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The State Of Materiovigilance 2025: Capability Gaps, Technology Momentum, And Outsourcing Readiness

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The State Of Materiovigilance 2025: Capability Gaps, Technology Momentum, And Outsourcing Readiness

Materiovigilance is entering one of the most transformative periods in its history. With the convergence of drug and device innovation, global regulatory reform, and rapid digital adoption, post-market safety surveillance now extends well beyond traditional medical devices.

Drug-device combination therapies, companion diagnostics, software as a medical device (SaMD), artificial intelligence, and connected digital platforms have dramatically expanded the scope of vigilance responsibilities. As products become more complex, so do the risks that emerge once they reach real-world use—shifting materiovigilance from a narrow technical discipline into a core strategic function within modern healthcare.

This rapid expansion has left many organizations strengthening their capabilities while actively navigating new compliance burdens. IQVIA's 2025 Materiovigilance and Technology Adoption Survey shows that **70% of organizations have 10 years or less of experience in materiovigilance**, reflecting the relative youth of the discipline across the industry. Compounding this challenge, **approximately two-thirds (70%) of respondents represent pharmaceutical or biotech organizations**, confirming that materiovigilance is no longer just a concern for the MedTech industry.

This represents a major shift in how safety is approached. According to Dr. Padmalakshmi Jnaneshwar, director of safety operations, lifecycle safety at IQVIA, materiovigilance is no longer simply about investigating mechanical malfunctions. It is increasingly about safeguarding patient experience across digitally-enabled, full-lifecycle therapies.

"Materiovigilance is evolving at a rapid pace due to the complexity of new devices, global regulatory pressure, and the shift toward patient-centric care and transparency," she says. "Newer device modalities, connected technologies, and software-based interventions require continuous surveillance, dynamic risk assessment, and new skill sets that many pharma and biotech companies are still building internally."

This report explores the results of the 2025 survey and reveals the areas where organizations remain behind, the operational hurdles they face, and the capabilities they will need to keep pace with global expectations.

METHODS

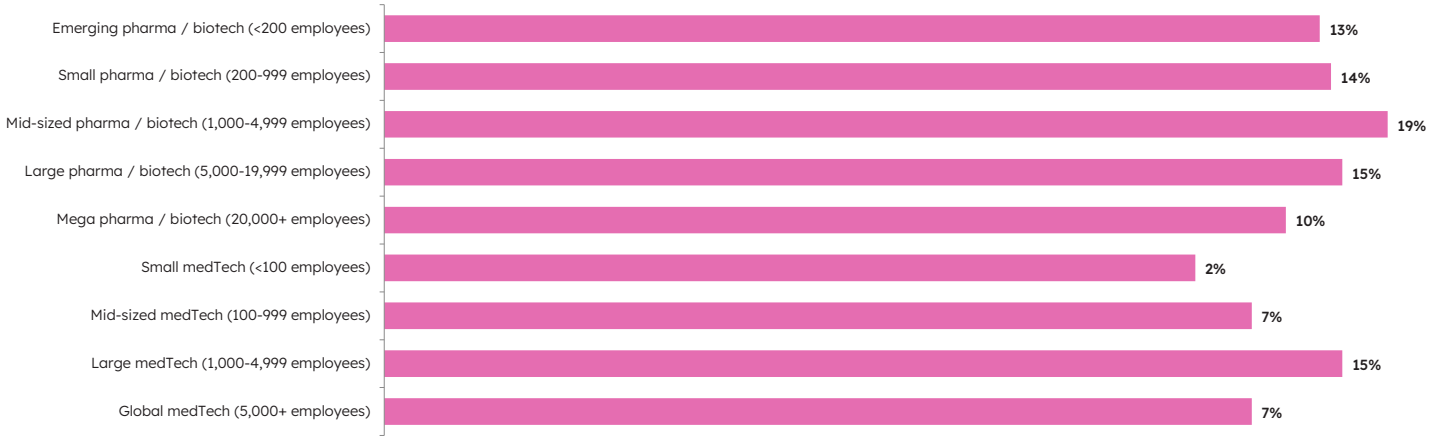
The data informing this report comes from the 2025 Materiovigilance and Technology Adoption Survey conducted by Citeline on behalf of IQVIA between September 30 and October 8, 2025. A total of 827 respondents participated. Of these, 102 met the inclusion criteria of director-level seniority or higher and direct involvement in materiovigilance, regulatory affairs, device safety oversight, call center leadership, or safety technology management.

RESULTS

1. Pharma And Biotech Are Now Central To Materiovigilance Oversight

The most significant shift detailed in this survey is the steep rise in pharmaceutical and biotechnology leadership of device safety functions. As previously noted, **approximately two-thirds (70%) of respondents represent pharmaceutical or biotech organizations**, signaling the widespread introduction of delivery systems, diagnostics, and digital tools into therapeutic pipelines.

Figure 1. Organization Type



These companies must now comply not only with well-established pharmacovigilance protocols, but also with specialized device vigilance frameworks that differ significantly in reporting structure, root-cause investigations, and lifecycle monitoring requirements.

The shift in accountability is occurring faster than skill sets are evolving, according to Dr. Jnaneshwar.

“Pharma and biotech companies are used to monitoring biological or chemical interactions,” she says. “But with devices, adverse events often stem from mechanical failures, usability challenges, or software issues. Understanding whether an incident was caused by the device, by a user handling mistake, or by an environmental factor requires device engineering knowledge and human-factors expertise that pharma teams may not yet possess.”

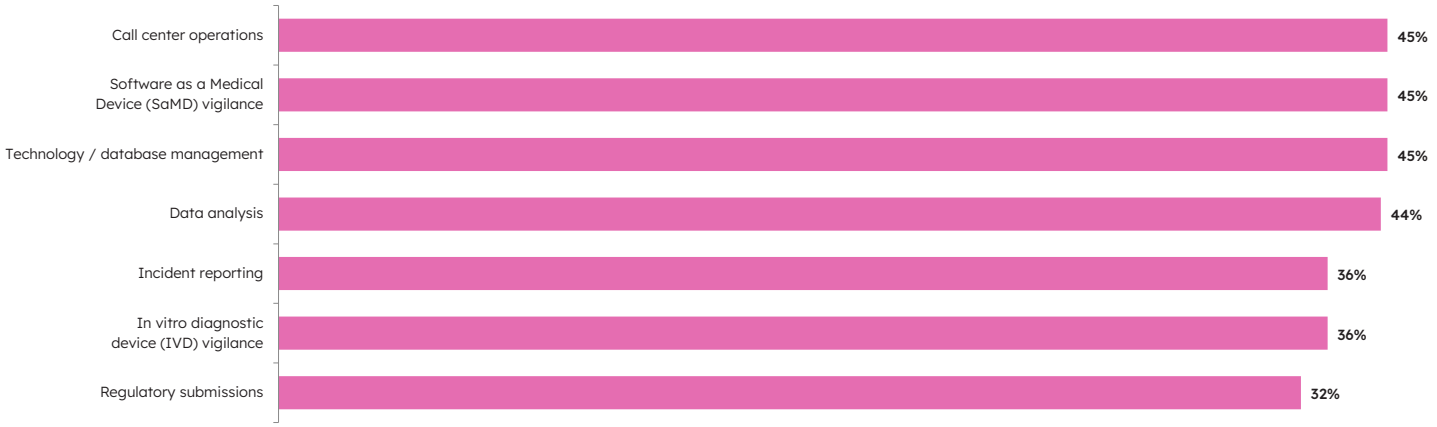
When confidence is limited, under-reporting or delayed reporting can occur—outcomes that carry significant regulatory and patient-impact consequences. “Pharma and biotech companies stepping into materiovigilance face a steep learning curve because device vigilance differs fundamentally from drug safety monitoring,” Dr. Jnaneshwar says.

2. Outsourcing Is A Core Operating Model

Rising operational complexity is driving a powerful shift toward external support. The report found that among the **84% of organizations that outsource some or all of their materiovigilance activities, 45% outsource their call center operations**, underscoring the view that internal capacity alone is insufficient to manage current obligations.

In addition to call center operations, surveyed organizations report that they commonly outsource SaMD vigilance, technology/database management, data analysis, incident reporting, regulatory submissions (Individual and Periodic reports) and more (see Figure 2).

Figure 2. Materiovigilance Outsourced Functions



Building in-house materiovigilance teams is expensive, Dr. Jnaneshwar says, and outsourcing helps address numerous challenges at once.

"External partners provide instant access to experienced safety scientists and device specialists who understand global Medical Device Regulation, the Food and Drug Administration, and International Medical Device Regulators Forum requirements," she says. "They also bring local regulatory knowledge and multilingual reporting capabilities, reducing compliance risk and inspection findings. Some countries require a local presence to perform reporting, which can be provided by external partners."

Additionally, she says, best practices increasingly include the use of validated safety databases and automation tools, which can help small and mid-size companies strengthen consistency and inspection readiness as portfolios expand. External partners can also maintain audit-ready documentation, SOPs, and compliance dashboards, helping sponsors stay prepared for regulatory inspections.

In addition to cost savings and access to greater expertise, responding organizations also considered several other factors when outsourcing materiovigilance services, including the ability to meet fluctuating workload demands, enhanced technology solutions, scalability, and faster case processing/ reduced turnaround times.

3. Various Operational Gaps Exist

The results demonstrate that operational gaps have not closed at the pace of regulatory expectations. Many organizations lack formal device-specific workflows, and internal governance systems are still heavily derived from pharmacovigilance frameworks.

"Missing links between complaint handling, risk management, and vigilance reporting create blind spots in safety oversight," Dr. Jnaneshwar says.

But the most common foundational error, she believes, is philosophical.

"The biggest underestimated gap is thinking materiovigilance is just pharmacovigilance with a different name," she says. "Materiovigilance demands new processes, technology, and skill sets tailored to device risks."

Devices, she says, require long-term monitoring, periodic safety updates, and vigilance, which is far more dynamic than drug pharmacovigilance.

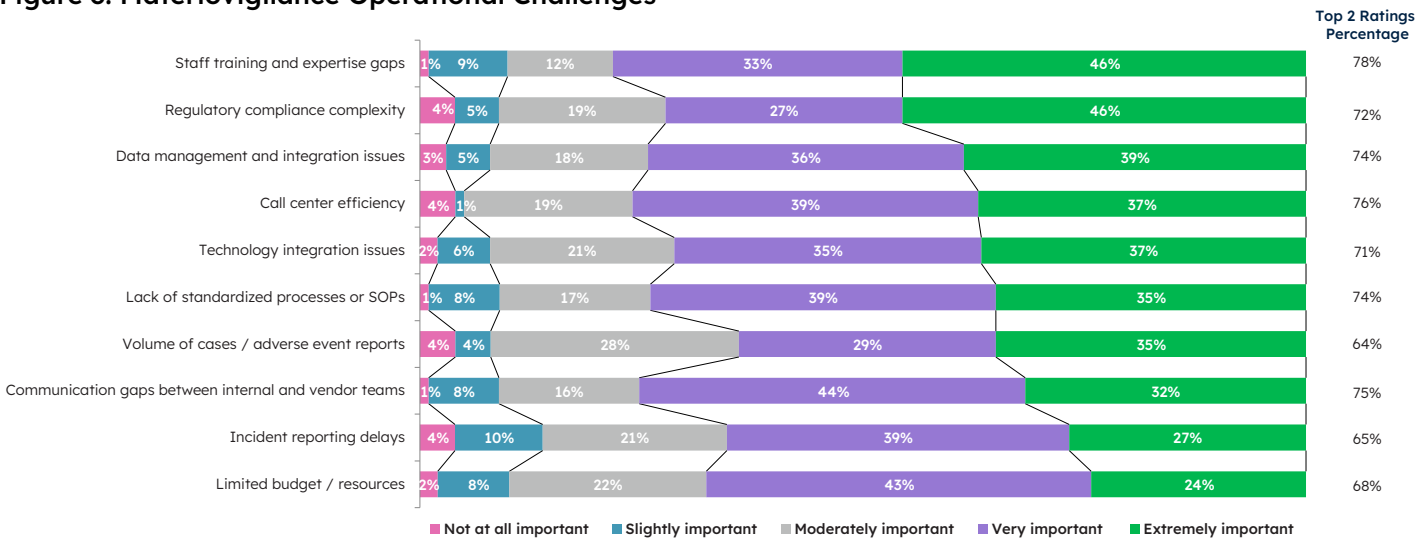
The survey found that the main reasons for these operational gaps include limited staff training and expertise, regulatory compliance complexity, data management and integration issues, call center inefficiency, technology integration issues, and others (see Figure 3).

"SOPs often fail to cover device-specific scenarios, like device deficiency, device recalls, or events related to failure in software updates," Dr. Jnaneshwar says.

Respondents reported that supply chain issues, cyber-attacks, and legacy systems also contribute to operational gaps.

"Many companies still rely on legacy pharmacovigilance systems that simply cannot handle device vigilance requirements," Dr. Jnaneshwar adds.

Figure 3. Materiovigilance Operational Challenges



4. Technology Transformation Is Rising, But Data Drags Behind

Roughly **88% of survey respondents expect technology to play a significantly greater role in materiovigilance over the next three to five years**, reflecting a growing recognition that automation and digital solutions are needed to support scale, improve quality, and reduce manual workload.

While many organizations still rely on manual processing today, **60% of respondents report that they see AI as a key future opportunity to enhance efficiency and insight**. Technology modernization is widely viewed as essential for the next stage of materiovigilance maturity.

Figure 4. Technology Evolution

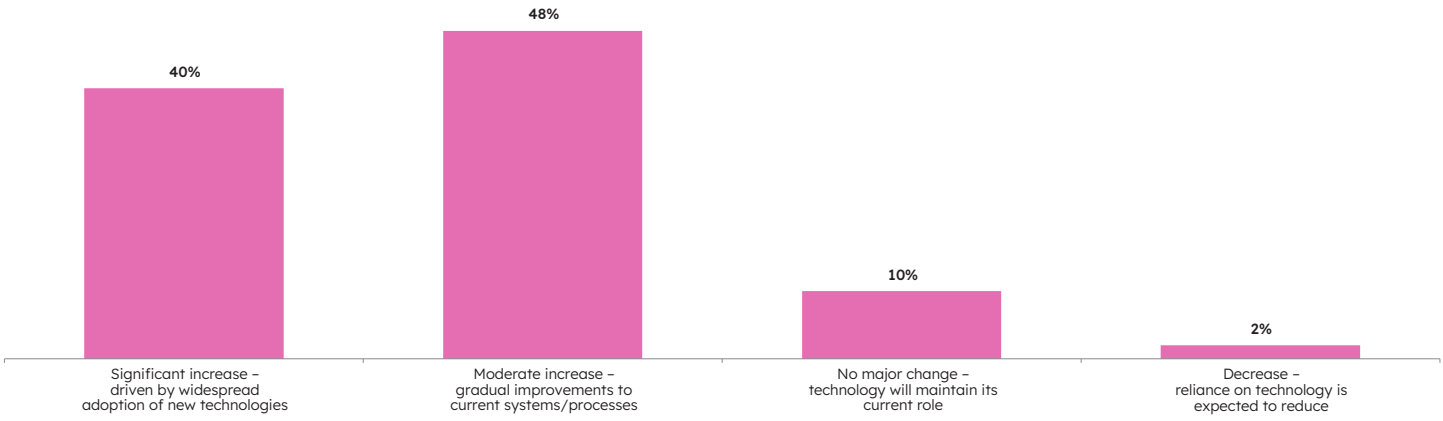
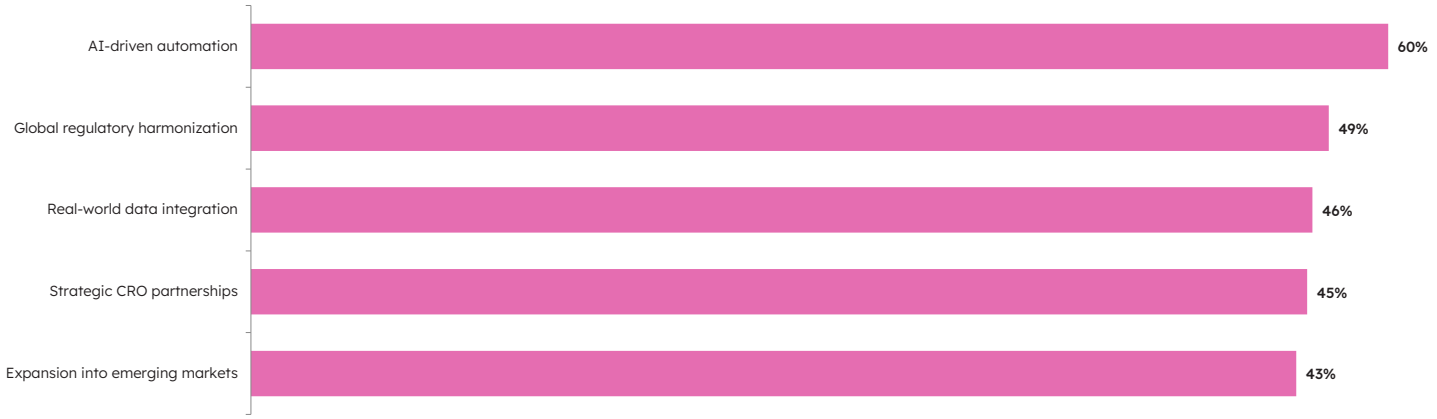


Figure 5. Strategic Opportunities



Dr. Jnaneshwar says that data is often fragmented across manufacturing, distributors, and healthcare systems, and "without harmonized coding systems… signal detection and trend analysis become unreliable". As organizations explore automation, data readiness will be one of the most important enablers of success.

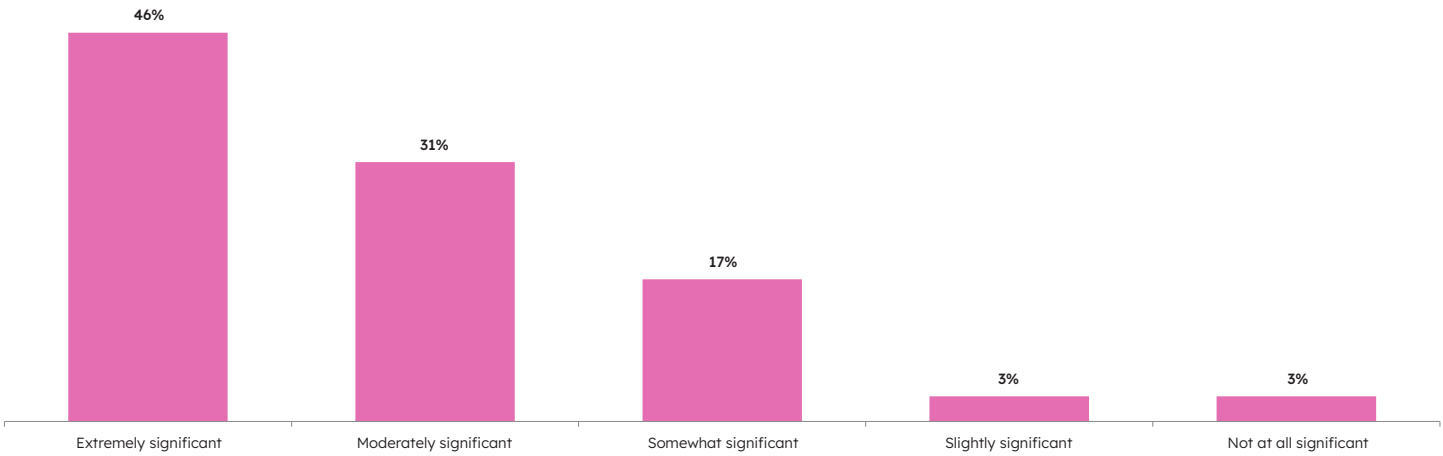
The survey found that organizations face multiple barriers when it comes to adopting technology, including data security and privacy concerns, budget constraints, system integration challenges, and an internal resistance to change.

That said, when asked to rank the top two benefits their organization realized or expects to realize by combining outsourcing with technology in materiovigilance, respondents cite operational efficiency and faster case processing/reduced cycle times. Improved compliance outcomes, cost savings, and better signal detection followed.

5. Regulatory Complexity Is The Most Universal Pressure Point

Regulatory requirements are increasingly demanding, driven by global harmonization and expectations for greater transparency, as well as the evolving enforcement of EU MDR and IVDR. Nearly every organization is feeling this strain: **97% report that regulatory compliance challenges impact their operations**, and **47% call this impact extreme**.

Figure 6. Regulatory Compliance Challenges

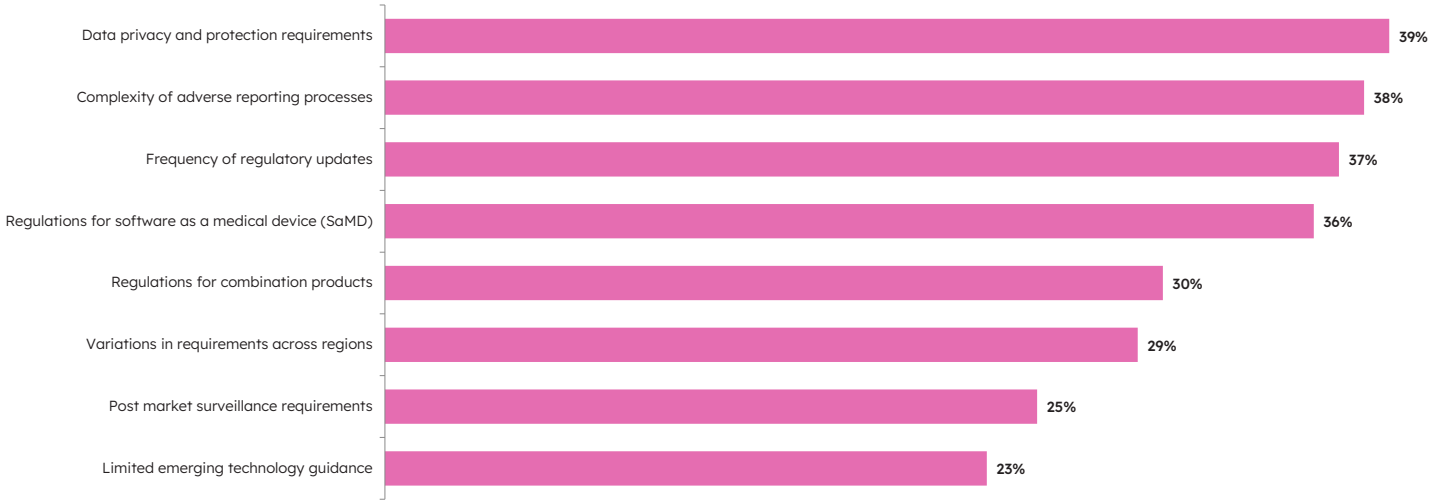


Dr. Jnaneshwar says that global harmonization and greater transparency expectations are changing the way organizations operate, particularly under evolving MDR and In Vitro Diagnostic Medical Devices Regulation (IVDR) requirements.

The survey found that the regulatory factors most impacting materiovigilance operations today include data privacy and protection requirements, the complexity of adverse reporting processes, the frequency of regulatory updates, regulations for SaMD, and regulations for combination products, among others.

This is where external regulatory support comes in. The areas in which survey respondents say external regulatory support would be most benefit their materiovigilance operations include inspection readiness, regulatory strategy consulting, technology-driven regulatory solutions, compliance training programs, and outsourced regulatory management.

Figure 7. Regulatory Factors Impacting Materiovigilance Operations



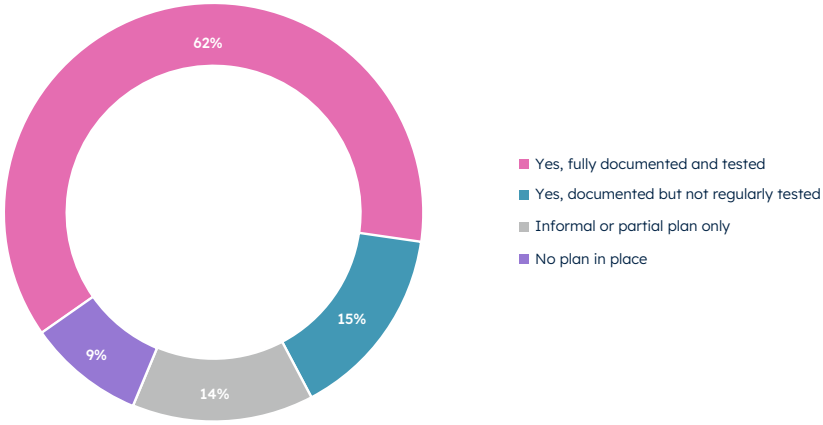
6. Lack Of Contingency Preparedness

Business continuity remains a weak point. Although documented backup systems are common, **38% of organizations do not routinely test their contingency plans**. This is particularly concerning given the dependence on real-time uptime for complaint intake, call routing, and escalation management. Disruptions due to cyber-incidents, outages, or vendor turnover can quickly make organizations vulnerable to regulatory findings, including safety reporting violations.

In an industry where timelines are often fixed by regulators, the data suggests that some organizations have not yet fully internalized the operational risk of unintended downtime in materiovigilance.

The main components of the back-up plan for the 77% of respondents who have one include storage backup, business continuity planning, and continued monitoring.

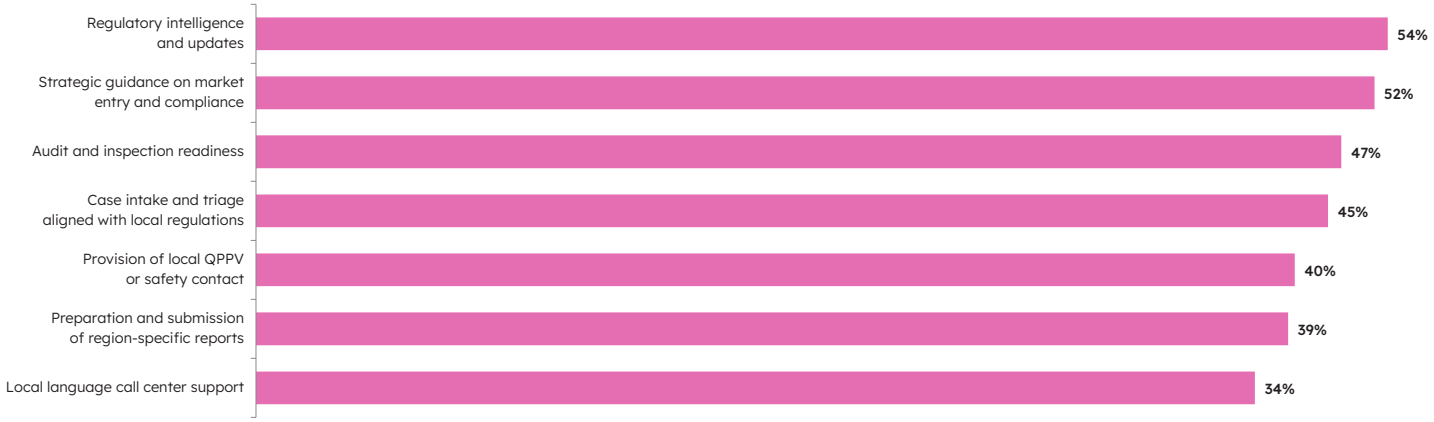
Figure 8. Established Contingency Or Back-Up Plan



7. External Partnerships Are Expanding To Address Regional Regulatory Demands

The survey findings make it clear that outsourcing is not just limited to call centers and case processing—**6 in 10 respondents are currently pursuing external vendors to enhance their materiovigilance capabilities**. When it comes to ensuring compliance with local materiovigilance markets, respondents expect a CRO to provide the following support methods: regulatory intelligence, strategic guidance on market entry, audit and inspection readiness, and others (see Figure 9).

Figure 9. Regulatory Tracking



The trend represents a widening of outsourcing strategy from tactical to strategic reliance. Organizations are no longer simply seeking efficiency gains, they are seeking regulatory confidence. Access to trusted CROs who operate globally has become a key mechanism for staying aligned with evolving regional requirements and mitigating the operational risks of non-compliance. As a result, vendor relationships are increasingly viewed as extensions of organizational capability, not just supplemental support.

Of the many reasons organizations seek external collaboration, those that survey respondents shared most were resource gaps (a shortage of internal talent and lack of specialized knowledge), operational efficiency and growth (to save time and money), critical business areas (cybersecurity, compliance, quality and data management), and security and compliance requirements (to ensure safety and maintain compliance standards).

CONCLUSION

The findings from the 2025 Materiovigilance and Technology Adoption Survey highlight a discipline transitioning into full maturity. Pharma and biotech companies entering the MedTech space are rapidly adapting to increased device reliance, yet many remain in early development stages for the systems and expertise necessary to operate successfully under modern regulatory demands.

Based on these survey results, the path forward is clear: pharma and biotech companies must rapidly mature their materiovigilance capabilities to match the expanding complexity of their product portfolios and regulatory obligations. For many, that means moving beyond fragmented workflows and reactive case handling toward more integrated surveillance models that enable earlier insight, faster response, and more consistent compliance performance.

The survey results reinforce that organizations must treat materiovigilance as a strategic priority—one that requires defined governance, sustained investment in device-specific expertise, and thoughtful use of external partners to stabilize operations during growth. So what does this mean for pharma and biotech companies going forward?

The survey findings suggest that pharmaceutical and biotechnology companies entering the device vigilance space should review whether their current materiovigilance approaches are aligned with increasing product complexity and global regulatory expectations. With many organizations still early in their maturity, there may be value in clarifying ownership, strengthening device-specific expertise, and assessing the scalability of existing processes. The prevalence of outsourcing and reliance on regional regulatory support highlight opportunities to reinforce operational consistency and compliance, particularly as portfolios expand across geographies.

At the same time, the findings point to a broader need for industry-wide collaboration, including the sharing of best practices and continued progress toward more harmonized standards, to help reduce fragmentation and support more consistent, effective materiovigilance across markets.

“Materiovigilance is moving toward a globally-harmonized, patient-focused system, where predictive safety and lifecycle monitoring become the norm,” Dr. Jnaneshwar says. “Vendor relationships will need to become a strategic partnership and evolve beyond transactional models.”

Technology modernization will be essential, but it must be paired with stronger data quality and cross-functional collaboration to ensure automation improves outcomes rather than create variability.

Ultimately, the organizations that embrace scale, specialization, and standardization now will be best positioned to deliver safe, reliable medical products in an environment where vigilance expectations continue to rise.

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