

A Market Analysis

The 2026 State of Regulatory Affairs and Compliance Report

Augmented Intelligence:
The New Era for Regulatory Excellence

REGASK



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Executive Summary

In 2026, the speed and volume of global regulatory change are testing the limits of legacy systems and siloed teams.

These cracks are already showing, with more than one third of regulatory senior leaders and operational teams saying their organization missed a regulatory requirement in the last 12 months. In this environment, companies that can interpret and act on new requirements faster will attain approvals sooner, enter markets earlier, and protect revenue more effectively.



This imperative is accelerating the digital transformation of Regulatory Affairs. As regulators themselves adopt AI, structured data, and real-time monitoring, organizations must now keep pace or fall behind. The most forward-looking teams are modernizing fast, integrating intelligence across functions, automating workflows, and deploying Agentic AI to navigate an increasingly volatile regulatory landscape. But this acceleration has an obstacle: alignment. Leadership's vision for an agile, insight-driven future is colliding with the manual, fragmented reality of their frontline teams.

Bridging this gap is now the central challenge for regulatory leaders, and the key to operationalizing AI and achieving regulatory agility.

This year's State of Regulatory Affairs and Compliance report examines what it will take to close it. Drawing on global data and first-hand insights, it explores five forces reshaping the function:

- **The Responsiveness Problem:** Why only a fraction of teams can mobilize within 48 hours, and what delays cost them.
- **The Perception Gap:** How leadership and operational teams see different versions of the same reality, and why that slows transformation.
- **The Structural Friction Point:** Why manual processes and siloed systems hinder the agility organizations urgently need.
- **The AI Shift:** Where adoption is gaining traction, what value early movers are capturing, and why many remain stuck in pilot mode.
- **The Autonomous Future:** How Agentic AI will redefine roles, elevate strategic influence, and transform compliance from gatekeeper to growth driver.

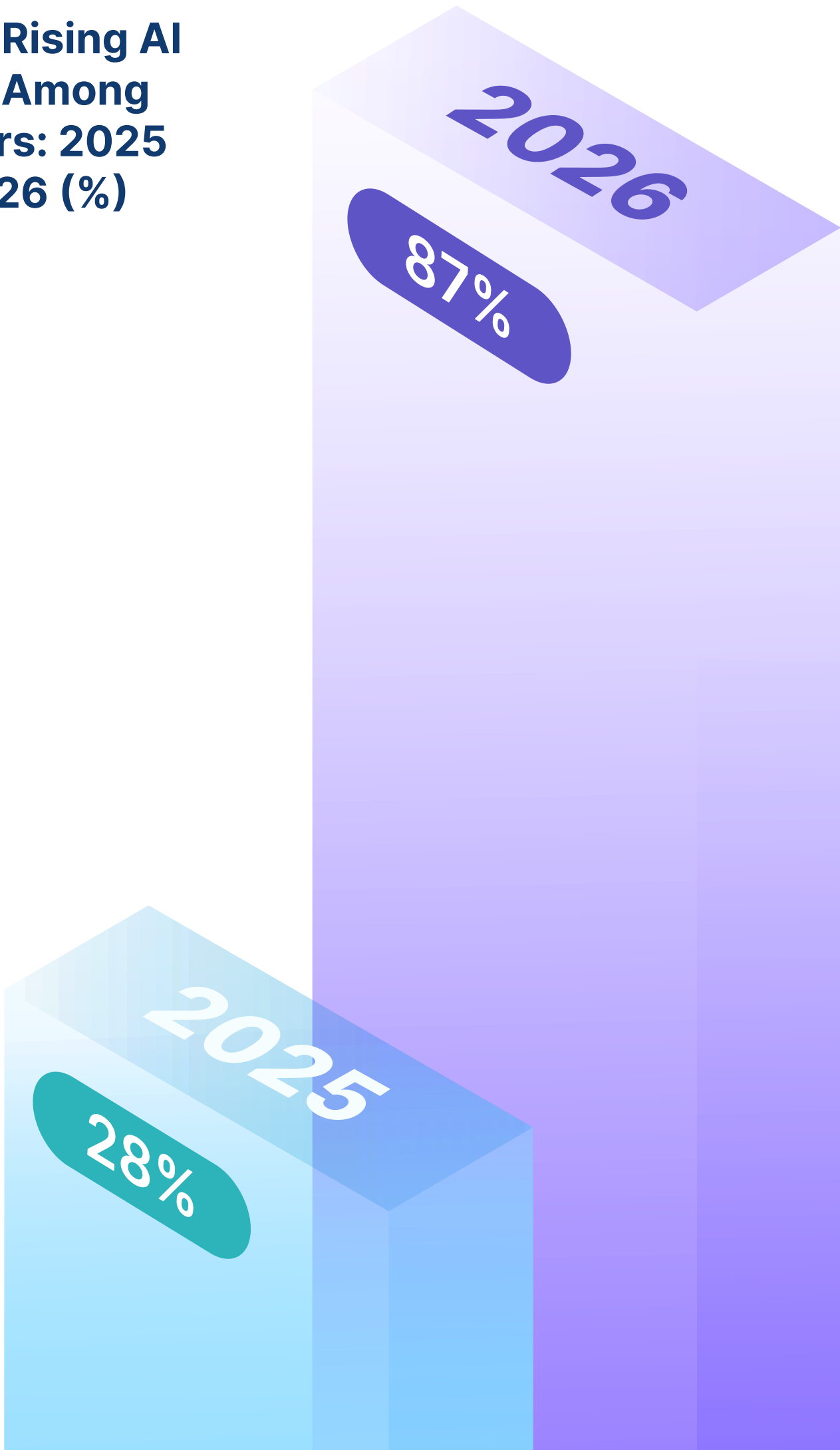
The pursuit for regulatory agility is underway. Those who align vision, data, and technology will set the new standard of regulatory excellence. Those who don't will be left reacting to it.

2025 vs 2026: From Ambition to Activation

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Figure 2:

Sharp Rising AI
Intent Among
Leaders: 2025
vs. 2026 (%)



In Just 12 Months, the AI Conversation Has Fundamentally Transformed

The conversation around AI has fundamentally changed in 12 months. In last year’s report, AI was seen as an emerging opportunity. Today, it is a strategic capability with 87% of senior leaders now using or planning to adopt it within the year, more than double the proportion from a year ago (28%). This momentum is also reflected in the adoption of vertical AI regulatory intelligence platforms, which has risen from 19% to 27%.

However, operationalizing AI remains a complex challenge. AI has long been part of many organizations’ strategic roadmaps, championed at the leadership level, but translating vision into execution takes time. The task ahead lies not in having the ambition to adopt AI, but in translating that ambition into deep, strategic integration across regulatory workflows.



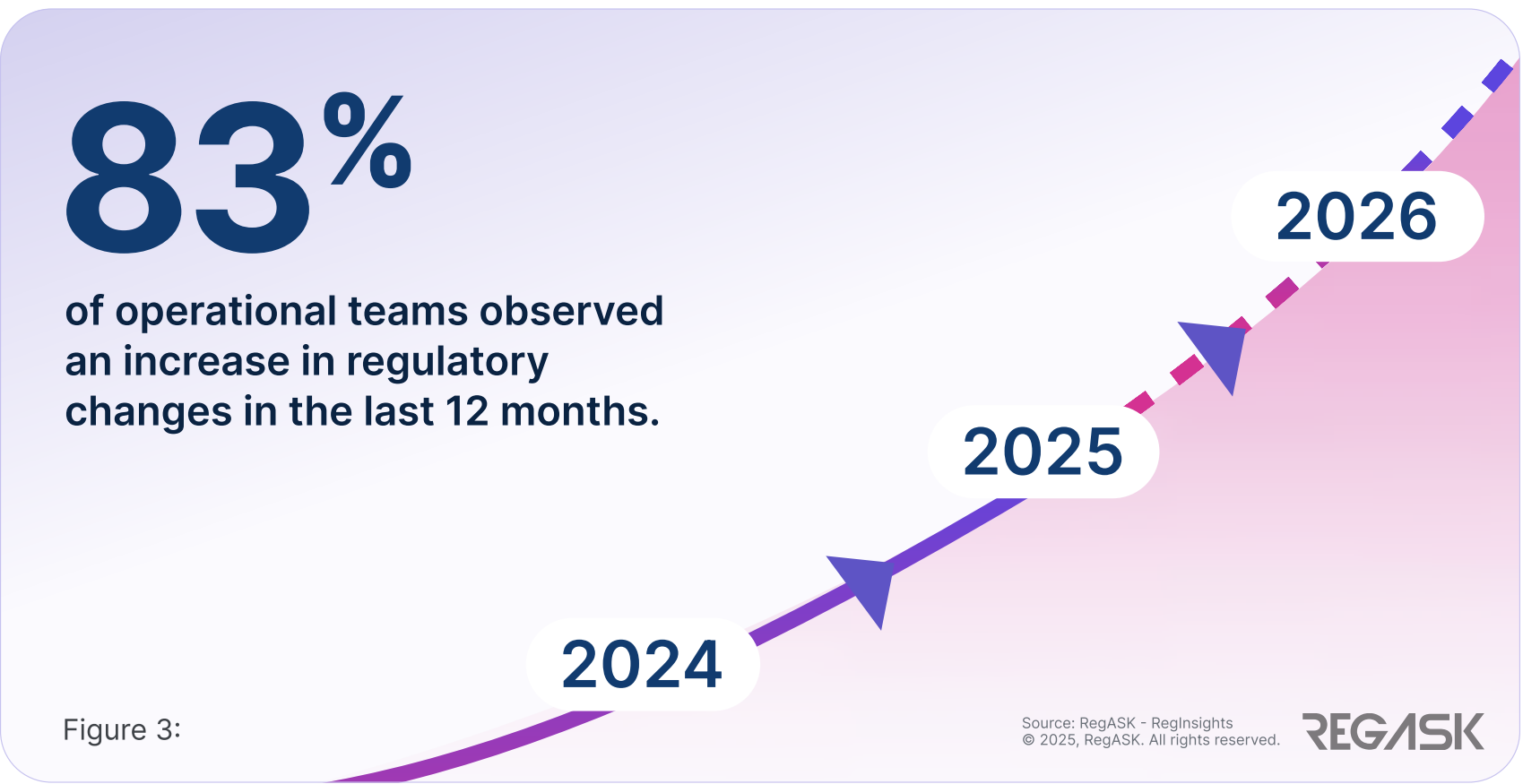
Lead with Agility:

Turning Regulatory Burden into Strategic Advantage

In today’s regulatory environment, an organization’s ability to stay compliant directly impacts its capacity for growth. The organizations that can identify, interpret, and operationalize regulatory changes quickly will have an edge. Yet, the research reveals a sobering reality: most companies are struggling to keep pace.

Regulatory Change Is Scaling Faster Than Teams Can Respond

More than four in five operational teams (83%) observed an increase in regulatory changes - a 34% increase compared with last year. This marks another year of rising regulatory change that underscores a sustained upward trend.



More regulations mean more monitoring, interpretation, and coordination. The result is a cascading effect where rising volume slows response times and amplifies risk.

It’s a challenge that leaders are acutely aware of. 59% of leaders identify delayed detection or response to regulatory changes as their top risk and 13% of them are not confident at all in their organization’s ability to stay compliant while scaling globally. This reveals ongoing uncertainty about regulatory readiness.

Global Turbulence Is Increasing Pressure on Compliance Teams

To add to the strain, operational teams are now facing a different kind of disruption - the downstream impact of global trade volatility.

Shifting tariff policies and evolving trade restrictions create regulatory consequences that teams must navigate in real time. This year, 70% of organizations were affected by trade-related disruptions, intensifying the pressure on compliance functions already operating at capacity.

One third (34%) of respondents had to urgently reassess sourcing or labeling strategies. Another 29% resubmitted documentation due to supplier or manufacturing shifts. Additionally, 22% incurred unplanned re-testing costs, 18% paused product launches, and 17% faced blocked market entry.

How Global Disruption Hits Compliance

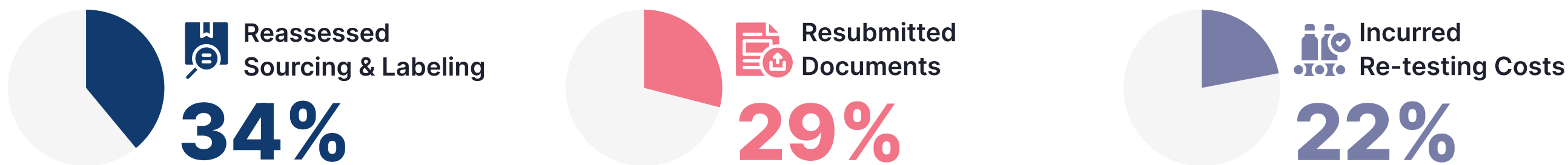


Figure 4:



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Teams are absorbing this impact without additional headcount, budget, or technology support, forcing them to operate in a perpetual reactive state while trade volatility accelerates.

Most Teams Are Struggling to Keep Pace

Given these challenges, only 7% of senior leaders and operational teams can identify a new regulation and execute a response plan within 48 hours. Most teams operate at a slower rate, with 16% taking more than a month to respond. Leaders point to resource constraints (47%) and siloed, manual systems (37%) as the main factors slowing progress.

Time to Detect and Respond to New Regulatory Changes

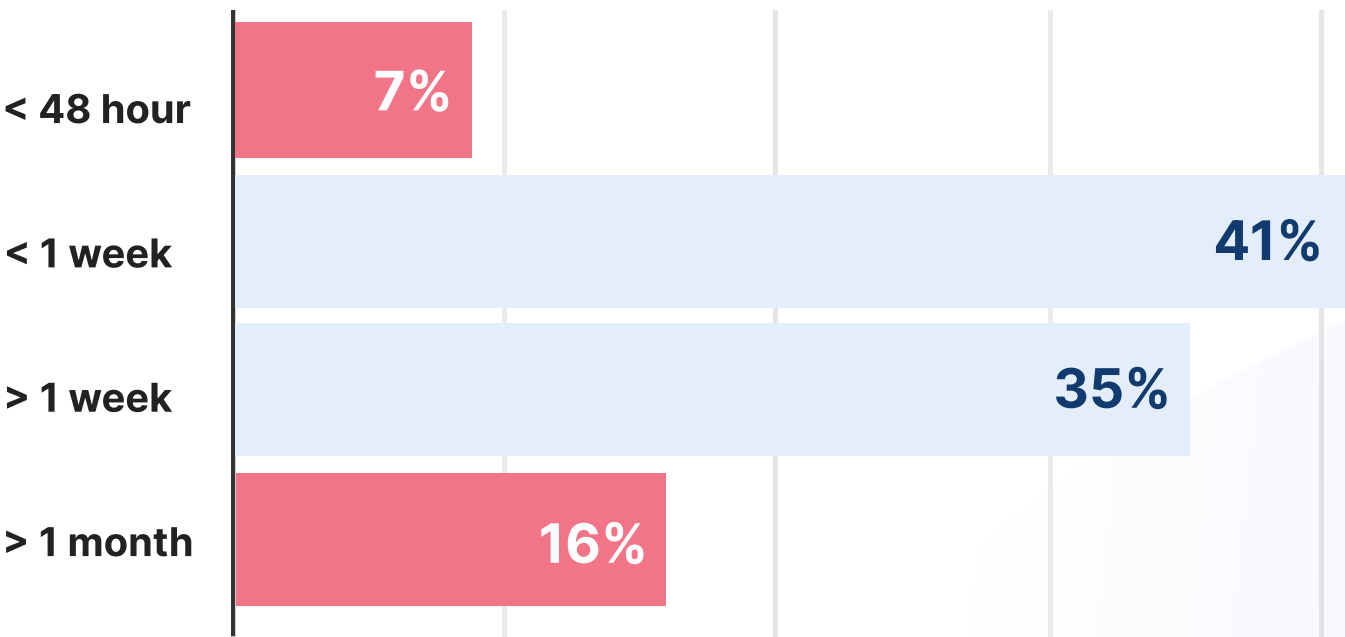
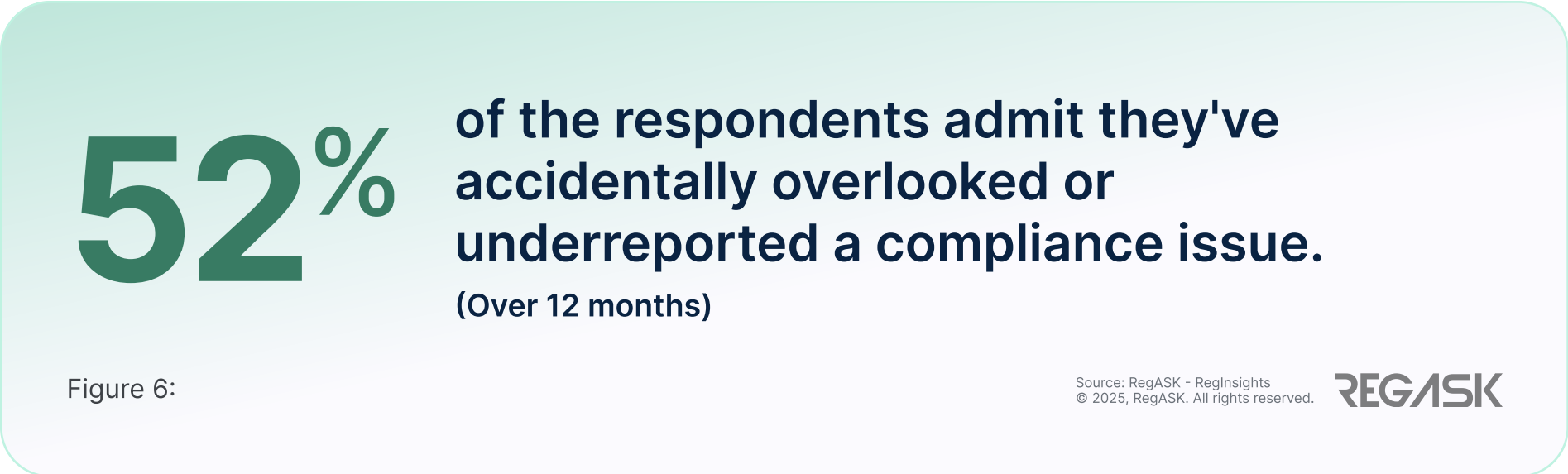


Figure 5:

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How Compliance Blind Spots Quietly Drain Budgets

The adverse effects multiply when response time and accuracy slip over time. 52% of the respondents admit they've accidentally overlooked or underreported a compliance issue. In the past year alone, 37% of senior leaders say their organization missed a regulatory requirement entirely. And the consequences were costly.



Among the senior leaders who experienced a miss, 46% faced delayed or canceled product launches. Another 39% experienced clinical trial disruptions. Over a third (36%) had product recalls, and a quarter (25%) suffered brand reputation damage. Half (50%) of the affected leaders estimate their financial losses to be between US\$500,000 and US\$1 million. What begins as operational inefficiency, if allowed to persist, soon translates into measurable financial losses.

Why Agility Now Defines Competitive Advantage

Regulatory agility is therefore no longer optional. It has become both a core business enabler and a buffer against financial loss. Senior leaders cite business growth (57%), operational efficiency (51%), and innovation (49%) as top priorities for the next 12 months, all of which depend on how quickly organizations can respond to market opportunities and regulatory shifts with both speed and accuracy.

Organizations that embed agility into their compliance processes turn regulation from a reactive burden into a proactive business advantage. Despite growing recognition of its value, most have not fully operationalized this shift.





Between Expectation and Execution:
The Hidden Strain on
Compliance Teams

The problem with regulatory agility isn't a lack of awareness, but a disconnect between what leaders believe is happening and what operational teams experience on the ground.

How Leadership Perceptions Differ from Team Reality

Looking at the data, it is clear that senior leaders and operational teams view the same compliance landscape through different lenses.

While leaders believe their teams can respond to new regulations within a week, operational teams share that response times often exceed a week, stretching to more than a month. What leadership sees as a quick turnaround, operational teams experience a slow, resource-intensive process. As a result, leadership often does not perceive an urgent need to implement a solution.



Agreement on the Problem, Divergence on Action

Both leadership and operational teams agree that AI holds the key to elevating regulatory work. When asked which tasks they would delegate to an AI agent, both groups identified monitoring and interpreting global regulatory changes as their top priority. 91% of operational teams say that a solution which automates regulatory intelligence and flags compliance updates would significantly enhance their teams' performance.



But their approaches diverge, with each group looking to leverage AI in different ways and progress along its own path.

Senior leaders prioritize AI for cost savings through automation (42%), greater accuracy and consistency (39%), and improved collaboration and visibility (33%). Regulatory operations teams share many of these priorities but are motivated by different needs. For them, AI is primarily about enabling faster regulatory responses (49%), followed by improving accuracy (38%) and achieving cost savings (33%).

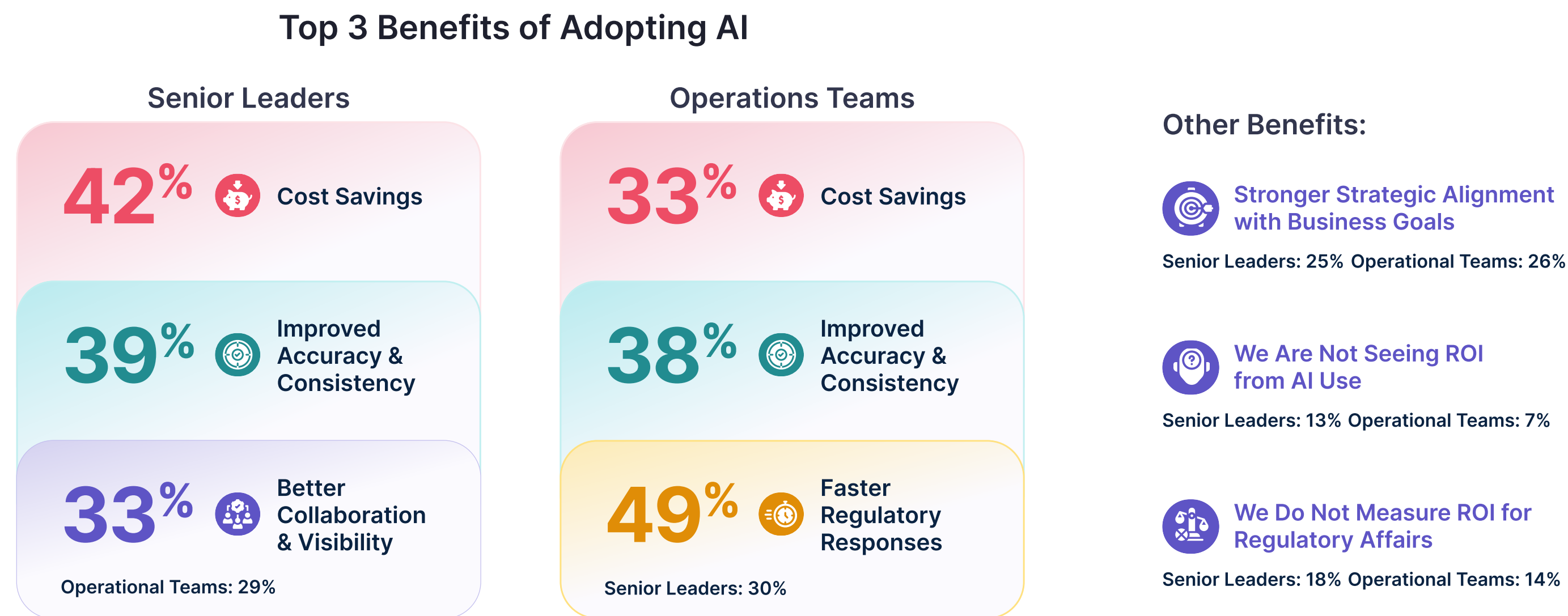


Figure 10:

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The AI Adoption Divide

Adoption patterns also reflect divergence. Leadership remains in an exploratory phase: 40% are piloting AI solutions, building business cases, and assessing organizational readiness. Operational teams, by contrast, are more pragmatic: 56% already use general-purpose LLMs in their daily work. They are not waiting for enterprise-wide rollouts despite the security and governance risks of shadow AI. They are solving immediate challenges with the tools they have.

This reveals a familiar pattern: when implementation slows at the top, innovation starts at the bottom. Frontline teams are adopting AI out of necessity, rather than direction, finding practical workarounds while leadership is still shaping the broader strategy. But without alignment between leadership and operational teams, the promise of an effective AI-enabled regulatory function will remain out of reach.

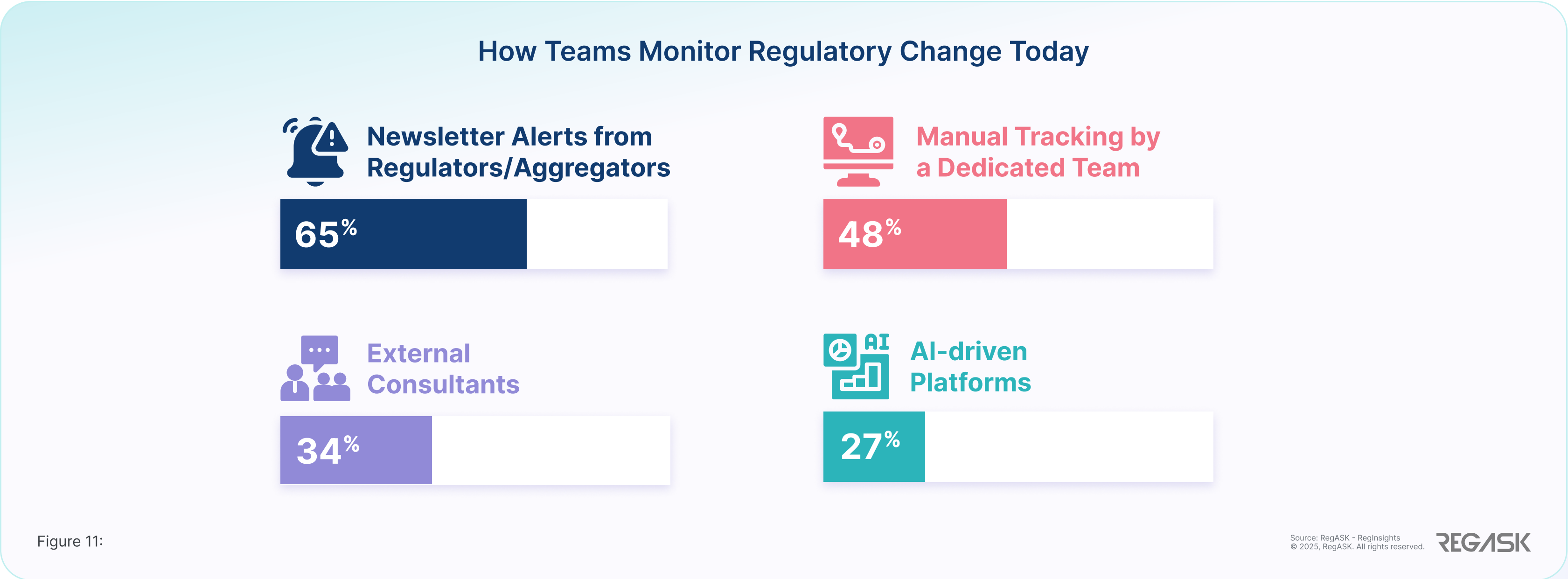


The Compliance Paradox:
Digital Ambitions,
Manual Reality

The Compliance Paradox: Digital Ambitions, Manual Reality

Despite rising regulatory volume and growing enthusiasm for AI, most compliance teams are still operating with manual workflows and siloed information that can't keep pace with the speed or complexity of today's regulatory changes.

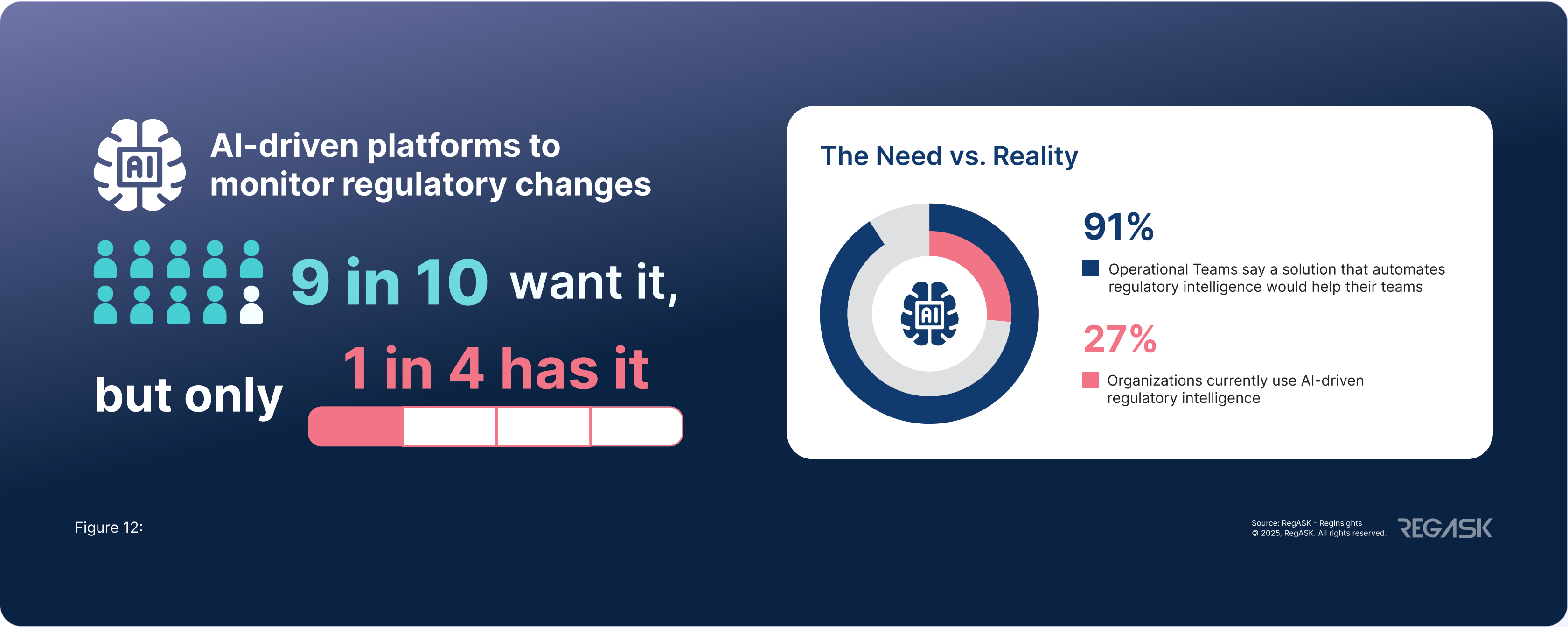
Nearly two-thirds (65%) of respondents still rely on newsletters from regulators or aggregators, which highlight changes but provide no interpretation. And nearly half (48%) depend on dedicated teams to manually track updates, scan for relevance, and translate implications across functions.



Siloed tools and fragmented workflows make the problem worse. Information arrives in pieces, requiring effort to assemble before action can be taken. This fragmentation increases the risk of loss of information, adds unnecessary complexities, and introduces delays at the very moment when speed matters most.

Current State of Regulatory Tech Adoption

Adoption of vertical AI regulatory intelligence platforms remains modest but is steadily gaining momentum across the industry. While 91% of operational teams say they want these capabilities, only one in four have implemented them. Still, progress is clear: 27% of organizations now use vertical platforms to monitor regulatory changes, a 42% increase from last year's 19%.



Organizations understand what is needed. Momentum is building, but true competitive advantage will belong to those who move beyond experimentation and commit to actual adoption.



The AI Uplift:

Compliance Enters Its First Wave of Intelligent Transformation

Organizations are beginning to close the adoption gap. Amongst all the respondents, around 30% are currently piloting AI solutions, with 87% of senior leaders stating that their teams are either using AI today or planning to adopt in the next 12 months. Budget allocation signals reinforce this trend: senior leaders expect their AI technology spending to increase in 2026, with 9% anticipating significant increase and 41% expecting moderate growth.

87% of senior leaders
say their teams are either using
AI today or plan to adopt it in the next 12 months.

Figure 13:

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Where AI Is Delivering Value Today

Early adopters are already seeing meaningful benefits, though leadership and operational teams emphasize different use cases. Senior leaders say AI delivers its greatest value in three areas: enhancing decision-making through data-driven insights (70%), monitoring and interpreting regulatory change (58%), and predicting regulatory risks and impacts (44%).

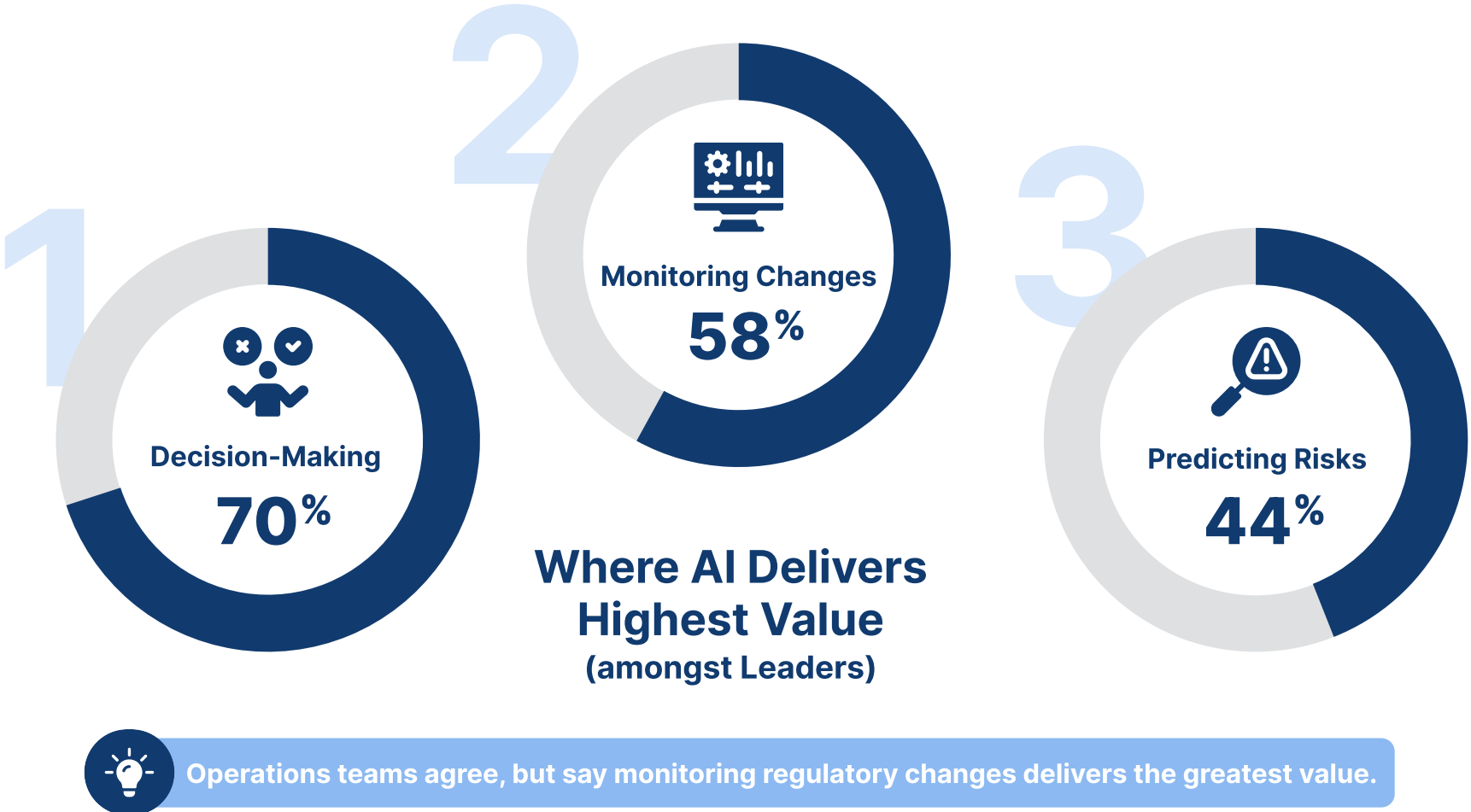


Figure 14:

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Interestingly, operational teams point to the same three areas, but prioritize them differently, placing regulatory monitoring first, followed by decision-making and risk prediction, reflecting the day-to-day pressures they face and the immediacy of their operational challenges.

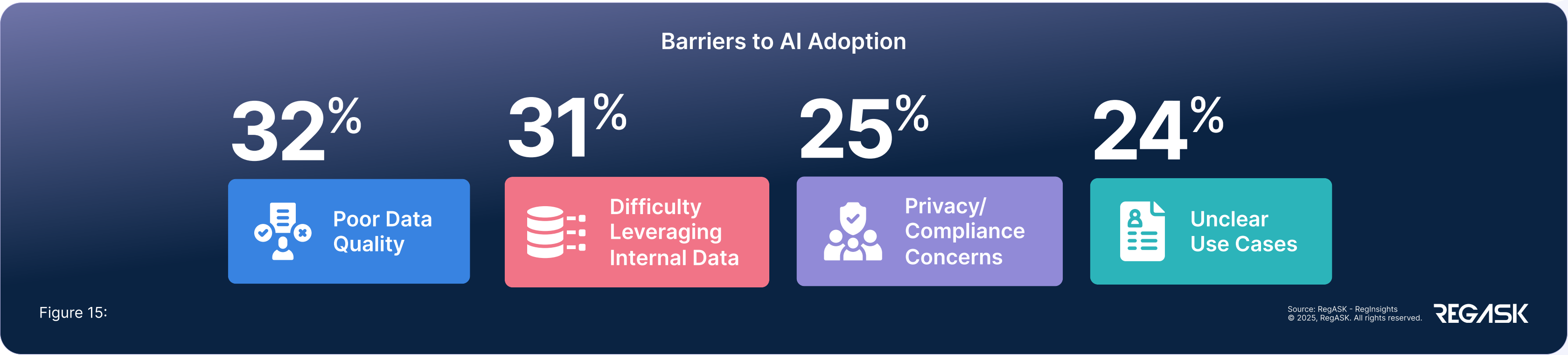
While leadership and operations may value different outcomes, they share a clear conviction: AI will help them do their jobs better. Whether it's driving cost efficiency at the top or speeding decision-making on the frontline, both groups see AI as an enabler of higher performance and more intelligent compliance.

As per Gartner®, "New solutions using GenAI are rapidly disrupting the regulatory intelligence market, with GenAI assistants able to leverage a corpus of data extracted from regulatory sites to provide real-time responses to regulatory queries. These approaches provide a significant advantage over legacy solutions, combining web scraping with auto enrichment into knowledge repositories that can then leverage GenAI and agentic solutions to deliver critical regulatory information and guidance on demand to regulatory affairs experts."

The Advanced AI Adoption Gap

AI adoption is accelerating, but teams are progressing at very different speeds. 40% of senior leaders are piloting AI for specific use cases, while others have already started embedding it into daily workflows. When it comes to advanced capabilities such as agentic AI, adoption remains nascent. Only 7% of senior leaders and 16% of operational teams report using it today, while more than one in three (39%) have never heard of the technology. This variation underscores a critical reality: AI maturity is still evolving across regulatory functions, and early adopters are already shaping the standards others will soon be expected to follow.

Progress now depends on the fundamentals. According to the senior leaders, the challenges to leveraging AI include poor-quality data (32%), difficulty accessing or using internal data (31%), data privacy and compliance concerns (25%), and uncertainty around how to apply AI to specific business use cases (24%). The organizations that solve these foundational issues will be the ones to turn agentic AI into a meaningful competitive advantage.



1. Gartner, Innovation Insight: GenAI in Life Science Clinical Development, Jeff Smith, 2 September 2025. GARTNER is a trademark of Gartner, Inc. and its affiliates.

Future Outlook:

From Reactive Compliance to Strategic Command

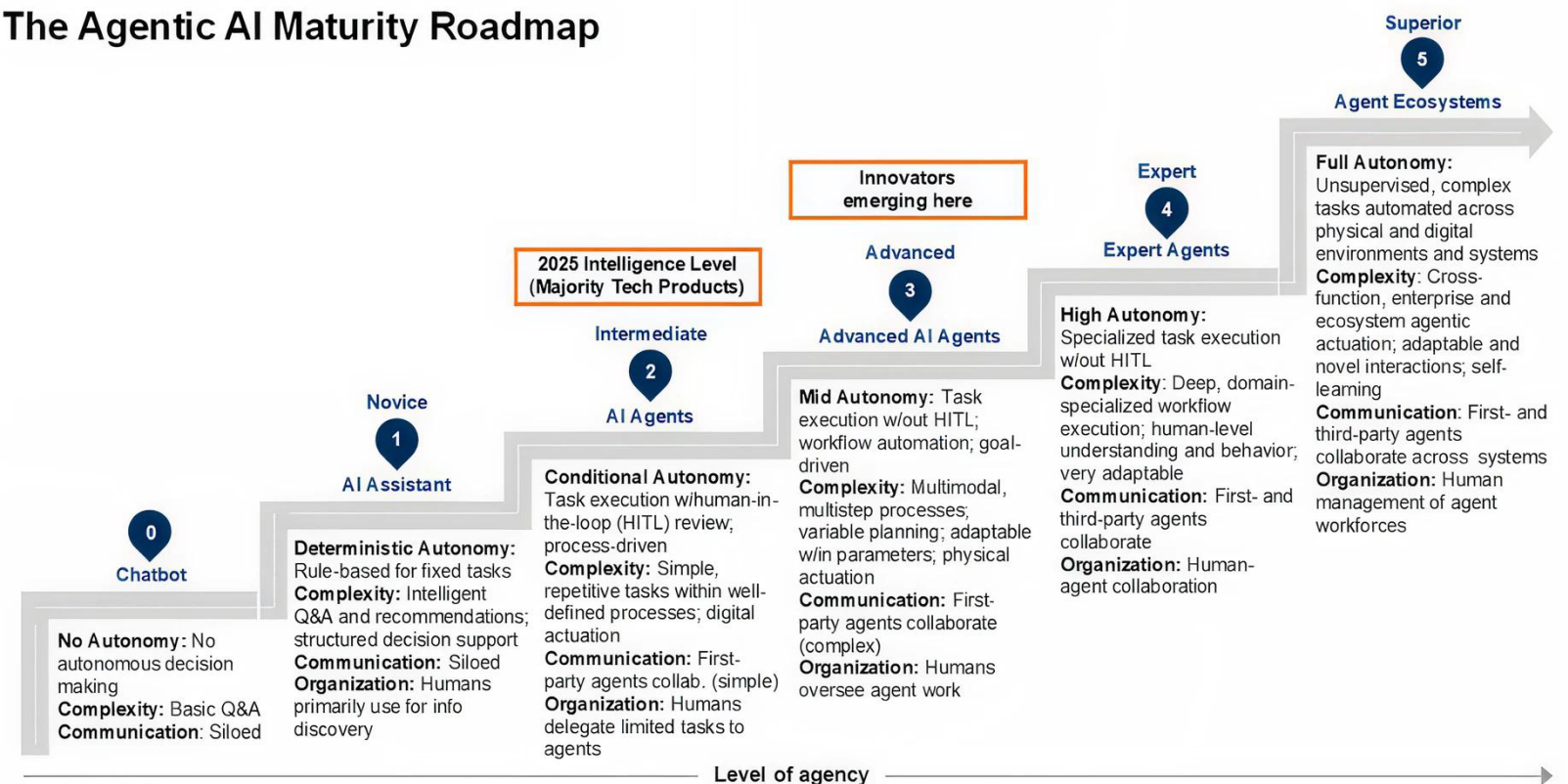
Future Outlook: From Reactive Compliance to Strategic Command

Over the next three years, Regulatory Affairs is poised to evolve from a reactive, analog cost-center into a strategic command function. AI is already freeing up time and providing the insights regulatory teams need to earn a seat at the table and influence core business decisions. The evolution is already visible across the industry.

The Gartner® graphic “illustrates the agency progression from Level 0 (L0) chatbots to Level 5 (L5) agent ecosystems over the next decade. A majority of the market is currently at L2 - intermediate agency, as demonstrated by the proliferation of AI agent offerings. There are also emerging innovators with advanced AI agents and the beginnings of expert AI agent capabilities.”

The report mirrors this trajectory. While 91% of operational teams recognize the need for AI, only 27% are currently using vertical regulatory AI platforms. Many organizations are still in the early stages of maturity, aware of the potential but yet to unlock its full impact.

The Agentic AI Maturity Roadmap



Source: Gartner
Note: Agency level — Rating considers automation level, complexity of task support, collaboration capacity and human-machine work relationship.
828291

Figure 16:



2024-2028: The Path to Autonomous Systems

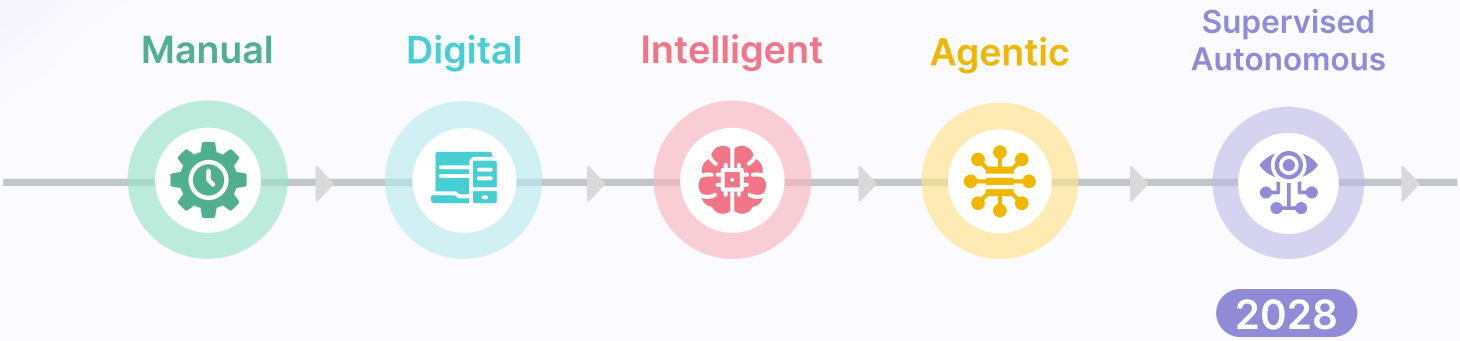


Figure 17:

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2. Gartner, Emerging Tech: Agentic AI Maturity Roadmap, Danielle Casey, Eric Goodness, George Brocklehurst, Alfredo Ramirez IV, Akhil Singh, Anushree Verma, Aakanksha Bansal, Annette Jump, 8 August 2025. GARTNER is a trademark of Gartner, Inc. and its affiliates.



The Emerging Skillset for the AI-Driven Compliance World

As AI takes over more of the execution, human expertise is shifting upstream, from doing the work to co-strategizing with AI, setting directions and governing outcomes. This evolution requires new skills and new ways of working.

Senior leaders highlight four critical competencies regulatory professionals now require: AI literacy (32%), the ability to manage AI-human collaboration (32%), oversight and quality assurance of AI outputs (31%), and ethical judgment and reasoning (28%). These capabilities will determine how effectively teams can harness AI while maintaining the accuracy, accountability, and trust that regulatory decisions demand.

Human oversight remains essential not because AI is lacking, but because its power demands supervision. As automated systems become more capable of interpreting context, assessing risks, and prioritizing actions, humans play a critical role in setting guardrails, auditing reasoning, resolving ambiguity, and aligning decisions with organizational values and regulatory expectations.

The regulatory professionals who thrive will be those who can work with AI as a strategic partner – steering, validating, auditing and translating automated intelligence into confident, high-impact business decisions.

From Reactive to Proactive

Looking ahead, both senior leaders and operational teams expect AI to have the greatest impact on three key areas: predictive intelligence that anticipates regulatory changes and risks (66%), real-time assistants supporting early product development (45%), and autonomous compliance agents (38%).

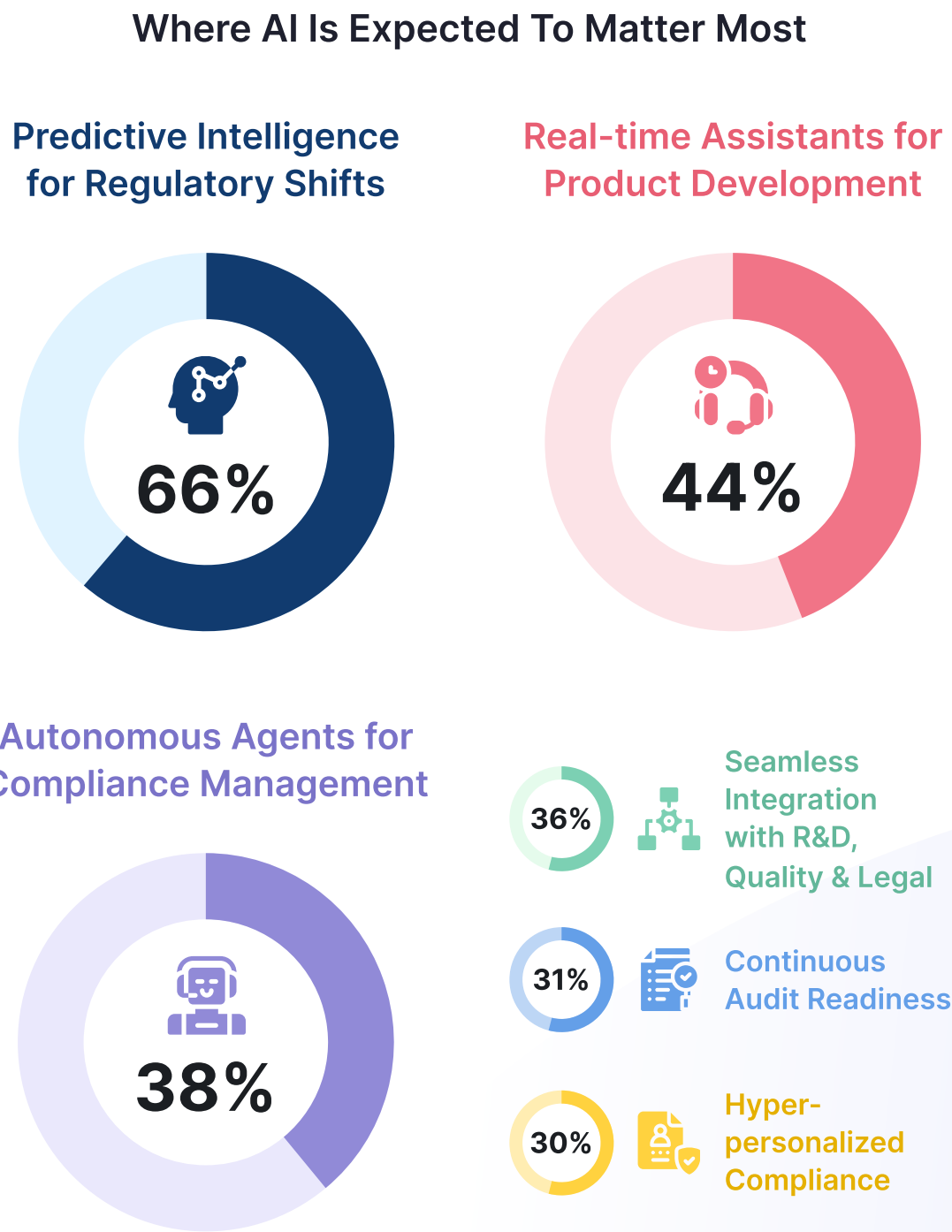


Figure 18:

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Future Outlook: From Reactive Compliance to Strategic Command

21

This will mark the shift from reactive monitoring to proactive strategy. Instead of discovering a regulatory change and scrambling to respond, teams will anticipate developments earlier, receiving signals, modelling scenarios, and preparing response plans before new requirements are finalized. As regulatory intelligence becomes more connected, cross-functional integration will ensure insights flow seamlessly across R&D, Quality, and Legal. This will eliminate silos, reduce rework, and enable compliance to shape business decisions rather than simply follow them. By 2028, these shifts could redefine the regulatory function entirely, transforming it from a back-end safeguard into a front-line driver of speed, foresight, and strategic advantage.

Humans Lead, AI Enables

When AI takes over the heavy lifting - monitoring, tracking, and first-pass analysis, regulatory teams can focus on what truly moves the business forward: interpreting ambiguous guidance, aligning stakeholders, shaping regulatory strategy, and turning complexity into clarity.

The benefits of this augmented model are real. Organizations can expand capacity without adding headcounts, respond faster without sacrificing quality, and scale globally without proportionally increasing resources.

The bottom line is that regulatory agility is fast becoming a driver of business performance. It boosts revenue, accelerates time to market, and transforms compliance from a gatekeeper function into a growth enabler.





Key Insights for Organizations

The research reveals several important takeaways for organizations:



Treat Regulatory Agility as a Strategic Capability, Not a Compliance Task

Organizations that excel are those that view regulatory responsiveness as a source of faster market entry, resilience, and competitive advantage. Moving from reactive tracking to proactive intelligence requires a mindset shift from “checking the box” to driving outcomes that strengthen business performance.



Close the Gap Between Leadership Plans and Operational Reality

To realize the value of AI, leadership strategies must be grounded in the day-to-day experiences of frontline teams. This requires embedding operational feedback into AI roadmaps and ensuring investments target real bottlenecks such as manual monitoring, fragmented workflows, delayed insights, and data gaps.



Grow AI Maturity Through Sequential, High-Impact Use Cases

With only 27% of organizations using vertical AI regulatory intelligence platforms, progress depends on starting specific and executing well. Identify one or two key problems such as predictive monitoring, automated impact assessment, or scenario modelling, and scale from there. Each success builds momentum and strengthens the internal capabilities required for more advanced applications like agentic AI.



Strengthen Human Capital for the AI-Augmented Function

The AI-augmented world is here, and the skills required to thrive in it are shifting upstream: AI literacy, managing AI-human collaboration, oversight and QA of AI outputs, and ethical reasoning. These competencies are now essential as teams evolve from executing to co-strategizing with AI, directing automation, validating outputs, and ensuring decisions remain accurate, explainable, and trusted.



Break Down Silos to Enable Connected, Cross-Functional Intelligence

Breaking silos between Regulatory, Quality, R&D, Legal and Commercial is key to achieving both speed and precision. Organizations must build integrated workflows where data flows seamlessly across teams and decisions move swiftly up and down the chain. Regulatory agility requires a connected ecosystem. It cannot be achieved in isolation.



Demographics & Methodology

Respondent Segments

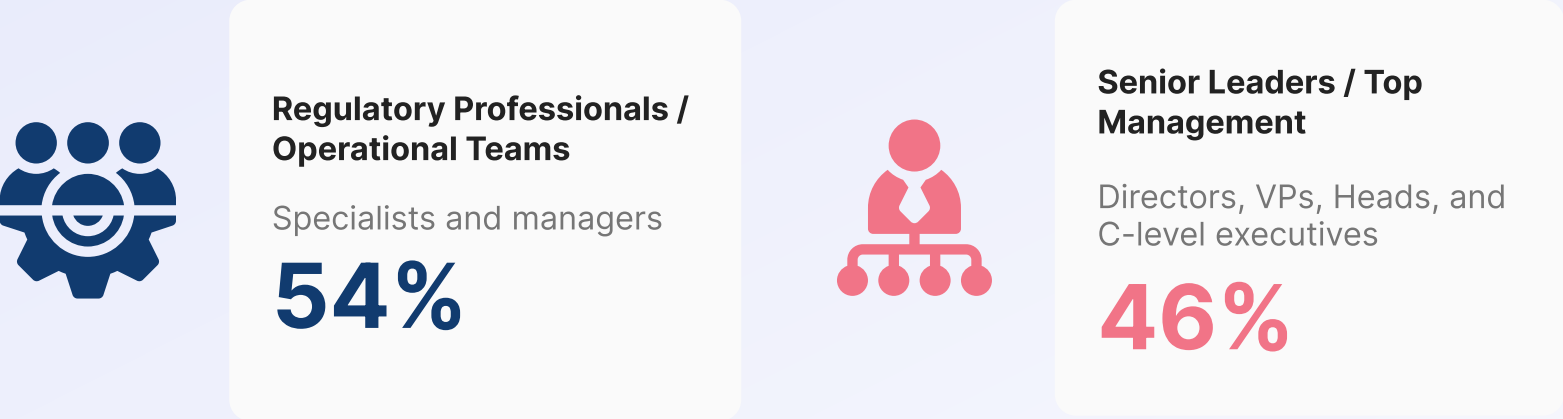


Figure 19:

Organization Headquarters

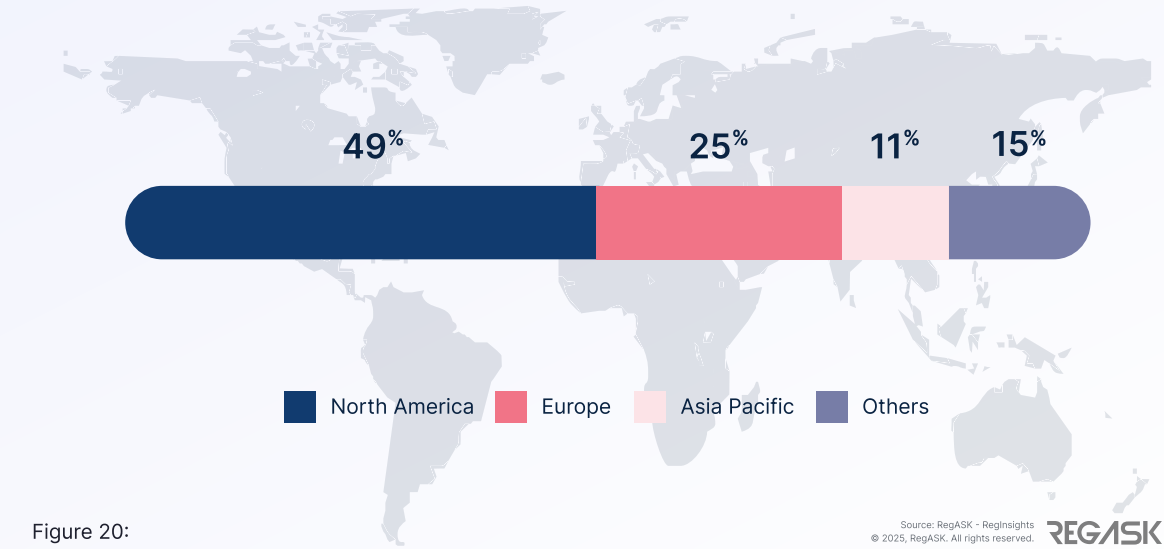


Figure 20:

Company Size

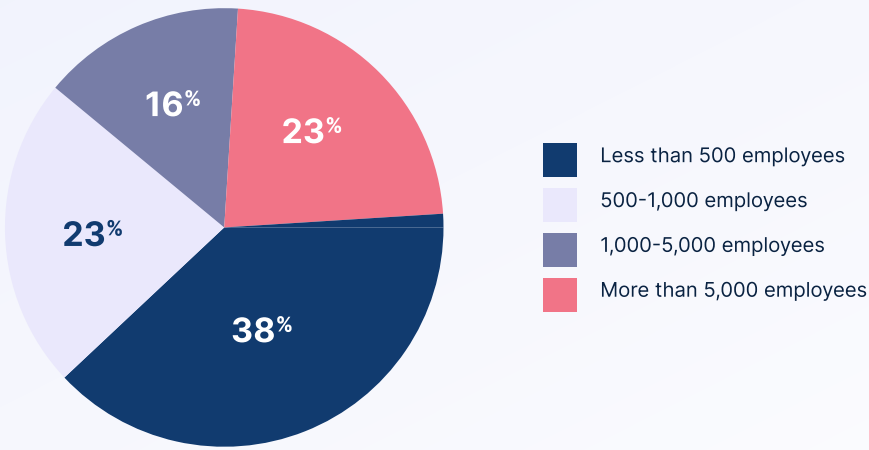


Figure 21:

Industry

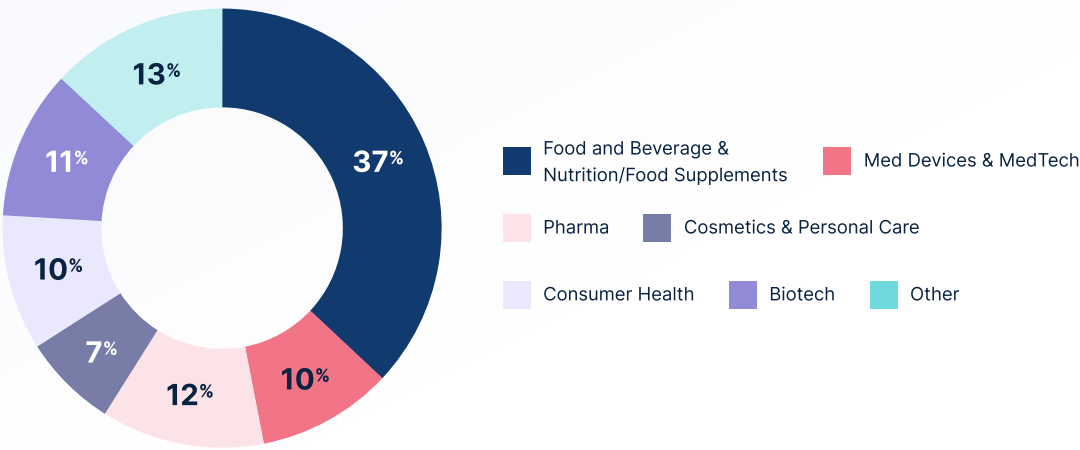


Figure 22:

Survey Period:

July – September 2025

Sample:

162 complete responses from regulatory affairs professionals in life sciences and consumer products across global organizations.

Respondent Segments:

Responses were analyzed across two cohorts to surface differences in perception, priorities, and experience:

- **Regulatory Professionals / Operational Teams (54%)** – Specialists and managers
- **Senior Leaders / Top Management (46%)** – Directors, VPs, Heads, and C-level executives



RegASK is an AI-driven platform enabling end-to-end regulatory intelligence and workflow orchestration. It automates regulatory intelligence with curated content, actionable insights, and workflow automation, while connecting a global community of over 1,700 subject matter experts for streamlined compliance execution. By combining Agentic AI efficiency with deep regulatory expertise, RegASK empowers organizations to proactively manage compliance and navigate complex regulatory landscapes with confidence.

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