2024

STATE OF VALIDATION

Validation Industry Annual Report

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Supported By:

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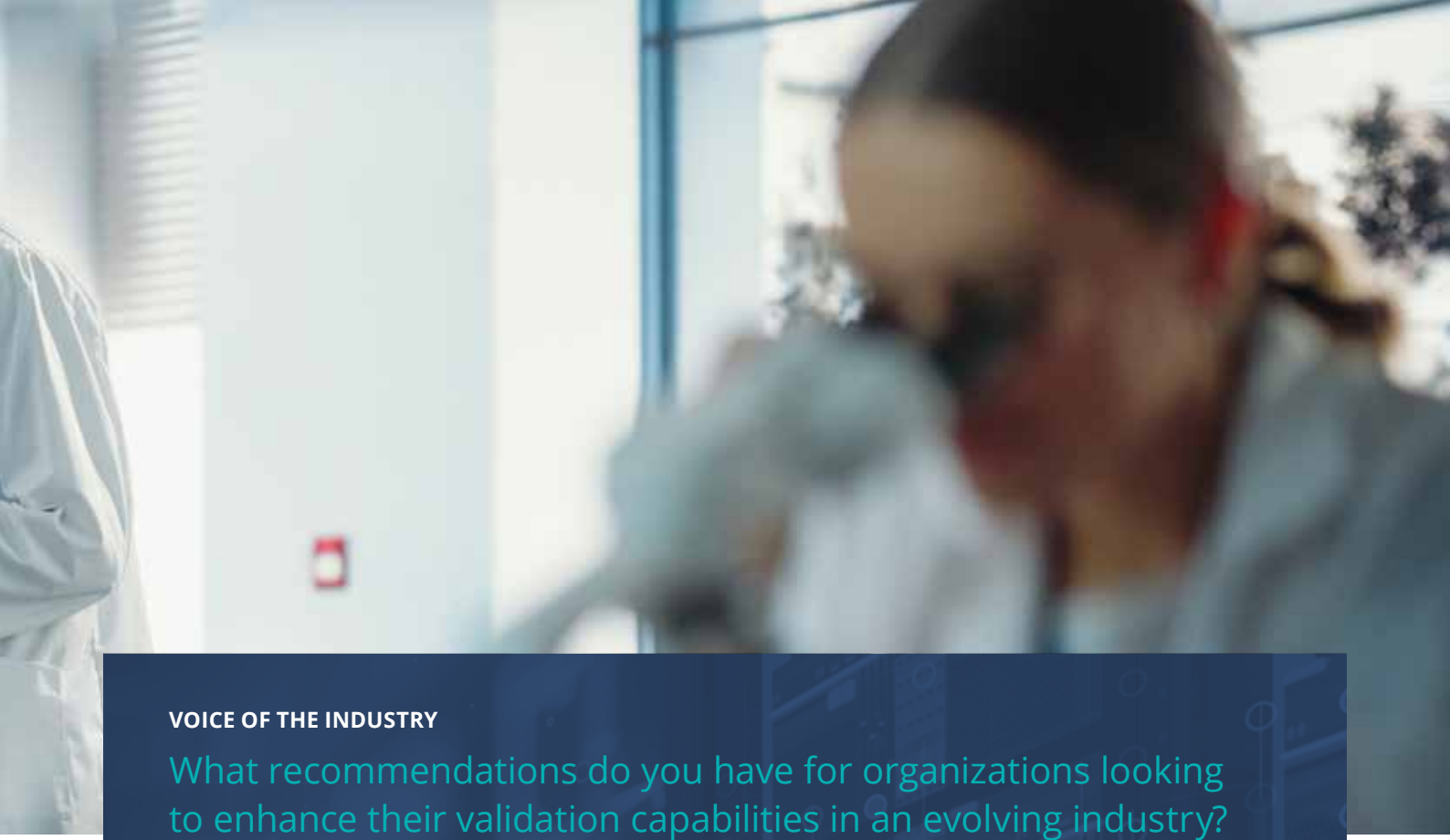
Background & Purpose

State of Validation 2024 is the third annual state of the industry report powered by Kneat Solutions. State of Validation illuminates the practices, trends, and challenges within the global validation industry, providing a long-term dataset that enables validation professionals to analyze their own validation programs against technological, regulatory, and practice benchmarks.

Authored by Jonathan Kay, a noted life sciences industry expert and Harvard alumnus, along with a dedicated team, the report draws from an extensive quantitative survey and in-depth qualitative “voice of the industry” interviews with validation professionals from around the world.

The study behind the 2024 report was developed with guidance from validation subject matter experts within the International Society of Pharmaceutical Engineering Paperless Validation Subcommittee, and leading validation service providing organizations, including Design Group, No Deviation, and PCI.

The 2024 State of Validation introduces new survey questions focusing on the governance models of digital validation systems, providing insights into whether organizations adopt centralized, decentralized, or balanced approaches. Additionally, the report explores the stated ROI compared to initial predictions and identifies which functional groups within organizations are responsible for managing digital validation systems. This spotlight on governance, ROI assessment, and management responsibility offers a deeper understanding of current trends and practices in digital validation.



VOICE OF THE INDUSTRY

What recommendations do you have for organizations looking to enhance their validation capabilities in an evolving industry?

> "Being **open to change** is my main recommendation. Understanding what's evolving and how to how to handle that and work that into your current processes. Have an open mind and be willing to step out to really come up with solutions that are going to help you advance as well."
>
> **— Validation Department Head, Multinational Healthcare Company, U.S.A**

The 2024 State of Validation also delves into the prevalence of remote regulatory audits over the past year, examining how organizations are adapting to remote auditing. Further, it assesses the current stage of Industry/Pharma 4.0 adoption, from early exploration to full integration, providing a view of technological advancements in the industry.

The 2024 survey saw participation from a diverse group of professionals in terms of years of experience, company size, job function, seniority, geographic location, and team size.

Most participants came from the life sciences sector; the survey also included other highly regulated industries, such as consumer-packaged goods, aerospace, food and beverage, and nuclear. This included professionals from both primary manufacturers and secondary service or product providers operating under stringent regulations.

For further information on methodology, please see the Appendix on page 83

Contents Summary

The State of Validation survey and report are structured into five sections, each providing a comprehensive look at different aspects of the validation landscape.

1. **People and Organizations:** Delves into the roles of individuals and organizations within validation processes. It examines team sizes, outsourcing practices, validation experience, and salary, providing demographic details such as company size, organization type, industry, role seniority, and job functions of the respondents.
2. **Validation Programs:** Focuses on the diverse validation programs and approaches that organizations employ. It covers the structure of validation programs, work processes, adoption rates of computer software assurance, budgets, team workloads, and identifies key challenges and opportunities for improvement.
3. **Goals and Growth:** Investigates the strategic goals and growth plans related to validation in organizations, including professional and organizational objectives, performance metrics, and factors influencing success and satisfaction.
4. **Industry Change and Digital Transformation:** Discusses the significant industry changes and the role of digital transformation. It explores the challenges and opportunities brought by the trend towards increased remote work in recent years, including remote regulatory assessments and the increased capability of remote monitoring technologies and other digital shifts, examining utilization and perceptions of the impact and benefits of new validation technologies and tools; including the adoption rate and management of digital validation systems and an evaluation of their stated return on investment (ROI) against initial expectations.
5. **The Future of Validation:** Provides foresight into the future direction of validation practices. It assesses emerging technologies and methodologies, like Industry/Pharma 4.0, and discusses anticipated industry evolution and upcoming challenges.

Each section includes an analysis of the findings, insights, and year-over-year trends and implications for the industry.

Table of Contents

Introduction from Kneat Solutions' CEO Eddie Ryan

A very warm welcome to the 2024 State of Validation, an annual snapshot of the global validation industry, powered by Kneat Solutions. My thanks to the author, Jonathan Kay, and the insight provided by validation industry leaders, Design Group, No deviation, and PCI — and special contribution from the International Society for Pharmaceutical Engineering's (ISPE) Paperless Validation Sub-Committee.

Thank you to all who took part in this year's study. Your participation in the State of Validation research is invaluable. It helps the industry gain a deeper understanding of its challenges and opportunities, paving the way for a stronger future. If you were unable to contribute your insights this year, we look forward to your participation in **next year's survey**.

Strategic Priorities and Challenges in Validation

Kneat Solutions' mission is to "Help Life Sciences develop, manufacture, and deliver therapies to their patients to the highest safety standard." Reflecting this mission, the 2024 State of Validation report reveals that validation professionals find "**Contributing to Life-Saving Therapies**" to be the most enjoyable and rewarding facet of their roles.

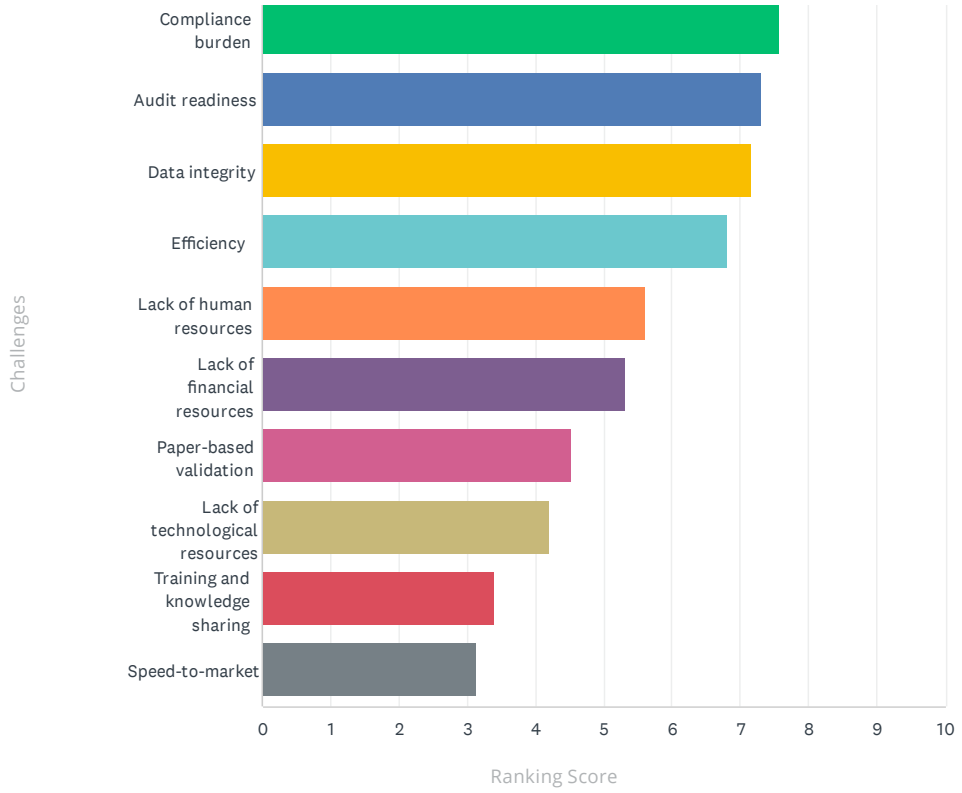
Efficiency, Audit Readiness, and Data Integrity

The 2024 State of Validation survey findings reveal a strategic pivot towards **efficiency and audit readiness** in validation programs, with validation professionals prioritizing process efficiencies and audit success.

When asked about the 'biggest validation challenge facing their business,' survey respondents cited "**compliance burden**" as the paramount challenge, followed by "**audit readiness**" and "**data integrity**" concerns among validation professionals. Notably, **data integrity** and **continuous audit readiness** are the most coveted benefits.

Top Validation-Related Challenges

In your opinion what is the biggest validation-related challenge that your business is facing today? Please rank all answer choices in order of preference, 10 being the highest.



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Trends in Validation Costs, Remote Audits, and CSA Processes

The 2024 survey findings indicate that **validation costs continue to pose a challenge**, with two-thirds of respondents reporting that validation expenses consume over eight percent of project budgets, often exceeding 10 percent. Despite these challenges, the emphasis on "**Cost Savings Achieved Through Efficient Validation Processes**" as a key performance indicator underscores a growing trend towards prioritizing cost efficiency in validation practices to mitigate financial impact while maintaining compliance with regulatory standards.

The survey also highlights a trend towards **remote regulatory audits and computer software assurance processes** with a majority reporting substantial adoption, likely illustrating the impact of recent U.S. Food and Drug Administration draft guidance for industry on each of these validation disciplines (FDA, 2024 "Conducting Remote Regulatory Assessments" and FDA, 2022 "Computer Software Assurance for Production and Quality System Software").

We encourage you to apply the insights from this report within your organizations, teams, and validation programs to drive growth and improvement.

Eddie Ryan

Eddie Ryan, CEO, Kneat Solutions

Executive Sponsor 2024 State of Validation

Insights and Recommendations for Industry

These conclusions are derived from a combination of quantitative and qualitative data collected through the survey, in-depth interviews, and analyzed with comprehensive industry knowledge and expertise.

Future Challenges in the Validation Industry

When asked about future challenges, respondents provided the following answers, which we have analyzed below:

Balancing Cost and Resource Constraints

The survey identifies balancing cost and resource constraints as the main future challenge for most respondents (57 percent). As validation processes become more complex and data-intensive, organizations must find ways to optimize resources and control costs without compromising quality. Implementing cost-effective validation solutions and leveraging automation can help address this challenge.

Attracting and Retaining Skilled Talent

Attracting and retaining skilled talent is a concern for 52 percent of respondents. The validation industry requires highly specialized knowledge and skills, and the competition for talent is fierce. Organizations need to invest in training, development, and mentoring programs to build a skilled workforce and create attractive career pathways to retain top talent. Embracing sustainable, digital technologies and modernizing validation processes can also make the field more appealing to younger professionals.

VOICE OF THE INDUSTRY

How does your organization keep pace with technological advancements?

> **"We form mixed teams of seasoned professionals and newcomers, fostering a mentoring culture that supports learning and growth.** The industry is moving towards scaled Agile methodologies, aiming for faster product releases. Understanding critical customer perspectives is essential, and we ensure this by maintaining a balanced team composition to leverage both experience and fresh insights."
>
> **— Quality Engineering Specialist, Top 10 Multinational Healthcare Company, U.S.A**

Keeping Pace with Technological Advancements

Keeping pace with rapidly changing technologies is a challenge for 43 percent of respondents. The validation industry must continuously evolve to incorporate new tools and methodologies. For example, further research, education, and the development of new validation strategies are required of validation teams to validate emerging technologies such as AI. GxP critical AI applications are increasingly common in drug discovery, R&D, clinical trials, and manufacturing, and require validation teams to design appropriate controls for data integrity, data quality, data models, machine learning models, algorithms, and other AI system features.

The balance of seasoned validation workers (38 percent have > 16 years of experience) with newer, early-career digital natives presents an excellent opportunity for knowledge sharing and collaboration to overcome the challenges presented by new technologies like AI.

The Role of Cross-Functional Collaboration

Importance of Effective Communication

Collaboration is highly valued in the validation industry, driven by digital transformation and expected to grow. However, ensuring effective alignment and collaboration remains a sizeable challenge. Forty-seven percent of respondents see **greater collaboration and information sharing across industries and geographies to drive standardization and best practices** as a notable trend in the next five years.

Enhancing Team Alignment and Collaboration

Ensuring alignment and collaboration across teams is a challenge for 31 percent of respondents. Implementing integrated validation systems and fostering a collaborative culture can help overcome this challenge. Regular cross-functional meetings, collaborative project management tools, and shared objectives can enhance team alignment and streamline validation processes.

Leveraging Digital Tools for Collaboration

Greater collaboration and information sharing among stakeholders in the validation process is the top-ranked impact of digital transformation in the validation industry. **Digital validation systems enable real-time collaboration and information sharing, making it easier for teams to work together effectively.** Cloud-based platforms, for example, allow team members to access and update validation documents from any location, improving flexibility and responsiveness. These tools also provide audit trails and version control, ensuring transparency and accountability in validation activities.

VOICE OF THE INDUSTRY

How does collaboration within your organization enhance the effectiveness and practicality of your validation processes?

> "We can't do our work in isolation. Simply putting a validation stamp on something doesn't mean it's functional for the end users. **Collaboration ensures that the validation process is thorough** and meets the practical needs of those who will use the software."
>
> **— IT Compliance Manager, Global Leader, In Vitro Diagnostics (IVD) & Biomarkers, U.S.A**

Embracing Digital Validation Systems

Benefits of Digitization

The survey data shows that organizations that have embraced digital validation systems report benefits, with continuous audit readiness, improved data integrity, and global standardization ranking as the top three respectively. Digital systems automate many manual validation tasks, reducing the risk of errors and speeding up the validation process. They also provide centralized repositories for validation data, making it easier to manage and retrieve information.

Measuring Return on Investment (ROI)

Organizations measure the ROI of digital validation systems by evaluating improvements in efficiency, compliance, and overall validation costs. Among respondents using a digital validation system, a **sizeable majority (63 percent) reported that the stated ROI met or surpassed their initial expectations, demonstrating a strong alignment between predicted and realized benefits.** This underscores the overall effectiveness and value of these systems in achieving desired financial outcomes. Continuous monitoring and optimization of these systems can further enhance their value and impact.

The Evolution of Validation Technologies

Increasing Adoption of AI and Machine Learning

Seventy percent of respondents believe AI and machine learning will play a pivotal role in the future of validation. While also presenting a validation challenge themselves, AI technologies such as generative natural language tools, are expected to revolutionize the execution of validation processes by authoring protocols and other documentation, while other tools can automate repetitive tasks, or provide predictive capabilities to improve decision-making and better manage risk. AI-driven systems can identify patterns and anomalies that might be missed by human analysis, ensuring more robust and reliable validation outcomes.

Role of Advanced Robotics and Automation

Advanced robotics and automation have moved up to the second position in 2024, with 50 percent of respondents highlighting their importance. These technologies enable precise and efficient validation testing and data collection. Robotics can perform complex validation tasks with high accuracy and consistency, reducing human error and increasing throughput. Automation also facilitates continuous validation processes, ensuring compliance and quality standards are maintained in real-time.

Cloud Computing and Its Impact

Cloud computing remains a significant technology, with 42 percent of respondents emphasizing its role in faster and more efficient data processing and analysis. The ability to access and analyze vast amounts of data in real-time from anywhere in the world enhances collaboration and decision-making. Cloud-based validation platforms provide scalability and flexibility, allowing organizations to adapt quickly to changing validation requirements and regulatory standards. Importantly, these platforms also incorporate robust security measures to protect sensitive data, ensuring compliance with stringent regulatory and industry standards.

VOICE OF THE INDUSTRY

How can embracing digital tools and sustainability help attract skilled talent to the field of validation?

> "The use of modern software in validation not only aligns with 21st-century practices but also makes the occupation seem more innovative and "cooler." This **digital shift helps attract and retain skilled talent** who are looking for careers that are both engaging and aligned with their values."
>
> **— IT Compliance Manager, Global Leader, In Vitro Diagnostics (IVD) & Biomarkers, U.S.A**

Trends in Validation Practices

Increasing Emphasis on Efficiency and Audit Readiness

Based on the 2024 data, **enhancing efficiency and ensuring audit readiness within validation programs**, were ranked amongst the top validation-related challenges by respondents. In 2022 and 2023, the top three validation-related challenges identified were "Shortage of Human Resources," "Efficiency," and "Lack of Technological Resources." This indicates a heightened focus on optimizing validation processes to save time and resources while maintaining high standards of compliance and audit readiness.

Increasing Emphasis on Data Analytics

The survey reveals a **growing emphasis on data analytics in validation practices**. Forty-one percent of respondents highlight the importance of leveraging big data analytics for predictive insights and decision-making. Advanced analytics tools can process large volumes of validation data, identify trends, and provide actionable insights to improve validation processes and outcomes.

Adoption of Continuous Validation

Continuous validation practices are gaining traction, with 33 percent of respondents indicating a shift towards more ongoing validation activities. This approach ensures validation is integral to the entire product lifecycle, maintaining compliance and quality standards. Continuous validation also enables organizations to respond more quickly to changes in regulations or product requirements.

Focus on Sustainability

Integrating sustainability and environmental practices into validation processes is a nascent opportunity, as just 19 percent of respondents identified sustainability as a consideration. Life Sciences organizations are actively implementing ways to reduce the environmental impact of their operations, though this appears less prevalent within the validation function. Despite this, digitalizing validation presents a tangible opportunity to minimize paper usage and reduce the carbon footprint of document storage facilities and travel for global validation projects. Opportunity exists for validation to better contribute to organizational sustainability initiatives, as new technologies such as digital validation also present business benefits alongside ecological ones.

Results and Year-Over-Year Analysis

The following five sections of the 2024 State of Validation report provide a comprehensive overview of the latest trends and developments in the validation industry. These sections highlight key findings from the current year and compare them to previous years, offering valuable insights into how the industry is evolving. By examining changes in validation practices, technology adoption, and regulatory compliance, this analysis helps organizations understand the shifting landscape and make informed decisions to stay ahead of the curve.

Section One: People and Organizations

This section explores the roles of individuals and organizations in validation processes. It covers team sizes, outsourcing practices, validation experience, and salaries. Additionally, it provides demographic details such as organization size, company type, industry, role seniority, and job functions of the respondents.

Respondents represent a variety of industries, with most working in life sciences and in Engineer or Specialist roles. There was a mix of organization sizes. Just over one third of participants have been in validation for six to 15 years.

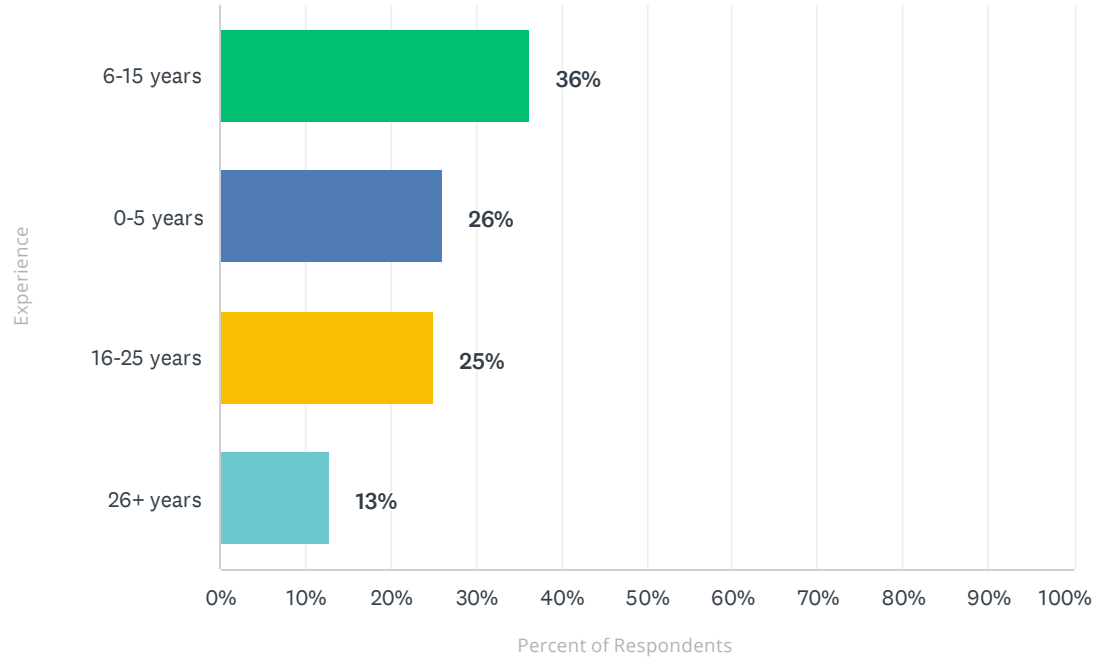
For further information on methodology and respondent profile, including respondent qualifications, company type, organization size, industry verticals, geography, role seniority, and job function please see the Appendix on page **83**.

Validation Experience

This section represents perspectives from validation professionals at all stages of their careers (see graph below).

Validation Industry Experience Measured in Year

How many years of experience do you have in validation? Please select one.



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When asked about their experience in validation, one in four reported being early in their validation careers, with five or fewer years of experience. Another one in three said they have 6-15 years of experience. An additional one in four reported having 16-25 years in the industry, and one in eight said they have 26 or more years of experience.

- **Thirty-eight percent of respondents have 16 or more years in the industry and represent a workforce rich in experience. This distribution of tenure reveals a deep reservoir of knowledge and stability within the validation field.** The veteran presence is crucial for mentoring and maintaining high standards.
- Meanwhile, **an influx of new entrants (those with 0-5 years of experience), indicates a healthy interest in the validation profession and presents an opportunity for training**, including from more experienced colleagues. Early-career employees need training. Their organizations should outline a path to success and enable them with professional development along the way. Companies have the potential to leverage junior staff, along with automation and AI (discussed later in this report) to generate productivity gains.

The survey reveals a wide range of experience levels in validation. That allows companies to organize functions according to the level of responsibilities and degree of complexity. The depth of exposure to the industry varies, presenting an **opportunity for companies to leverage their more experienced employees for more complex roles and management positions.** Seasoned employees are an internal asset to organizations who decide to establish informal or formal mentoring programs to train, develop, and retain less-experienced staff and lay out a path for their career success.

VOICE OF THE INDUSTRY

How does your organization support continuous professional development for its validation team members?

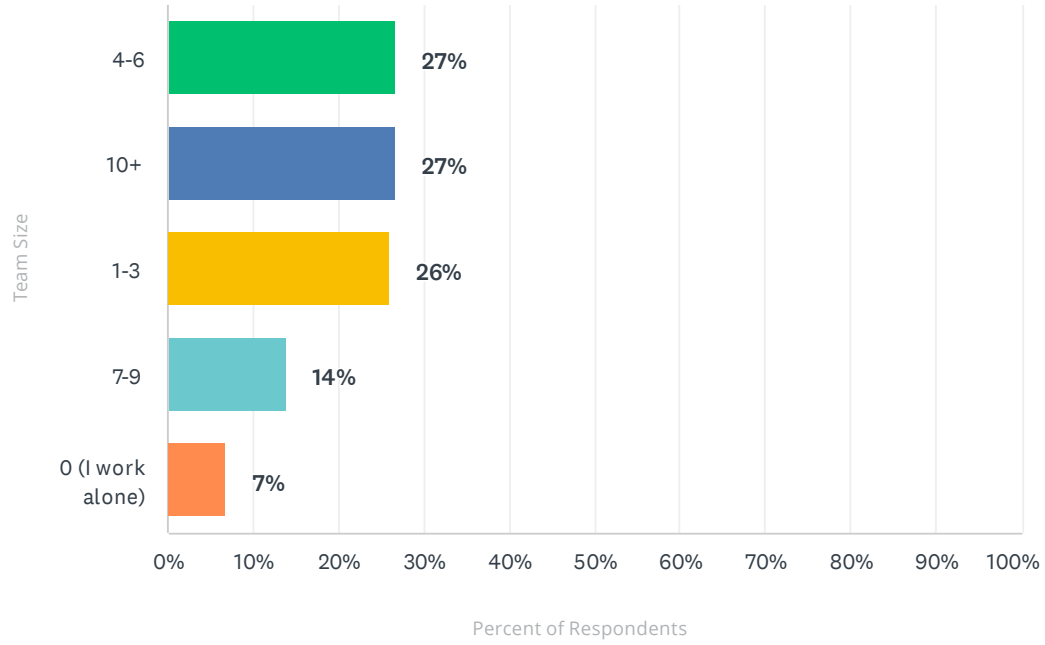
> "Our organization doesn't actively facilitate ongoing training, so as validation professionals, it's **up to us to stay informed about industry trends and regulatory updates.** We often make the case for additional training when costs are involved. Typically, we rely on free resources like webinars and stay updated with materials released by the FDA and other regulatory bodies."
>
> **— Senior Validation Manager, Global Medical Equipment Manufacturer, U.S.A**

Validation Team Size

Organizational size and structure vary among validation teams. This section focuses on the size of those teams. First, we will examine team size (see graph below) and look at three-year trends in team size.

Validation Team Size

How many validation professionals are in your team? Please select one.



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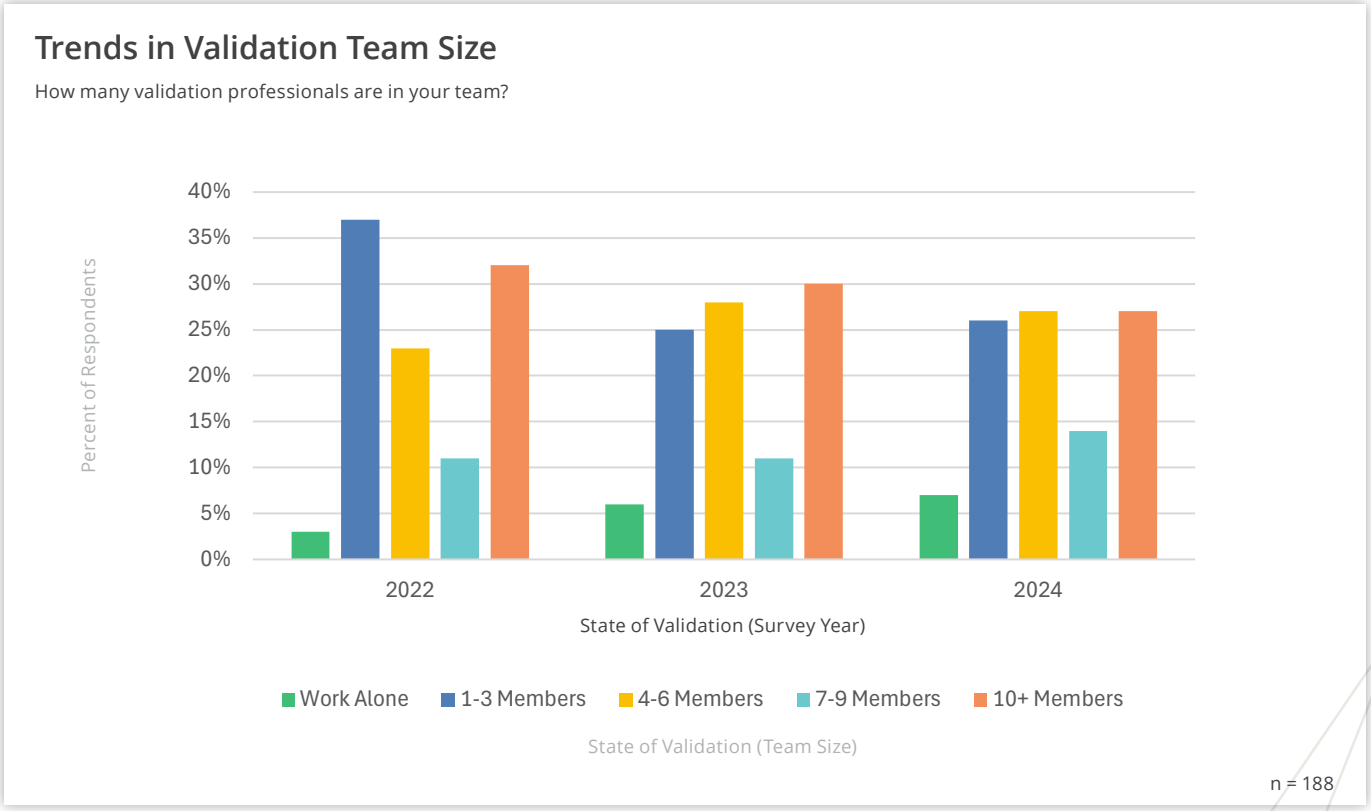
Team size varies, and it may be **driven by a variety of factors, such as organizational preferences, overall company size, and available resources.** Companies face the challenge of optimizing validation team size based on organizational goals, resources, and project requirements.

- **Solo:** A small percentage (7 percent) of professionals work alone, indicating a niche segment or specialized roles requiring solitary work.
- **Small Teams:** Teams of 1-3 members (26 percent) of respondents provide agility that is useful to adapt quickly to changing validation needs.
- **Medium Teams:** Team sizes of 4-6 members (27 percent) and 7-9 members (14 percent) together represent 41 percent of the respondents. Medium teams offer the opportunity for increased individual specialization and greater total capacity.
- **Large Teams:** Teams of 10+ members (27 percent) are larger and therefore can handle more complex, large-scale validation projects requiring extensive collaboration and diverse expertise.

Overall, the data underscores the **importance of team size in optimizing validation processes and aligning with project requirements and organizational goals.**

Trends: Team Size

Three-year survey trends show **slight increases among solo workers and larger teams, while mid-sized teams are declining** (see chart below).



- **Growing Trend Towards Solitary Work:** The percentage of professionals working alone gradually increased (from three percent in 2022 to seven percent in 2024), indicating growth towards solitary work, possibly due to specialized roles or remote work setups.
- **Decline in Small Teams (1-3 Members):** Small teams have seen a decline (from 37 percent in 2022 to 26 percent in 2024), suggesting a shift towards Medium and Large Teams.
- **Growth in Medium-Sized Teams (4-9 Members):** In combination, the cohort of mid-sized teams (4-6 and 7-9 members) remained relatively stable and grown (from 34 percent in 2022 to 41 percent in 2024), showing a steady preference for medium-sized teams that balance flexibility and comprehensive skill sets.
- **Decrease in Large Teams (10+ Members):** Large teams offer greater potential for collaboration and complex activities. This group showed a modest decrease (from 32 percent in 2022 to 27 percent in 2024), reflecting a possible shift towards more efficient, smaller teams or resource optimization. This decline may be the result of sampling and the mix of organization sizes that participated in this year's survey.

VOICE OF THE INDUSTRY

How does your organization ensure validation activities are prioritized and valued?

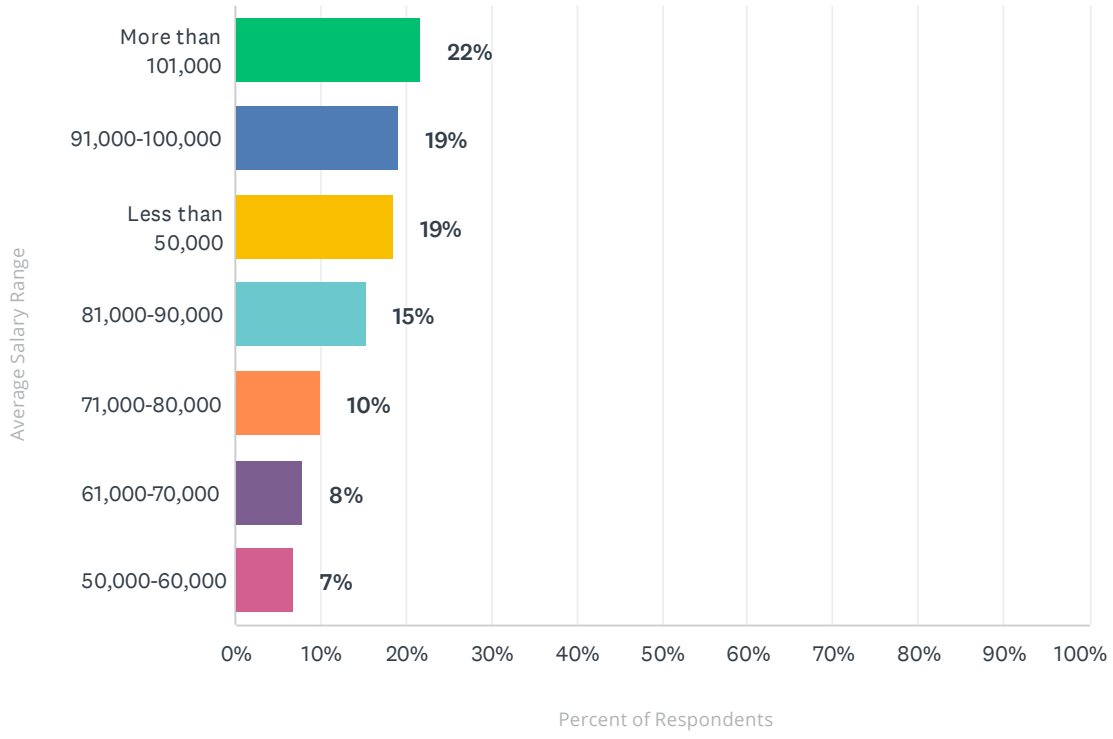
> "The best way to lead that is by **making sure that we're adequately staffed**. So, the company supports it through human resources and capital in terms of making sure we have the tools that we need to execute the type of validation studies we need to complete."
>
> **— Validation Department Head, Multinational Healthcare Company, U.S.A**

Average Salary Range

Average salary ranges vary among validation professionals. First, we will examine average salary ranges (see chart below) and then we will explore salary range by organization size.

Average Salary Range

What is the average salary range for a validation professional in your organization? ($ USD) Please select one.



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In 2024, the most **prevalent salary range for validation professionals who took the survey is over $101,000 per annum**, representing 22 percent of respondents.

Additionally, 19 percent reported earning between $91,000 and $100,000, and another 19 percent earn less than $50,000 per annum. **These figures, all in USD, reflect a strong emphasis on competitive compensation for validation roles.**

The data indicates that many **organizations recognize the specialized skills and expertise required for validation**, offering attractive salary packages. With most respondents earning above $101,000, even at non-executive levels, **it is clear that validation is valued as a critical function for ensuring quality and compliance.**

Offering competitive salaries helps attract and retain top talent in the field, essential for maintaining high standards and driving success. Although the level of salary may also vary by country due to differing economic conditions or cost of living, **organizations should continuously monitor market trends and adjust compensation packages to support the growth and effectiveness of their validation teams.**

Salary Range by Organization Size

Insights highlight the disparity between salary based on organization size, with larger enterprises offering significantly higher salaries. This could reflect the resources available to larger companies and the need to attract top talent for complex validation roles.

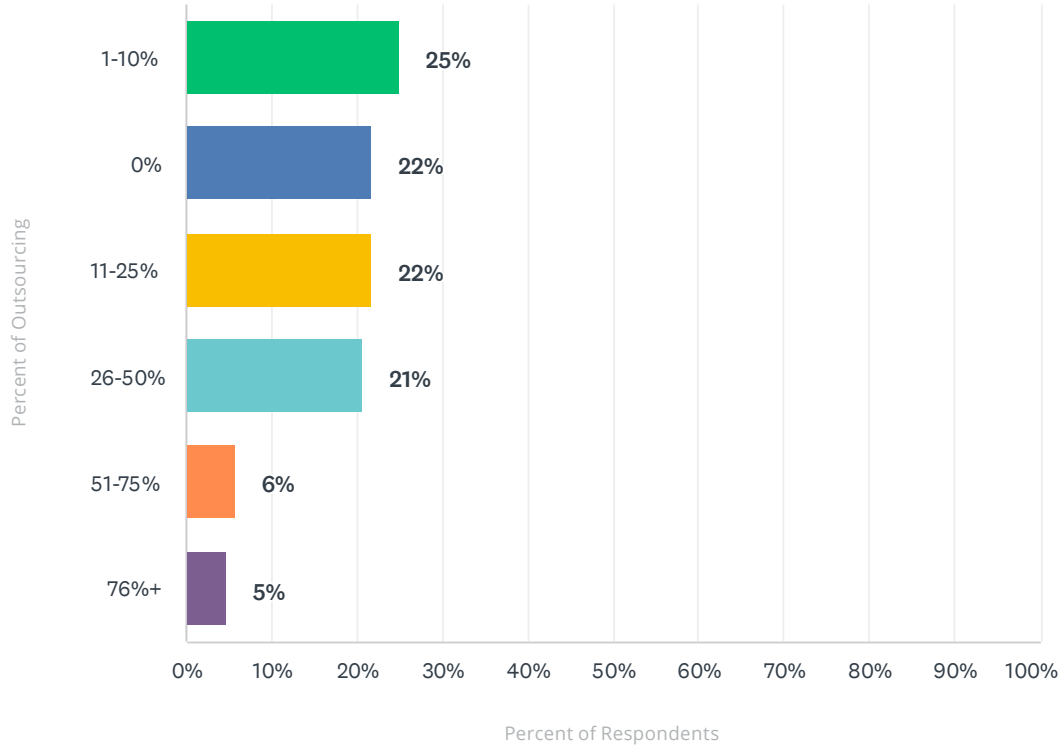
- A majority (51 percent) of validation professionals in **enterprise organizations** (5,000+ employees) report having salaries of **over $101,000.**
- For **medium-sized organizations** (100-1,000 employees), 47 percent reported earning between **$71,000 and $80,000.**
- **Small organizations** (up to 100 employees) most commonly offered salaries in the **$50,000 to $60,000** range, **similar to large organizations** (1,000-5,000 employees), where 31 percent reported this range.

Validation Outsourcing

Levels of outsourcing vary. This section focuses on the percentage of validation efforts outsourced to a managed services firm or consulting firm. First, we will examine outsourcing levels (see graph below) and look at three-year trends in validation outsourcing. Then we will explore outsourcing levels by organization size.

Outsourcing Levels

What percentage of your validation efforts are outsourced to a managed services firm or consulting firm? Please select one.



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Most companies outsource some validation work, and often up to 10% of validation labor. Thirty-two percent of respondents outsource over a quarter of their validation activities. In a dynamic industry with a changing regulatory landscape and innovative technology development, these insights suggest **outsourcing is a prevalent strategy to manage workload, access specialized expertise,** and **maintain efficiency.**

VOICE OF THE INDUSTRY

How is your organization leveraging external expertise to enhance your validation processes and stay ahead of industry trends?

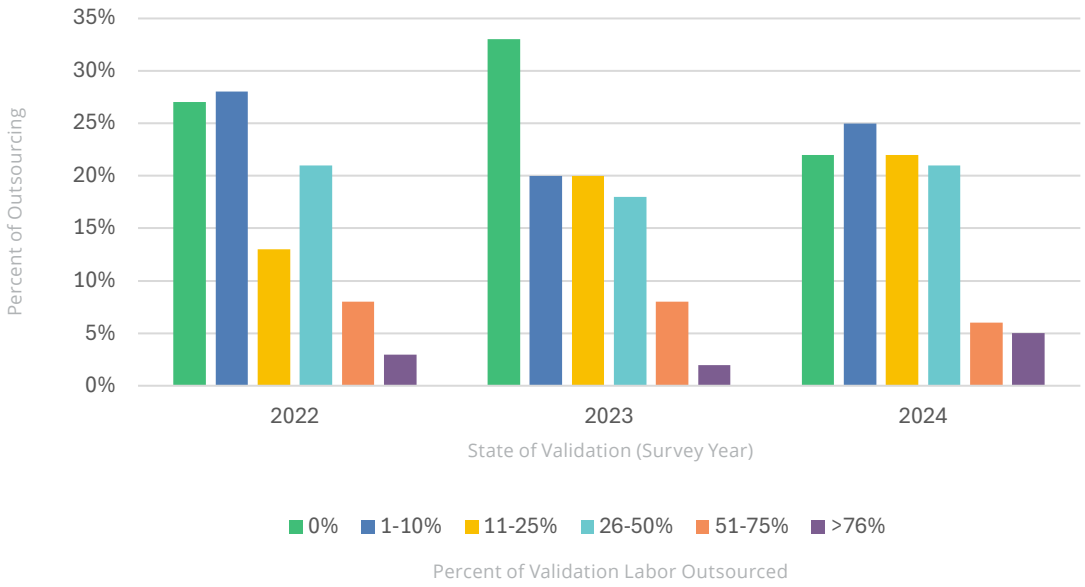
> "Although we have experienced professionals within our industry, **collaborating with external experts provides valuable insights and helps us adopt better approaches.** This collaboration allows us to benefit from diverse experiences and stay at the forefront of industry trends, ultimately leading to more robust and effective validation practices."
>
> **— Computer System Validation Engineer, Large Pharmaceutical Company, U.S.A**

Trends: Validation Outsourcing

Year over year, there appears to be a continuing increase in the outsourcing of validation labor (see graph below).

Trends in Validation Outsourcing

What percentage of your validation efforts are outsourced to a managed services firm or consulting firm?



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Fewer are exclusively relying on internal capabilities and **most companies rely on some outsourcing**. From 2022 to 2024, companies who are not outsourcing (see 0% in graph) fell from 33 percent to 22 percent, indicating a growing reliance on external resources.

- **Increase in Low-Level Outsourcing:** Outsourcing 1-10% rose to 25 percent.
- **Growth in Moderate-Level Outsourcing:** Outsourcing 11-25% increased to 22 percent.
- **Rise in High-Level Outsourcing:** Notably, those outsourcing over 76% grew from two percent to five percent, highlighting a trend towards higher outsourcing levels.

Companies may find that **leveraging expert, external validation resources help them address complex validation needs and optimize internal team capacity.**

Percentage of Outsourcing by Organization Size

The overwhelming majority of organizations, regardless of size, outsource their validation processes. Here are the percentages by organization size:

- **Enterprise** (5,000+ employees): 86 percent
- **Large** (between 100-1000 employees): 71 percent
- **Medium** (between 100-1000 employees): 75 percent
- **Small** (up to 100 employees): 72 percent

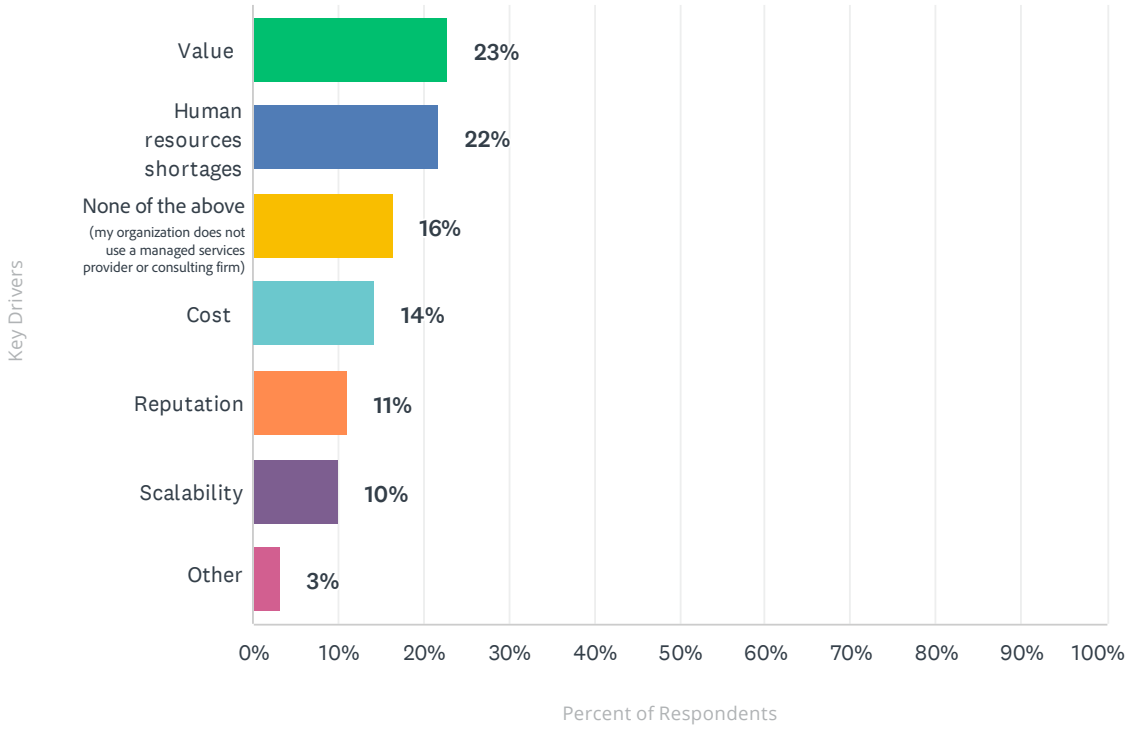
This data indicates that outsourcing validation processes is a **prevalent strategy across organizations of all sizes**, with the highest adoption among enterprise-level companies at 86 percent. This trend suggests that outsourcing is seen as a crucial approach to managing validation challenges efficiently, **allowing companies to focus on core activities while leveraging external expertise.**

Primary Driver for Outsourcing Validation Labor

The **primary drivers for outsourcing validation labor are strategic and tactical.** This section focuses on the primary drivers that lead to outsourcing to a managed services firm or consulting firm. First, we will examine key drivers (see graph below), then explore outsourcing drivers by team size.

Key Drivers for Outsourcing Validation Labor

What is the primary driver for selecting a managed services provider or consulting firm to perform your validation? Please select one.



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The primary drivers for selecting a managed services provider or consulting firm for validation are **value** (23 percent) and **human resources shortages** (22 percent).

Based on these responses, cost (14 percent) is important but not dominant (although value may be differentiating and may indicate cost-effectiveness or cost-savings). **Organizations should look for validation service providers that offer a clear and compelling value proposition.** Assess their track record, client testimonials, and the tangible benefits they bring to ensure they align with your organization's goals.

Organizations that face HR shortages should prioritize providers that offer skilled personnel and flexible staffing solutions. This can help mitigate the impact of internal resource constraints and maintain validation quality.

The 2024 State of Validation data indicates that while cost is a factor, it is not the primary driver for outsourcing validation labor. Strategic drivers, such as value, and tactical drivers, like HR shortages, play a more significant role.

Trends in Primary Divers for Outsourcing Validation Labor by Size of Team

The primary drivers for outsourcing validation labor vary significantly by team size (see table below).

Primary Drivers for Outsourcing by Team Size			
Validation Team Size	**#1 Driver**	**#2 Driver**	**#3 Driver**
Solo	Human Resource Shortages	Value / Cost*	Reputation
1-3	Value	Cost	Reputation / Human Resource Shortages*
4-6	Value	Cost	Human Resource Shortages
7-9	Human Resource Shortages	Cost / Scalability*	Reputation
10+	Human Resource Shortages	Value	Scalability
TOTAL (2024)	Value	Human Resource Shortages	Cost
TOTAL (2023)	Value	Cost	Cost

*Ranked equally by respondents.

Note: Participation rates varied by team size and for many team sizes, the results are based on a small sample that should be considered anecdotal or directional. There is no 2022 data as this survey question was added in 2023.

- **Small Teams** (1-3 members) prioritize **value**, followed by **cost** and **reputation/human resource shortages**. Their main concern is achieving high-quality validation at a reasonable cost.
- **Medium Teams** (4-6 members) focus on **value** and **cost**, but **human resource shortages** become a notable factor. These teams balance financial constraints with staffing needs.
- **Larger Teams** (7-9 members) face **human resource shortages** most acutely. They also consider **cost** and **scalability**, indicating a need for flexible solutions to accommodate growth.
- **Very Large Teams** (10+ members) are driven by **human resource shortages**, with **value** and **scalability** as secondary concerns. These teams require extensive support to manage large-scale operations effectively.

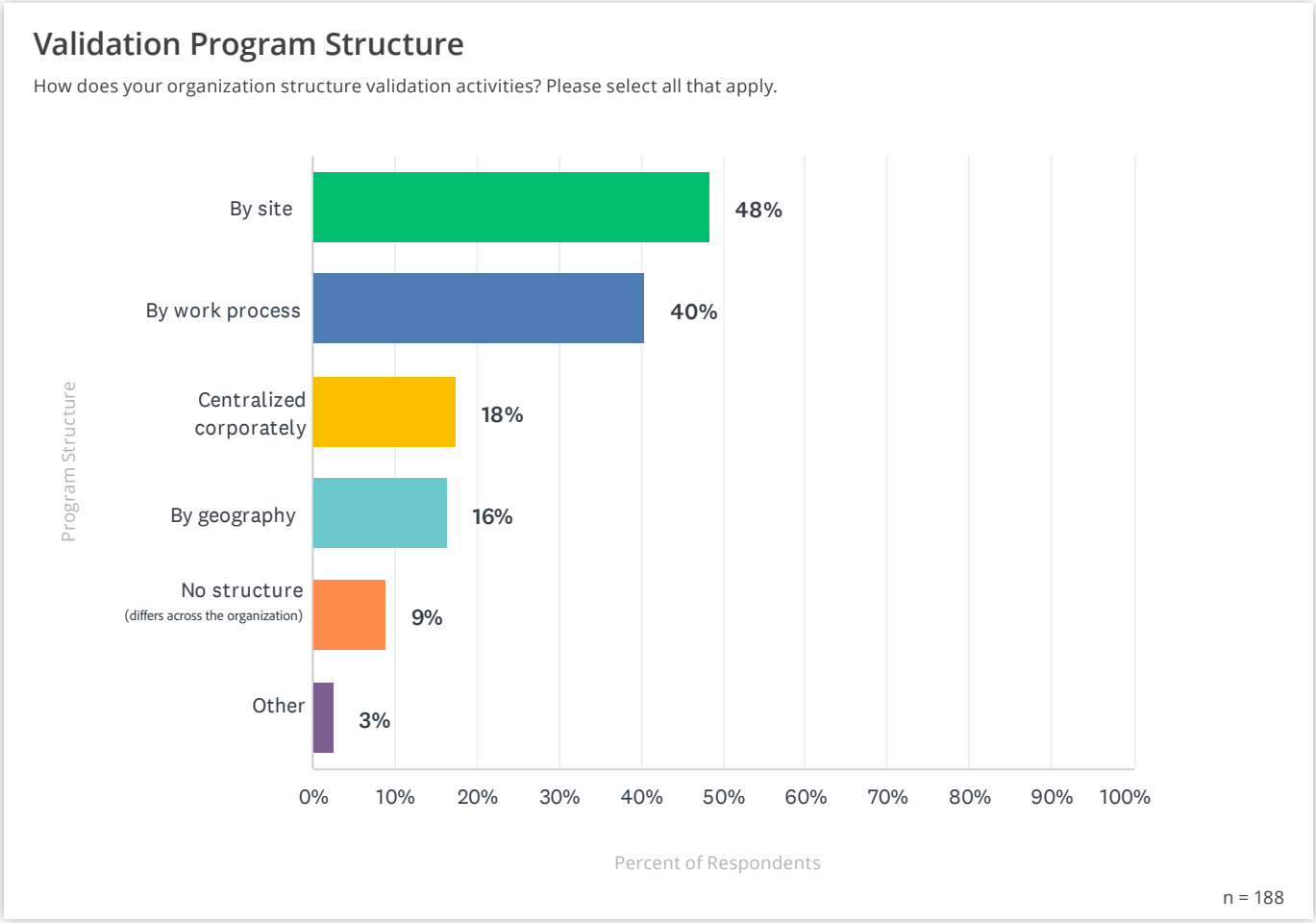
Overall, **value, human resource shortages and cost considerations dominate as team sizes increase**, highlighting the need for scalable, cost-effective validation solutions across different organizational structures.

Section Two: Validation Programs

This section focuses on the diverse validation programs and approaches used by organizations. It covers the structure of these programs, work processes, adoption rates of computer software assurance, budgets, team workloads, and identifies key challenges and opportunities for improvement.

Most Prevalent Validation Program Structure

This section focuses on validation program structures. First, we will examine the most prevalent validation program structures (see chart below). Then we will explore program structures by organization size.



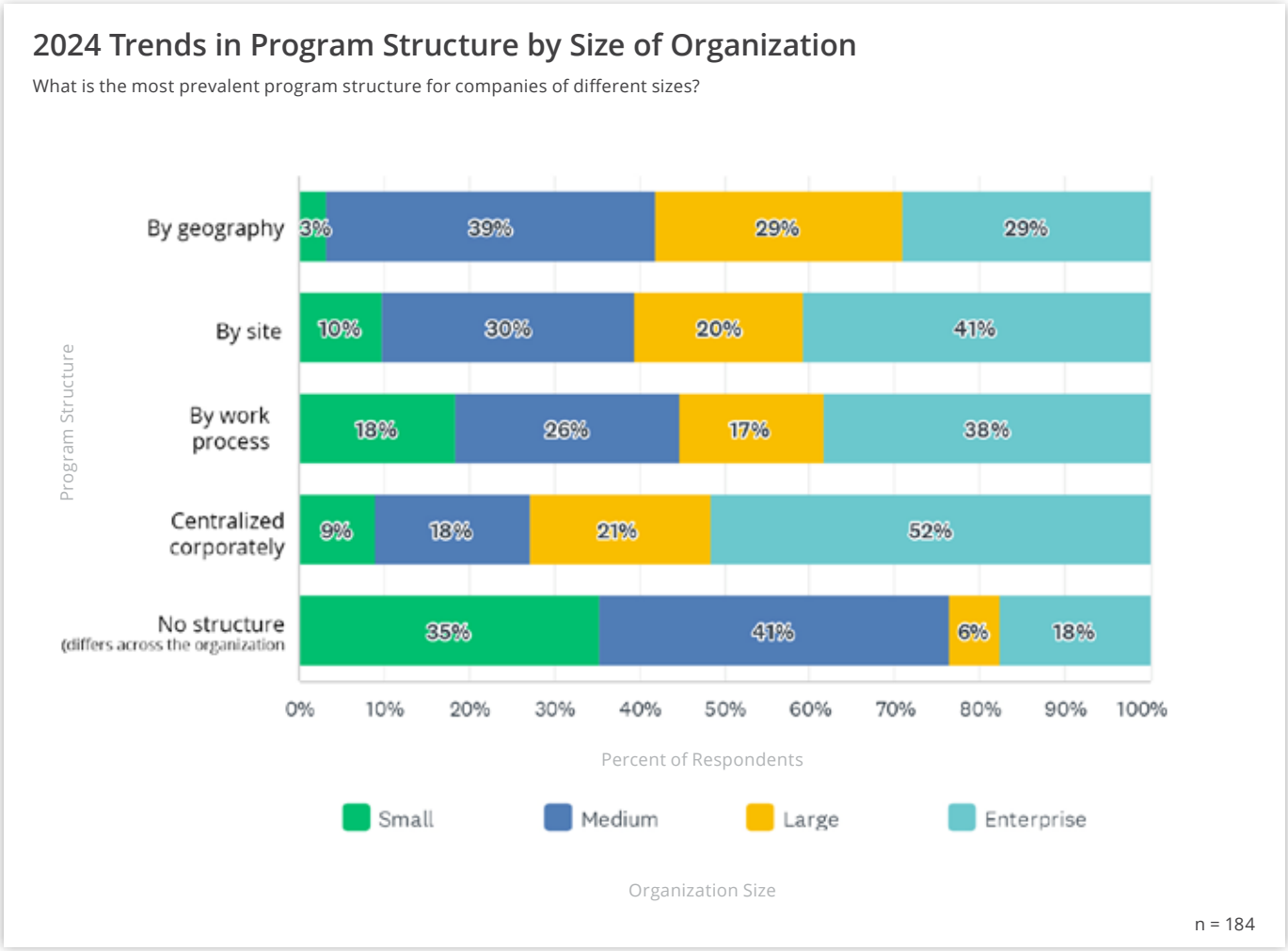
The analysis of validation program structure reveals a **deviation from the traditional best practice of centralized harmonization**. The chart illustrates the distribution of structures used by organizations for validation processes. **The most common structure is "By site"** (48 percent), followed by "By work process" (40 percent). Less common are "Centralized corporately" (18 percent), "By geography" (16 percent), "No structure (differs across the organization)" (nine percent), and "Other" (three percent).

- **Prevalence of Site-Specific Validation:** Nearly half of the organizations structure their validation processes by individual sites. This approach allows for tailored procedures that can adapt to specific site requirements and challenges, ensuring compliance and efficiency.
- **Process-Oriented Approach:** A substantial portion (40 percent) uses a process-oriented structure. This method can standardize validation across various sites, leading to consistency and potentially reducing redundant efforts.
- **Centralized vs. Decentralized Approaches:** While some organizations prefer a centralized structure (18 percent) for a unified approach, others opt for a decentralized structure (16 percent), which can tie to a strategy that prioritizes flexibility and a need to adapt to local and regional needs and regulatory requirements.
- **Lack of Uniformity:** nine percent of organizations have no consistent structure, reflecting potential challenges in standardization and quality assurance.
- **Minority Approaches:** A small percentage (three percent) use other methods, suggesting niche or innovative validation strategies. Other structures as listed by respondents included: "by Individual or Team", "Product Lifecycle and Business Units", and "Some Parts Are Centralized, Some Parts Differ Across the Organization." Small companies that are still figuring out their approach and have not yet standardized their validation processes are also represented in these diverse methods.

The lack of a unified validation framework may lead to variations in quality and regulatory adherence, highlighting a need for organizations to reconsider their validation strategies and move towards a more integrated and standardized approach.

Trends: Validation Program Structures by Organization Size

The data indicates that there has been **no significant alteration in the structuring of validation programs between 2022 and 2024.**



This stability indicates that there is still a mix of methodologies, and the industry hasn't yet settled on a single best way for organizing validation activities. It implies that organizations might be changing their validation program structures and trying new approaches to fulfill their operational needs and regulatory requirements.

- **Hypothesis:** The structure of validation programs is tied to the size of the company, potentially reflecting the maturity of the business.
- **Trends:**
  - Enterprise, large, and some medium-sized companies have prioritized setting up programs by geography, site work, and process, or centrally.
  - Small and some medium-sized companies are most likely to have no consistent structure.

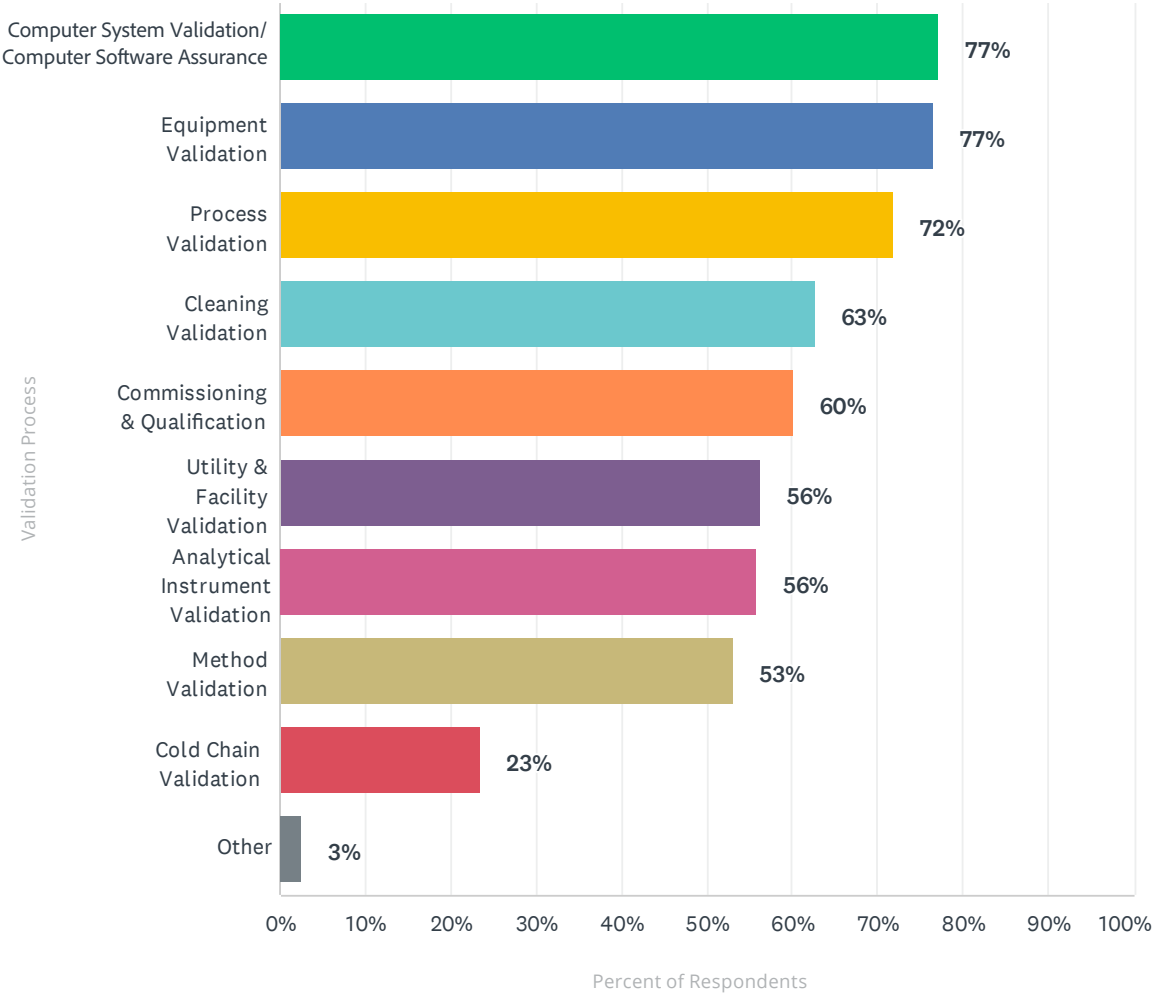
These insights can guide validation professionals in aligning their program structures with **organizational size, balancing local adaptation, consistency, and centralized control** to optimize validation processes.

Most Prevalent Validation Work Processes

This section focuses on validation work processes. First, we will examine the most commonly managed work processes (see chart below) and then look at three-year trends.

Managed Validation Work Processes

Which of the following validation processes does your organization manage? Please select all that apply.



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When asked, a majority of companies stated they manage multiple validation processes.

- The most commonly managed validation processes are **Computer System Validation/ Computer Software Assurance** (77 percent), closely followed by **Equipment Validation** and **Process Validation**. This highlights the **critical role of technology and the increasing integration of digital systems and equipment** in maintaining regulatory compliance and operational efficiency.
- The cohort of **digital validation system users generally report higher percentages across all validation processes**, suggesting that digital systems may drive more comprehensive and thorough validation management.

Trends: Validation Work Process

The data reveals a clear trend: **Computer System Validation (CSV) continues to dominate as the top validation work process from 2022 to 2024**, underscoring its indispensable role in regulated industries. The same processes have appeared consistently in the top three since 2022. They are: **Computer System Validation (CSV and CSA), Equipment Validation, and Process Validation.**

Furthermore, the consistent prominence of **Equipment Validation** in the top three reinforces the vital importance of robust technological infrastructure.

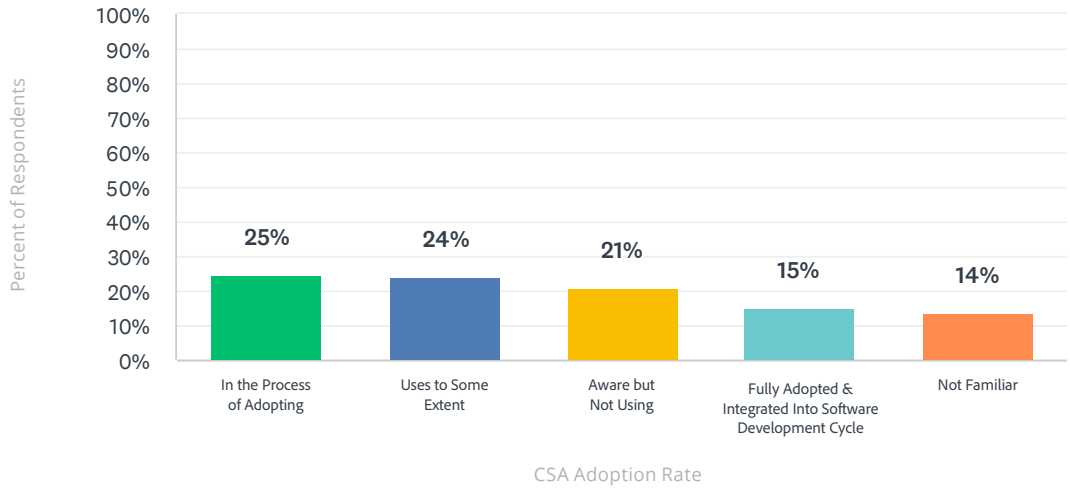
Adoption Rate of Computer Software Assurance (CSA) Processes

In September 2022, the FDA released draft guidance on Computer Software Assurance (CSA) for Production and Quality System Software, aiming to enhance the efficiency and effectiveness of risk-based Computer System Validation (CSV). The CSA guidance emphasizes patient and product safety, focusing on assessing risks based on their potential impact. It advocates for a minimal documentation approach, significantly reducing paperwork through unscripted and ad-hoc testing. This streamlined methodology ensures that the validation process remains rigorous while alleviating administrative burdens.

This section focuses on the varying levels of adoption of CSA processes. First, we will examine levels of adoption in organizations (see graph below) and look at two-year trends in CSA adoption rates, then explore CSA adoption rates by company type.

CSA Adoption Rate

Which of the following statements best describes your adoption of Computer Software Assurance processes? Please select one.



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CSA adoption rates vary among organizations, however most organizations (64 percent) **either use or are adopting CSA processes.**

These findings suggest that while CSA is gaining traction, there is still **considerable room for growth in its adoption** and a growing recognition of the importance of CSA in enhancing validation practices.

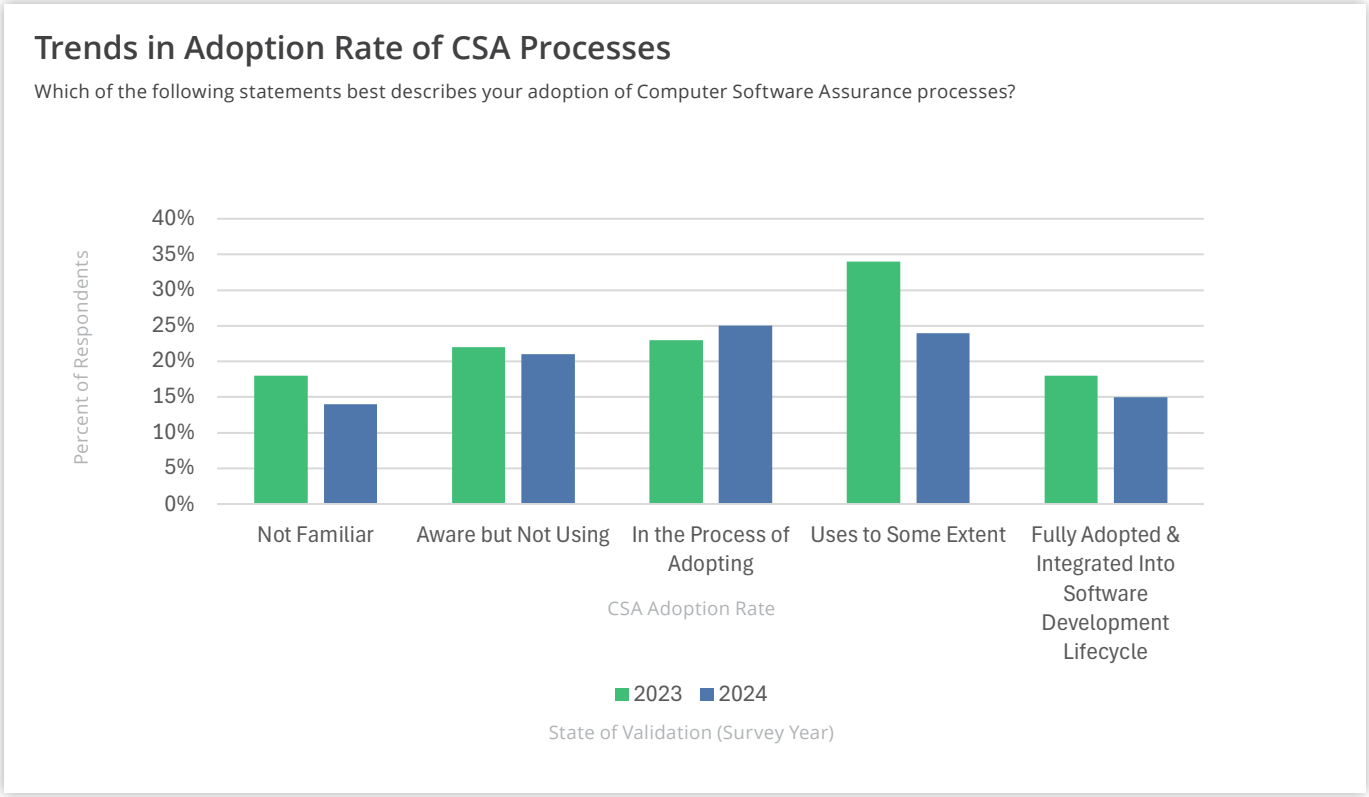
- **Ongoing Adoption:** A sizeable portion of organizations (25 percent) are currently adopting Computer Software Assurance (CSA) processes. This indicates a growing recognition of the importance of CSA in enhancing validation practices.
- **Current Usage:** Nearly a quarter of respondents (24 percent) report that their organizations already use CSA processes. This suggests that CSA is being increasingly integrated into validation frameworks.
- **Awareness vs. Full Adoption:** While 21 percent of respondents are aware of CSA processes, only 15 percent have fully adopted them. This gap highlights an opportunity for further education and implementation support to move from awareness to full integration.
- **Lack of Familiarity:** A notable 14 percent of respondents are not familiar with CSA processes. This underscores the need for more outreach and training initiatives to raise awareness and understanding of CSA benefits.

Validation professionals should **focus on promoting CSA awareness and facilitating the transition from awareness to full adoption to optimize validation practices** across the industry. From the results, a market segmentation begins to emerge in terms of their adoption progress, readiness, and the gaps they acknowledge in resources and knowledge.

Companies should benchmark and take action to accelerate programs through education, training, and access to other internal and external capabilities. Then they should track their progress and course correct as needed.

Trends: Adoption Rate of CSA Processes

Importantly, the percentage of organizations in the process of adopting CSA has risen slightly from 23 percent to 25 percent, indicating persistent interest (see graph below).*



*Note: There is no 2022 data as this survey question was added in 2023.

- However, there is a decline in those using CSA to some extent (34 percent to 24 percent) and in full adoption (18 percent to 15 percent), suggesting potential challenges in fully integrating these processes.
- While the percentage of those unfamiliar with CSA has decreased from 18 percent to 14 percent, awareness has not significantly translated into usage, with 21 percent still aware but not using the processes.

Validation professionals should **focus on supporting organizations through the adoption phase and addressing barriers to full integration to optimize software development lifecycles.** Once adopted, professionals should focus on compliance, best practices, and ongoing performance improvement.

Trends in Adoption Rate of CSA Processes by Type of Company

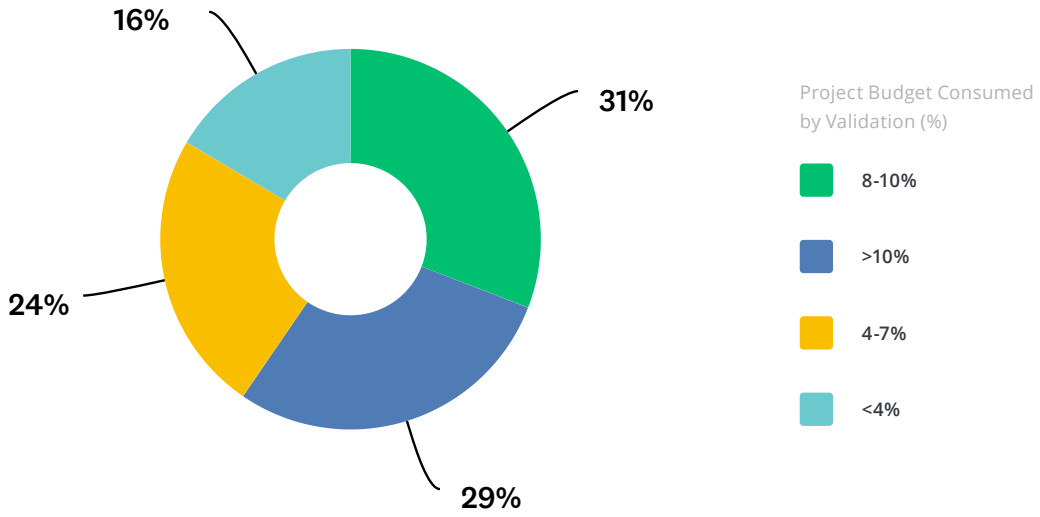
The pharmaceutical sector overwhelmingly leads in CSA adoption across all stages. This is evident with 69 percent fully adopted, 59 percent currently using, and 62 percent in the process of adoption. This trend underscores the critical importance of CSA in ensuring compliance and quality in pharmaceutical manufacturing, particularly given the stringent pharma-specific regulations and timelines for compliance, as well as the different penalties for non-compliance.

Project Budgets

This section focuses on project budgets consumed by validation. First, we will examine the average percentage of project budget consumed by validation expenses (see graph below) and then look at three-year trends.

Project Budget Consumed by Validation Activity

Approximately, what average percentage of your project budget is consumed by validation activity? Please select one.



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Thirty-one percent of respondents report that 8-10% of their project budgets are consumed by validation activities. This indicates inefficiencies may be a consistent challenge in the validation process resulting in high costs.

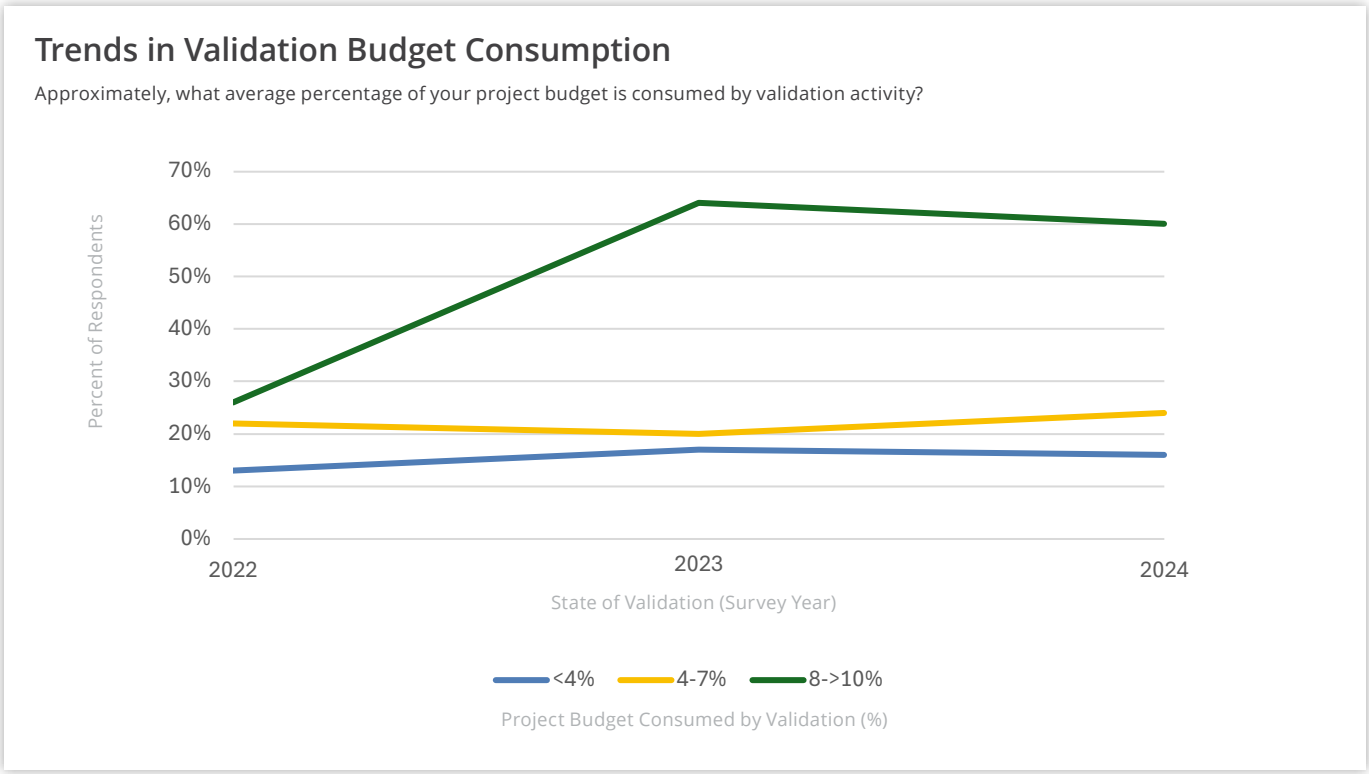
- **High-Impact Validation:** 29 percent of organizations allocate more than 10% of their budgets to validation. This underscores the critical importance of validation processes in certain industries, reflecting their commitment to rigorous standards and thorough testing and regulatory compliance.
- **Moderate Investment:** Approximately 24 percent of respondents spend 4-7% of their project budgets on validation. This suggests a balanced approach where validation is important but not as resource intensive as in other organizations.
- **Minimal Allocation:** Only 16 percent of respondents allocate less than 4% of their budgets to validation. This could indicate either highly efficient validation processes or potentially less stringent validation requirements in certain sectors.

For validation professionals, these insights highlight the **need to evaluate the efficiency and effectiveness of validation processes.**

Understanding the budgetary impact can help in optimizing resource allocation, ensuring that validation efforts are both cost-effective and robust enough to meet regulatory standards.

Trends: Project Budget Consumption

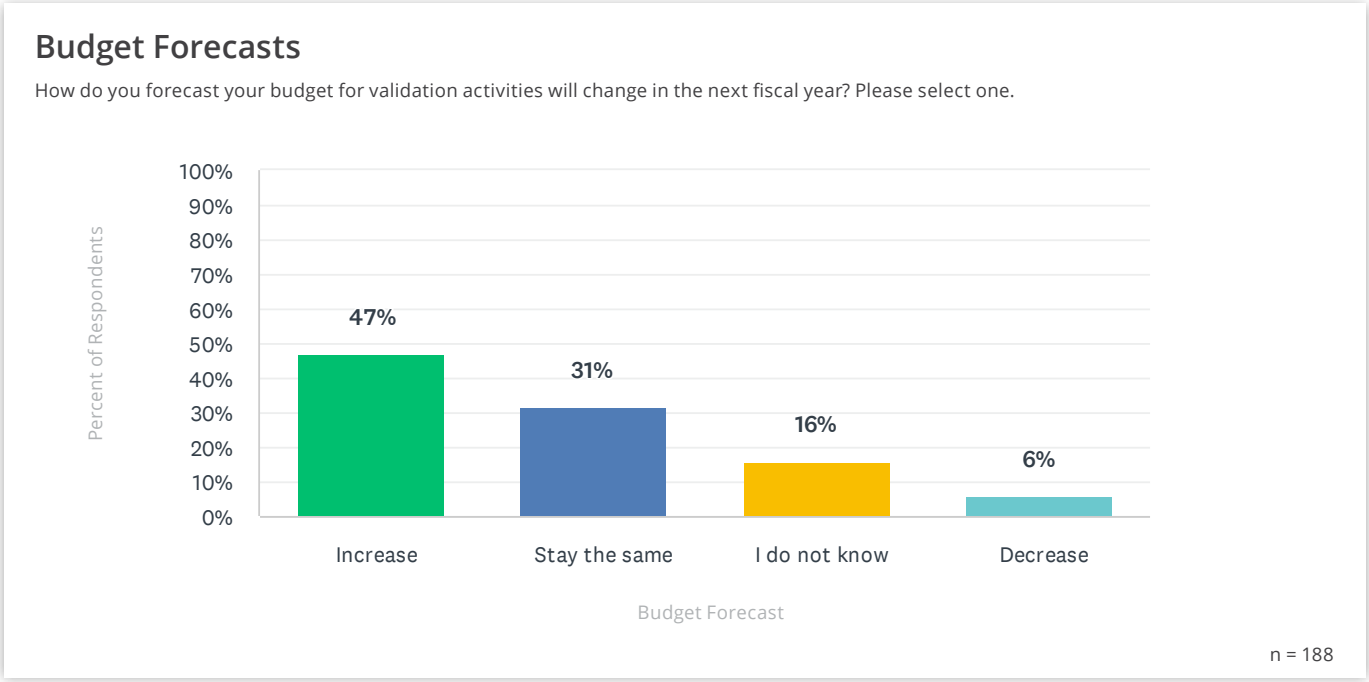
These year-over-year trends emphasize an increasing investment in validation activities (see graph below).



The percentage of projects dedicating 8 to >10 percent of their budget to validation grew from 26 percent in 2022 to 64 percent in 2023 and then dipped slightly to 60 percent in 2024, highlighting a **trend towards allocating more budget to validation processes over the last two years.**

Budget Forecasts (2024/25)

This section focuses on validation budget forecasts for 2024/25. First, we will examine budget forecasts (see graph below) and then we will look at three-year trends.



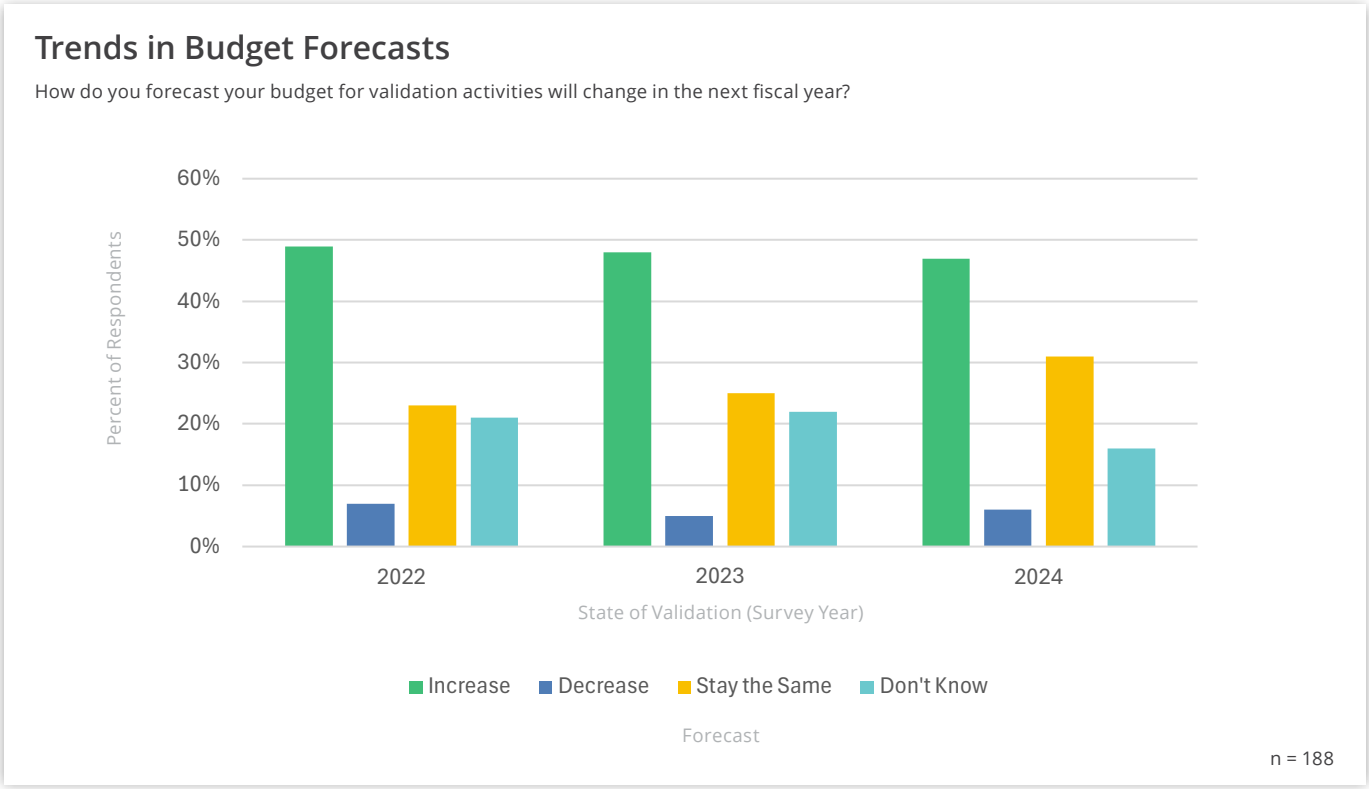
Nearly half (47 percent) of respondents anticipate an increase in their validation budgets for the next fiscal year. This suggests that many organizations are recognizing the growing importance of robust validation processes and are willing to invest more resources to enhance their validation activities.

- **Stability in Budget:** 31 percent of respondents expect their validation budgets to remain the same. This stability indicates that these organizations are likely satisfied with their current validation efforts and budget allocations, maintaining a steady approach to compliance and quality assurance. It seems we may be getting to a point where some number of companies are undergoing digital transformation and sometimes those projects require multi-year commitments.
- **Few Indicate Decreases:** Only six percent of respondents forecast a decrease in their validation budgets.
- **Uncertainty:** 16 percent of respondents are uncertain about future budget changes. This uncertainty could be due to various factors, including the result of the level or function of particular respondents, market volatility, pending regulatory changes, or internal budgetary reviews.

Professionals should prepare for potential budget increases by planning for enhanced validation processes, tools, and training. Additionally, maintaining a flexible approach to address uncertainties will be crucial for adapting to any unforeseen budgetary changes.

Trends: Validation Budget Forecasts

These trends highlight the **importance of preparing for sustained or increasing investment in validation activities** (see graph below).



There is a decline in the percentage of respondents who are uncertain about their future validation budgets, from 21 percent in 2022 to 16 percent in 2024. This decrease suggests that organizations are becoming **more confident and clearer about their validation budget planning.** Since some digital transformation initiatives are multi-year, adoption reduces near-term budget uncertainty.

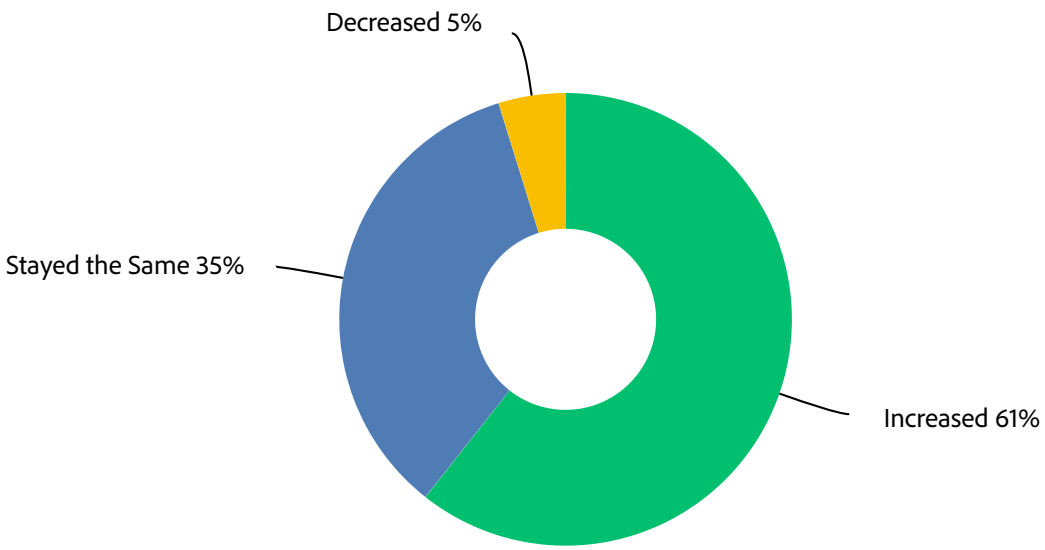
- **One In Two Expect Budget Increases:** The percentage of respondents forecasting an increase in their validation budgets remains relatively stable, slightly declining from 49 percent in 2022 and 47 percent in 2024. This consistency indicates a sustained commitment to enhancing validation processes over the years.
- One In Three Expect Budget Stability: **The percentage of respondents expecting their budgets** to stay the same has steadily increased from 23 percent in 2022 to 31 percent in 2024. This trend indicates that a growing number of organizations are finding their current validation budget levels adequate for their needs.
- **Few Indicate Decreases:** The percentage of respondents expecting a decrease in their validation budgets is consistently low, fluctuating between five percent and seven percent. This stability suggests that most organizations recognize the importance of maintaining or increasing their validation investments.

Validation Workload (Previous 12 Months)

This section focuses on validation workload changes over the past 12 months. First, we will examine workload change (see graph below) and then we will look at three-year trends.

Workload Change (Past 12 Months)

Over the past 12 months, how has your validation workload changed? Please select one.



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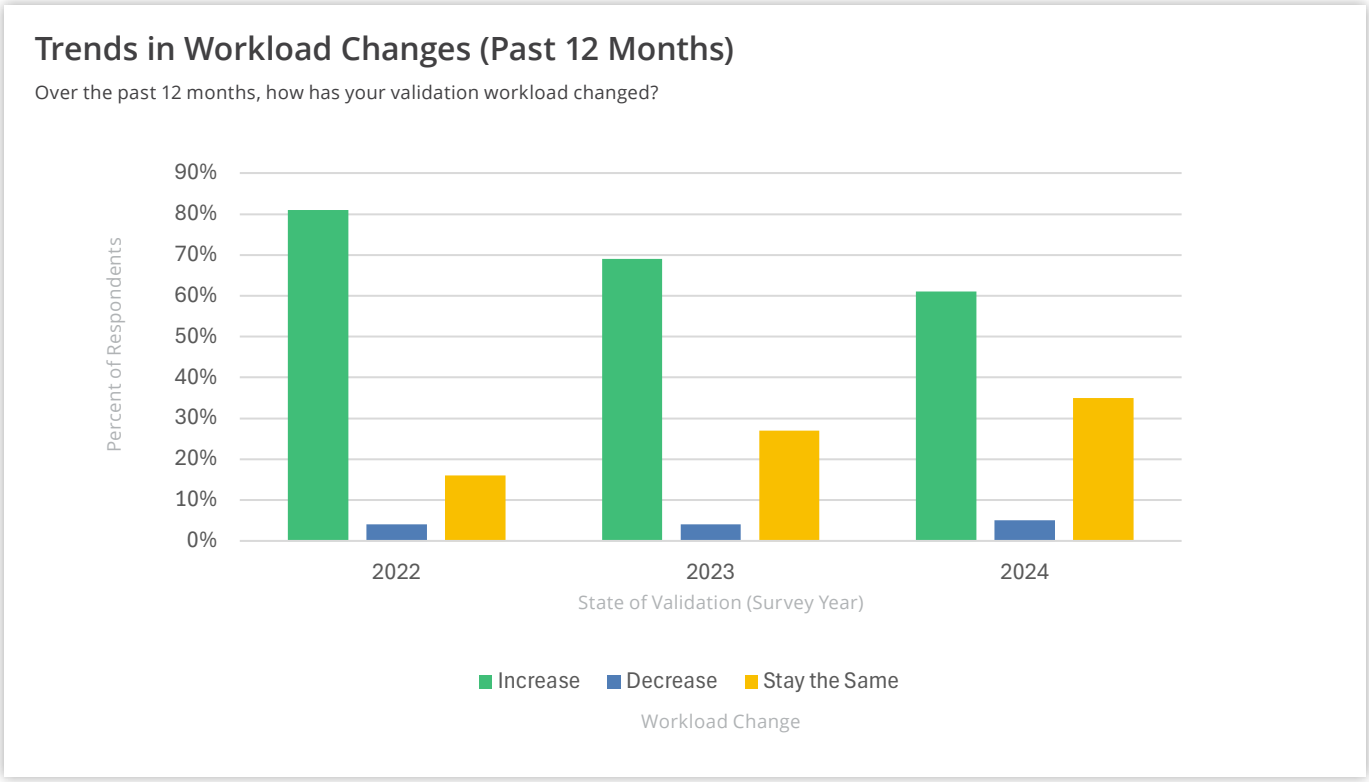
Most respondents (61 percent) reported an increase in their validation workload over the past 12 months. This trend suggests that organizations are likely experiencing heightened regulatory requirements, increased product development, or expansions in operational activities necessitating more rigorous validation efforts. Decisions related to organizational change, restructuring, demands on performance, or other budget impact could also factor.

- **Stability:** 35 percent of respondents indicated that their validation workload has remained the same. This stability might reflect well-established processes that are effectively managing current demands without the need for increased workload.
- **Few Indicate Decrease:** Only five percent of respondents reported a decrease in their validation workload. This small percentage indicates that while some organizations may have optimized their processes or experienced reduced validation needs, it is not a widespread trend.

The **increase in workload highlights the necessity for efficient resource management, potentially leveraging automation and advanced validation tools to handle the increased demand.** Additionally, maintaining flexibility and readiness to adapt to changing validation requirements will be crucial for managing the evolving workload effectively.

Trends: Validation Workload (Previous 12 Months)

These trends highlight a **shift towards more stable workloads after a period of rapid growth** (see graph below).



- **Declining Trend in Workload Increases:** The percentage of respondents reporting an increase in their validation workload has steadily decreased from 81 percent in 2022 to 61 percent in 2024. This downward trend suggests that while validation demands are still growing, the rate of increase is slowing. Organizations might be reaching a plateau in workload expansion or improving efficiency to manage these demands better.
- **Consistent Low Reports of Workload Decrease:** The percentage of respondents reporting a decrease in their workload remains consistently low, fluctuating slightly between four percent and five percent over the three years. This consistency indicates that few organizations are experiencing a reduction in validation activities, reflecting the ongoing importance of these processes.
- **Growing Stability:** The percentage of respondents whose workload has stayed the same has increased substantially from 16 percent in 2022 to 35 percent in 2024. This increase in stability suggests that more organizations have reached an equilibrium in their validation workloads, possibly due to post-digital transformation. Some companies are reaping the benefits of those investments and changes, improved processes, better resource allocation, or stabilization of regulatory demands.

Workload increases are still an important issue in a majority of companies, but they are becoming less prevalent and **may provide an opportunity to focus on refining and optimizing current validation processes.** Ensuring that validation activities are efficient and scalable will be crucial to managing future demands. Additionally, **maintaining a balance between increased workload and operational efficiency** will be key to sustaining high standards in validation practices.

VOICE OF THE INDUSTRY

What are the main factors driving increased workloads in validation teams?

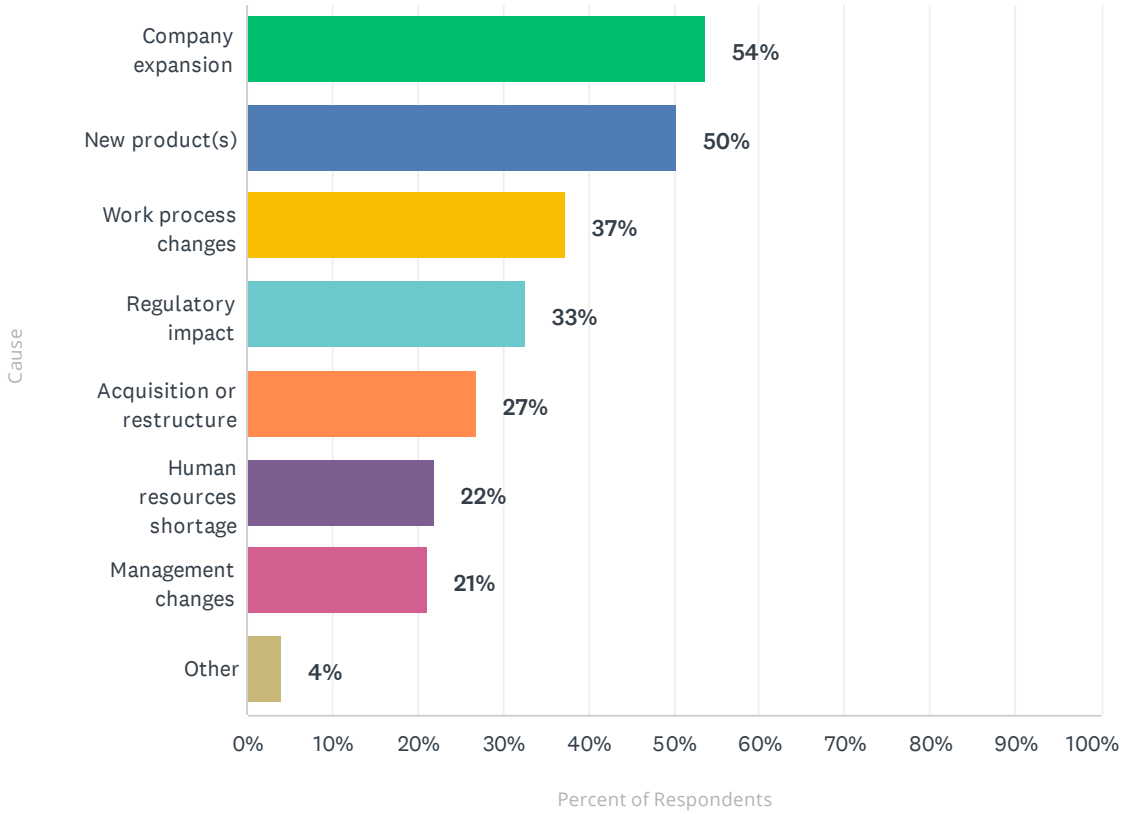
> "The workload has increased in the Quality department, and I'm observing **more execution errors.** These errors often stem from tasks being performed by undertrained staff who skip essential preparatory steps like properly documenting and conducting dry runs. **This rush to meet deadlines without adequate upfront planning leads to increased paperwork and more issues during execution.** Ultimately, the principle of getting it right the first time is being compromised, costing more in the long run."
>
> **— Quality Engineering Specialist, Top 10 Multinational Healthcare Company, U.S.A**

Most Prevalent Causes for Workload Change (Previous 12 Months)

This section focuses on the most prevalent cause for workload changes over the past 12 months (see chart below).

Causes of Workload Change (Past 12 Months)

In your opinion, what was the cause of your workload change during the past 12 months? Please select all that apply.



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The **most prevalent cause of workload change**, as indicated by 54 percent of respondents, is **company expansion**. This underscores how growth initiatives directly impact validation workloads, necessitating more resources and efficient processes to handle increased demands.

- **Introduction of New Products:** 50 percent of respondents attribute workload changes to the launch of new products. This highlights the critical role of validation in ensuring new products meet regulatory and quality standards, requiring significant validation efforts.
- **Work Process Changes:** Changes in work processes have influenced workload for 37 percent of respondents. This suggests that modifications in operational methodologies can significantly impact validation activities, either by increasing efficiency or necessitating additional validation steps.
- **Regulatory Impact:** 33 percent of respondents cite regulatory changes as a cause for increased workload. This reflects the ongoing need to stay compliant with evolving regulatory requirements, which can add to the validation burden.
- **Acquisitions or Restructuring:** 27 percent of respondents report workload changes due to acquisitions or restructuring. Mergers and organizational changes often require re-validation to ensure continued compliance and integration of processes.
- **Human Resources and Management Changes:** Shortages in human resources (22 percent) and management changes (21 percent) are also important factors. Personnel and leadership shifts can disrupt validation workflows and increase workload.

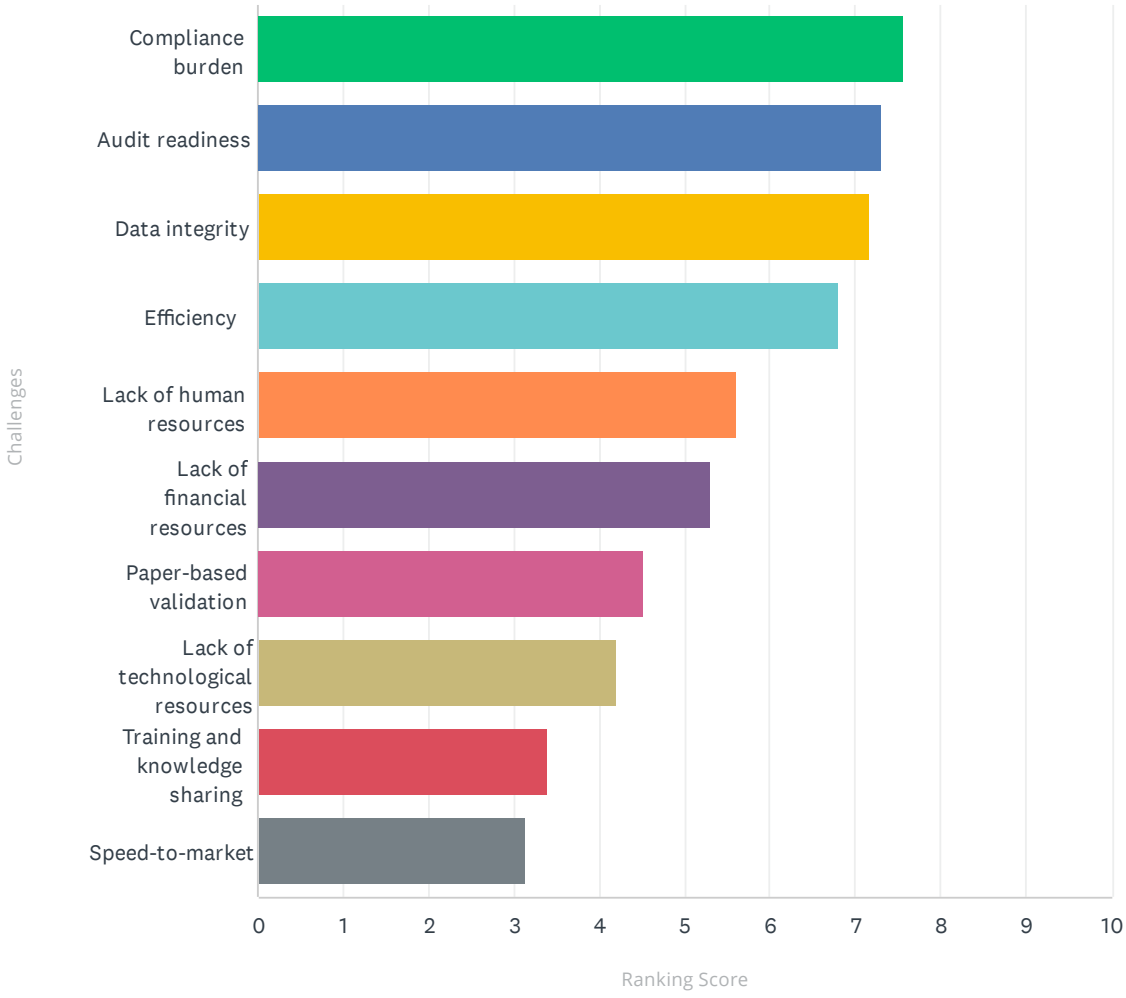
These insights highlight the **need to anticipate and plan for changes related to company growth, new product introductions, and regulatory updates.** Additionally, **maintaining flexibility and readiness to adapt to organizational changes** will be crucial for managing validation workloads effectively.

Biggest Validation-Related Challenge Facing Organizations

This section focuses on validation-related challenges facing organizations. First, we will look at validation-related challenges (see graph below) and then we will examine three-year trends.

Validation-Related Challenges

In your opinion, what is the biggest validation-related challenge that your business is facing today? Please rank all answer choices in order of preference, 10 being the highest.



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The top three challenges identified were:

1. **Compliance Burden:** Ranked as the top challenge by respondents, reflecting the high importance and complexity of meeting regulatory requirements.
2. **Audit Readiness:** Closely following compliance, audit readiness is critical for organizations to demonstrate adherence to regulations and standards during inspections.
3. **Data Integrity:** Ensuring data integrity is a major concern, highlighting the need for reliable, accurate, and secure data management practices.

- **Efficiency:** Ranked fourth, efficiency indicates a strong need for optimizing validation processes to save time and resources while maintaining high standards.
- **Resource Limitations:**
  - **Lack of Human Resources:** A substantial challenge, pointing to the need for skilled personnel to handle validation tasks.
  - **Lack of Financial Resources:** Financial constraints can hinder the ability to invest in necessary validation tools and technologies.
  - **Lack of Technological Resources:** Reflects the necessity for advanced tools and technologies to streamline and enhance validation processes.
- **Paper-based Validation:** Still a notable challenge, emphasizing the need to transition to digital solutions to improve efficiency and reduce errors.
- **Training and Knowledge Sharing:** Highlighted as a challenge, suggesting the importance of continuous education and effective communication within teams.
- **Speed-to-Market:** Indicating the pressure to expedite validation processes to bring products to market faster.

For validation professionals, these insights underscore the **need to focus on compliance, audit readiness, and data integrity** while seeking ways to enhance **efficiency** and overcome resource limitations. **Investing in digital solutions, training, and optimizing processes** can help address these challenges effectively.

VOICE OF THE INDUSTRY

What has been the most challenging aspect of managing compliance amidst multiple projects, and how have you addressed it?

> "In my current role at the company, the greatest challenge is just **the size and scope of changes and having multiple projects going on at the same time.** How we address it is through **frequent team meetings and escalating where necessary** to ensure we're always staying in compliance and meeting the project's needs."
>
> **— Validation Department Head, Multinational Healthcare Company, U.S.A**

Trends: Validation-Related Challenges Facing Organizations

The **compliance burden has emerged as the top challenge in 2024**, replacing shortage of human resources, which was the primary concern in 2022 and 2023 (see table below). This shift **indicates increasing regulatory pressures.**

Ranked Trends in Validation-Related Challenges			
Validation-Related Challenge	**2022**	**2023**	**2024**
#1	Shortage of Human Resources	Shortage of Human Resources	Compliance Burden
#2	Efficiency	Efficiency	Audit Readiness
#3	Lack of Technological Resources	Lack of Technological Resources	Data Integrity
#4	Lack of Financial Resources	Lack of Financial Resources	Efficiency
#5	Data Integrity	Data Integrity	Shortage of Human Resources

Shortage of human resources was the top challenge in 2022 and 2023 and it dropped to fifth place in 2024. Possibly that indicates human resource staffing gaps have been mitigated through a mix of hiring and automation and process efficiency and outsourcing. In addition, tech-savvy sectors that experienced layoffs in the past one to two years might be compensating for the hiring shortages observed in the 2022 and 2023 survey results.

VOICE OF THE INDUSTRY

What strategies has your company implemented to bridge the gap for new hires who lack experience in regulated environments?

> "Our biggest challenge has been finding qualified personnel, particularly those experienced with AI technology and regulated products. Many of our new hires come from tech giants like Google or Apple, with no background in regulatory compliance. Transitioning these individuals to our highly regulated environment is akin to teaching calculus to kindergartners.
>
> To address this, **we've implemented comprehensive onboarding and internal training programs focused on design controls and regulatory requirements.** In critical cases, we also send employees to external courses from reputable organizations like AME."
>
> **— Quality Engineering Specialist, Top 10 Multinational Healthcare Company, U.S.A**

These trends emphasize the **need to prioritize compliance, enhance efficiency, and ensure data integrity while continuing to address resource constraints:**

- **Consistent Importance of Efficiency:** Efficiency remains a concern, consistently ranking high across the years, highlighting the ongoing need for process optimization.
- **Evolving Resource Challenges:** The lack of human resources and technological resources, while previously top challenges, have become less prominent, suggesting some improvements in these areas.
- **Data Integrity's Rising Concern:** Data integrity has steadily become more critical, reflecting the growing emphasis on reliable and secure data in validation processes.

VOICE OF THE INDUSTRY

What has been the most challenging aspect of tracking compliance within your validation program, and how have you managed it?

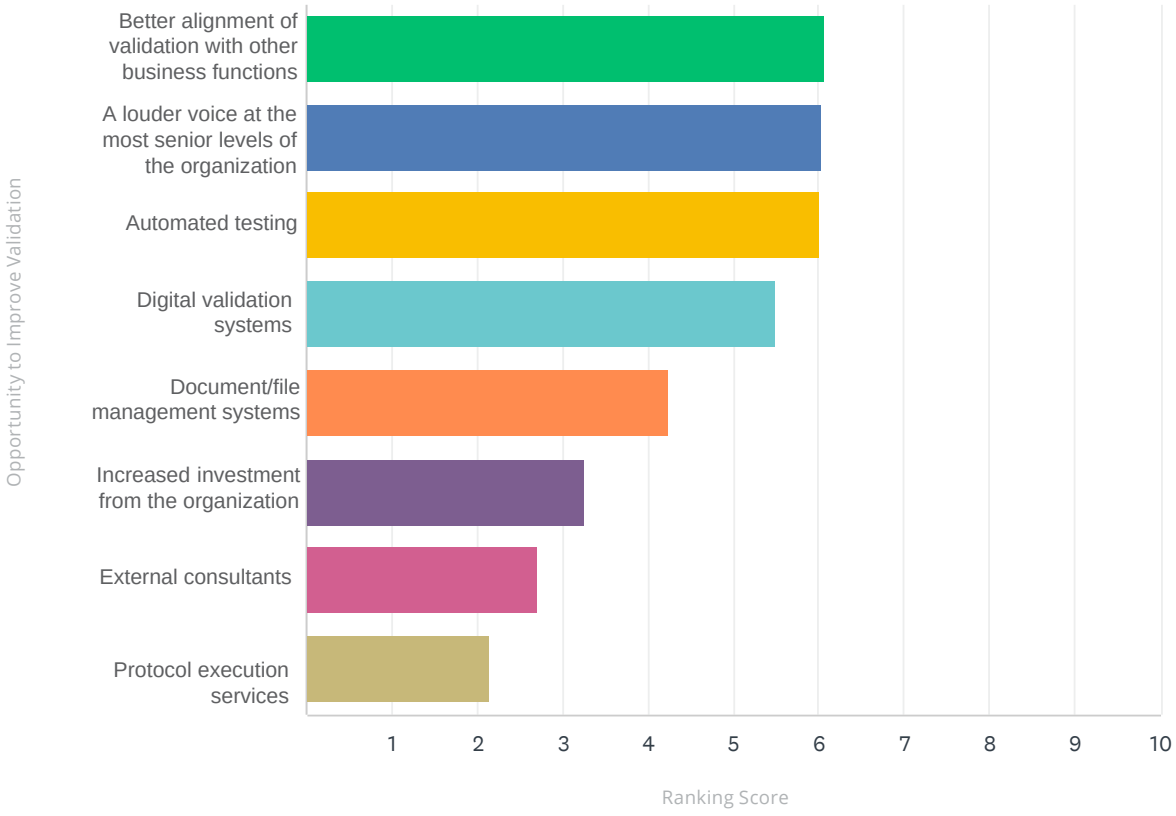
> "The most challenging aspect of maintaining compliance within our validation program has been **keeping track of what we have in our company.**
>
> To address this, we have focused on **consolidating all validation information into one centralized location.** By organizing everything in one place, we ensure we are more compliant and better prepared to present validation information when needed."
>
> **— Computer System Validation Engineer, Large Pharmaceutical Company, U.S.A**

Biggest Opportunity to Improve Validation

This section focuses on opportunities for organizations to improve validation. We will look at the top opportunities (see graph below).

Top Opportunities

In your opinion, where does the biggest opportunity lie to improve validation at your organization? Please rank all answer choices in order of preference, 10 being the highest.



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The top five opportunities identified were:

1. Better alignment of validation with business objectives
2. A louder voice at the most senior levels
3. Automated testing
4. Digital validation systems
5. Document/file management systems

- **Automated testing and digital validation systems are key opportunities.** The adoption of these technologies can streamline validation processes, reduce errors, and increase efficiency.
- **Enhanced document/file management systems are also seen as a key improvement area,** indicating a need for better organization and accessibility of validation documentation.

These insights emphasize the importance of integrating validation efforts with business goals, advocating for executive support, and investing in advanced technologies and systems.

VOICE OF THE INDUSTRY

What has been the biggest challenge with the time-consuming, paper-based validation process, and what steps have you taken to address it?

> "The most challenging aspect of maintaining compliance within our validation program has been the time it takes to complete the validation process. Our process is paper based, requiring document approvals, obtaining certified copies, and executing the process. If there is an event or variation, **additional paperwork is needed, further extending the time.** This lengthy process is our biggest problem. To address this, we are exploring digital solutions to streamline document management and reduce the time required for validations and qualifications."
>
> **— Validation Engineer, Leading Global CDMO for Pharma & Biotech, U.S.A**

VOICE OF THE INDUSTRY

Can you share an example of a recent innovation or improvement in your validation processes?

> "We recently updated our templates, making them much easier to use and complete. This improvement has streamlined our validation processes significantly."
>
> **— Validation Engineer, Leading Global CDMO for Pharma & Biotech, U.S.A**

Section Three: Goals and Growth

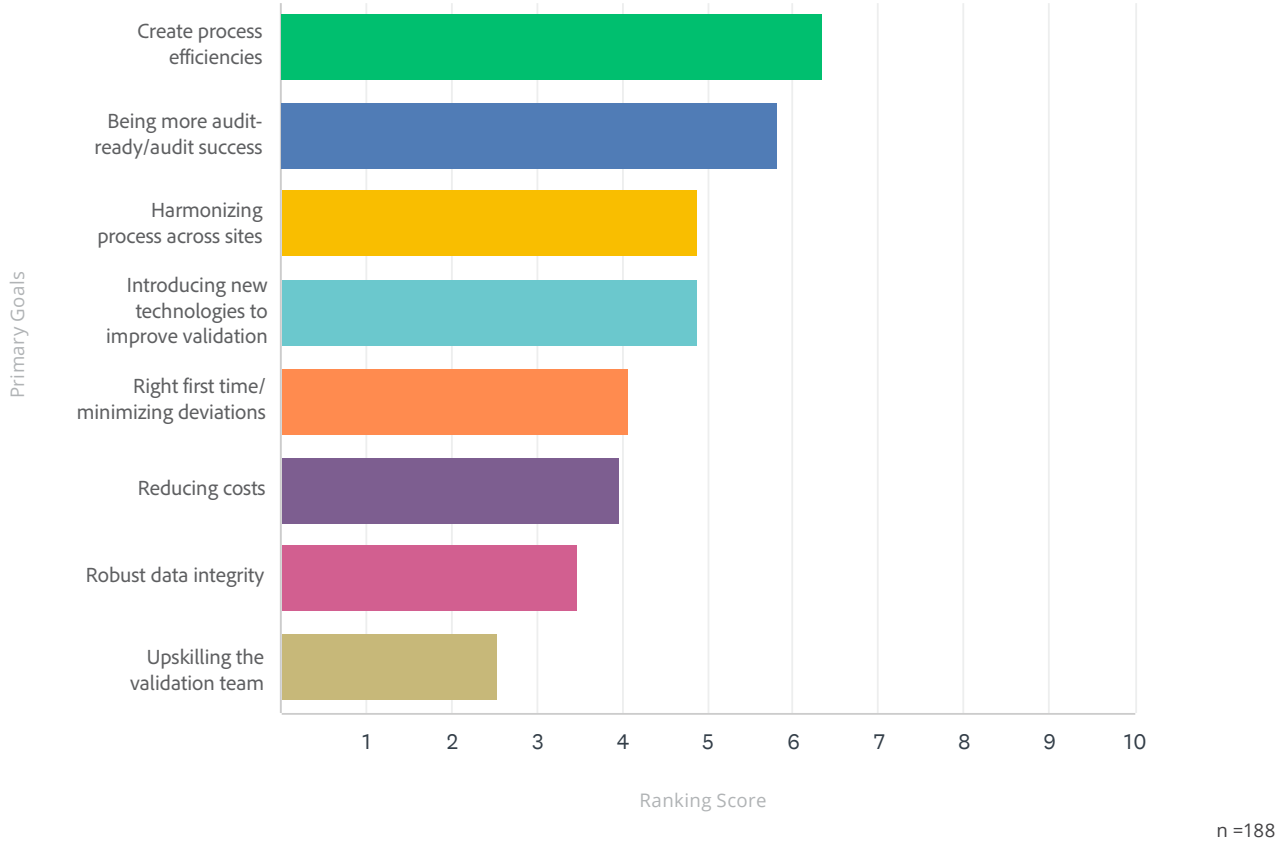
This section explores the strategic goals and growth plans related to validation within organizations. It analyzes responses concerning professional and organizational objectives, performance metrics, and factors influencing success and satisfaction.

Primary Goals of Organizations' Validation Programs

Survey results represent perspectives on key goals of validation programs from validation professionals (see graph below). In this section we also look at three-year trends in primary goals.

Top Goals of Validation Programs

What are the primary goals of your organization's validation programs? Please rank all answer choices in order of preference, 10 being the highest.



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The primary goal for validation programs in 2024 is to create process efficiencies. This indicates a strong focus on optimizing validation workflows to save time and resources while maintaining high standards. The second-highest priority is **being more audit-ready and ensuring audit success.** This underscores the importance of maintaining compliance and being prepared for regulatory inspections.

- **Harmonizing processes across different sites** is an important goal, reflecting the need for standardization and consistency in validation practices across multiple locations.
- **Introducing new technologies** is another key goal, highlighting the industry's drive towards innovation and leveraging advanced tools to improve validation processes.
- Ensuring that validation processes are done **right the first time and minimizing deviations** is crucial, indicating a focus on quality and reducing errors.
- **Reducing costs** remains a priority, reflecting the ongoing need to balance quality and compliance with financial efficiency.
- **Robust data integrity** and **upskilling the validation team** are also important goals, emphasizing the need for reliable data and continuous professional development.

These insights highlight the importance of focusing on **efficiency, audit readiness, standardization,** and **technology adoption. Ensuring quality, reducing costs,** and **maintaining robust data integrity** while investing in team development will be key to achieving these goals.

VOICE OF THE INDUSTRY

What are the primary goals for your validation team in the next one to two years?

> **"Our primary goal is to transition to paperless validation.** We are exploring digital validation tools to reduce the overwhelming amount of paperwork, which is especially challenging to manage across multiple sites.
>
> For instance, coordinating validation between sites involves a tedious process of sending, reviewing, correcting, and scanning paper documents. This inefficiency often turns a two-day task into over a week. The quality validation group sees substantial benefits in digital validation tools, not only for software validation but also for equipment validation. These tools come with built-in templates and user-friendly interfaces, guiding users through necessary forms and documentation, ensuring nothing is overlooked.
>
> Digital validation tools also ensure compliance with regulatory requirements, capturing all necessary information in one centralized location. This centralized approach simplifies access to documents and makes it easier for regulatory agencies to review our processes."
>
> **— Computer System Validation Engineer, Large Pharmaceutical Company, U.S.A**

Trends: Primary Goals of Organizations' Validation Programs

The analysis of top goals for 2024 shows notable shifts from 2023 (see table below).

Ranked Trends in Validation-Related Challenges			
Top Goals	**2022**	**2023**	**2024**
1	Create Process Efficiencies	Create Process Efficiencies	Create Process Efficiencies
2	Right First Time/ Minimizing Deviations	Right First Time/ Minimizing Deviations	Being More Audit Ready / Audit Success
3	Upskilling the Validation Team	Robust Data Integrity	Harmonizing Processes Across Sites

Note: 2022 placement of goals is based on frequency of mentions rather than a forced-choice rank (the method applied in 2023 and 2024). This change allows for a clearer understanding of the primary objectives that organizations prioritize in their validation programs.

- While "**Right First Time/Minimizing Deviations**" was the second priority in 2022 and 2023, it was replaced by "**Being More Audit Ready/Audit Success**" in 2024. This shift indicates an increasing emphasis on compliance and audit preparedness, likely driven by the FDA's January 2024 draft guidance on remote regulatory assessments and focus on electronic audit enablement.
- The third goal evolved from "**Upskilling the Validation Team**" in 2022 to "**Robust Data Integrity**" in 2023 and "**Harmonizing Processes Across Sites**" in 2024. This trend reflects a growing focus on standardization and ensuring reliable data across multiple locations.

The FDA's heightened expectations for comprehensive electronic audit trials, as outlined in the February 2024 draft guidance for industry entitled "Conducting Remote Regulatory Assessments — Questions and Answers," appear to have prompted organizations to prioritize audit readiness and process harmonization. **Ensuring robust, consistent validation processes across sites has become critical for meeting regulatory standards and achieving compliance efficiently.**

VOICE OF THE INDUSTRY

What are the key advantages of digitalizing validation processes in terms of industry standards and inspections?

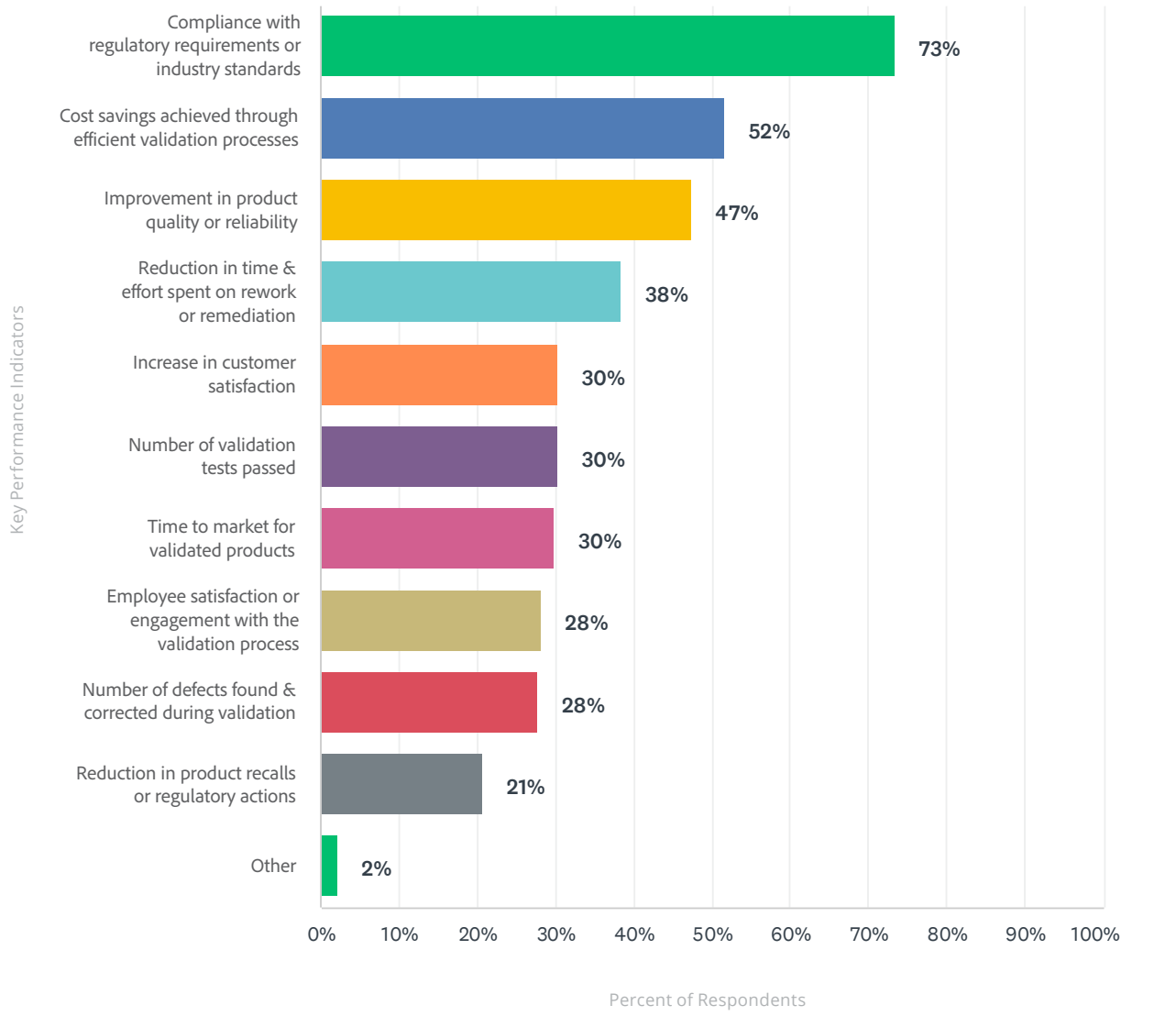
> **"Digitalization ensures consistent execution of validation processes across the industry.** Organizations can better align with industry standards and practices.
>
> It facilitates **easier sharing of information with inspection agencies. Standardized processes and improved transparency lead to less scrutiny during inspections,** especially when compared to similar businesses."
>
> **— Quality & CSV Manager, Top 10 Global Biopharmaceutical Company, U.S.A**

Top Key Performance Indicators (KPIs) Used to Measure Success of Validation Programs

This section focuses on top KPIs that organizations use to measure the success of validation programs. First, we will look at top KPIs (see graph below) and then we will examine two-year trends.*

KPIs That Measure Success of Validation Programs

What are the top key performance indicators (KPIs) used to measure the success of your validation programs? Please select all that apply.



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Survey results highlight a consistent trend across 2023 and 2024. Beyond the expected priority of "Compliance With Regulatory Requirements or Industry Standards," "**Cost Savings Achieved Through Efficient Validation Processes**" and "**Improvement in Product Quality or Reliability**" emerged as the most prevalent KPIs among respondents.

- **Compliance is by far the top KPI (73 percent). The second most common selection is 52 percent (cost savings)**, emphasizing the financial benefits of effective validation processes.
- **Improvement in Product Quality or Reliability (47 percent):** Nearly half of the respondents consider this a key measure, underlining the importance of validation in enhancing product performance.
- **Reduction in Time & Effort Spent on Rework (38 percent):** This KPI highlights the value placed on efficiency and minimizing rework through validation.
- **Increase in Customer Satisfaction (30 percent):** Equal emphasis is placed on this KPI, along with others below, showcasing the importance of customer satisfaction in validation efforts.
- **Number of Validation Tests Passed (30 percent):** Indicates a focus on the success rate of validation tests as a measure of effectiveness.
- **Time to Market for Validated Products (30 percent):** Reflects the importance of reducing time-to-market through validation processes.
- **Employee Satisfaction or Engagement with Validation Processes (28 percent):** Highlights the significance of internal stakeholder engagement and satisfaction.
- **Number of Defects Found & Corrected (28 percent):** Emphasizes the role of validation in identifying and rectifying defects.
- **Reduction in Product Recalls or Regulatory Penalties (21 percent):** Shows a focus among one in five on reducing negative outcomes such as recalls or penalties.
- **Other (two percent):** A minimal number of respondents selected other KPIs (such as "Number of Qualification or Validation Performed/Scheduled" and "Right-first-time Validation"), indicating that the provided options cover the primary concerns effectively.

VOICE OF THE INDUSTRY

What key metrics does your organization use to evaluate the timeliness and performance of its validation programs?

> "We primarily use two key metrics to measure the effectiveness of our validation programs:
>
> 1. **Time to Release:** We evaluate whether we can release our products on time, considering the project's overall schedule. This metric helps us understand our efficiency in meeting deadlines without compromising on validation quality.
> 2. **Feature Completion:** We assess whether we are delivering 100% of the expected features. If we are unable to include all features, we measure how many were omitted. This helps us ensure that our validation process does not compromise the functionality or quality of the final product.
>
> These metrics, which focus on time and performance, allow us to gauge the success of our validation efforts and identify areas for improvement."
>
> **— Digital Compliance Manager, Multinational Information Technology Services & Consulting Company, France**

Trends: Top KPIs Used to Measure the Success of Validation Programs

The trends data from 2023 to 2024 highlights a consistent focus on **Compliance With Regulatory Requirements or Industry Standards, Cost Savings Achieved Through Efficient Validation Processes, and Improvement in Product Quality or Reliability** as the top three KPIs.

Notably, there is a **shift in priority** from the Number of Defects Found and Corrected During Validation in 2023 to Reduction in Time and Effort Spent on Rework or Remediation and Increase in Customer Satisfaction Ratings in 2024, **indicating a growing emphasis on efficiency and customer-centric outcomes.**

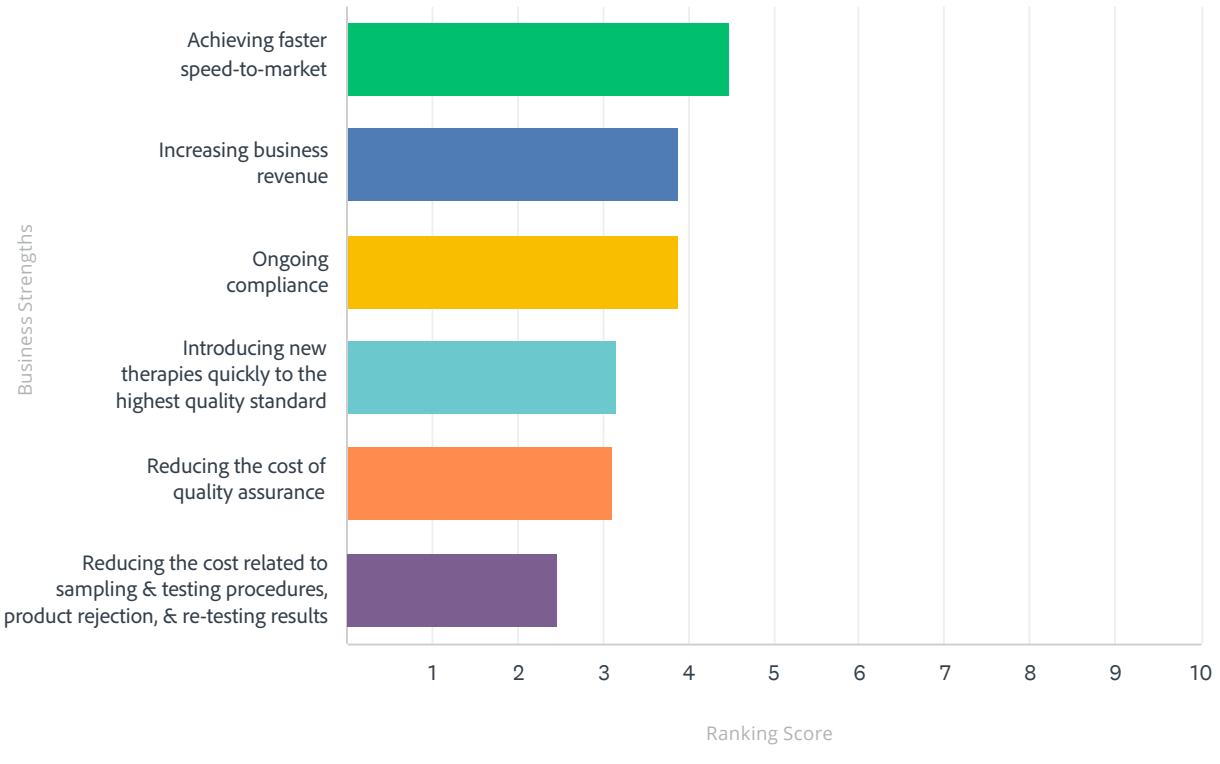
*Note: There is no 2022 data as this survey question was added in 2023.

Business Strengths Most Impacted by Validation

This section focuses on business strengths most impacted by validation activity.
First, we will look at the highest ranked business strengths for all respondents (see graph below).
Then we will examine the three-year trends.

Most Impacted Business Strengths

What business strengths do you think are most impacted by validation performance at your organization?
Please rank all answer choices in order of preference, 10 being the highest.



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Validation performance is crucial for meeting or accelerating product launch timelines. Survey respondents collectively ranked "**Achieving Faster Speed-to-Market**" as the business strength most significantly impacted by validation performance, indicating that validation performance significantly contributes to reducing the time it takes to bring products to market. Faster speed-to-market is critical for gaining competitive advantage and meeting market demands promptly.

Time to launch or release is not just a time metric; it's also a revenue generation driver. Delayed launch affects trial and adoption and market share of new therapies in life sciences and new products or services in other categories. The time to launch and the trajectory at launch determine near-term post-launch potential for product uptake and adoption.

- **Increasing Business Revenue** is ranked second, underscoring that validation performance is seen as a key driver of revenue growth. Efficient validation processes can lead to quicker product launches, higher quality products, and improved customer satisfaction, all of which contribute to increased revenue.
- **Ongoing Compliance** is ranked third. Effective validation ensures that products meet all regulatory requirements, reducing the risk of non-compliance penalties and enhancing the company's reputation.

The survey data underscores the importance of validation performance in achieving faster market entry, driving revenue growth, ensuring ongoing compliance, and introducing new therapies quickly.

Additionally, it highlights the cost-saving benefits of efficient validation in quality assurance and sampling/testing processes. These insights reflect the critical role of validation in enhancing both operational and financial performance across various industry sectors.

Digital validation systems play a pivotal role in enhancing these areas: these systems streamline processes, ensure quality and compliance, and drive financial performance. The ability to leverage digital validation systems to achieve these strengths underscores their critical importance in today's competitive and regulatory landscape.

VOICE OF THE INDUSTRY

What specific metrics does your organization use to measure the efficiency and effectiveness of its validation programs?

> "We measure the effectiveness of our validation programs primarily by **tracking the start-to-finish time** — from project kickoff to the signing of the validation or qualification summary report.
>
> Additionally, we **monitor how long it takes to complete each document.** This is a crucial KPI because delays are often due to system owners' availability rather than the validation team. We track the time spent on validation tasks outside the validation team's control, as the company typically prefers to keep validation resources focused on their primary responsibilities in the labs. This KPI helps us address frequent pushbacks related to resource allocation."
>
> **— Lead CSV Consultant, Consulting Services Company, U.S.A**

Trends: Business Strengths Most Impacted by Validation

The trends data from 2022 to 2024 illustrate an evolving landscape (see table below) where **validation performance is increasingly seen as a catalyst for faster market entry and revenue growth**, without compromising the importance of compliance.

Ranking Trends in Impacted Business Strengths			
Business Strengths	**2022**	**2023**	**2024**
#1	Ongoing Compliance	Ongoing Compliance	Achieving Faster Speed-to-Market
#2	Achieving Faster Speed-to-Market	Increasing Business Revenue	Increasing Business Revenue
#3	Reducing the Cost of Quality Assurance	Achieving Faster Speed-to-Market	Ongoing Compliance

- **Shift in Priorities:** Compliance was the top priority in 2022 and 2023 and dropped to third place in 2024. Meanwhile, Achieving Faster Speed-to-Market rose to first place in 2024. This indicates a growing emphasis on agility and responsiveness in the market.
- **Consistency in Revenue Focus:** Increasing business revenue has consistently grown in importance, reflecting the recognition of validation performance as a critical driver of financial success.
- **Enduring Importance of Compliance:** While ongoing compliance has shifted to third place in 2024, it remains a crucial strength, underscoring that adherence to regulatory standards is always a foundational requirement.

Organizations recognize that **efficient validation processes can provide a competitive edge** by speeding up product launches and driving financial performance, all while ensuring they meet necessary regulatory standards.

VOICE OF THE INDUSTRY

How has digitalization impacted the efficiency of your processes, particularly in terms of faster time-to-market?

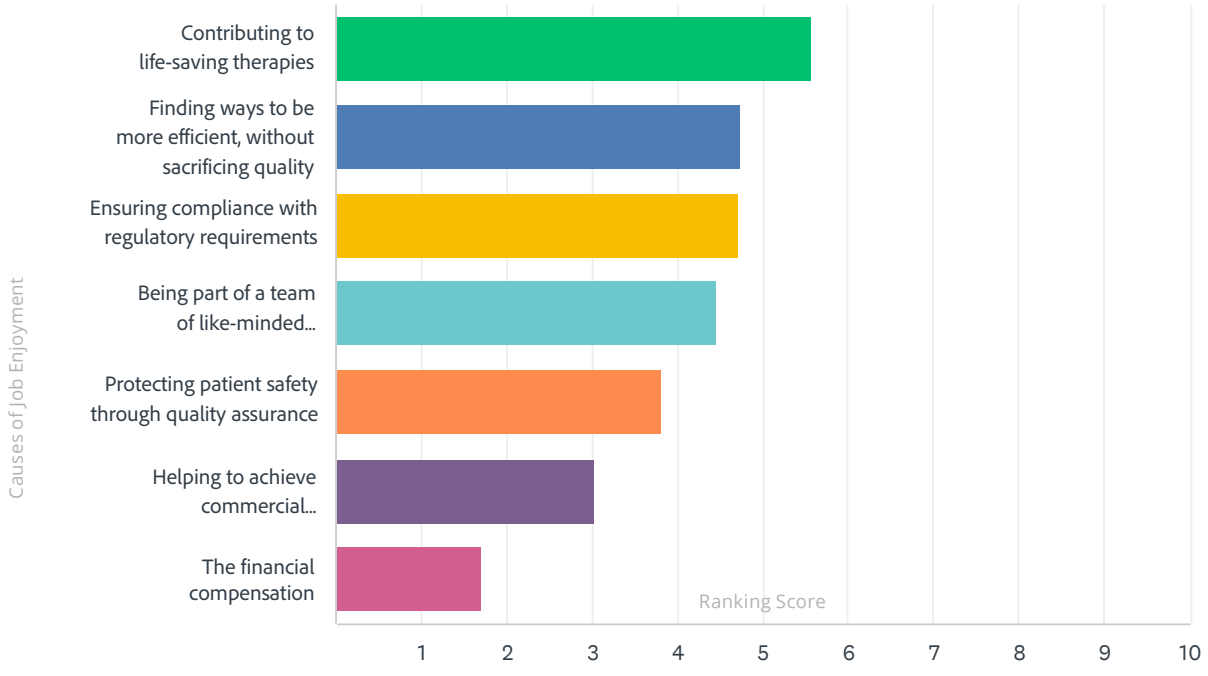
> "We have very aggressive time schedules, utilizing agile methodology to push out updates every three months. For regulated products, this is remarkably fast, achievable only with automated testing.
>
> However, if the automated testing isn't set up correctly, it can cause significant delays due to numerous failed tests without clear reasons. Despite this, automated testing allows us to fail faster and learn faster, enhancing our overall efficiency."
>
> **— Quality Engineering Specialist, Top 10 Multinational Healthcare Company, U.S.A**

Job Enjoyment

Survey results reveal perspectives on job enjoyment from validation professionals (see graph below).

Causes of Job Enjoyment

What do you enjoy most about being a validation professional? Please rank all answer choices in order of preference, 10 being the highest.



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Validation professionals found "**Contributing to Life-Saving Therapies**" to be the most enjoyable and rewarding facet of their roles. This indicates validation professionals find immense satisfaction in knowing their work directly impacts the development and delivery of life-saving therapies, highlighting a strong alignment with altruistic and impactful outcomes.

Overall, the data underscores that validation professionals are deeply committed to making a positive impact through their work, prioritizing efficiency, compliance, teamwork, and patient safety over financial compensation:

- **Emphasis on Efficiency and Compliance:** Finding ways to improve efficiency and ensuring compliance with regulations are highly valued, reflecting the critical nature of these aspects in their roles.
- **Importance of Teamwork and Patient Safety:** Collaboration with like-minded colleagues and ensuring patient safety are also notable sources of job satisfaction.
- **Financial Compensation is Secondary:** While financial rewards are necessary, they are not the primary motivator for validation professionals. Their satisfaction largely derives from the intrinsic value and impact of their work.

VOICE OF THE INDUSTRY

How has your organization shifted towards a culture that prioritizes validation activities?

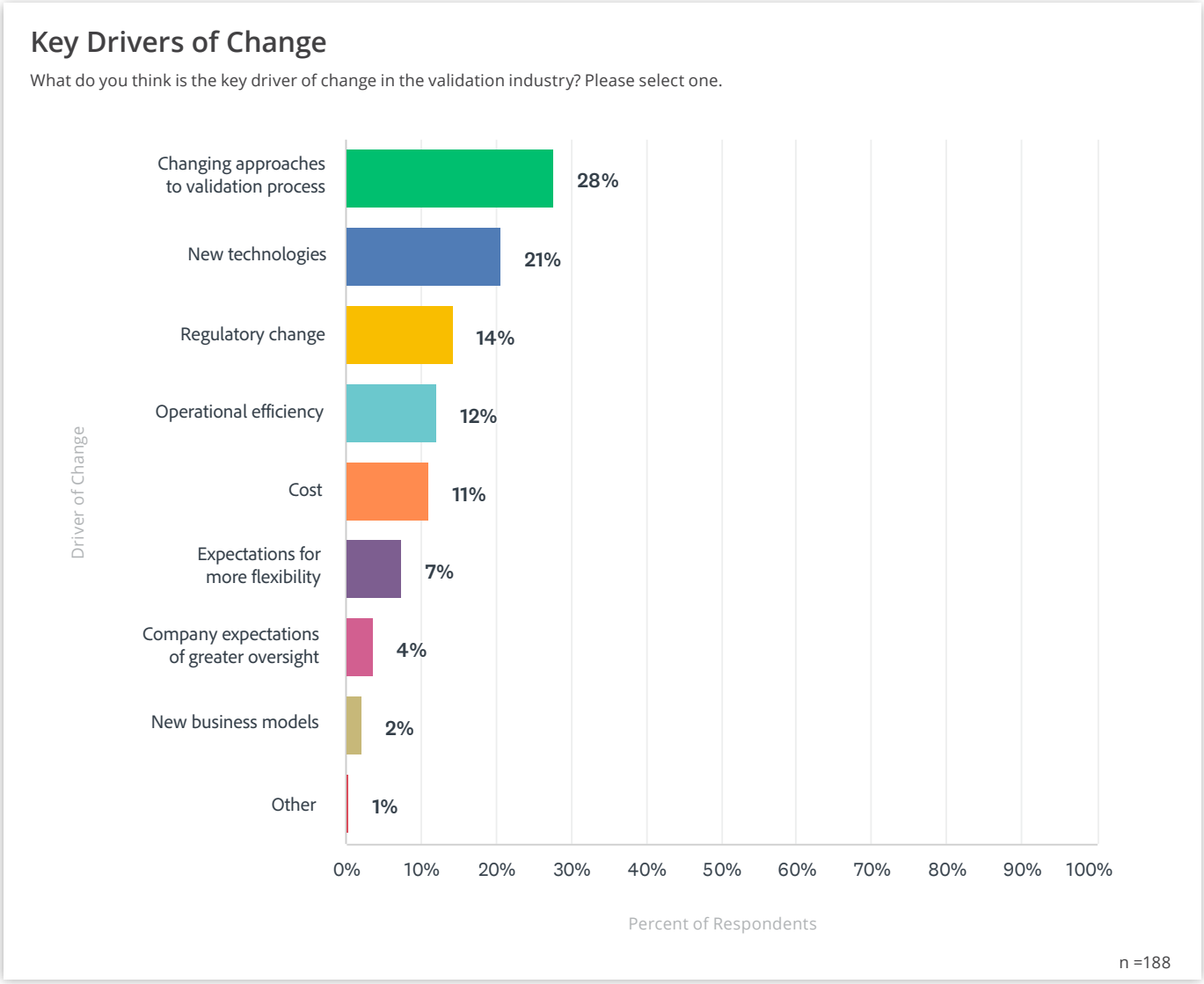
> "I've noticed a significant shift towards prioritizing validation activities. Our validation group is now involved upfront, determining what needs to be validated based on risk assessments and whether it pertains to GxP equipment or software.
>
> **We are increasingly working towards a comprehensive approach, making everyone aware that validation must be an integral part of the process from the beginning.** It's not just about bringing validation in at the end; we need to be involved from the start to evaluate risks and ensure all bases are covered."
>
> **— Computer System Validation Engineer, Large Pharmaceutical Company, U.S.A**

Section Four: Industry Change and Digital Transformation

Section four discusses significant industry changes and the role of digital transformation, including key drivers of change in the validation industry. It explores the challenges and opportunities presented by remote regulatory assessments and other digital shifts. The discussion includes the utilization and perceptions of new validation technologies and tools, their adoption rates, and the management of digital validation systems. Additionally, it evaluates the return on investment (ROI) of these systems compared to initial expectations.

Key Drivers of Change in the Validation Industry Today

This section focuses on key drivers of change in the validation industry. First, we will look at the top drivers of change (see graph below) and then examine the three-year trends.



The data highlights the top three key drivers of change in the validation industry as **changing approaches to validation process** (28 percent), **new technologies** (21 percent), and **regulatory changes** (14 percent).

- **Adapt to Evolving Practices:** With changing approaches to validation being the leading driver, professionals should stay updated on new methodologies and best practices to enhance efficiency and compliance.
- **Embrace Technological Advancements:** As new technologies play an important role, integrating innovative tools and systems into validation processes can improve accuracy and streamline operations.
- **Stay Ahead of Regulatory Changes:** Given the impact of regulatory changes, maintaining a proactive approach to understanding and implementing new compliance requirements is crucial for sustaining validation excellence.

These insights underscore the importance of continuous learning, technological integration, and regulatory awareness in navigating the dynamic landscape of the validation industry.

Trends: Key Drivers of Change in the Validation Industry

In both 2023 and 2024, the **foremost driver of change** became the **evolving methodologies in validation processes**, having shifted from New Technologies which was the top driver of change in 2022. This indicates a **growing emphasis on refining and optimizing validation techniques**, likely in response to increasing complexity and the need for greater efficiency and accuracy.

Technological innovation influences process design; regulations are created to respond to new technology. This dynamic interplay between technology, process innovation, and regulatory demands shapes the evolving landscape of the validation industry.

VOICE OF THE INDUSTRY

How is your organization ensuring audit readiness amidst evolving validation landscapes and the increased use of remote regulatory assessments?

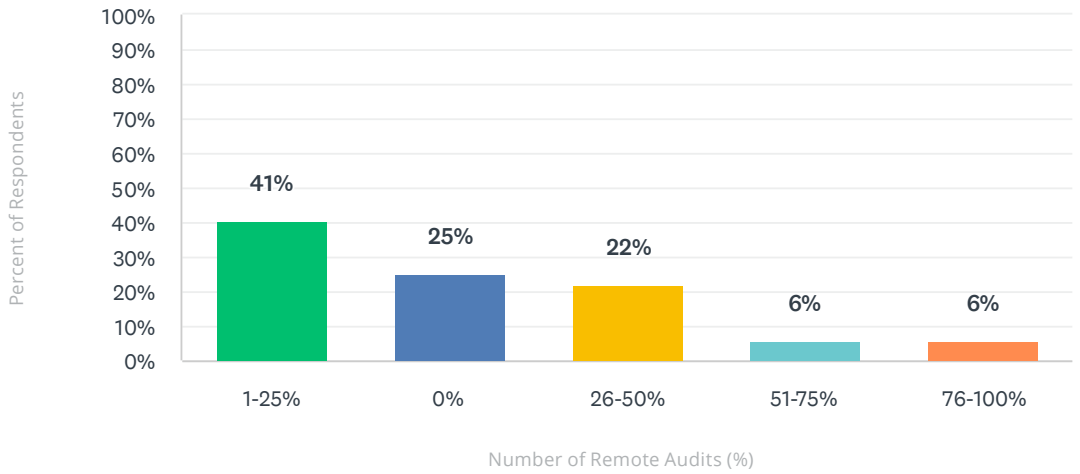
> "We are well-prepared for audits, even with little advance notice, because we have all necessary documentation organized in one place. Previously, we had to over-analyze and organize paper documents and emails, which often led to gaps such as missing signatures or incomplete memos.
>
> **With the shift to digitized validation, preparing for an audit is almost effortless.** I feel confident that I could be informed of an audit today and be ready by Monday, regardless of which application they inspect. Our digitized system ensures all signatures, SOPs, and references are easily accessible and up to date."
>
> **— IT Compliance Manager, Global Leader, In Vitro Diagnostics (IVD) & Biomarkers, U.S.A**

Percentage of Organizations' Regulatory Audits Conducted Remotely in the Previous 12 Months

This section about remote regulatory audits highlights a **slow but growing adoption of remote audits** (see graph below).

Percentage of Regulatory Audits Conducted Remotely

In the past 12 months, approximately what percentage of your organization's regulatory audits were conducted remotely? Please select one.



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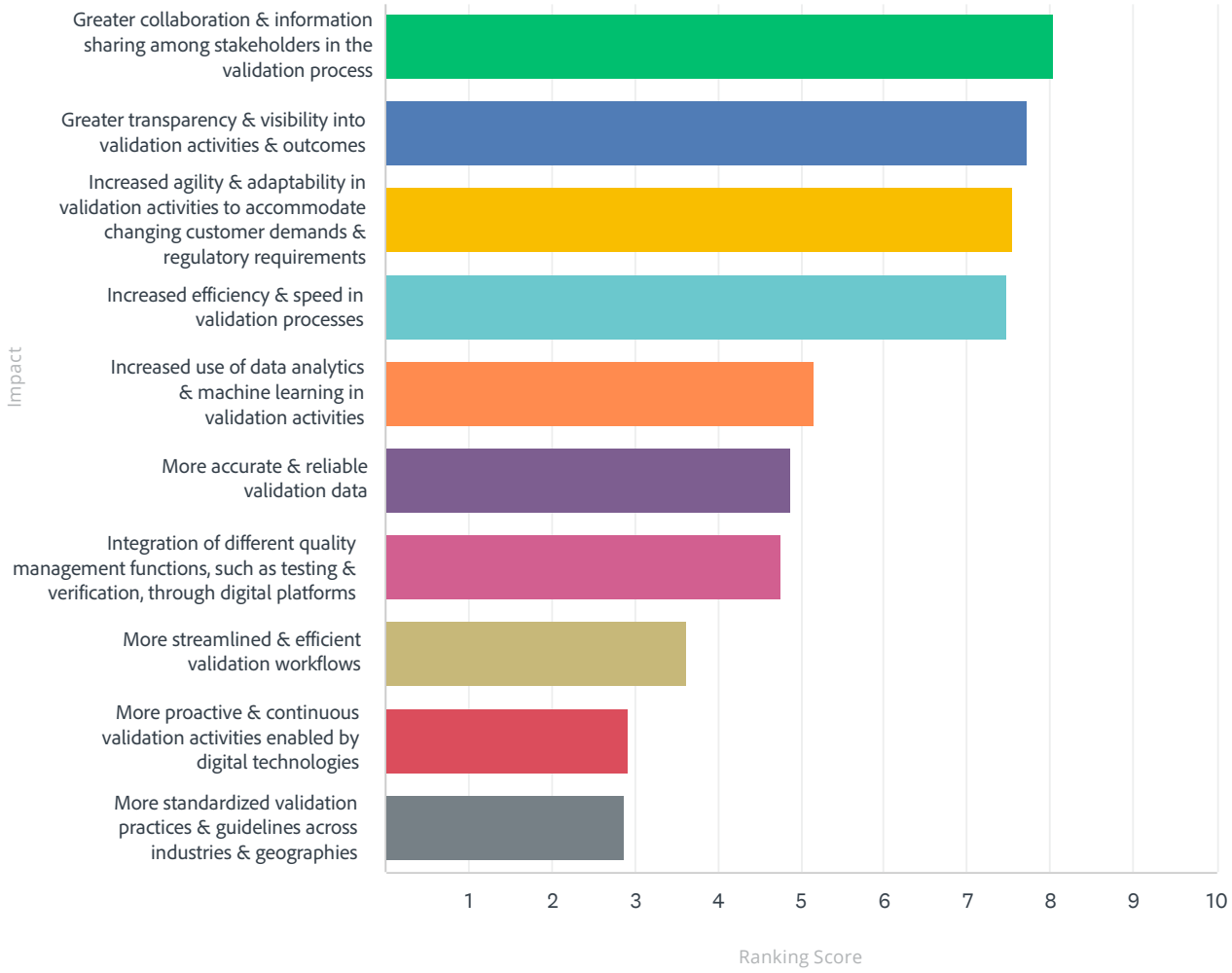
- Three-quarters of respondents conducted **some remote audits**.
- A substantial portion of respondents (41 percent) reported that only **1-25% of their audits were conducted remotely.**
- Twenty-five percent of respondents indicated that **none of their audits were conducted remotely.**

The Impact of Digital Transformation on the Validation Industry

This section dives into the state of digital transformation across the validation industry. It analyzes the perceived benefits, impacts, and challenges associated with digital transformation. First, we will examine the most impactful changes brought by digital transformation (see graph below). Then we will look at the impact of digital transformation for different company types.

Impact of Digital Transformation

What impact has digital transformation had on the validation industry? Please rank all answer choices in order of preference, 10 being the highest.



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The survey data reveals the top three most impactful changes brought by digital transformation in the validation industry: **Greater collaboration, greater transparency, and increased agility.**

- **Enhanced Collaboration and Information Sharing:**
  The greatest impact of digital transformation is the enhancement of collaboration and information sharing. This indicates that digital tools significantly improve teamwork and communication within the industry, fostering a more connected and cooperative work environment.
- **Increased Transparency and Visibility:** The second most valued impact of digital transformation is greater transparency and visibility in processes. Digital transformation enables clear and open operations, making it easier for organizations to monitor and understand their validation activities. This increased visibility helps in maintaining high standards and accountability.
- **Increased Agility and Adaptability:** Ranked third, increased agility and adaptability highlight how digital transformation allows organizations to respond more swiftly and flexibly to changes and challenges. This ability to quickly adjust to new circumstances is crucial in an industry that often faces evolving regulations and technological advancements.

Increased efficiency and speed in processes is also highly regarded, showing that digital tools are crucial in streamlining operations and reducing time requirements.

Impact of Digital Transformation for Different Company Types

The impact of digital transformation on the validation industry varies across different company types, highlighting distinct priorities and benefits. **Collaboration, transparency, and efficiency** are impacts that transcend many industries (see table below).

Digital Transformation Impact by Company Type

Company Type	#1 Impact	#2 Impact	#3 Impact
Pharmaceutical, Biotechnology, or Medical Device Manufacturer	Greater Collaboration	Greater Transparency	Increased Efficiency & Speed
Clinical Trial/ Research Organization	Greater Collaboration / Increased Efficiency*	Increased Use of Data Analytics & Machine Learning in Validation Activities	Greater Transparency
CDMO/CMO	Increased Agility	Greater Collaboration	Greater Transparency
Hospital or Health Service	Greater Collaboration	Greater Transparency	Increased Efficiency & Speed
Manufacturing Equipment & Technology Provider	Greater Collaboration	Greater Transparency	Increased Agility
Packaging	Increased Efficiency & Speed	Greater Collaboration	More Accurate & Reliable Validation Data
Professional Services & Consulting	Greater Collaboration	Increased Efficiency & Speed	Greater Transparency
Regulatory Body	Greater Transparency	Increased Use of Data Analytics & Machine Learning in Validation Activities	Increased Agility

- **Pharmaceutical, Biotechnology, or Medical Device Manufacturers** highlight collaboration and information sharing, transparency, and efficiency improvements as key impacts.
- **Clinical Trial/Research Organizations** prioritize greater collaboration and information sharing, alongside increased efficiency and speed in validation processes. They also value the increased use of data analytics and machine learning, and enhanced transparency and visibility into validation activities.
- **CDMOs/CMOs** emphasize increased agility and adaptability to meet changing customer demands and regulatory requirements, followed by enhanced collaboration and information sharing, and improved transparency.
- **Hospitals or Health Services** focus on greater collaboration and information sharing, improved transparency, and increased efficiency and speed in validation processes.
- **Manufacturing Equipment & Technology Providers** also prioritize collaboration, transparency, and agility to adapt to changing demands.

- **Packaging** companies see increased efficiency and speed as the most meaningful impact, followed by improved collaboration and more accurate and reliable validation data.
- **Professional Services & Consulting** firms emphasize collaboration, efficiency, and transparency.
- **Regulatory Bodies** focus on greater transparency and visibility, increased use of data analytics and machine learning, and improved agility to adapt to changing demands.

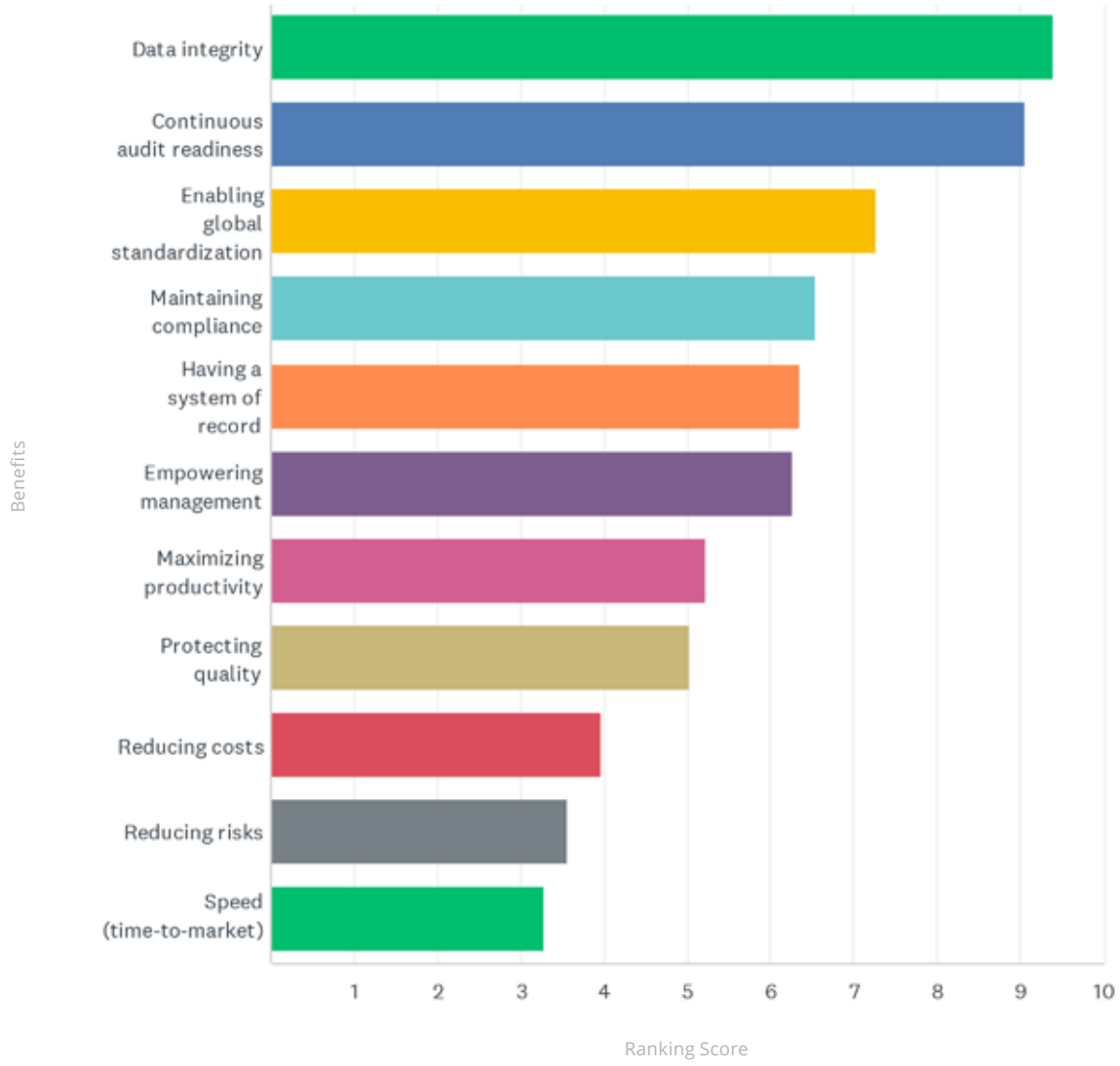
The variety of priorities by type of company underscores the particular benefits digital transformation brings to each sector.

The Leading Benefits of Digitizing Validation

This section focuses on the leading benefits of digitizing validation. First, we will look at the top benefits (see graph below), and then we will examine the three-year trends.

Benefits of Digitizing Validation

In your opinion, what are the leading benefits of digitizing validation? Please rank all answer choices in order of preference, 10 being the highest.



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The top three benefits of digitizing validation as perceived by industry professionals are: **data integrity, continuous audit readiness,** and **enabling global standardization.**

- **Data Integrity:** Data integrity is ranked as the highest benefit, emphasizing the critical importance of accurate and reliable data in the validation process. This underscores how digital tools ensure validation data remains precise and trustworthy.
- **Continuous Audit Readiness:** Continuous audit readiness is the second most valued benefit, reflecting the need for organizations to be always prepared for audits. Digital transformation facilitates this readiness by enabling ongoing compliance and easy access to necessary documentation and records.
- **Enabling Global Standardization:** Enabling global standardization ranks third, indicating digitization helps organizations align their processes with international standards. This ensures consistency and uniformity across global operations, making it easier to meet regulatory requirements worldwide.

This highlights the critical role of digital tools in maintaining accurate data, ensuring perpetual compliance, and achieving consistent processes across organizations to meet governance goals.

Trends: The Leading Benefits of Digitizing Validation

From 2022 to 2024, the perceived leading benefits of digitizing validation have evolved significantly (see table below).

Ranking Trends in Digital Validation Benefits

Leading Benefits	2022	2023	2024
#1	Protecting Quality	Protecting Quality	Data Integrity
#2	Speed (Time-to-Market)	Speed-to-Market	Continuous Audit Readiness
#3	Reducing Costs	Reducing Risks	Enabling Global Standardization

In 2022 and 2023, "**Protecting Quality**" consistently ranked as the top benefit, highlighting a strong focus on maintaining high standards. "**Speed (Time-to-Market)**" was also highly valued during these years, reflecting the industry's emphasis on accelerating product launches.

None of the top three from 2022 or 2023 remained in the 2024 top three. **By 2024, priorities shifted**, with "**Data Integrity**" **emerging as the foremost benefit**, underscoring the increasing importance of accurate and reliable data. This could indicate a shift away from a product focused view towards a wider organizational analysis.

"**Continuous Audit Readiness**" and "**Enabling Global Standardization**" also gained prominence, indicating a **growing need for ongoing compliance, preparedness for audits, and uniform processes across global operations.**

VOICE OF THE INDUSTRY

What benefits have you realized from digitized validation, and has it met your expectations?

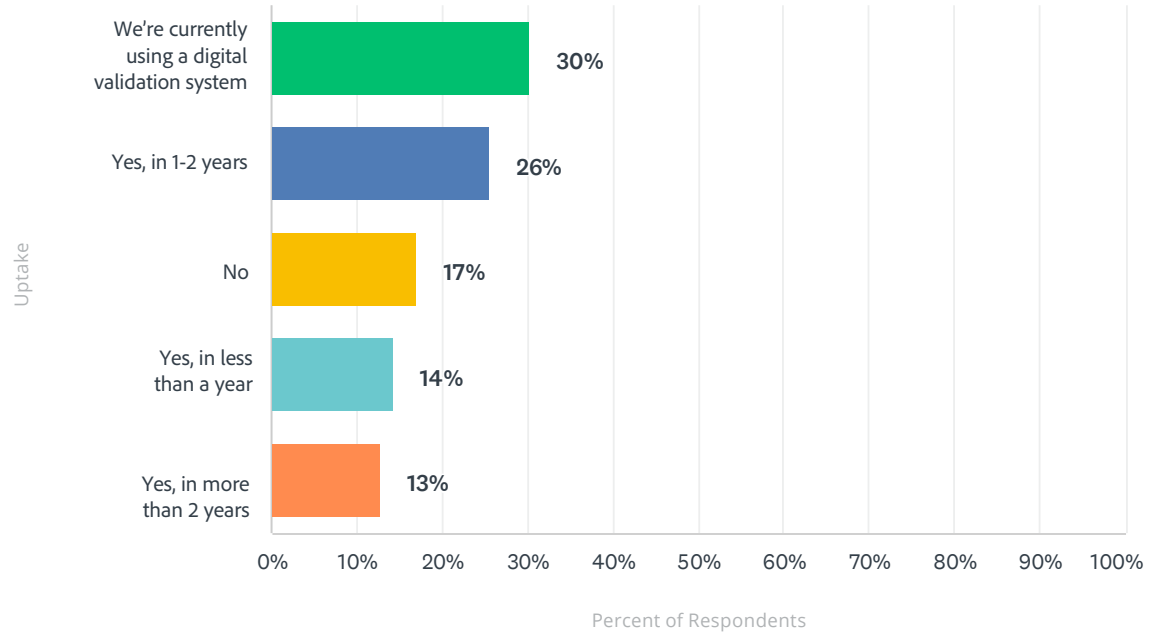
> **"Digitalization has significantly accelerated validation processes, reduced documentation requirements, enhanced collaboration, and enabled the adoption of new technologies.** It also allows reliance on external experts who possess specialized knowledge beyond internal capabilities."
>
> — **Digital Compliance Manager, Multinational Information Technology Services & Consulting Company, France**

Technologies Supporting Validation Work Processes: Digital Validation Systems

This section focuses on digital validation technology supporting validation work processes. First, we will look at the uptake of digital validation systems in industry today (see graph below) and the types of digital validation solutions used by teams, then examine the three-year trends and the tendency toward digital validation technology in organizations of different sizes.

Uptake of Digital Validation Systems

Does your organization have any plans to adopt a digital validation system? Please select one.



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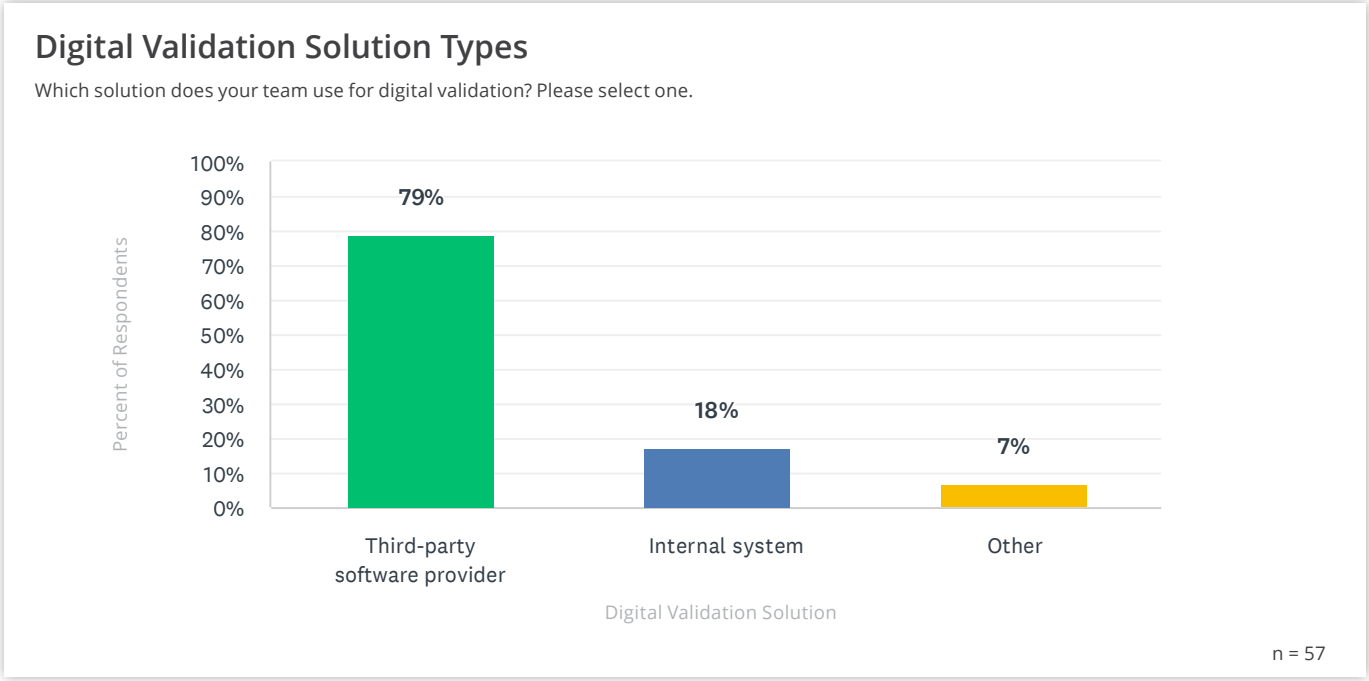
Survey results underscore a sizeable shift towards digital validation in the industry. An overwhelming 83 percent of respondents are embracing digital validation, split between 30 percent who have already implemented digital validation systems and 53 percent who are planning to.

Seventeen percent of respondents have no current plans to adopt a digital validation system. This minority suggests some organizations may face barriers such as budget constraints, lack of expertise, or resistance to change from staff.

While 53 percent of respondents plan to adopt a digital validation system within the next year, or 1-2+ years, today 70 percent of respondents perform all validation processes without a digital validation solution.

When considered alongside the findings in the next section, "Other Validation Technologies & Tools Used by Validation Teams," it's **likely other systems** such as Document Management Systems and/or Quality Management Systems, **are being used in tandem with paper-based processes** to sustain a hybrid process.

Solutions Used by Teams for Digital Validation



- **Among those using digital validation, a substantial majority (79 percent) of validation professionals rely on third-party software providers** for digital validation solutions. This highlights the industry's preference for specialized, externally developed tools, likely due to their advanced features and support.
- Only 18 percent of respondents use internal systems, indicating that fewer organizations have the resources or desire to develop in-house solutions. Additionally, seven percent selected other solutions, which may reflect niche requirements.

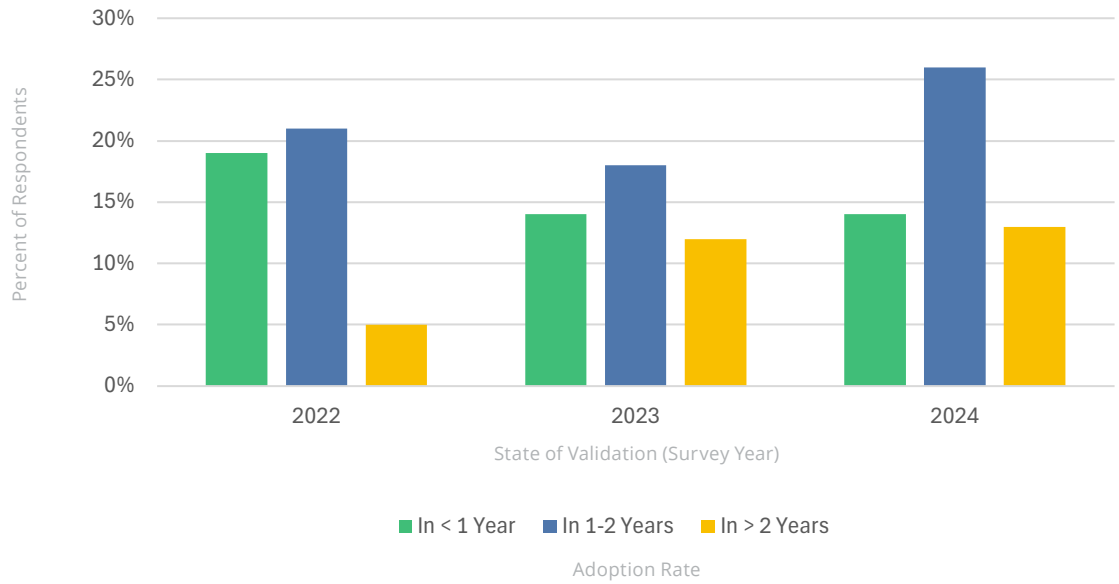
The relatively low use of internal systems points to potential challenges in developing and maintaining proprietary tools.

Trends: Digital Validation Adoption Rate

In 2022, 19 percent of organizations planned to adopt digital validation within a year, which decreased to 14 percent in both 2023 and 2024, indicating a **stabilization in immediate adoption** (see chart below).

Digital Validation Solution Types

Which solution does your team use for digital validation? Please select one.

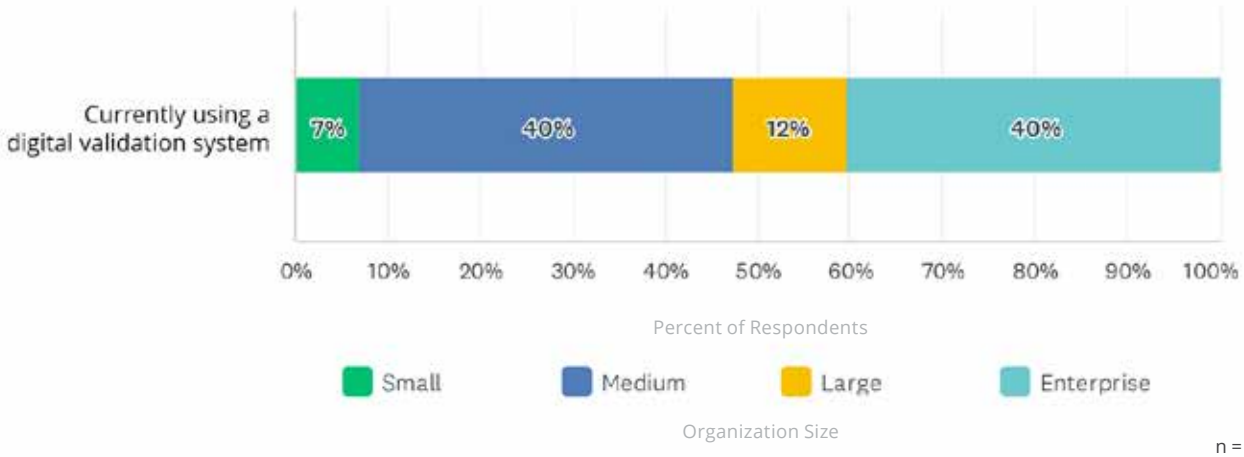


Conversely, **plans to adopt within 1-2 years rose** from 21 percent in 2022 to 26 percent in 2024 and **adoption plans for more than 2 years increased substantially** from five percent in 2022 to 13 percent in 2024.

Tendency Toward Validation Technology in Smaller vs Larger Organizations

Trends in Uptake of Digital Validation Systems by Organization Size

Does your organization have any plans to adopt a digital validation system?



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Note: Asked of those who said their organizations use third-party or in-house digital validation.

- It is interesting to note that of the 79 percent of respondents who indicated their organizations are managing their validation activities by using a third-party or in-house proprietary digital validation solution, **most of these validation professionals are found within organizations at medium and enterprise levels.**
- Specifically, 40 percent of respondents are from medium-sized companies (100-1000 employees) and another 40 percent are from enterprise-level companies (5000+ employees). Smaller companies (up to 100 employees) represent approximately seven percent of the respondents, while 12 percent come from large companies (1000-5000 employees).

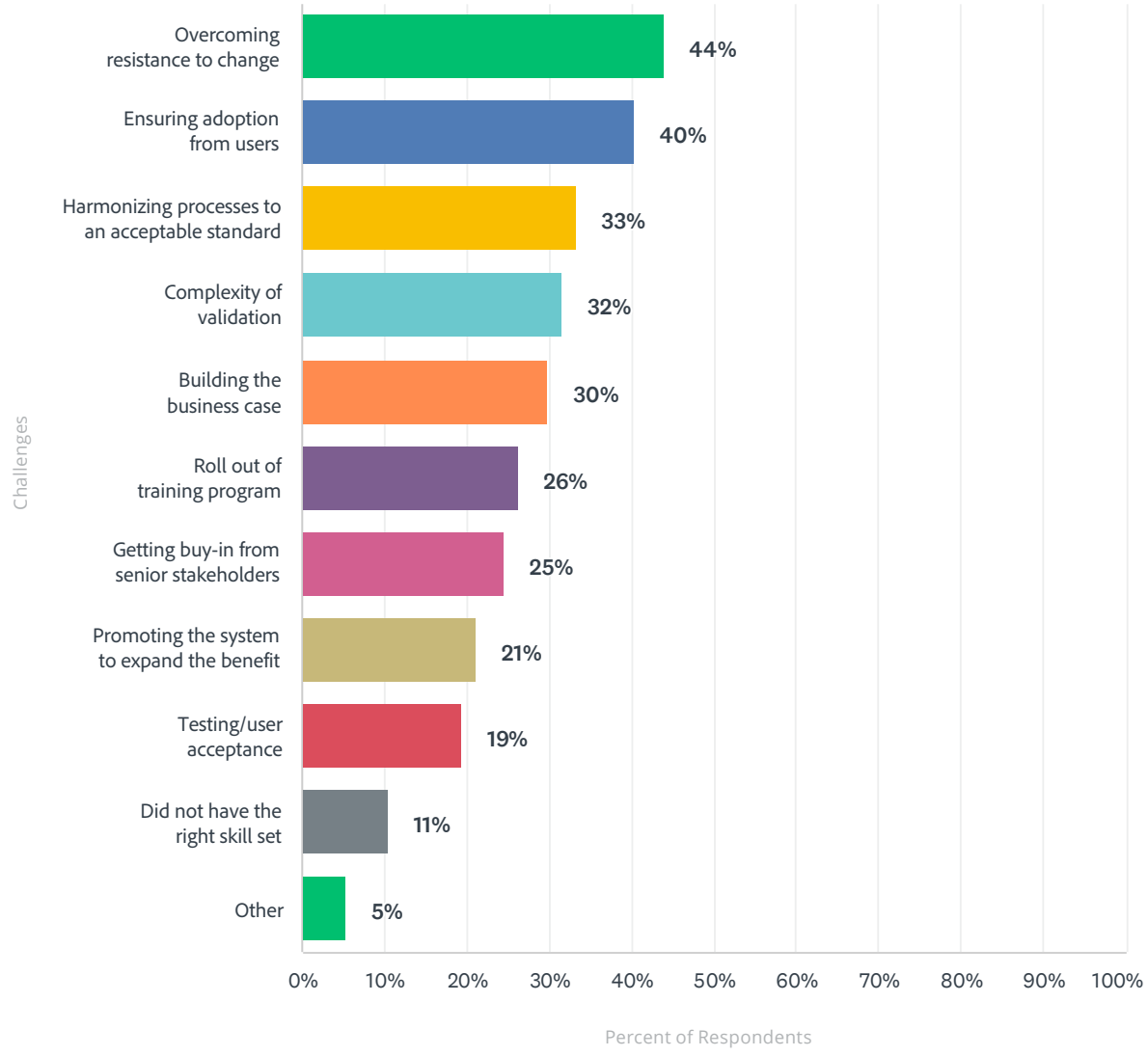
The broad adoption across various company sizes highlights the universal value and scalability of digital validation systems in enhancing compliance and efficiency.

Biggest Challenges Managing the Implementation Project for Digital Validation System

This section focuses on the biggest challenges managing digital validation system implementation. First, we will look at the top challenges for all respondents (see graph below), followed by challenges for organizations of different sizes.

Top Challenges When Implementing Digital Validation

Which of the following validation processes does your organization manage? Please select all that apply.



n = 57

The survey data highlights the significant challenges organizations face when implementing digital validation projects.

- The top challenge is **overcoming resistance to change**, cited by 44 percent of respondents, indicating cultural and behavioral adjustments are major hurdles.
- **Ensuring adoption from users** follows closely at 40 percent, emphasizing the need for user engagement and training. **Harmonizing processes to an acceptable standard** (33 percent) and the inherent **complexity of validation** (32 percent) also pose substantial difficulties.
- **Promoting the system into new sites and divisions to expand the benefit** and **tester/ user acceptance** are also noteworthy, at 21 percent and 19 percent, respectively. A smaller percentage (11 percent) highlighted a **lack of the right skill set,** underscoring the need for skilled personnel.

VOICE OF THE INDUSTRY

Can you share a successful collaboration between your validation team and another department within your organization?

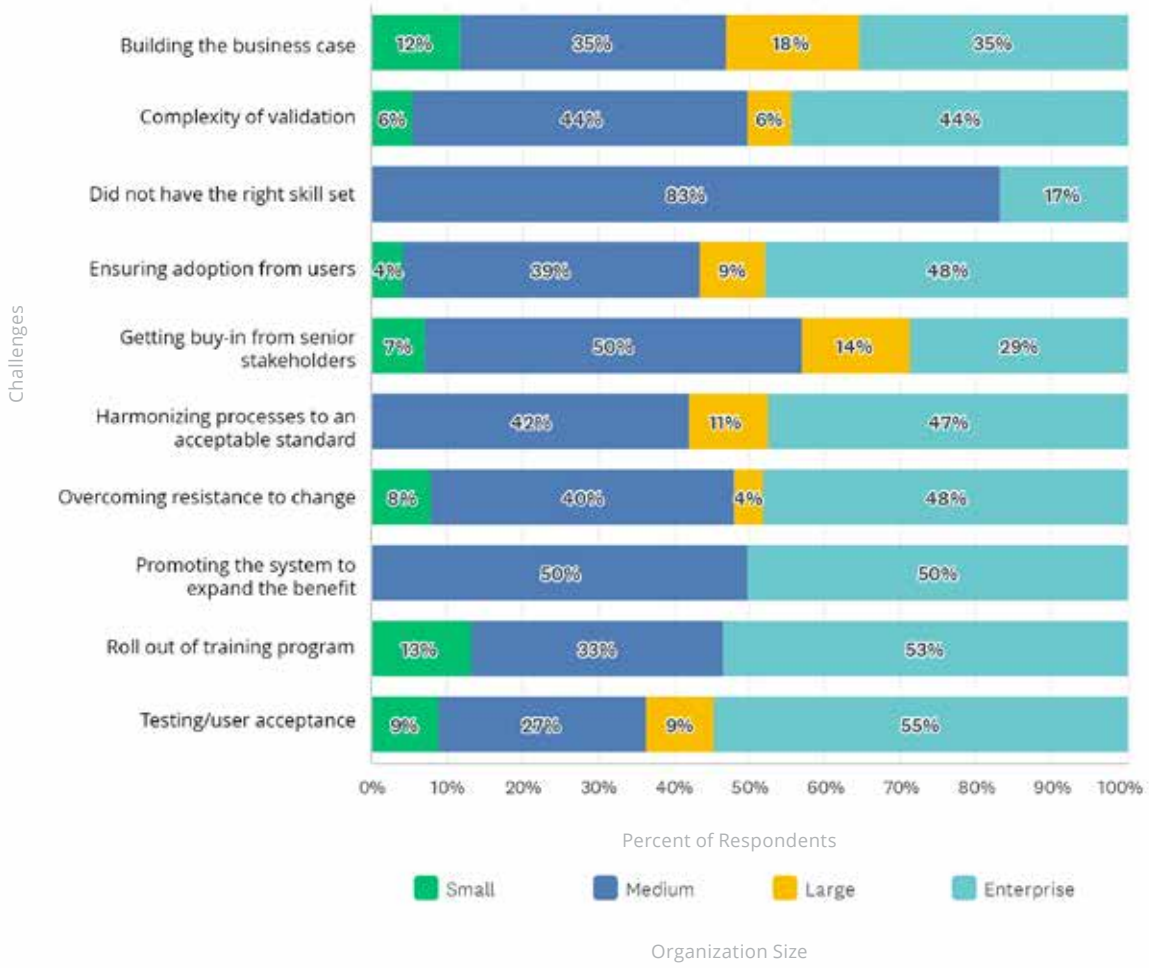
> "My role involved implementing a digital validation system across multiple sites, including deploying training for team members. All sites that were onboarded appreciated the significant simplification in their validation processes. **The success of the implementation can be attributed to maintaining an open and constant communication channel between myself (part of the Global Deployment Team) and the sites."**
>
> **— Quality & CSV Manager, Top 10 Global Biopharmaceutical Company, U.S.A**

Top Challenges When Implementing Digital Validation for Organizations of Different Sizes

The biggest challenges in managing digital validation implementation projects vary by organization size (see chart below).

Trends in Uptake of Digital Validation Systems by Organization Size

Does your organization have any plans to adopt a digital validation system?



- For **small companies**, the top issues are **building the business case** (12 percent) and **user adoption** (four percent).
- **Medium-sized companies** struggle most with the **complexity of validation** (44 percent) and **not having the right skill set** (63 percent).
- **Large companies** face challenges in **getting buy-in from senior stakeholders** (50 percent) and **promoting the system** (50 percent).
- **Enterprise-level organizations** highlight **ensuring user adoption** (48 percent) and **overcoming resistance to change** (48 percent) as important hurdles.

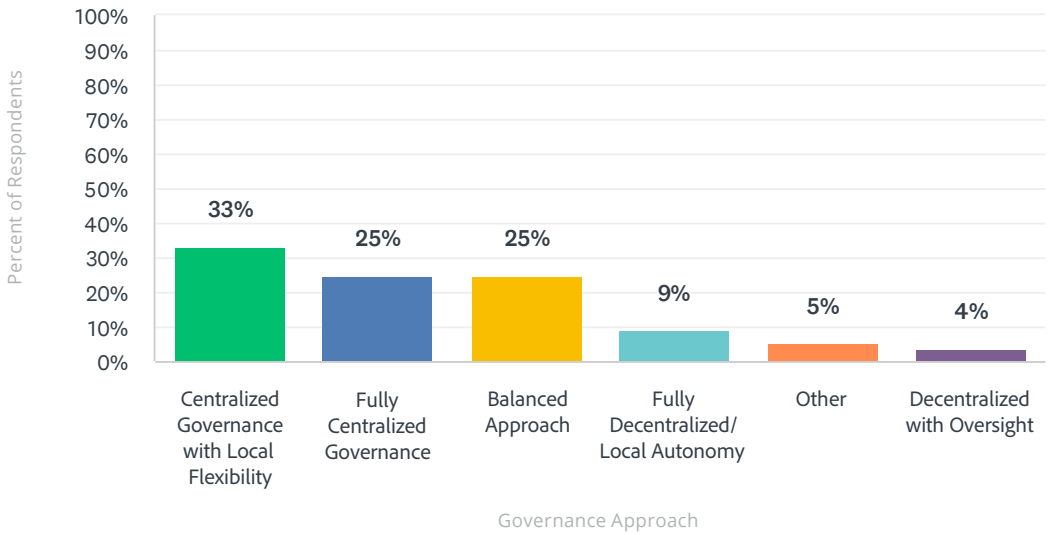
Across all sizes, harmonizing processes and rolling out training programs are also common challenges.

Governance Approach of the Digital Validation System

This section focuses on the governance approach of digital validation systems by organizations. We will look at the type of governance approach used by organizations (see graph below).

Digital Validation Governance

Do you have a global approach for governance of the digital validation system, or do you let sites configure the system to their specific needs? Please select one.



n = 57

Most organizations favor centralized or balanced governance approaches for digital validation systems, indicating a need for standardization with local flexibility, while fewer organizations opt for fully decentralized governance due to concerns over consistency and compliance.

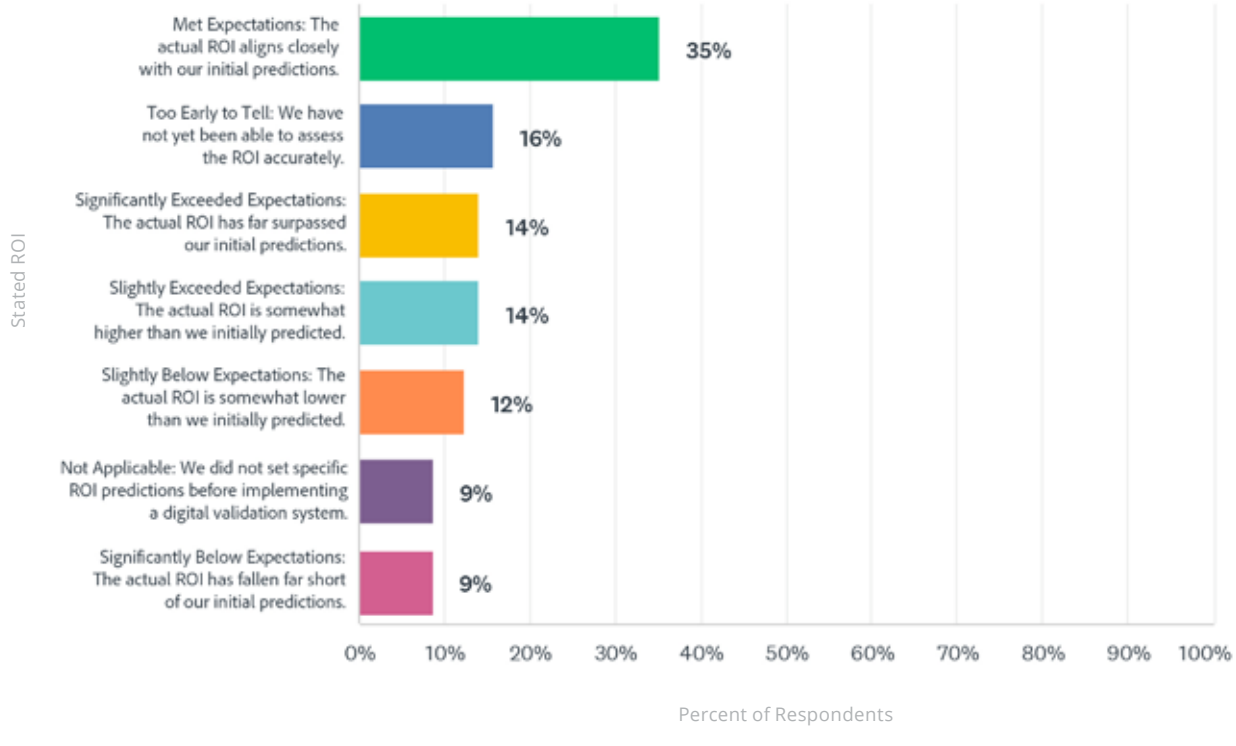
- A sizeable portion (33 percent) of respondents prefer a "**Centralized Governance with Local Flexibility,**" balancing uniformity with site-specific needs.
- Twenty-five percent adopt a "**Fully Centralized Governance**" model, emphasizing standardization and control across all sites.
- An equal percentage (25 percent) employ a "**Balanced Approach,**" integrating both centralized and decentralized elements.
- Additionally, nine percent of respondents opt for "**Fully Decentralized/Local Autonomy,**" allowing individual sites complete control over their systems.
- A small fraction (five percent) specified other methods, and four percent use a "**Decentralized with Oversight**" approach, where local sites have autonomy but under central oversight.

ROI From Implementing a Digital Validation System Compared to Initial Predictions

The survey data on the stated return on investment (ROI) from implementing digital validation systems compared to initial predictions reveals mixed outcomes (see graph below).

Stated ROI From Digital Validation

How does the actual ROI from implementing a digital validation system compare to your initial predictions? Please select one.



n = 57

A plurality (35 percent) of respondents reported the stated ROI **met their expectations.**

- Another 16 percent indicated it's **too early to tell**, suggesting ongoing evaluations.
- Notably, 14 percent reported the ROI **significantly exceeded expectations**.
- An equal 14 percent found it **slightly exceeded expectations**, highlighting positive outcomes for a sizable portion of users.
- Conversely, 12 percent experienced **slightly below expected ROI**, and nine percent **significantly below**, indicating some challenges.
- Additionally, nine percent **did not set initial ROI predictions**, making it difficult to gauge their success.

While many organizations see positive returns, others may need to address specific challenges and change course along the way to fully realize the potential benefits of digital validation.

Companies should determine in advance: Do they have the right metrics? Are their goals realistic? What are the vulnerabilities they should anticipate? How can they mitigate? And what are the strengths to leverage?

VOICE OF THE INDUSTRY

How does your organization manage expectations around the time and effort required for validation activities?

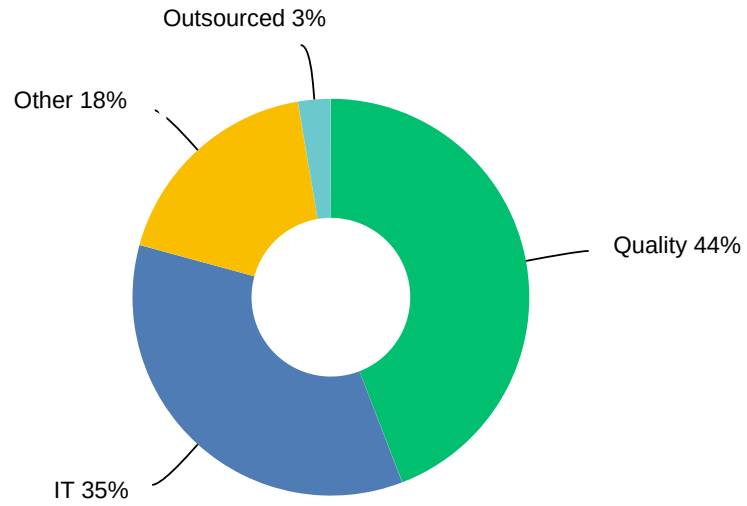
> "**Most of the organization doesn't fully understand the time and effort required for validation.** We often have to push back when project teams expect us to compress our validation timeline. For example, if we quote two weeks for validation, they sometimes assume it can be done in two days if their design runs over. We have to firmly remind them that the quoted time is necessary to ensure thorough and effective validation."
>
> **— Senior Validation Manager, Global Medical Equipment Manufacturer, U.S.A**

Management of Digital Validation Systems Within Organizations

The data reveals how different functional groups within organizations own and manage digital validation systems, and that is **primarily between Quality and IT** (see chart below).

Digital Validation Management Within Organizations

Which functional group within your organization does or would "own" and "manage" the digital validation system? Please select one.



n = 188

Most organizations (44 percent) have the **Quality department** managing the digital validation systems. This is likely because quality assurance plays a critical role in ensuring that validation processes meet regulatory standards.

- A substantial portion of organizations **rely on IT** to manage these systems (35 percent). This makes sense as digital validation systems require technical expertise for implementation, maintenance, and troubleshooting.
- A notable percentage of organizations have other **unspecified departments** managing their validation systems (18 percent). This could include **specialized teams or hybrid groups combining quality, IT, and operational functions.**
- A small fraction of organizations **outsources** the management of their digital validation systems (three percent), possibly to leverage external expertise or reduce internal workload.

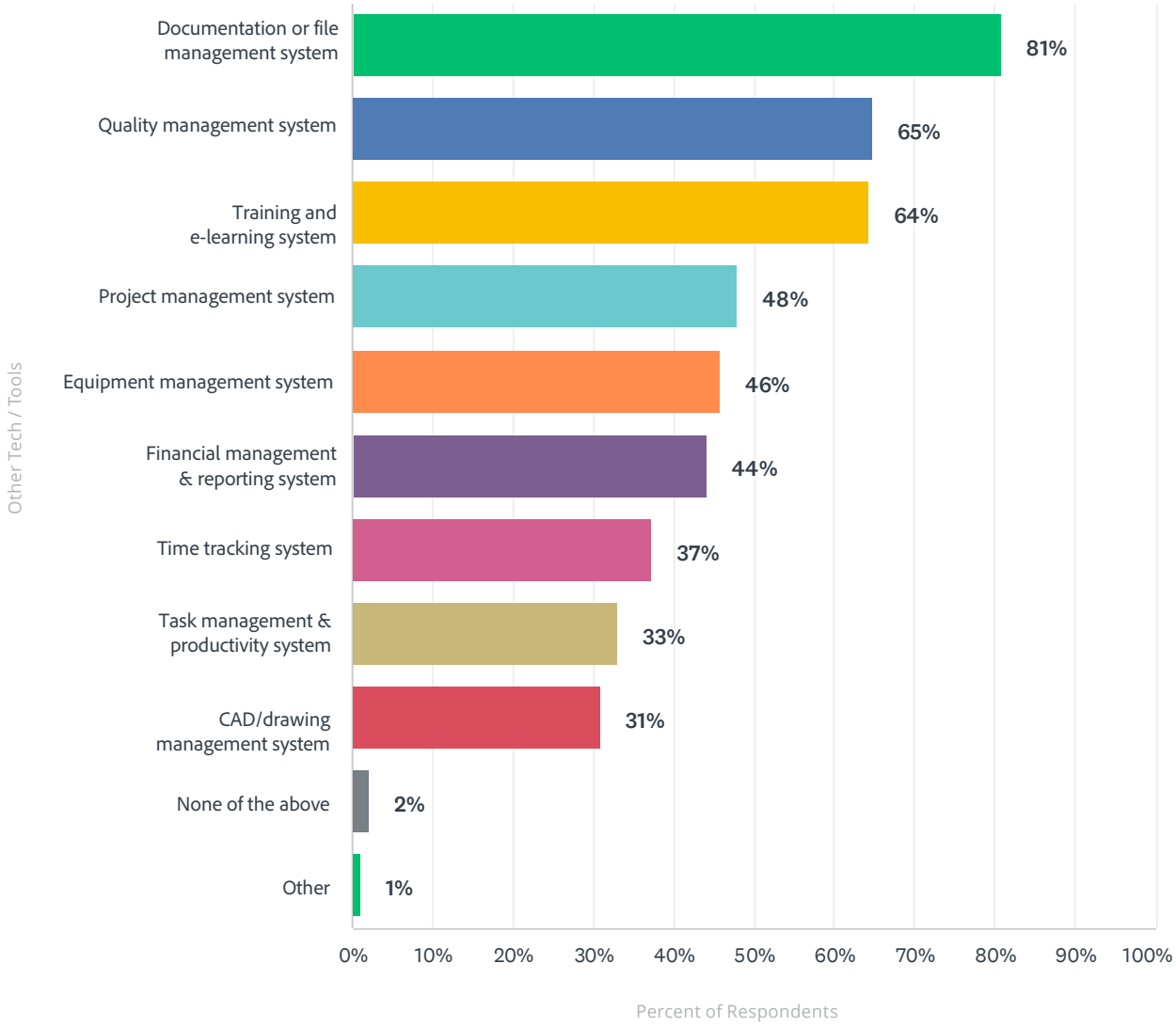
Understanding these trends can help organizations optimize their validation system management by **aligning responsibilities with departmental strengths and improving cross-functional collaboration.**

Other Validation Technologies & Tools Used by Validation Teams

This section focuses on other validation technologies and tools, outside of digital validation systems, used by validation teams (see graph below).

Other Technologies and Tools Used by Validation Teams

Which of the following technologies does your team currently use (if any)? Please select all that apply.



n = 188

Documentation or File Management System (81 percent) is the most widely used technology, indicating a strong emphasis on maintaining organized and accessible documentation.

The prevalent use of **Quality Management Systems** (65 percent) reflects the importance placed on maintaining high standards and ensuring compliance with quality protocols.

Training and e-Learning Systems are also widely used (64 percent), highlighting the commitment to ensuring team members are well-trained and up to date with industry practices.

- **Project Management System (48 percent):** Nearly half of the teams use project management tools, emphasizing the need for efficient project coordination and tracking.
- **Equipment Management System (46 percent):** Indicates a notable focus on managing and maintaining equipment, crucial for operational efficiency.
- **Financial Management & Reporting System (44 percent):** Shows the importance of financial oversight and accurate reporting within teams.
- **Time Tracking System (37 percent):** Reflects the need to monitor and manage time effectively to ensure productivity and accountability.
- **Task Management & Productivity Tools (33 percent):** Used by a third of the teams, highlighting the importance of task organization and productivity enhancement.
- **CAD/Drawing Management System (31 percent):** Essential for teams involved in design and engineering, ensuring accurate and accessible design documentation.

The high adoption of documentation and quality management systems indicates a strong focus on maintaining organized records and ensuring quality standards. Additionally, the emphasis on training and e-learning systems, along with project management tools, highlights the value placed on continuous learning and efficient project execution.

VOICE OF THE INDUSTRY

How is your organization preparing to integrate Pharma 4.0 Into your validation processes?

> **"We're making significant progress in preparing for Pharma 4.0 by identifying critical parameters and determining the necessary management strategies.** We're implementing AI-based vision systems and algorithms that frequently adapt based on the data they collect and analyze.
>
> To ensure compliance while leveraging these advanced technologies, we're developing guardrails. These measures will help us maintain regulatory standards and fully utilize the benefits of AI for process control and enhanced understanding."
>
> **— Validation Department Head, Multinational Healthcare Company, U.S.A**

Section Five: The Future of Validation

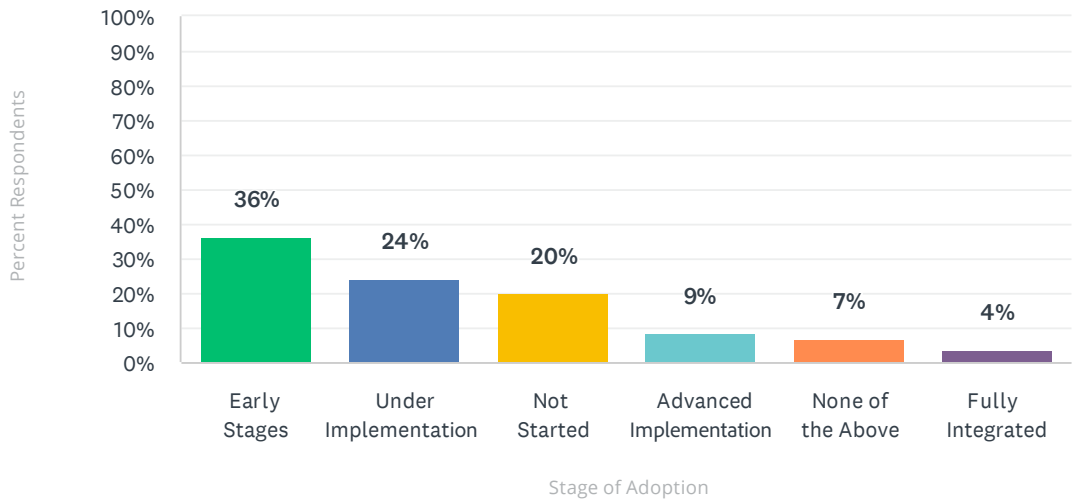
This section provides insights into the future direction of validation practices. It evaluates emerging technologies and methodologies, such as Industry/Pharma 4.0, and discusses the anticipated evolution of the industry along with upcoming challenges.

Current stage of Industry/Pharma 4.0 adoption Within Organizations

The data indicates growing awareness and initial efforts to implement Industry/Pharma 4.0 technologies (see graph below).

Current Stage of Industry/Pharma 4.0 Adoption

How would you describe the current stage of Industry/Pharma 4.0 adoption within your organization? Please select one.



n = 188

A sizeable **portion** of organizations are in the **early stages of adoption** (36 percent). Thirteen percent are fully integrated or actively implementing, and another 60 percent are in the early stages.

Nearly **a quarter (24 percent)** of organizations are **actively implementing** these technologies, showing a commitment to integrating modern practices.

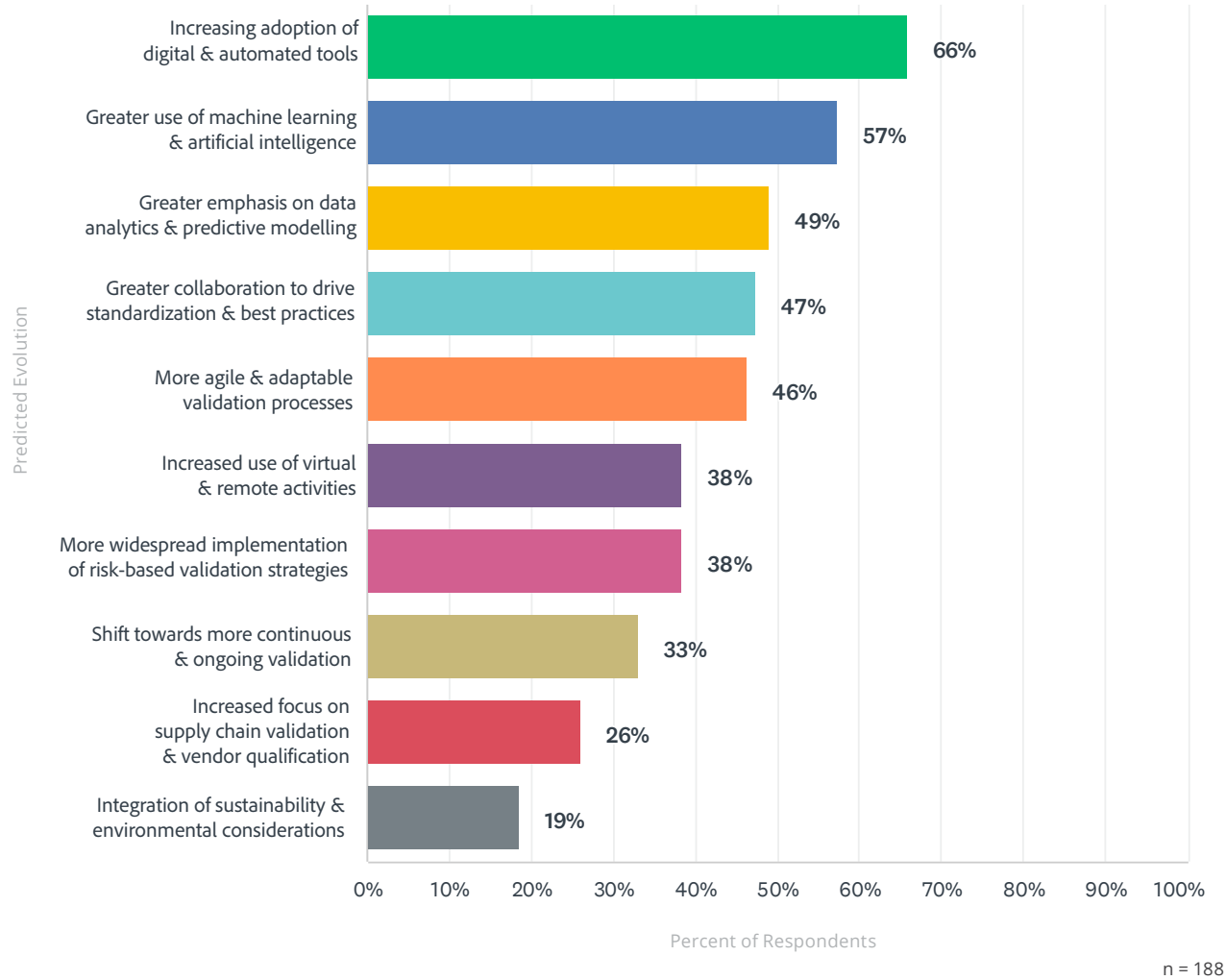
- **One-fifth of organizations** (20 percent) have **not yet started the adoption process**, suggesting potential barriers such as lack of resources or knowledge.
- A **smaller percentage** of organizations are **at an advanced stage** (nine percent), indicating some have made significant progress in their adoption journey.
- Only a **few organizations** (four percent) have **fully integrated Industry/Pharma 4.0**, reflecting the complexity and time required for complete adoption.

Evolution of the Validation Industry Over the Next Five Years

The data reflects various trends anticipated in the validation industry over the next five years, including advancement and adoption of artificial intelligence technologies, other digital tools and data analytics (see graph below).

Predicted Evolution of the Validation Industry

How do you see the validation industry evolving over the next five years? Please select all that apply.



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A sizable majority (66 percent) foresee a **rise in the use of digital and automation technologies**, indicating a shift towards more efficient and streamlined validation processes.

Over half of the respondents (57 percent) expect **an increase in machine learning and AI**, highlighting the growing importance of advanced analytics and intelligent systems in validation. Nearly half (49 percent) emphasize the need for **enhanced data analytics capabilities**.

- **Collaboration and Information Sharing (47 percent):** Many see greater collaboration and information sharing as critical, likely driven by the need for integrated systems and cross-functional teamwork.
- **Agile and Adaptable Validation Processes (46 percent):** Flexibility and adaptability in validation processes are anticipated to be key, reflecting the dynamic nature of the industry.
- **Increased Use of Virtual and Remote Tools (38 percent):** The use of virtual and remote tools is expected to grow, aligning with the broader trend towards remote work and virtual collaboration.
- **More Continuous and Ongoing Validation (33 percent):** There is a shift towards continuous validation practices, ensuring ongoing compliance and quality.
- **Increased Focus on Supply Chain Management (26 percent):** Supply chain management is gaining attention, emphasizing the need for robust validation processes throughout the supply chain.
- **Integration of Sustainability and Environmental Practices (19 percent):** A smaller yet notable portion highlights the integration of sustainability and environmental considerations into validation processes.

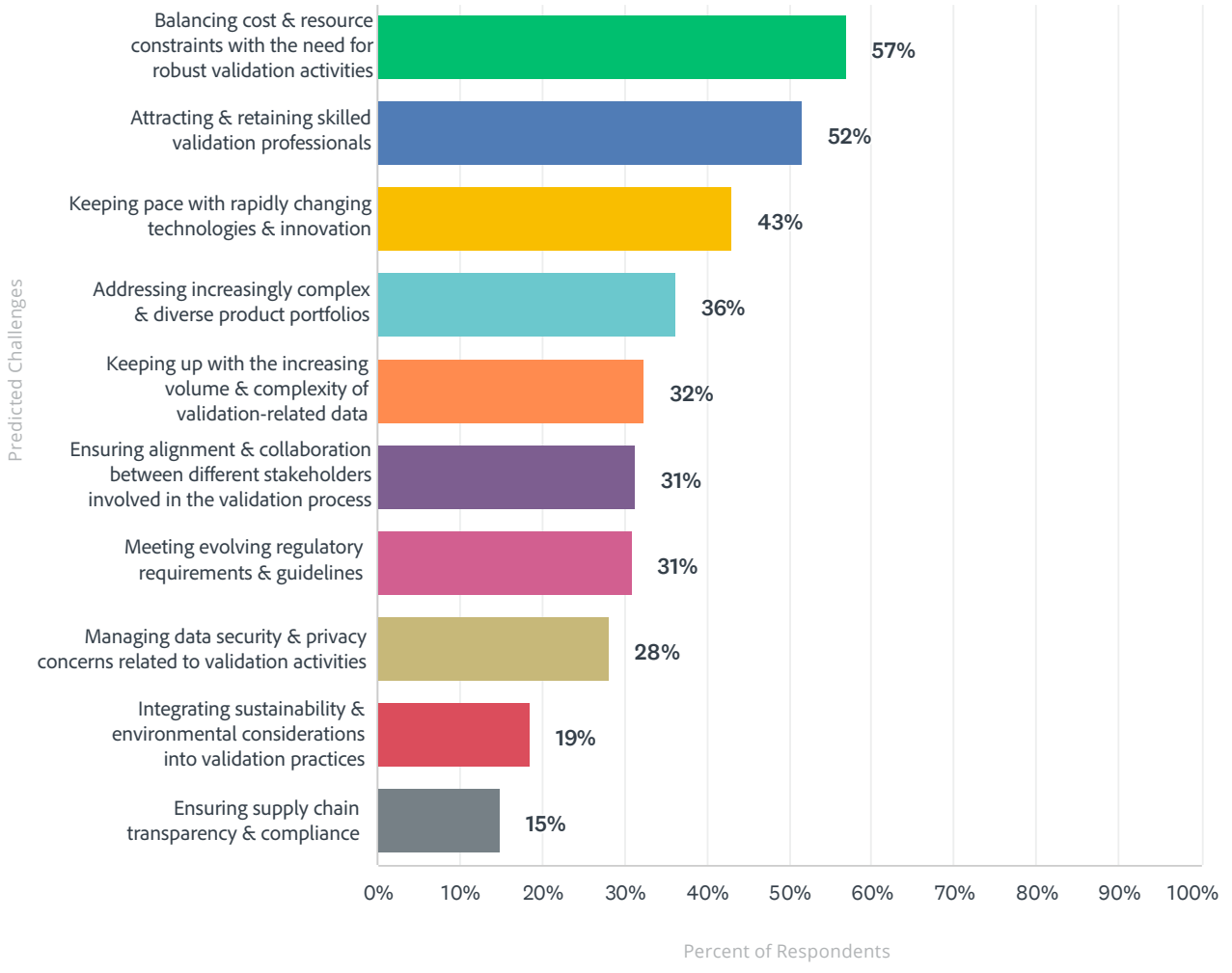
The validation industry is **poised for technological advancements, with a strong emphasis on digital tools, AI, and data analytics.** Collaboration and adaptability will be crucial, along with a growing focus on continuous validation and supply chain management. Sustainability, while less prioritized, is emerging as an important consideration.

Future Challenges Facing the Validation Industry

The data highlights several primary challenges the validation function will face in the future (see graph below).

Future Primary Challenges for the Validation Industry

What are the primary challenges that the validation industry will face in the future? Please select all that apply.



n = 188

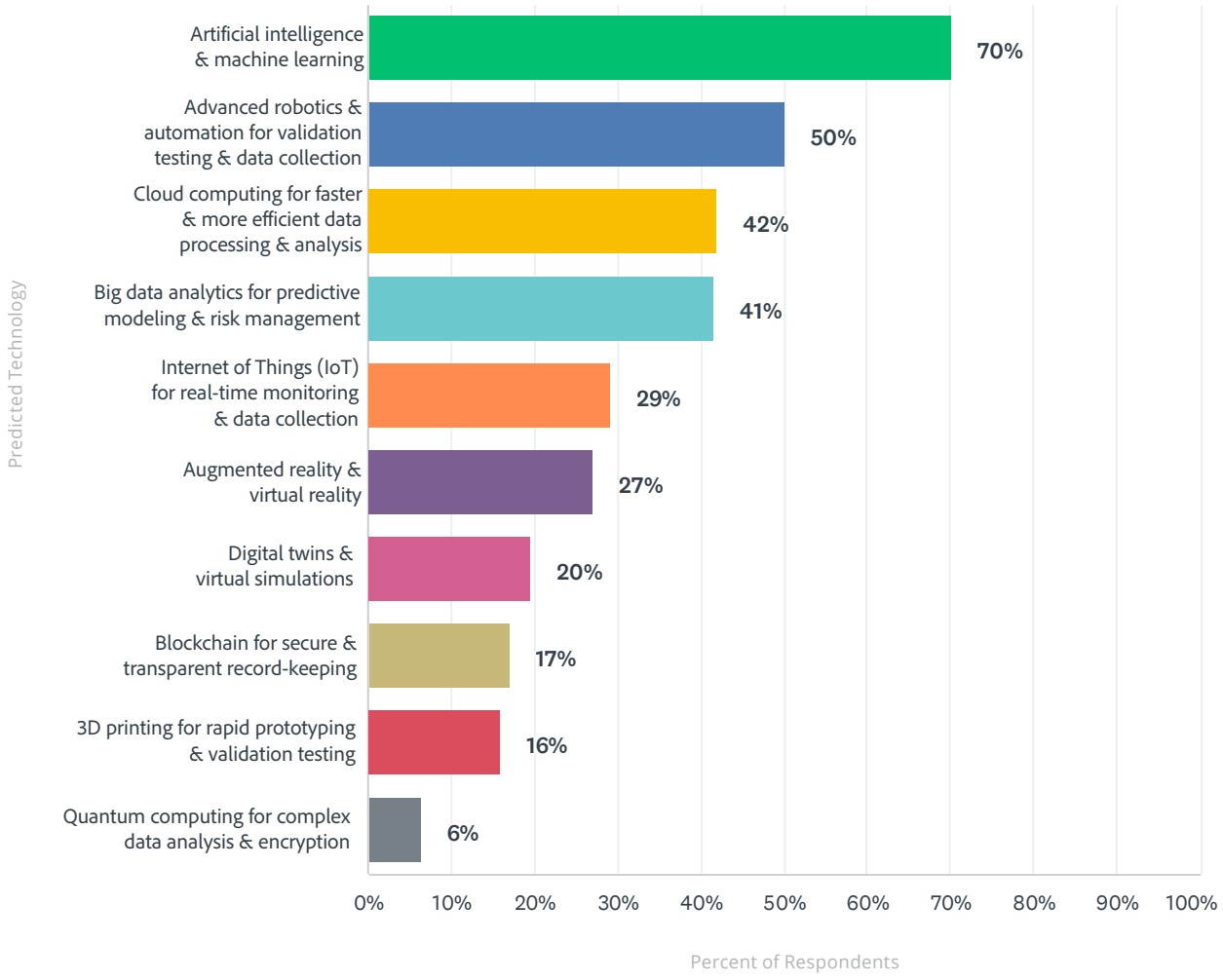
- "**Balancing Cost and Resource Constraints**" (57 percent) is the top challenge, indicating a strong need for cost-effective solutions and efficient resource management.
- "**Attracting and Retaining Skilled Talent**" (52 percent) is a major concern, emphasizing the importance of building a skilled workforce to meet validation demands.
- Staying updated with technological advancements is crucial, as it impacts validation processes and tools, as reflected by 43 percent of respondents selecting "**Keeping Pace With Rapidly Changing Technologies.**"

New Technologies in the Validation Industry

The data reveals which new technologies respondents believe will be used in the validation industry (see graph below).

Predicted New Technologies Used in Validation

What new technologies do you think will be used in the validation industry? Please select all that apply.



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Artificial Intelligence and Machine Learning (70 percent) is the most anticipated technology, while half of the respondents (50 percent) expect significant use of **advanced robotics and automation.** This emphasizes a shift towards more efficient, precise, and automated validation procedures.

- **Cloud computing** (42 percent) is seen as crucial for faster and more scalable validation, facilitating remote access, real-time collaboration, and enhanced data management.
- The importance of **big data analytics** is also highlighted (41 percent): predictive analytics and improved data insights are expected to play an important role in validation.

The validation industry is **poised to enable or adopt a wide range of advanced technologies**, with AI and machine learning leading the way. The adoption of advanced technologies will likely result in more efficient, accurate, and secure validation processes, transforming the industry's landscape.

Trends: New Technologies in the Validation Industry

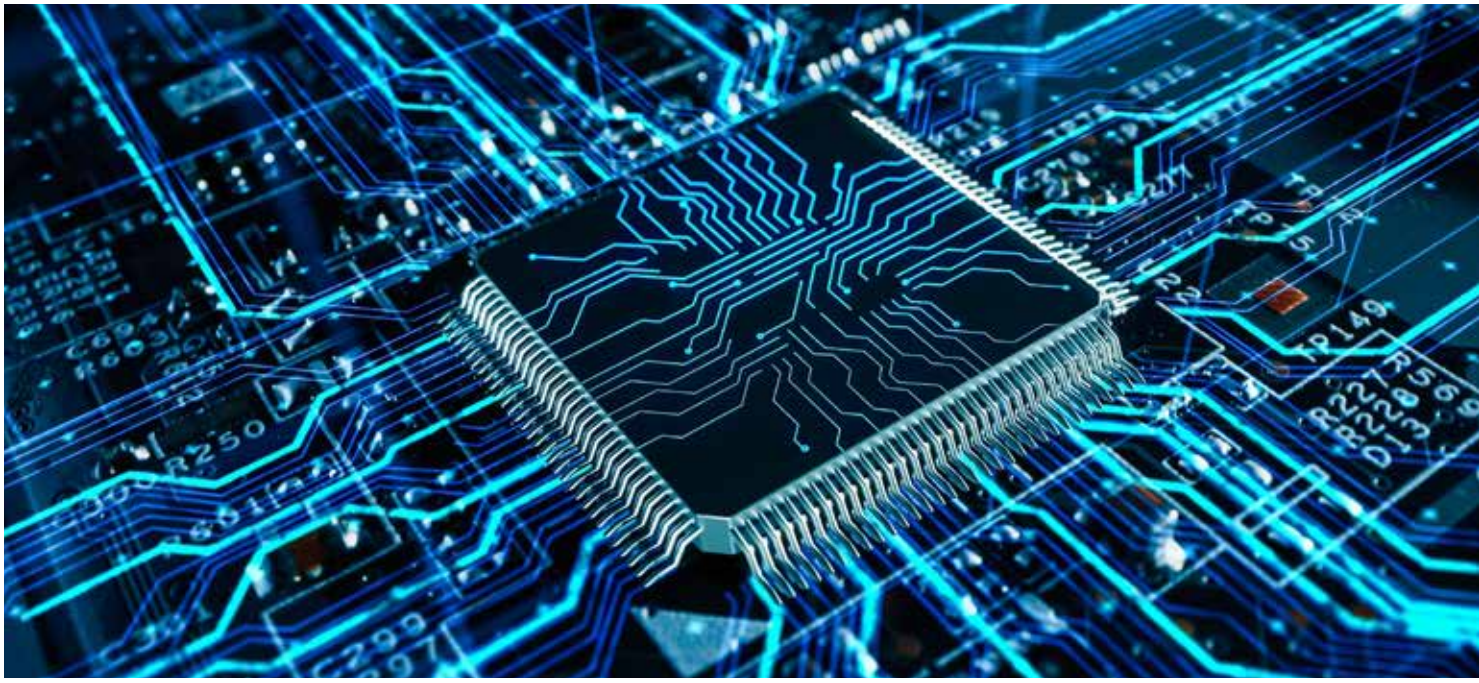
This trend suggests a balanced integration of AI, robotics, and cloud solutions to drive future advancements in validation processes (see table below).*

Trends in New Technologies		
New Technologies	**2023**	**2024**
#1	Artificial Intelligence & Machine Learning	Artificial Intelligence & Machine Learning
#2	Cloud Computing for Faster & More Efficient Data Processing & Analysis	Advanced Robotics & Automation for Validation Testing & Data Collection
#3	Internet of Things (IoT) for Real-time Monitoring & Data Collection	Cloud Computing for Faster & More Efficient Data Processing & Analysis

* Note: There is no 2022 data as this survey question was added in 2023.

The trends from 2023 to 2024 show a continued strong emphasis on **Artificial Intelligence and Machine Learning,** maintaining its top position as the most impactful technology in the validation industry. This underscores its critical role in automating processes, enhancing predictive analytics, and improving decision-making.

- In 2024, **Advanced Robotics and Automation** move up to the second position, reflecting a growing focus on precision and efficiency in validation testing and data collection.
- **Cloud Computing** remains notable but shifts to third place in 2024, highlighting its ongoing importance for data processing and analysis, yet indicating a relative rise in the perceived impact of robotics and automation.



Conclusion

The 2024 State of Validation survey provides a comprehensive view of the validation industry's current status and future direction, highlighting key trends, challenges, and opportunities. Across the five sections — People and Organizations, Validation Programs, Goals and Growth, Industry Change and Digital Transformation, and The Future of Validation — the report underscores the industry's evolving priorities and strategic focuses.

While the cause-and-effect relationship may not be obvious, the industry is dynamic, characterized by evolving regulations, processes, and technology. These changes also enable, encourage, and reward new workforce priorities.

In the **People and Organizations section**, the validation workforce is rich in experience, with 74 percent of 2024 respondents reporting six or more years of validation experience. This depth of expertise is crucial for mentoring and maintaining high standards. However, the data also shows a notable influx of new talent, highlighting the need for targeted training and effective onboarding to equip these newer entrants with necessary skills. The section also reveals diverse team sizes and the prevalence of outsourcing, particularly among larger enterprises, reflecting a strategic approach to managing workload and accessing specialized expertise.

The **Validation Programs section** emphasizes the diverse approaches organizations take in structuring their validation activities, with a significant focus on site-specific and process-oriented structures. The persistent prominence of Computer System Validation (CSV) highlights the critical need for maintaining data integrity and compliance. The adoption of Computer Software Assurance (CSA) processes is growing, driven by the FDA's draft guidance, though there remains considerable room for further adoption. Investment in validation continues to increase, with many organizations increasing the portion of their project budgets to validation activities, underscoring its critical role in ensuring compliance and quality.

Goals and Growth highlights a consistent focus on creating process efficiencies, audit readiness, and harmonizing processes across sites. The data reveals a shift from solely focusing on compliance to also emphasizing operational efficiency and financial performance. This section underscores the industry's strategic priorities, reflecting a mature approach to validation that integrates it more closely with overall business objectives.

Industry Change and Digital Transformation illustrates the shift towards digital validation and remote regulatory audits. An overwhelming majority of respondents are embracing digital solutions, indicating a long-term transformation in the validation landscape. Digital validation systems are valued for their ability to enhance data integrity, continuous audit readiness, and collaboration among stakeholders. However, overcoming resistance to change remains a sizeable challenge. The section also highlights the industry's positive reception of new technologies like AI and machine learning, cloud computing, and IoT, which are expected to further revolutionize validation practices.

The Future of Validation provides insights into emerging trends and anticipated challenges. The adoption of Industry/Pharma 4.0 technologies is still in its early stages, with many organizations engaged in initial research and pilot projects. The data points to a future where digital and automated validation tools will become increasingly prevalent, driving greater efficiency and collaboration. However, balancing cost and resource constraints, attracting and retaining skilled professionals, and keeping pace with rapidly changing technologies are identified as primary challenges.

In conclusion, the 2024 State of Validation reveals a **dynamic industry that is adapting to technological advancements and evolving regulatory landscapes.** The consistent focus on process efficiencies, audit readiness, and harmonization of processes highlights the strategic integration of validation with broader business goals.

The shift towards digital validation systems and the adoption of new technologies signals a transformative period for the industry, promising enhanced efficiency, compliance, and collaboration. However, addressing resource constraints and ensuring a skilled workforce will be crucial for sustaining these advancements.

The insights from this report provide a valuable roadmap for validation professionals navigating this evolving landscape. By addressing these challenges and leveraging new technologies, organizations can enhance their validation processes, ensure compliance, and achieve operational excellence.

2025 State of Validation

Thank you to all who participated in the 2024 State of Validation survey and report.

If you are a validation professional, we encourage your participation in the 2025 State of Validation survey. In 2025, we aim to continue to increase the number of sectors and total participation overall, expand subgroup analysis and track year over year change.

Your expertise and insights are essential for driving our industry forward.
Sign up to participate in the 2025 State of Validation survey now.

SIGN UP NOW ›

About the Author

Jonathan Kay is a trusted advisor to life sciences and digital health companies. Jonathan has supported the successful development, launch, and commercialization of dozens of biotech and pharmaceutical therapies, medical devices, diagnostics, and vaccines to address unmet needs in cancer, cardiovascular disease, infectious disease, rare disease, and more. He founded the consultancy Health Market Experts, LLC, with a mission to advance new technologies that save and improve lives and expand access, equity, and value. He does that by helping clients understand complex landscapes through market research and market strategy.

In 1999, Jonathan co-founded one of the first online medical market research firms, helping to digitally transform that industry. That firm was acquired by the Interpublic Group. Subsequently, he served in leadership roles in the US and globally in WPP agencies, including Kantar Health (now Oracle Life Sciences).

Jonathan earned a B.A. from Cornell and a Master in Public Policy from the Harvard Kennedy School of Government. He is fascinated by the application of artificial intelligence to healthcare and completed studies of “Artificial Intelligence: Implications for Business Strategy” at MIT. Jonathan recently concluded a four-year term as board member of the Brem Foundation to Defeat Breast Cancer and is a volunteer mentor to CEOs of start-ups at the Maryland Tech Council.

Supporting Organizations Acknowledgement

Content contributors included Design Group, Kneat Solutions, No deviation, and PCI.

Barry-Wehmiller Design Group is a fully integrated engineering, construction, automation, and compliance consulting firm serving the life science industry, providing regulatory services including Commissioning and Qualification, Computer System Validation, Quality Engineering and Auditing, and Kneat Implementation, Training, Subject Matter Expertise, and Process Mapping.

Kneat Solutions is an end-to-end validation data management company providing a compliant cloud-based SaaS solution that digitalizes the validation lifecycle, revolutionizing the speed, accuracy, intelligence, transparency, and management of validation. Its digital validation platform, Kneat Gx offers solutions for all validation work processes, streamlining validation data management for highly regulated industries around the world, including eight of the world's Top-10 life sciences organizations and Fortune 500 companies.

No deviation is a patient-centric solution provider for the pharmaceutical and bio tech industry for the Asia and Europe region. Specializing in Process Engineering, Commissioning Qualification Validation (CQV), Digitization and Paperless Validation Solutions, Quality Compliance and Regulatory, and Training and Education.

PCI can help you develop high-performance teams and highly effective organizations. As one of the first with hands-on experience leading the implementation of Kneat Gx, we understand the requirements, challenges, and benefits of implementing an intelligent document management system throughout the appropriate junctures for maximum benefit to our clients.

Appendix

Methodology

The State of Validation survey combines a comprehensive primary market research survey with qualitative in-depth interviews. Conducted globally, the survey methodology ensures a broad and inclusive perspective on the validation industry, capturing insights from various sectors, organizational sizes, and geographic locations.

Participant Demographics and Limitations

The target population is professionals currently employed in a relevant, quality, or compliance function, under which compliance to the following principles, guidelines, and regulations apply:

- ALCOA+
- EU GMP Annex 11, 15
- FDA 21 CFR Part 11, 210, 211
- FDA 2022 Draft Guidance on Computer Software Assurance for Production and Quality System Software
- FDA 2024 Draft Guidance on Conducting Remote Regulatory Assessments
- GAMP 5
- International Council for Harmonisation (ICH)

While the sample is not scientific, it is expansive and provides a window into the validation industry. The sample of 188 participants represents an increase of 23 percent over the 2023 study.

Data Collection

Quantitative Data

Quantitative data was collected via an online survey, which was designed and distributed with assistance from Supporting Organizations and the ISPE's Paperless Validation Subcommittee. The survey was sent to hundreds of potential participants, including the professional networks of supporting organizations, via email.

The audience was qualified to provide insights into these five key topics:

People & Organizations

Industry Change & Digital Transformation

Validation Programs

The Future of Validation

Goals & Growth

The survey was fielded from March 13 through April 10, 2024.

All respondents were credentialed (they work in or adjacent to the industry and were unique respondents) through a screening process to protect the integrity of study findings.

To attract responses, an incentive to complete the survey in the form of a low-value gift card was provided to participants who passed a respondent screening process.

All respondents were required to provide an email address, and consent to the identification of their unique IP address to participate. Respondents who provided a valid email address, from a relevant regulated organization, were included in the results. Any respondent who provided a valid email address, but whose IP address appeared more than once, had their response de-duplicated and their data was removed.

The margin of error is +/-7.1% at a 95% confidence interval and greater for analysis of subgroups. The consistent use of the same methodology as the 2022 and 2023 surveys allows us to monitor trends over time. This consistency enhances the reliability of year-over-year comparisons, providing valuable insights.

Qualitative Data

The research team conducted 10 interviews from April 8 to April 26, 2024, with survey respondents who gave their consent to a follow up interview. The interviews provided depth, description, and narrative experience to supplement the survey data.

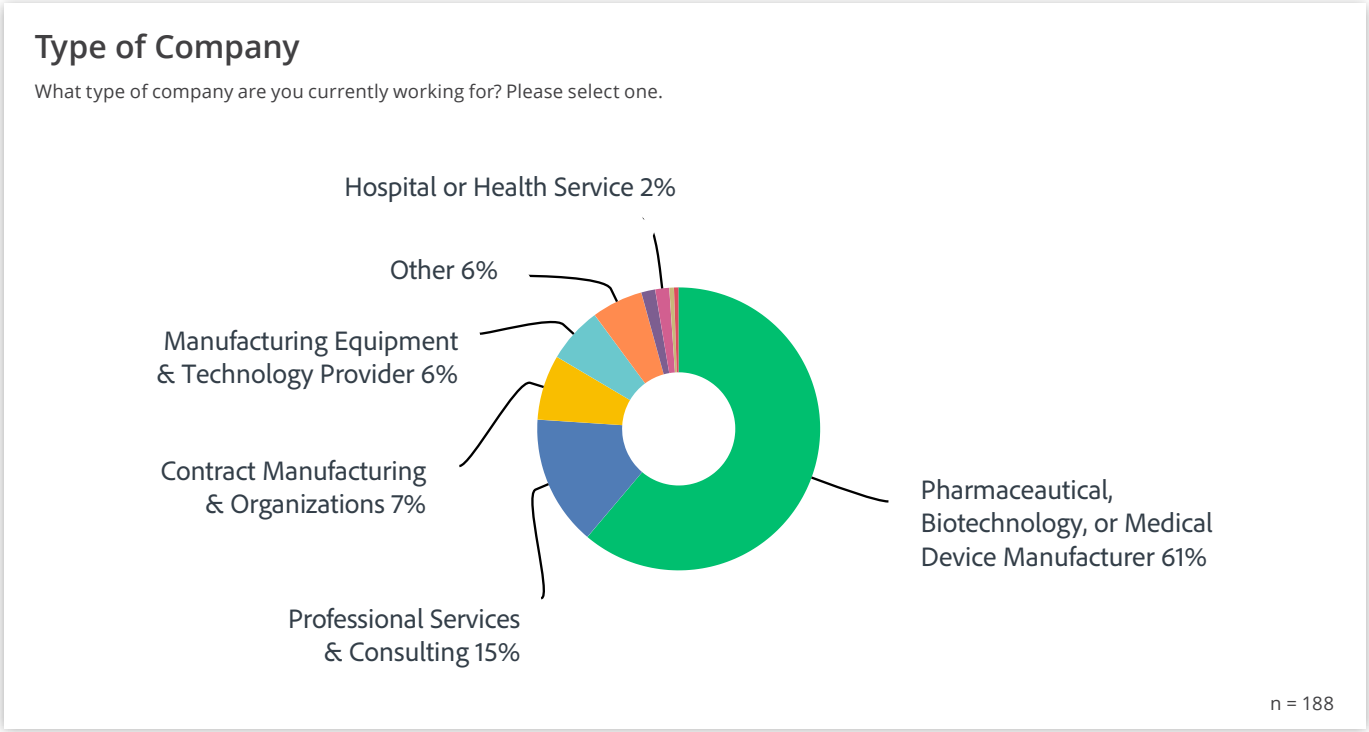
Data Analysis and Question Logic

All survey data was analyzed. Wherever relevant, cross-tabulations have been established to test and identify preferences, patterns, and trends among respondent groups for analysis and discussion purposes.

Respondent Profile

Company Type

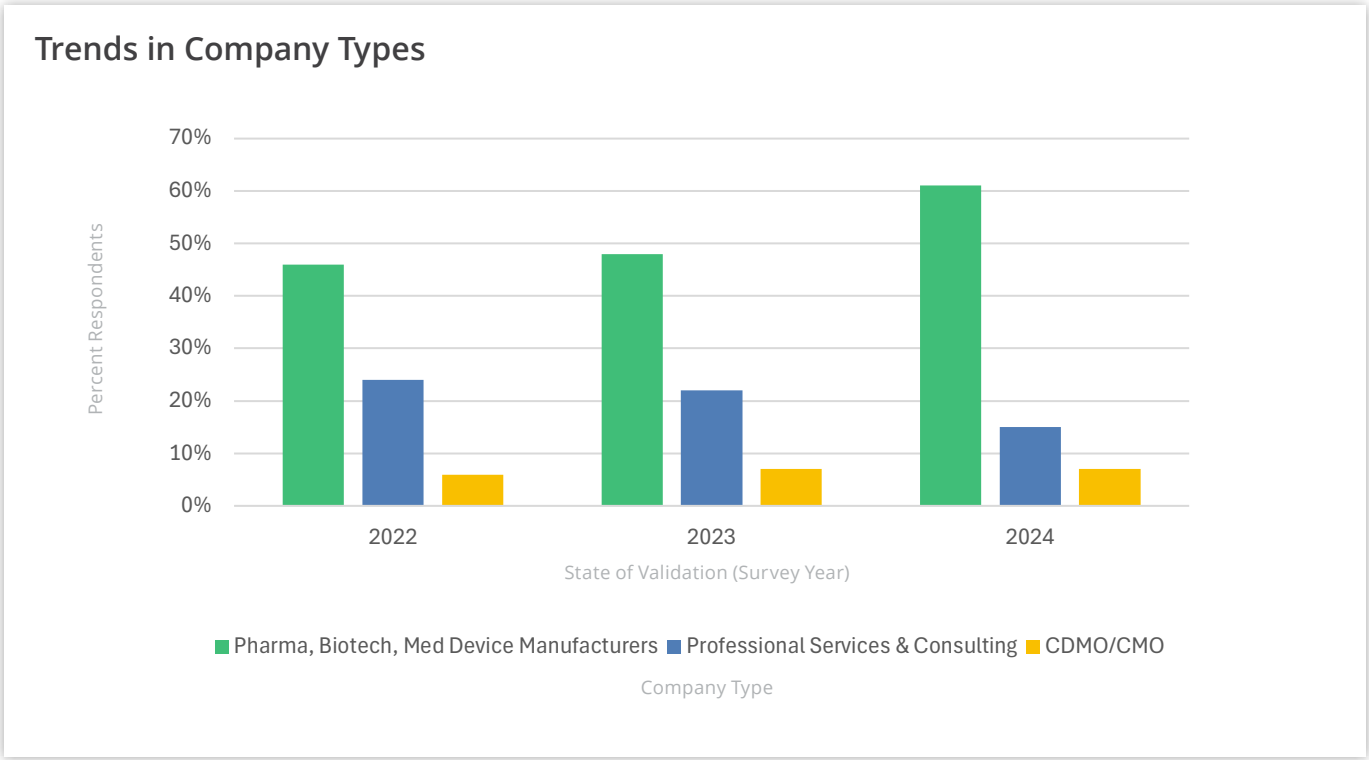
The survey was completed by respondents from eight company types within 12 highly regulated industry verticals (see chart below).



The vertical with the most representation was **Pharmaceutical, Biotechnology, or Medical Device Manufacturer** (61 percent), followed by **Professional Services & Consulting** (15 percent), and **Contract Development & Manufacturing Organization** (seven percent). This distribution is largely similar to the previous two years.

Efforts will be made to include various sectors to capture a comprehensive understanding of the validation landscape in the 2025 State of Validation survey.

Trends: Company Type



- From 2022 to 2024, there has been a notable increase in representation from **Pharmaceutical, Biotechnology, and Medical Device Manufacturers**, rising from 46 percent to 61 percent of total respondents.
- Conversely, **Professional Services and Consulting** saw a decline from 24 percent to 15 percent of total respondents.
- The participation of **Contract Development and Manufacturing Organizations (CDMO/CMO)** remained stable at around seven percent.

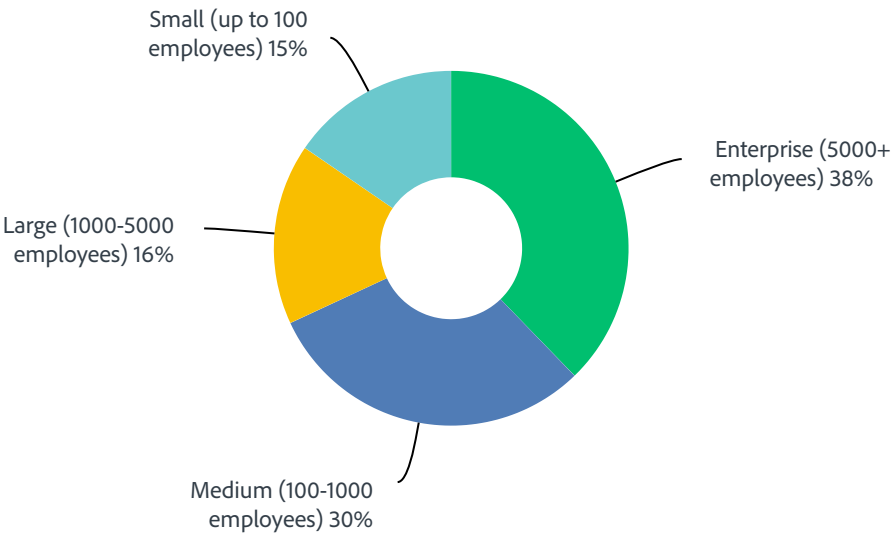
This shift indicates a growing focus on validation within manufacturing sectors, emphasizing the critical role of these industries in the validation landscape.

Organization Size

The sample included professionals from a range of sizes (see chart below).

Size of Organization

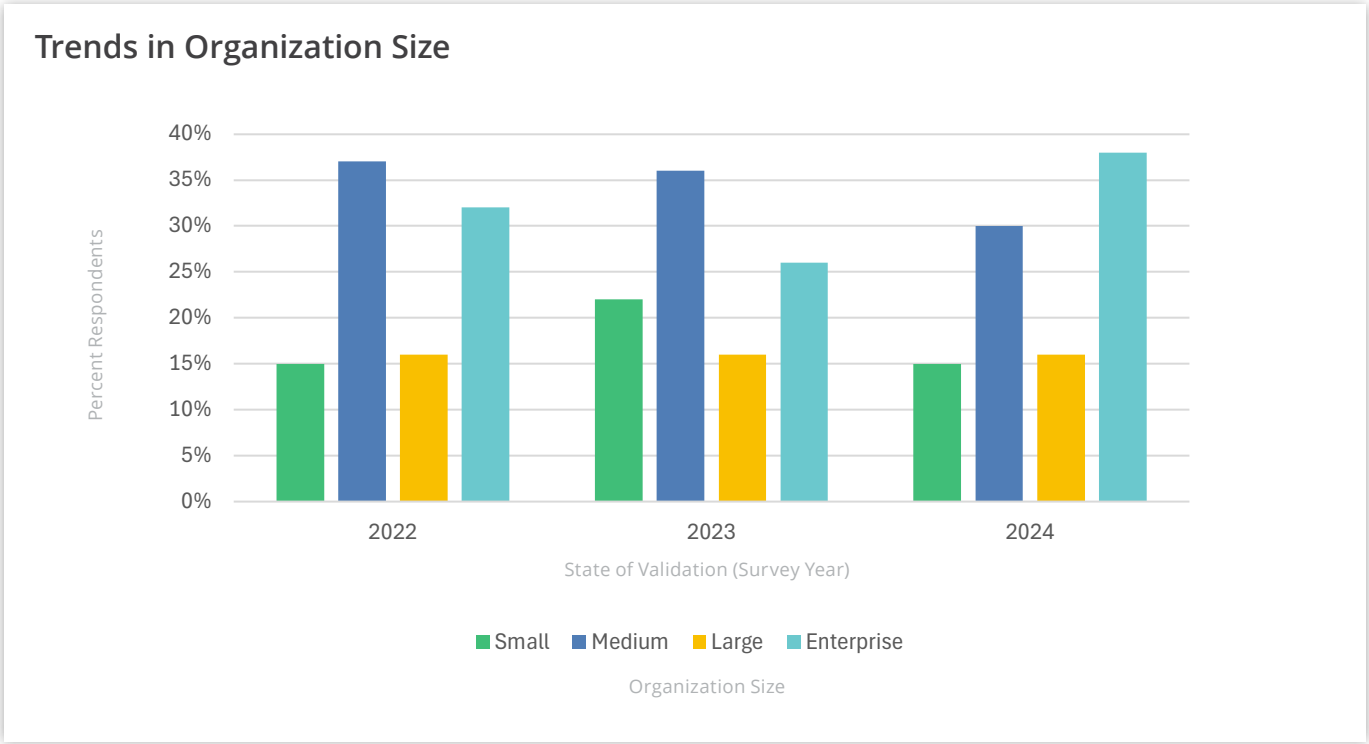
What is the size of your company? Please select one.



n = 188

- Fifteen percent of respondents are employed by **small organizations** with fewer than 100 employees.
- Another 30 percent work for **medium-sized organizations**, which have 100 to 1000 employees.
- Sixteen percent are with **large organizations** that have 1,000 to 5,000 employees.
- Thirty-eight percent are part of **enterprise-level organizations** with over 5,000 employees.

Trends in Organization Size

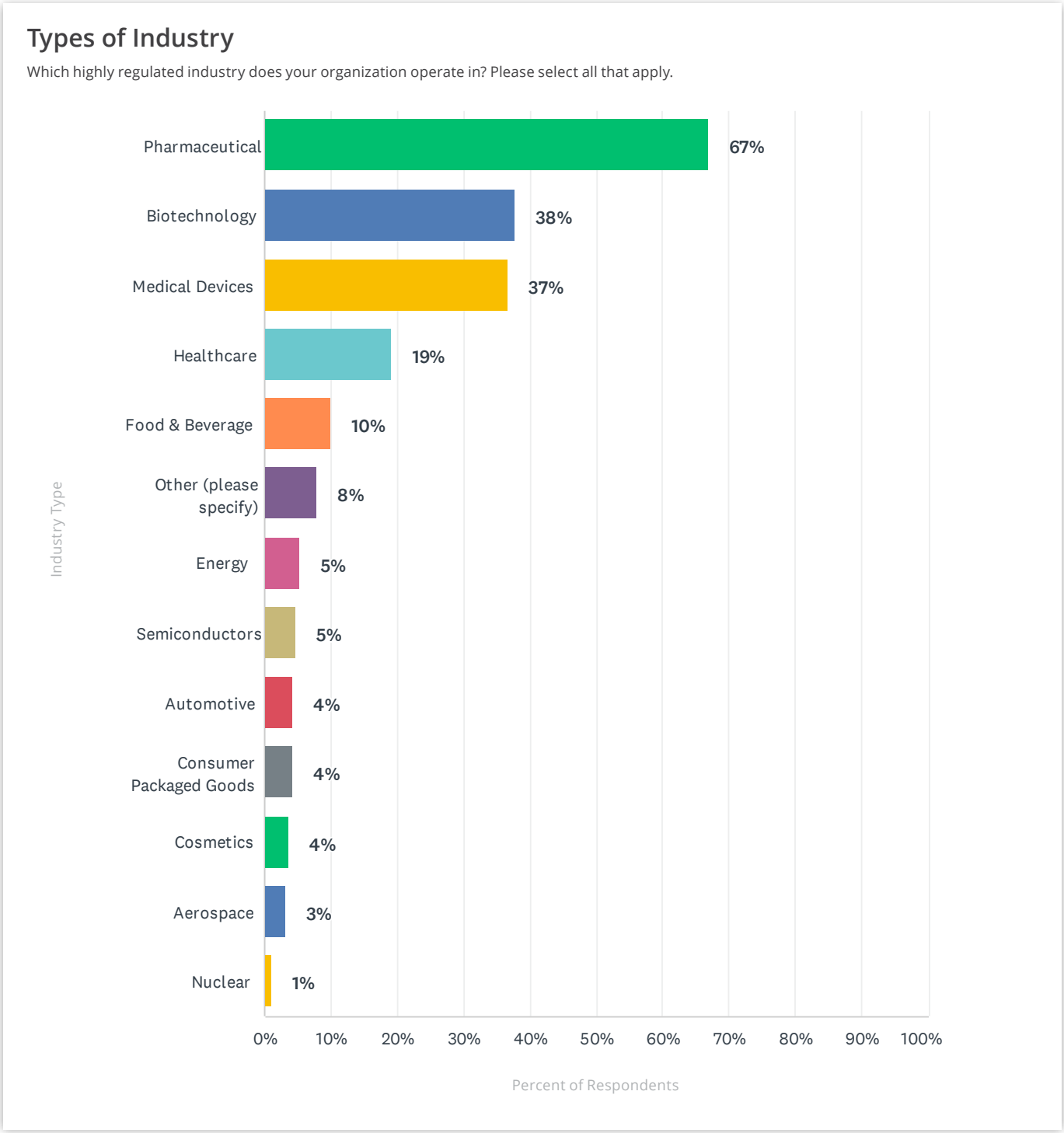


- The percentage of participants from **small organizations** returned to 15 percent, reflecting a decrease from the previous year.
- The representation from **medium-sized organizations** continued its decline, dropping to 30 percent, while **large organizations** maintained a stable 16 percent.
- Conversely, there was a sizeable increase in respondents from **enterprise-level organizations**, rising to 38 percent.

Understanding the needs of organizations of different sizes remains crucial. **The industry's landscape is constantly evolving, and it is important to provide tailored resources and support to all types of organizations.** Engaging large and enterprise-level companies while addressing the unique challenges faced by small and medium-sized businesses will be key to fostering balanced industry growth.

Industry Type

The sample included professionals from a range of industry types (see graph below).



Overall, industry participation remained consistent and included professionals from both primary manufacturers and secondary service or product providers. The 2024 survey saw 12 industry verticals represented, spanning from Pharmaceutical to Automotive, Aerospace, Food and Beverage, and Consumer-Packaged Goods.

"Other" industries represented included "Machine Supplier, Vendor," Manufacturing, Computer-Related," "Engineering Databases and Security," "Toxicology Test," "Cancer Screening," and "Pharmaceutical Transportation."

Geography

Fifty-nine percent of 2024 respondents were based in the U.S. Other areas represented included Singapore (five percent), India (five percent) Ireland (five percent), Germany (four percent), Canada (three percent), and the UK (three percent).

Trends: Geography

In both 2023 and 2022, the country with the highest level of participation in the survey was the U.S., maintaining a dominant position with 66 percent each year (see table below).

Trends in Geographical Representation			
Country With Highest Level of Participation	**2022**	**2023**	**2024**
#1	USA (66%)	USA (66%)	USA (59%)
#2	Ireland (6%) & Canada (6%)	India (9%)	Ireland (5%), Singapore (5%), & India (5%)
#3	India (3%)	Singapore (5%)	Germany (4%)

Meanwhile, emerging players like India have shown notable growth, moving from three percent in 2022 to nine percent in 2023, and maintaining a strong presence at five percent in 2024, alongside Ireland and Singapore.

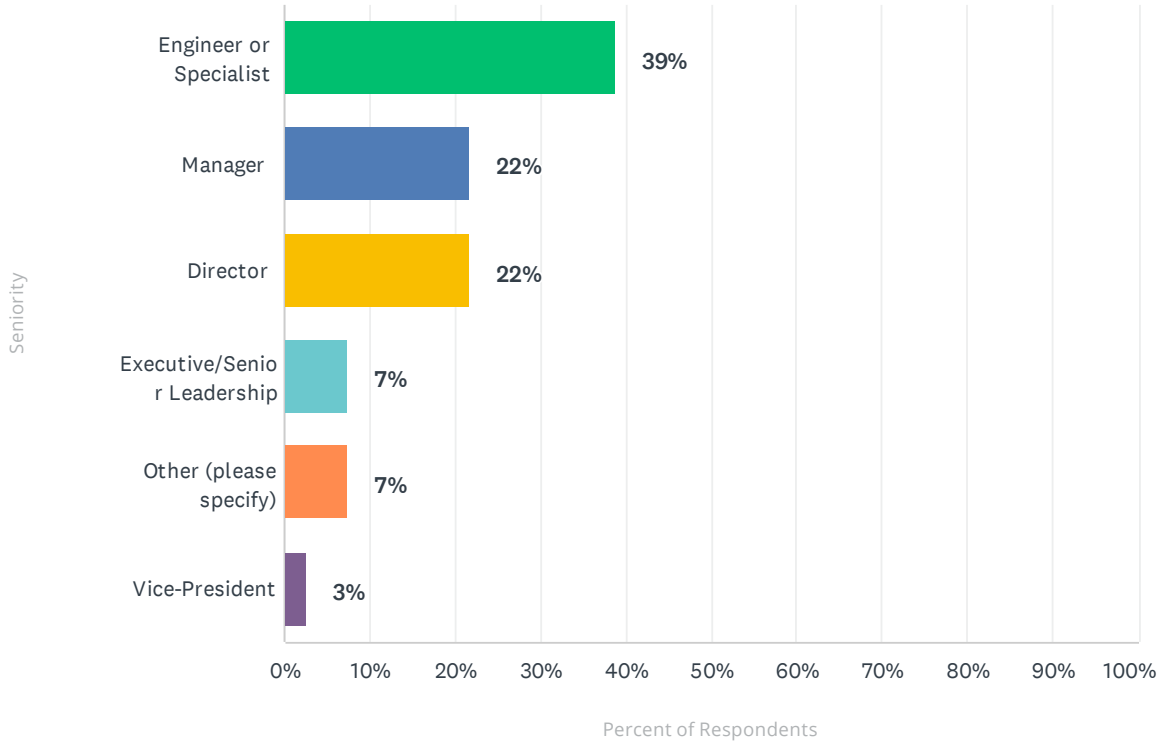
This highlights the **diverse and expanding landscape of validation expertise globally**, emphasizing the importance of international collaboration and cross-border understanding.

Role Seniority

The sample included professionals from a range of seniorities (see graph below).

Seniority

How would you define your current role's position in the organization structure? Please select one.



n = 188

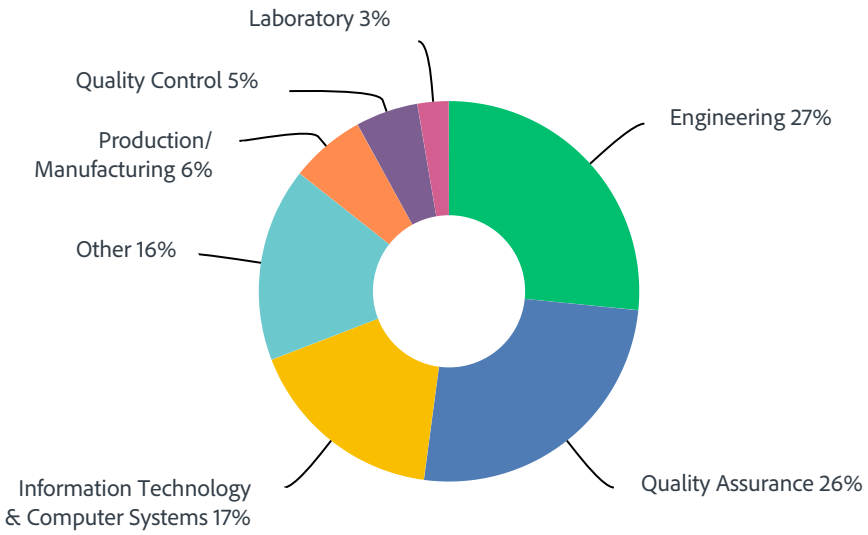
- The data indicates the largest group of respondents, 39 percent, identify as **Engineers or Specialists**, suggesting a strong technical focus within participants.
- **Managers** and **Directors** each represent 22 percent of respondents, indicating a balanced presence of middle management and leadership roles.
- Additionally, **Executive/Senior Leadership** and **Other** categories both account for seven percent.
- **Vice-Presidents** make up the smallest group at three percent, highlighting a relatively small executive representation.

Job Function

The sample included professionals from a range of functions (see chart below).

Job Functions

How would you define your job function? Please select one.



n = 188

The data illustrates that although participation in 2024 declined slightly, **Engineering** remains the most represented of all the functions (27 percent), followed by **Quality Assurance** (26 percent), indicating a strong emphasis on these functions within the organization.

- **Information Technology & Computer Systems** also play an important role, comprising 17 percent of the respondents.
- **Quality Control** (five percent), **Production/Manufacturing** (six percent), and Laboratory (three percent) roles are less represented, suggesting these areas might be more specialized or have smaller teams compared to the more dominant functions of Engineering and Quality Assurance.
- The "**Other**" category accounts for 16 percent, reflecting a diverse range of additional roles.

Job Function	Number of Respondents
Product Management	1
Regulatory Affairs & Quality Assurance	1
Validations & Manufacturing Software	1
Business Consulting	1
Regulatory	1
Executive Role	1
CQV Consulting	1
Management	1
Finance	1
Sales/Marketing	2
Consulting	1
Validation	7
Kneat Rollout	2
Technical	1
Quality Validation	1
Computer Systems Validation	1
C&Q, CSV	1
Commissioning, Qualification Validation Consultant	1
Toxicologist	1
Validation, Calibration, Quality Engineering	1
Public Health Research	1
CSV & QA	1
Manufacturing Science & Technology	1

n = 31

2024 “Other” Functions

Organizations can support these other functions by providing **specialized training, mentorship,** and **career development programs**. Promoting **cross-functional collaboration** can **improve communication, foster innovation**, and lead to more **robust validation outcomes.**

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