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Why clear AI policy is the new catalyst for Life Sciences R&D

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Regulators need confidence that AI-enabled processes remain auditable and compliant



Artificial intelligence (AI) is no longer a future possibility for the life sciences industry, it is rapidly becoming a foundational capability. From accelerating drug discovery and optimizing clinical trials to strengthening quality management and regulatory compliance, AI is poised to transform every stage of the pharmaceutical value chain.

Despite the various opportunities offered by AI, a less-discussed factor is emerging as the true differentiator between AI leaders and laggards – policy clarity. Today, the biggest challenge AI adoption in life sciences is facing is not technological readiness. It is the absence of clear frameworks that enable organizations to innovate confidently while remaining compliant, ethical, and accountable.

The industry's enthusiasm for AI is undeniable. According to Archimedis Digital's State of Digital Transformation in Indian Pharma 2025 report, 64 percent of pharmaceutical companies identify Data Analytics and AI as their top area of digital investment. More than half of surveyed organisations are already planning or piloting AI and Machine Learning initiatives, even though only 11 percent have deployed these technologies at scale. This gap between interest and implementation tells an important story: companies recognise AI's transformative potential, but many remain uncertain about how to operationalise it within evolving regulatory boundaries.

The reality is that AI is fundamentally different from previous waves of digital transformation. Implementing a Laboratory Information Management System (LIMS) or digitising quality workflows involves relatively well-defined validation pathways. AI systems, however, introduce new questions around transparency, explainability, accountability, data governance, model validation, and regulatory acceptance.

Without clear policy guidance, organisations face a difficult choice between moving cautiously and risk falling behind competitors, or accelerate adoption while navigating uncertainty. Neither option is ideal for an industry where patient safety, product quality, and regulatory compliance remain non-negotiable.

This challenge has emerged as the challenge of the hour as AI begins reshaping pharmaceutical R&D. The ability to analyse massive biological datasets, identify novel therapeutic targets, predict molecule behaviour, and optimise clinical trial design could significantly reduce development timelines and costs.

Global studies have already shown that AI-driven approaches can improve success rates in early-stage drug discovery and streamline decision-making across research programs. However, realising these benefits requires trust. Researchers need confidence that AI-generated insights are scientifically reliable. Regulators need confidence that AI-enabled processes remain auditable and compliant. Leadership teams need confidence that investments made today will align with tomorrow's regulatory expectations. This is where policy becomes an innovation enabler rather than a constraint.

Well-defined AI governance frameworks create the conditions necessary for responsible experimentation. They provide clarity on data usage, model validation, cybersecurity requirements, risk management protocols, and accountability structures. Most importantly, they reduce organisational hesitation by establishing a common language between technology teams, quality leaders, regulators, and business stakeholders.

The importance of this alignment is already visible across the industry. Archimedis Digital's research found that regulatory concerns evolve as organisations advance in their digital maturity journey. Companies that have achieved significant digital transformation increasingly cite cybersecurity, validation requirements, and regulatory clarity around emerging technologies such as AI and cloud platforms as critical considerations.

Interestingly, confidence in digital roadmaps rises substantially among organisations that have successfully implemented and integrated digital systems, demonstrating that certainty and measurable outcomes reinforce adoption momentum. India is uniquely positioned to benefit from this shift.

As one of the world's largest pharmaceutical manufacturing hubs and an increasingly important center for drug innovation, India has the opportunity to establish itself as a leader in responsible AI adoption. Recent regulatory modernisation efforts and the growing focus on digital quality infrastructure are encouraging signals.

However, the next phase requires collaborative engagement between regulators, industry associations, technology providers, and life sciences companies to develop practical AI governance frameworks that encourage innovation while maintaining patient trust.

The future of life sciences R&D will not be defined solely by who develops the most advanced AI models. It will be defined by who creates the most trusted environment for AI to thrive. Organisations often view policy as a response to innovation. In reality, for AI-driven life sciences, policy is becoming the catalyst that unlocks innovation at scale.

The companies that recognise this early—building robust governance structures alongside technical capabilities—will be best positioned to accelerate discovery, improve quality outcomes, and bring therapies to patients faster. In an industry where every breakthrough matters, clarity may prove to be the most valuable innovation of all.

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