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â??In life sciences, sustainable AI leadership will belong to organisations that balance innovation with compliance while delivering measurable business, regulatory and patient outcomesâ?•

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As artificial intelligence (AI) continues to reshape the life sciences and healthcare sectors, organisations are increasingly focused on balancing innovation with quality, governance and regulatory compliance. From accelerating drug development and improving operational efficiency to enabling next-generation digital platforms, AI is creating new opportunities across the healthcare value chain. However, realising its full potential requires robust validation, transparency and trust. In an interaction with BioSpectrum India, Duraisamy Rajan Palani (Durai), Founder & CEO of Archimedis Digital, who recently presented at the Lifesciences & Healthcare Innovation Forum (LHIF) organised by the NASSCOM Centre of Excellence â?? AI & IoT, shares his perspectives on AI adoption, digital transformation, compliance challenges and the foundational capabilities needed to drive sustainable innovation in the life sciences ecosystem.

At a session at LHIF, you observed that data is the mother of AI and compliance strategy is the father. What, then, is the DNA of trustworthy AI?

The DNA of trustworthy AI consists of transparency, traceability and accountability. Transparency ensures organisations understand how decisions are generated. Traceability provides visibility into data sources, model changes and system actions. Accountability establishes ownership, governance and oversight throughout the AI life cycle.

Together, these principles create AI systems that are explainable, auditable and compliant. In regulated environments, trust cannot be treated as an afterthought. It must be designed into the system from the outset.

Data provides the intelligence that powers AI, while compliance strategy establishes the controls and governance necessary to ensure reliability. When these elements come together, organisations can build AI systems that are innovative, trustworthy and fit for regulated decision-making.

How can organisations assess whether their data is sufficiently deep, diverse and compliant for trustworthy AI in GxP environments?

Organisations should evaluate data across three dimensions: quality, representativeness and compliance readiness. Data must be accurate, complete, traceable and relevant to the intended use case. It should also represent the diversity of real-world scenarios the AI system is expected to encounter to minimise bias and improve reliability.

In GxP-regulated environments, data quality alone is not enough. Companies must also demonstrate data lineage, audit trails, access controls and governance processes. If an organisation cannot explain where its data originated, how it was transformed and how its integrity is maintained throughout the life cycle, trust in AI outputs becomes difficult to establish.

In today’s business environment, data integrity and audit readiness remain among the strongest drivers of digital transformation. This reinforces a simple reality: trustworthy AI starts with trustworthy data.

Are Indian companies primarily building proprietary AI products or implementing third-party technologies?

The market today reflects a combination of both approaches. Many organisations continue to implement and customise third-party AI technologies, including large language models and foundation models. At the same time, there is a growing shift towards proprietary platforms, accelerators and domain-specific AI applications designed specifically for life sciences workflows.

As AI models become increasingly accessible, value creation will shift from the model itself to how effectively organisations apply it within regulated environments. In life sciences, competitive advantage comes from combining technology with scientific understanding, validated processes and trusted data assets.

How are Indian AI companies differentiating themselves from global competitors, and is cost still a key advantage?

Cost remains an advantage, but it is no longer the primary differentiator. Indian AI companies are increasingly competing through domain expertise, implementation agility, regulatory understanding and customer proximity.

Our report found that pharmaceutical companies increasingly view digital transformation as a driver of compliance, audit readiness and data integrity rather than simply a cost-saving initiative. This reflects a broader shift in buyer expectations. Organisations are looking for partners who can help them navigate complex regulatory requirements while delivering measurable business outcomes.

Indian companies often possess a unique advantage because they understand both global regulatory expectations and local operational realities. Their ability to rapidly configure solutions around GxP requirements, data integrity standards and quality management frameworks enables faster deployment and stronger adoption. The strongest players are moving beyond cost-based competition and differentiating themselves through innovation, scientific expertise and regulatory credibility.

From a regulatory perspective, does the origin of an AI platform matter, or is compliance determined by validation and evidence?

Regulators are primarily concerned with evidence rather than geography. Whether an AI platform originates in India, Europe or the United States, regulatory acceptance depends on its ability to demonstrate compliance, transparency, reliability and control.

Key requirements include validation documentation, auditability, traceability, data integrity, cyber security safeguards, change management controls and ongoing performance monitoring. Regulatory frameworks such as FDA 21 CFR Part 11, EU Annex 11 and broader GxP requirements focus on proving that systems perform consistently and remain under control throughout their life cycle.

This is why I often say that compliance strategy is the father of AI. Compliance provides the governance framework that transforms AI from an experimental technology into a trusted enterprise capability. In regulated industries, trust is built through evidence, not through geography or marketing claims.

What are the most important criteria life sciences organisations should evaluate before trusting an AI platform for regulated decision-making?

The first criterion is data quality and integrity. Organisations must understand where the data comes from, how it is governed and whether it is fit for purpose.

The second is compliance readiness. This includes validation methodologies, audit trails, documentation, cyber security controls and alignment with regulatory expectations.

The third is operational trustworthiness. This encompasses explainability, performance monitoring, risk management, change control and governance frameworks.

Our research shows that validation, data integrity and cyber security remain among the most significant concerns for pharmaceutical organisations pursuing digital transformation. The same principles apply directly to AI adoption. Organisations should trust AI only when they can trust the data, the controls and the governance mechanisms supporting it.

What were the biggest validation, auditability and data integrity challenges in your Generative AI and Agentic AI transformation case study?

One of the biggest challenges was adapting traditional validation approaches to systems that continuously evolve and generate dynamic outputs. Unlike conventional software, Generative AI and Agentic AI systems may produce different responses depending on context, making validation considerably more complex.

Maintaining auditability, ensuring traceability of decisions and preserving data integrity across multiple AI interactions required robust governance frameworks. We had to establish clear controls around model behaviour, prompt management, human oversight and decision tracking.

These challenges reflect broader industry concerns. Our research found that validation, system compliance, cyber security and regulatory clarity continue to be among the most significant barriers as organisations advance their digital maturity.

The key lesson is that innovation and compliance must evolve together. AI cannot succeed in regulated environments unless governance evolves at the same pace as technology.

As AI models become commoditised, will proprietary domain-specific data become the primary source of competitive advantage?

Absolutely. As foundation models become increasingly accessible, differentiation will shift towards proprietary data, scientific expertise and validated workflows.

Life sciences is a highly specialised industry where context matters enormously. Proprietary datasets, quality records, process intelligence and regulatory knowledge provide insights that generic AI models cannot easily replicate.

Our report found that 64 per cent of pharmaceutical companies prioritise investments in data analytics and AI tools, making them the most preferred technology category for future investment. This reflects growing recognition that data-driven intelligence will become a critical source of competitive advantage.

In the future, the most valuable asset will not be the model itself. It will be the trusted data ecosystem, scientific expertise and governance framework that enable organisations to generate meaningful and compliant insights.

Looking ahead five years, who will emerge as the leaders in life sciences AI, and what will determine the winners?

The future is unlikely to be dominated by a single category of player. Global technology companies will continue to provide foundational AI capabilities, while specialised life sciences companies—including emerging Indian AI product firms—will build differentiated solutions tailored to industry-specific needs.

What gives me confidence about India’s prospects is the momentum visible across the industry. AI adoption in pharmaceutical quality functions remains relatively early, but interest is accelerating rapidly as organisations move from experimentation to enterprise-scale deployment.

The winners will not be determined by geography. They will be determined by who best combines proprietary data, scientific expertise, regulatory credibility, integrated digital ecosystems and robust governance.

In life sciences, sustainable AI leadership will belong to organisations that balance innovation with compliance while delivering measurable business, regulatory and patient outcomes. The industry is moving from documentation to decision intelligence, from reactive quality management to predictive quality management, and from compliance-driven operations to confidence-driven innovation.

Narayan Kulkarni

narayan.kulkarni@mmactiv.com