digital Maturity & The Paper Gap

- Only 13% fully digital across all record types.
- Hybrid environment are the norm — even in digitally progressed organizations.
- Most paper-persistent records: logbooks (41%), batch records (35%), validation protocols (33%).

Maturity Level	2026 (n = 614)
Level 3 - Maturing (hybrid paper-digital model)	25%
Level 4 - Optimizing (predominantly digital)	23%
Level 2 - Defined (early adoption, predominantly paper-based)	21%
Level 1 - Initial (primarily paper-based)	17%
Level 5 - Transformed (fully digital and automated)	12%
Don't know	2%

AI — Arrival & Accountability

USE CASES | CONCERNS | THE 2030 HORIZON



AI Has Arrived in GxP Validation

- **The turning point:** for the first time more respondents are actively using AI in GxP (22%) than have no AI strategy at all.
- **"Not considering AI"** collapsed from 46% to 19% in a single year.
- **Active use cases:** protocol drafting, data review, traceability, deviation narratives, test case generation.

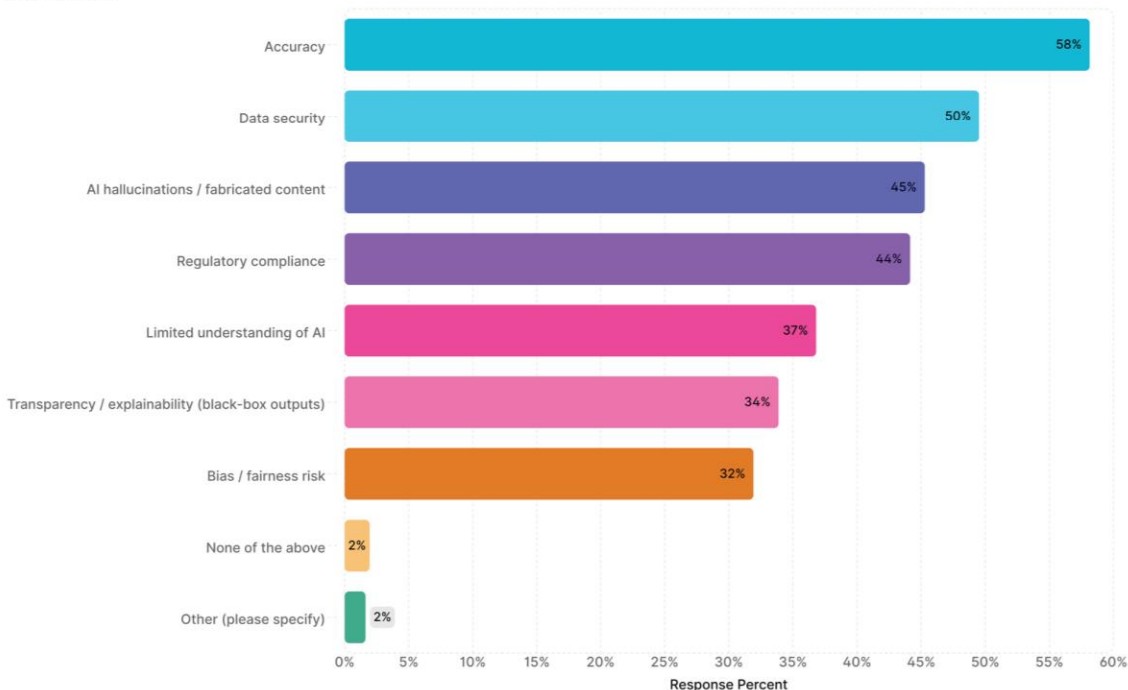
AI Status	2026	2025
Yes - planning to implement AI in validation / quality (GxP)	24%	28%
Yes - currently using AI in validation / quality (GxP)	22%	16%
No - not currently considering AI in any area	19%	46%
No - but using AI in other (non-GxP) areas	18%	10%
Yes - piloting / evaluating AI for validation / quality (GxP)	17%	-

Note: 2026 response options were expanded to include a separate "piloting/evaluating" category not present in 2025.

AI Concerns — What the Industry Is Worried About

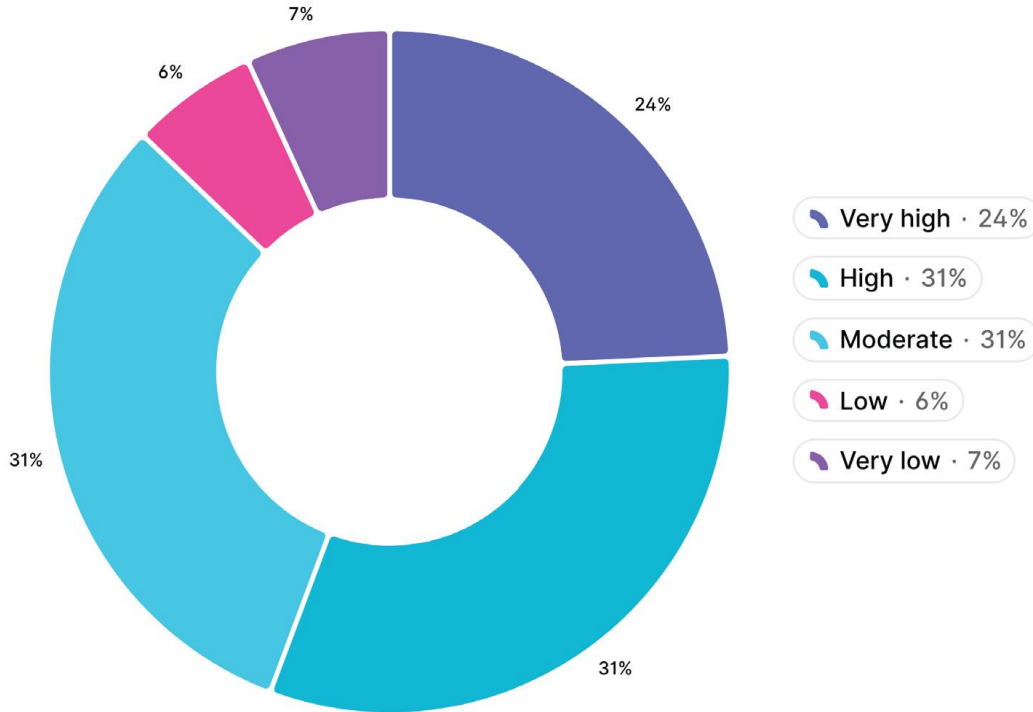
Response Percent

Answer Choices



- **Key signals:**
 - 58% accuracy (core GxP risk)
 - 50% data security
 - 45% hallucinations (new 2026 category)
 - 2% "none of the above" (concern is near-universal)

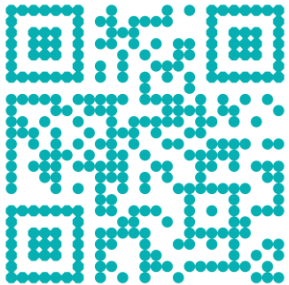
Risk-Aware. Committed. The 2030 Horizon.



- 78% very or somewhat confident AI will be standard in validation by 2030.
- The industry is not blind to the risks — it simply believes AI integration is coming, and the work is building the frameworks.

Launching Now: The 2026 State of Validation Report

Thank you to all **contributors, survey respondents, and interviewees** whose insights contributed to the report.



Be among the first to access the **2026 report** — scan the QR code to download your copy now or visit stateofvalidation.com

