

REGASK

A Market Snapshot

The 2025 State of Regulatory Affairs and Compliance Report

A look at organizations' AI adoption and
biggest challenges heading into 2025



Executive Summary

2025 is set to be an active year for regulations. The rise of AI adoption, personalized medicine, gene therapy advancements, reliance on real-world evidence, data privacy and security concerns, and other trends will impact the life sciences regulatory landscape. Organizations in the consumer product sector will also see heightened regulatory activity as food supply, safety and sustainability continue to become top concerns. We're also coming out of a **historic year for global elections^[1]**, and the new governments formed will lead to regulatory changes in many countries.

These developments are driving significant regulatory complexity. Are organizations prepared to navigate this challenge?

To answer this question, RegASK surveyed 145 regulatory affairs professionals, senior leaders and C-suite executives from the life sciences and consumer products industries. The 2025 State of Regulatory Affairs and Compliance Survey Report reveals that many senior leaders are increasingly concerned about their organization's ability to manage the growing regulatory complexity and the risk of missing critical requirements. These concerns are driven by the serious consequences of non-compliance, which can negatively impact the company's stock price and earnings per share (EPS).

RegASK's report also suggests that while some organizations are investing in AI technology and resources to manage this dynamic landscape, there's still much more progress to be made.

1. Koh, E. (2023, December 28). The Ultimate Election Year: All the Elections Around the World in 2024.

Retrieved from <https://time.com/6550920/world-elections-2024/>

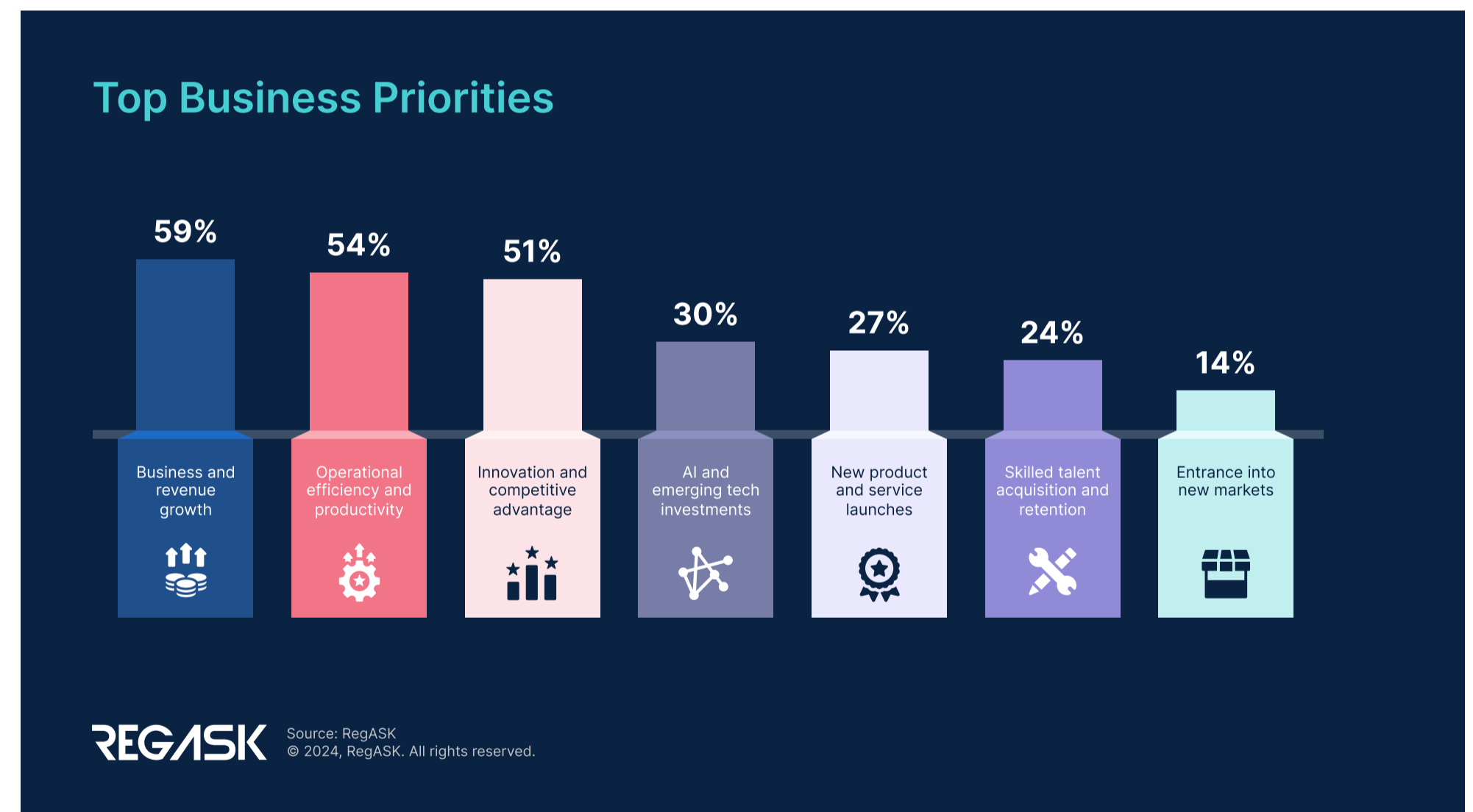
In the past year alone, 62% of regulatory affairs professionals report an increase in the number of regulations and requirements they must meet. Yet only half (53%) of regulatory affairs professionals noted an expansion of internal and external resources to help navigate the regulatory landscape. The lack of growing resources increases the risk of non-compliance and could threaten business priorities.

Revenue growth, for example, is, not surprisingly, senior executives' number one priority (59%) over the next 12 months. Innovation and competitive advantage (51%) and operational efficiencies and productivity (54%) follow closely behind.

Regulations directly impact these strategic priorities, posing risks to innovation, market access, financials, growth, and competitiveness. However, regulatory activity won't slow down soon. Twenty-seven percent of senior executives that RegASK surveyed anticipate regulatory risks will have the biggest impact on businesses in 2025. A [recent Protiviti survey^{\[2\]}](#) found that heightened regulatory changes and scrutiny were in executives' top five risks for 2024 and will still be there in 2034, which suggests regulatory and non-compliance risk will continue to be a top area of concern for at least the next decade.

“Missing a regulatory requirement or taking action too late can halt critical business initiatives, such as research and development or product launches. Enhancing your capability to effectively stay ahead of relevant regulations and properly integrate this in your workflow can keep your organization competitive and accelerate growth,” said Caroline Shleifer, RegASK's Founder & CEO.

This means that strengthening the organization's ability to effectively and proactively manage the evolving regulatory landscape and new requirements is key for success and staying competitive.

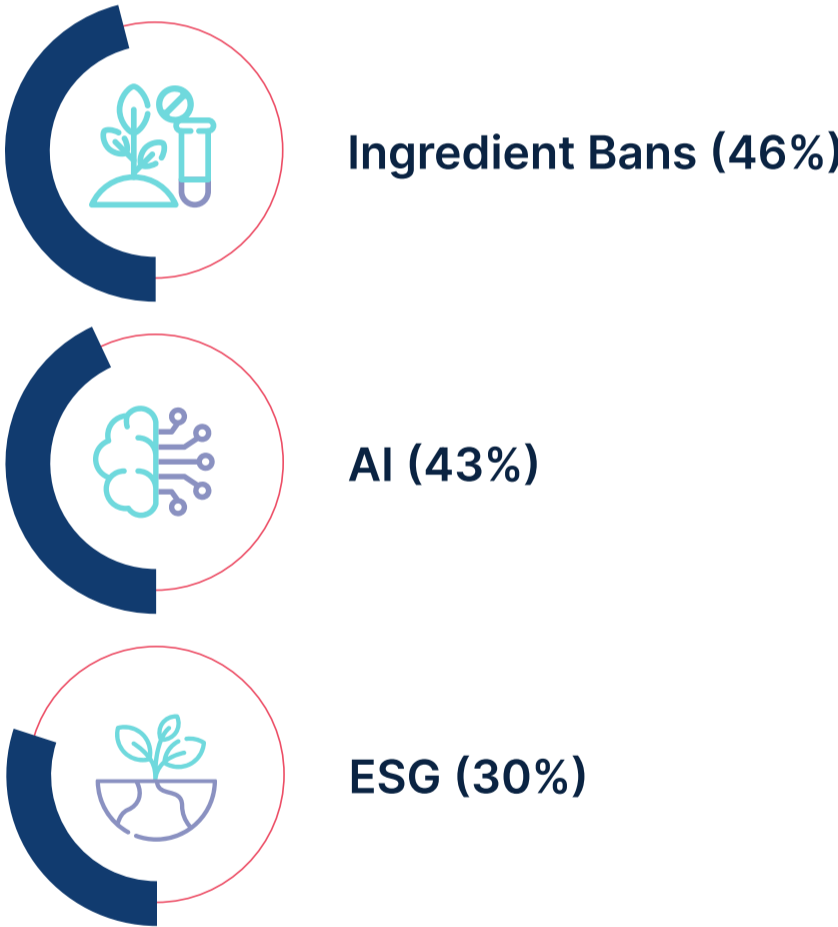


2. (2024). Executive Perspectives on Top Risks for 2024 and 2034. Retrieved from <https://www.protiviti.com/us-en/survey/executive-perspectives-top-risks>

Looking Ahead: Regulations on the Rise

RegASK's data reveals that the scope of regulated topics is expanding, driven by rapidly advancing technology and growing stakeholder expectations for responsible business practices. This has introduced new areas, such as AI and ESG regulations, to an already complex regulatory landscape.

In 2025, senior executives anticipate an increase in regulations related to

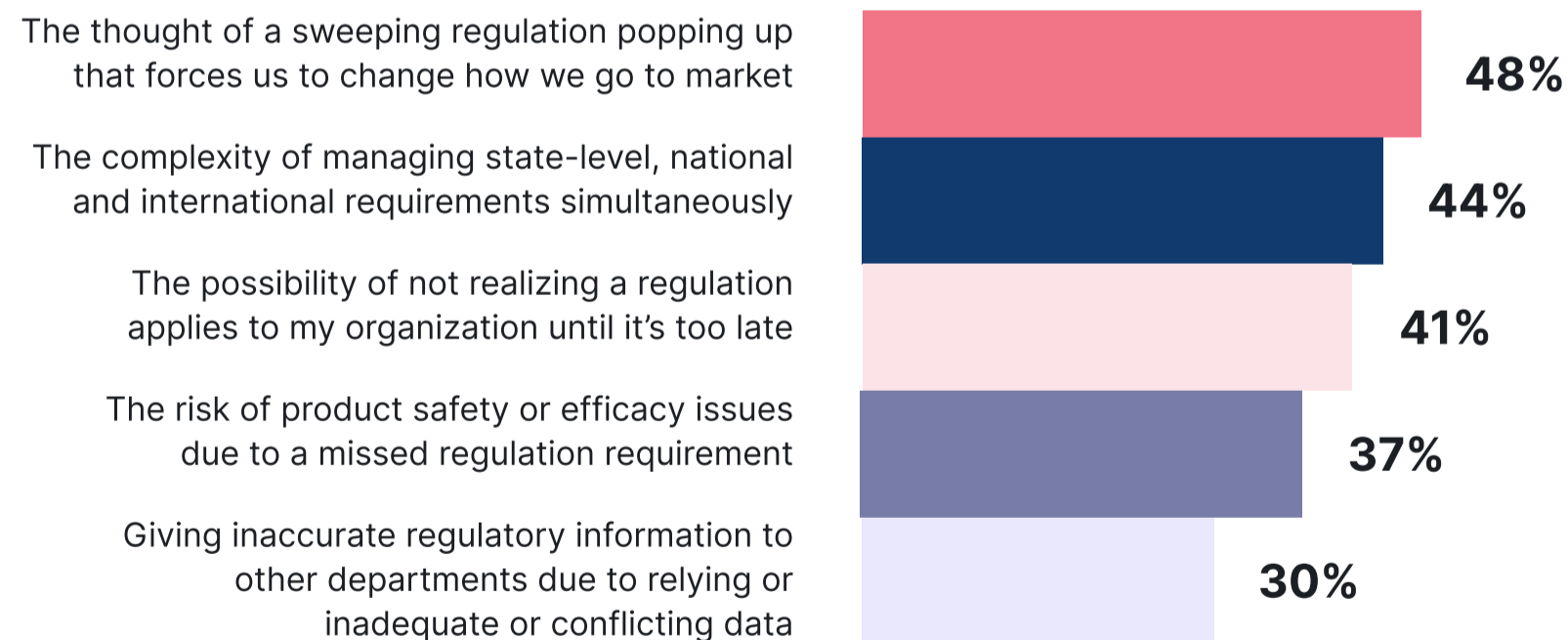


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The fast-changing regulatory landscape is creating intense pressure on regulatory affairs teams, with many concerned about their capacity to manage this complexity and keep pace with regulatory demands successfully. Nearly half (48%) of senior regulatory leaders (VPs, heads, and C-levels in regulatory roles) lose sleep over the possibility of a sweeping regulation that would require a shift in the organization's market approach. Additionally, 41% worry about realizing too late that a new regulation applies to them, and 44% are concerned about the challenge of navigating state, national, and international requirements simultaneously.

What Keeps Senior Regulatory Affairs Leaders Up at Night?



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These fears are illustrated by the fact that 38% of regulatory affairs professionals (directors, managers, and specialists in regulatory affairs roles) express they feel at risk of non-compliance because they may be unaware of specific regulations. Additionally, nearly a third (31%) say they are currently at risk of non-compliance due to the complexity of requirements and uncertainty about the actions needed to address them.

Nearly half (42%) of regulatory affairs respondents at all levels (specialist through C-level) admit that their organization has already missed a regulatory requirement.

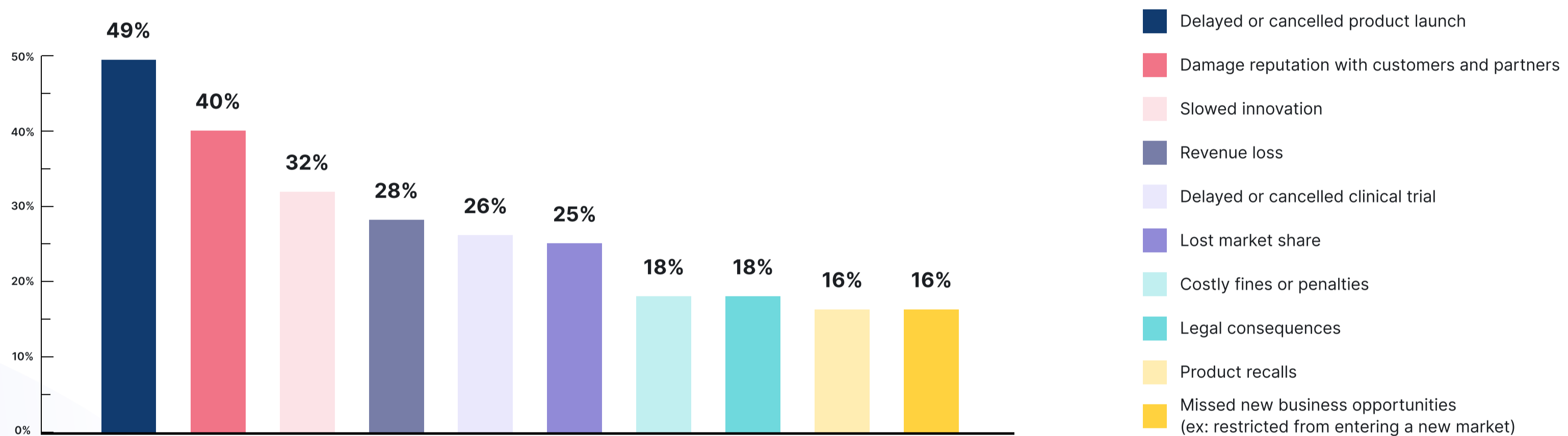
This is a serious signal for the C-suite, boards and other decision makers, as the inability to effectively manage regulatory requirements directly impacts financial performance, reputation and operations. Such oversights make achieving growth targets and key objectives (OKRs) increasingly difficult.

Only 63%
of **senior regulatory affairs leaders trust** that their organization fully complies with its regulatory requirements and that the data used to assess compliance is accurate.



Regulatory affairs respondents who reported missing regulatory requirements noted impacts such as delayed or canceled product launches (49%), damage to reputation with customers and partners (40%), hindered innovation (32%) and delayed clinical trials (26%). Organizations also often face substantial financial losses from these consequences. For instance, a delayed clinical trial can cost between **\$600,000 to \$8 million per day**^[3].

Consequences of Missing a Regulatory Requirement



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These outcomes - and the high rate of missed requirements - aren't surprising given that a significant percentage of regulatory affairs respondents still rely on traditional tools such as email, spreadsheets, and search engines to monitor and manage regulatory requirements (26%), or continue to manually check online databases (25%). Only 17% of respondents to date have adopted regulatory intelligence platforms to streamline this process.

3. Lawrence CE, Bruce VM, Salberg LD, Edwards T, Morales C, Palm M, Bernard GR. (2023, September 6). Quantitative assessment of the impact of standard agreement templates on multisite clinical trial start up time. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10565190/#:~:text=Estimates%20of%20the%20cost%20due,a%20potential%20drug%20%5B3%5D>

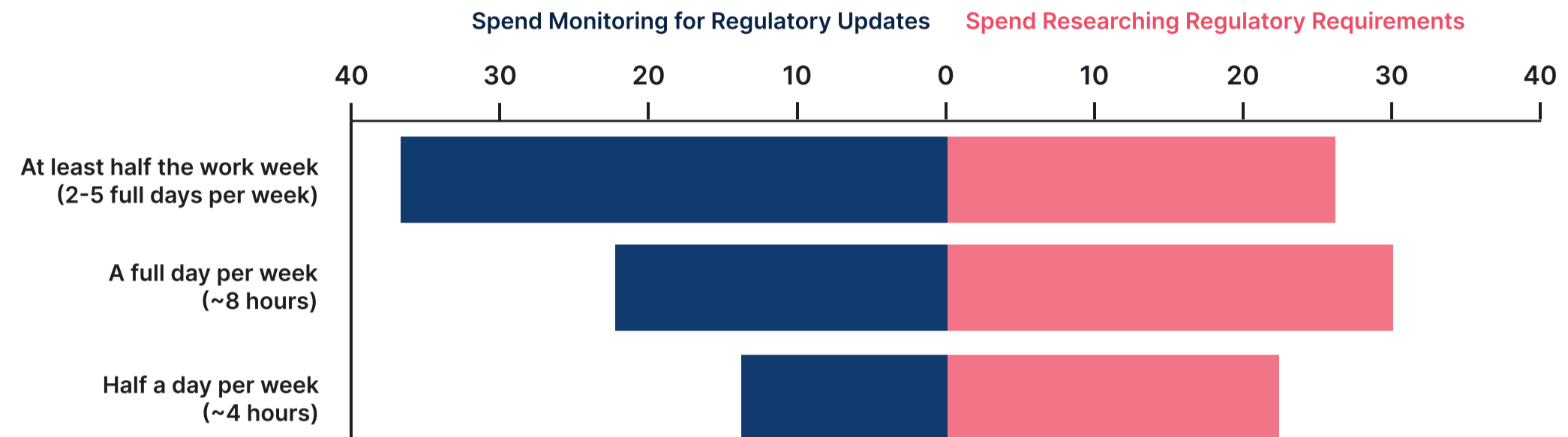


Given the high volume of regulatory changes and the fragmented, manual workflows, there's an undeniable need for transformation.

RegASK's research suggests that for a team of five regulatory affairs professionals, many teams are spending at least 40% of their work week solely on researching regulations - a considerable amount of time for a task representing just a fraction of these teams' broader responsibilities. The time spent equates to at least \$240K per year.

Specifically over half (56%) of managers and specialists in regulatory affairs roles report that their teams spend at least one full day per week, on average, solely researching applicable regulatory requirements. Moreover, 59% indicate that their teams dedicate the same amount of time monitoring regulatory updates. This significant time commitment leads to higher costs, increased risk and missed opportunities for value creation within the business.

Amount of Time Regulatory Affairs Managers and Specialists Collectively



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Regulatory affairs professionals are increasingly looking to technology such as generative AI for support and to streamline these everyday processes. More than half (53%) of those allowed to use ChatGPT have sought its guidance on compliance with specific regulations. However, confidence in AI-generated responses remains low, with only 22% of professionals fully trusting ChatGPT's answers. While RegASK's research focused on ChatGPT, numerous other public generative AI tools are also available to regulatory teams.

These findings point to a clear demand for reliable, enterprise-grade and tailored AI solutions to streamline workflows. Although public generative AI tools are available and could be appealing to professionals for their time savings benefits, using these tools for researching requirements carries risk. Regulatory affairs professionals may base decisions or take actions based on incomplete or inaccurate information. Additionally, these tools often fail to provide sufficient actionable insights to help teams understand how requirements apply to their organization and what specific steps are needed to achieve compliance.



In fact, when asked how the right AI solution could most transform their daily work, regulatory affairs professionals highlighted that AI would be most valuable in summarizing regulatory requirements and adapting them to their organization's specific scope and context (33%). Additionally, professionals noted that AI would be particularly beneficial for answering questions about specific regulations and requirements (32%) and for automatically monitoring and tracking regulations relevant to their organization (32%).

“Our research underscores the vast potential for AI and regulatory intelligence platforms to ease resource-intensive workflows in regulatory affairs and highlights the growing demand for enhanced AI and GenAI solutions. By saving time, regulatory teams could shift focus toward strategic risks, document submissions, and supporting the organization’s top objectives,” added Caroline Shleifer, RegASK Founder & CEO.

AI Adoption: Unlocking Untapped Potential

Currently, 39% of regulatory affairs respondents are using AI. Among them, 68% plan to expand its use due to its clear benefits. Key drivers behind the growing adoption of AI are the enhanced efficiency, improved collaboration, and streamlined workflow management that AI offers.

While 61% of regulatory affairs respondents aren’t using AI today to manage the regulatory landscape, it’s promising that 41% of those companies say they plan to adopt the technology within the next 12 months. This indicates that organizations that took a ‘wait and see’ approach to AI adoption are seeing promise in the technology’s ability to enhance regulatory affairs roles. The findings also suggest that the pace of AI adoption will grow as the use cases for AI in regulatory affairs become even clearer.

Top Use Cases for AI in Regulatory Affairs

- 1 Regulatory intelligence research
- 2 Data collection, curation and analysis
- 3 New and emerging requirements summarization
- 4 Identification of the business impact of regulations
- 5 Identification of innovation opportunities
- 6 Trends identification
- 7 Regulatory guidance analysis
- 8 A “Chat-GPT” like experience

A 2019 RegASK survey highlighted data gathering and information analysis as top challenges for regulatory affairs teams, with a strong need for advanced solutions to accelerate research and anticipate regulatory changes. A lack of mature technology previously hindered significant improvements, but since early last year, advancements in AI have started to bring real solutions to the forefront. These developments promise transformative changes for regulatory affairs, addressing long-standing challenges in data gathering, analysis, and regulatory foresight.

*Based on a separate survey RegASK ran in April 2024

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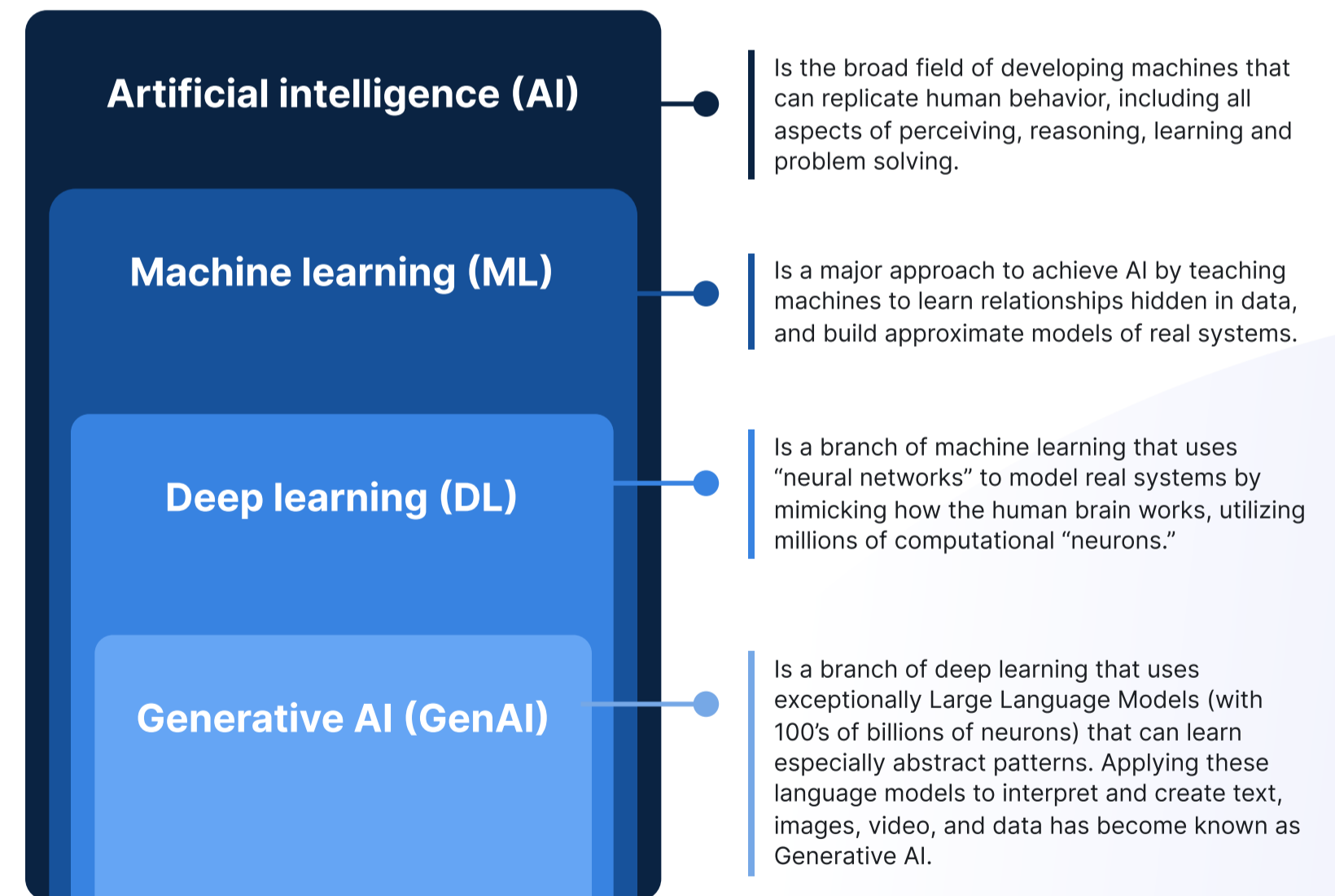


Key challenges facing regulatory affairs teams today include coordinating with other departments to gather compliance information (36%), securing adequate staffing and training for regulatory teams (34%), and efficiently researching regulatory requirements (33%).

AI has the potential to directly address each of these challenges. By streamlining data collection, simplifying compliance research, and facilitating cross-functional collaboration, AI can support already-stretched thin regulatory affairs teams. More broadly, AI can enhance productivity by handling mundane administrative tasks, freeing regulatory affairs professionals to focus on maximizing efficiency and driving innovation. As AI technology advances, it offers a transformative path for regulatory affairs to evolve and meet future demand with agility and innovation.

As regulatory complexity intensifies in 2025 and beyond, organizations that swiftly and strategically embrace AI will be much better equipped to stay on top of the landscape and secure a competitive edge. Our advice: Champion AI adoption and prioritize the right use cases now. With a strong link between effective regulatory compliance and the ability to achieve strategic goals, adopting AI can unlock new opportunities for organizational success.

Decoding Intelligence: AI to GenAI



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Only 20%

of C-Suite executives surveyed say they have complete visibility into the regulatory requirements affecting their business.

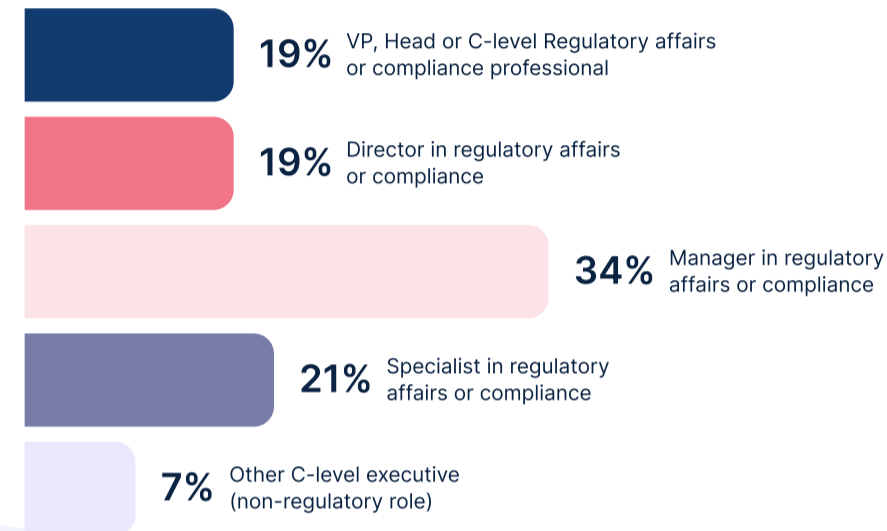
This level of visibility is insufficient for company leadership given regulatory requirements directly impact strategic priorities. AI can help close the gap and maximize the value of organizations' data by providing deep insight into regulatory data and trends. This enables executives to anticipate risks, make proactive, confident, and smart regulatory decisions, and build better compliance strategies.



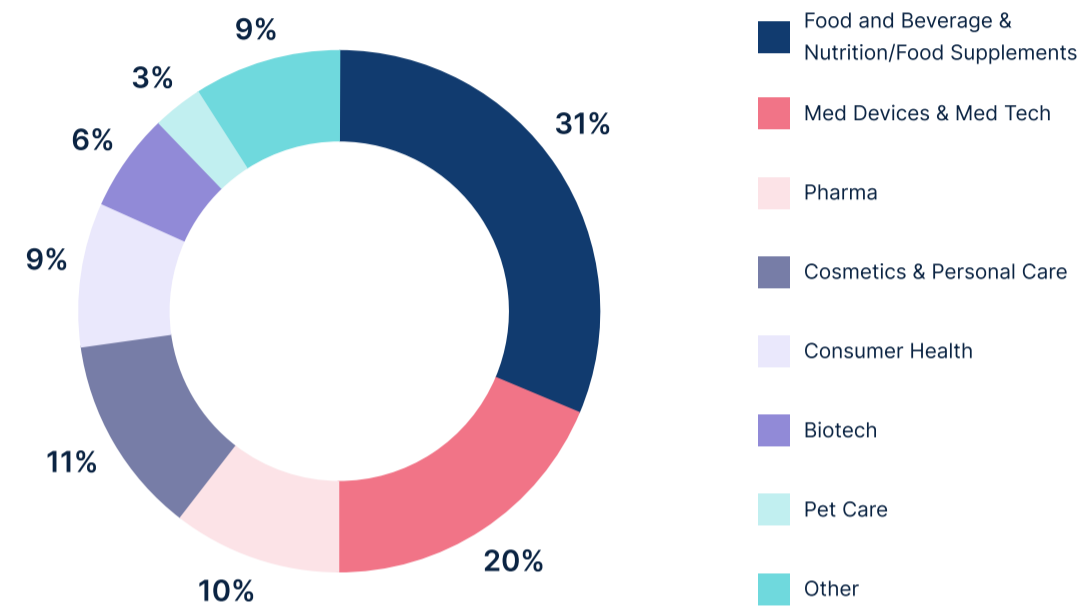
The research reveals several important takeaways for organizations:

- **Regulatory risk is a reality, but the true challenge (and opportunity) lies in how you manage it.** As regulatory demands continue to increase, an organization's ability to handle these requirements more effectively than its peers can create a competitive advantage and propel strategic goals forward. Those who manage regulatory requirements more effectively will discover that it can drive success and innovation. Integrating regulatory risk management into the broader business strategy enables organizations to anticipate challenges and transform them into growth opportunities.
- **Step away from manual processes.** Even the highest-performing organizations can't keep pace with today's dynamic regulatory landscape relying on manual-only processes. The sheer volume of regulatory updates makes it impossible to stay fully informed manually, let alone interpret what each update means for your specific organization. Invest in the right technology now to empower your team before non-compliance hits you. The cost of inaction far outweighs the initial investment in digital transformation.
- **Invest in AI and your team – and do it soon.** AI has the potential to transform regulatory affairs, but success depends on more than technology alone. To maximize impact, integrate AI into workflows, train your team effectively, hire AI-ready talent, and collaborate with the right partner to align AI with your specific needs. Organizations that act swiftly will gain a competitive advantage, while those who lag will struggle to keep pace as the regulatory landscape evolves.
- **Focus on context-driven, tailored Generative AI solutions.** Simply digitalizing a process without addressing its unique challenges offers limited benefits, so working with a partner who can guide you through each step - from identifying your needs to smoothly integrating AI within your workflow is essential. Choose solutions that deliver relevant insights exactly when and where they're needed. For AI to add real value, your team must feel confident using it and trusting the data it provides. By aligning generative AI with your business and regulatory goals, you can improve decision-making, reduce risks, and boost productivity. A context-driven approach to AI will have a much more significant impact than a one-size-fits-all solution.
- **Choose the right vertical-AI partner.** Select a regulatory partner who not only provides the right technology but also deeply understands your industry, AI, regulatory affairs, your pain points and the nuances. The ideal partner will guide you through the complexities of technology and compliance, offering expert counsel at every step and seamlessly integrating into your workflow. Look for a partner who acts as an extension of your team, bringing extensive expertise and a collaborative approach.

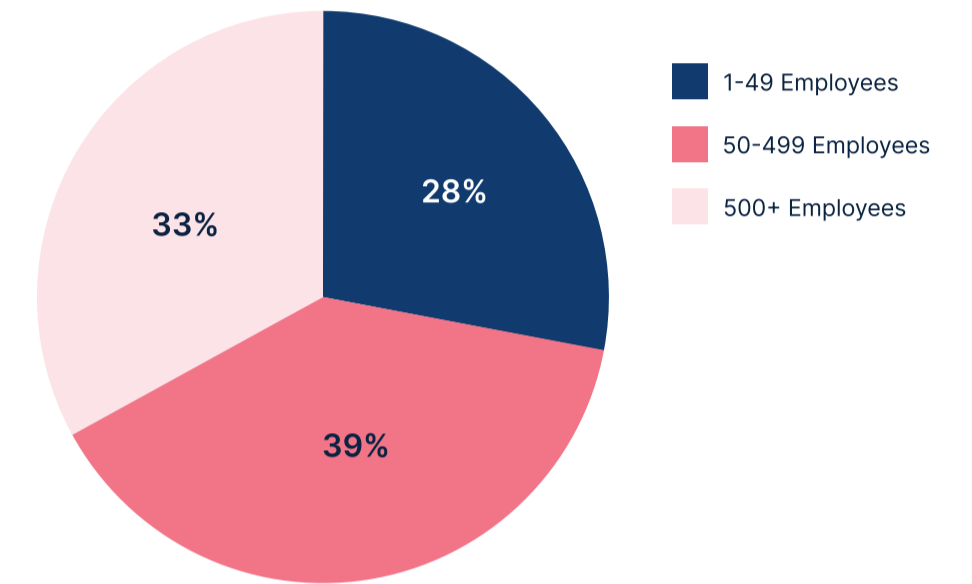
Role



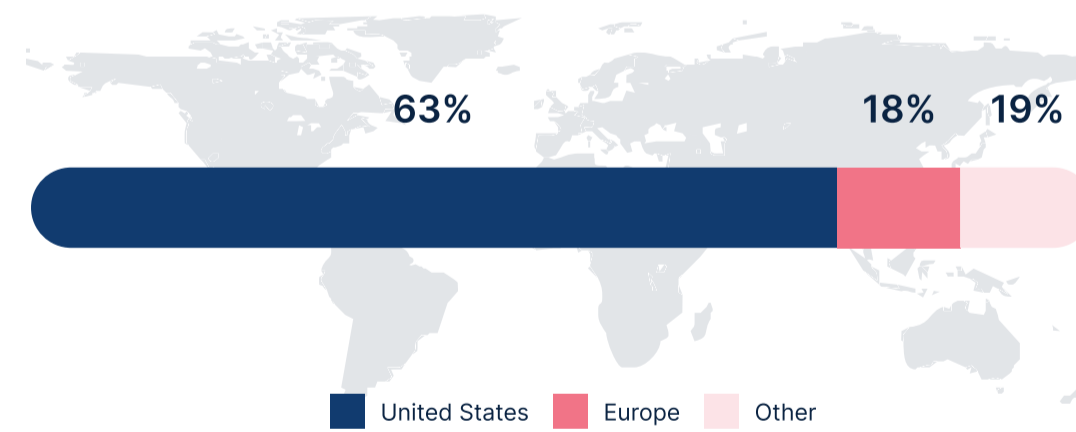
Industry



Company Size



Company Headquarters



REGASK

RegASK is an AI-driven solution enabling end-to-end intelligent regulatory workflow orchestration: automating regulatory intelligence with curated content and actionable insights, smart documentation, and a connected community of over 1,700+ subject matter experts for streamlined regulatory execution globally. RegASK augments Regulatory Affairs teams, combining AI efficiency and community-driven intelligence to streamline compliance across the product lifecycle.

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