Arcondis

Opinion:

AI You Can Trust: Why Validation Is Non-Negotiable In Life Sciences?

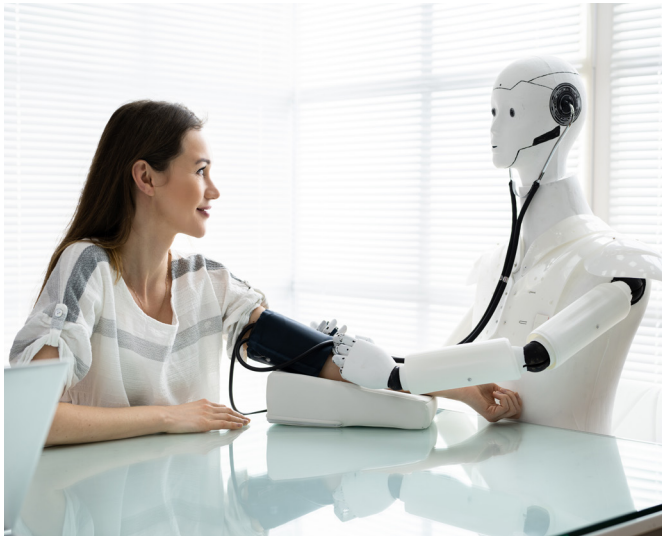
By Claudio D'Antonoli, Global Head of GxP Lifecycle Automation, Arcondis

Imagine stepping into a hospital and being greeted not by a doctor, but by an AI-powered agent – an intelligent assistant providing a diagnosis with precision. Today, big tech pioneers race toward this future vision that will be built on agentic AI workflows. Yet without rigorous validation, this promising vision leads to uncertainty. Would you trust your health in a future that is untested?

BALANCING INNOVATION WITH SAFETY

AI validation in healthcare is essential to ensure patient safety, regulatory compliance, and clinical trust. It verifies that AI systems are accurate, unbiased, and reliable across diverse populations, reducing the risk of harm and legal liability. Validation also supports adoption by proving that AI tools deliver clinically relevant and consistent results, even as data and medical practices evolve.

Left unchecked, AI carries risks of errors from data drift and biases that can impact diagnoses and patient care (FDA, 2023; European Commission, 2023). Organisations must embrace continuous validation as a fundamental practice, aligning AI development with regulatory frameworks such as the FDA's Total Product Lifecycle (TPLC) and Good Machine Learning Practice (GMLP), ensuring reliability and patient trust (FDA, 2023).



7 ESSENTIAL STEPS TO ENSURE AI VALIDATION IN HEALTHCARE

To implement AI safely within the regulated healthcare environment (GxP), consider these critical validation steps:

1

Clearly Define Objectives
Identify precise healthcare problems and ensure alignment with regulatory requirements.

2

Guarantee Data Quality & Diversity
Secure robust and comprehensive datasets to minimise biases.

3

Build Explainable and Transparent Models
Employ explainability tools like SHAP or LIME to build confidence and regulatory compliance.

4

Early & Frequent Validation
Continuously test AI from development through deployment to maintain accuracy.

5

Deploy with Risk Safeguards
Launch AI systems within controlled and closely monitored environments initially.

6

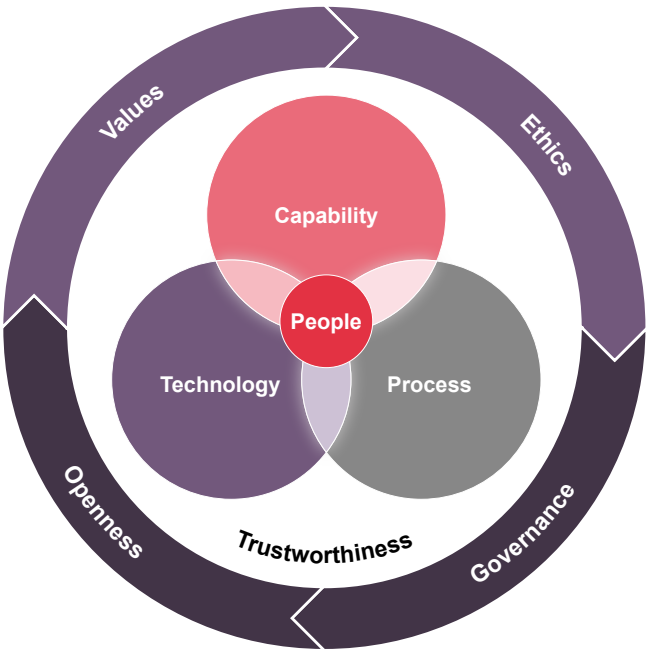
Ongoing Performance Monitoring
Implement constant surveillance of AI systems to detect and address performance issues proactively.

7

Regular Re-validation
Adapt validation practices consistently as new data and regulatory updates emerge.

THE AI FRAMEWORK FOR VALIDATION

AI validation is fundamentally about people and built on a foundation of trust. It is supported by capability, technology, and processes, guided by core principles of ethics, governance, and shared values.



ENHANCING VALIDATION THROUGH AUTOMATION

Integrating automation into the validation process significantly increases efficiency, accuracy, and compliance.

- **Continuous Performance Tracking:** Monitor AI behaviour in real-time to immediately detect deviations.
- **Automated Compliance Documentation:** Generate essential documentation systematically, simplifying regulatory adherence.
- **Standardised Validation Practices:** Consistently apply validation procedures to reduce errors and improve trustworthiness (Arcondis, 2025).

KEY FACTORS FOR RELIABLE AI VALIDATION

Consider these critical components to implement an effective validation approach:

- **Comprehensive Risk Assessment:** Evaluate AI systems for data integrity, algorithmic bias, interoperability, and ethical concerns.
- **Regulatory Alignment:** Ensure validation methods meet guidelines such as FDA's GMLP, TPLC, and the EU AI Act (European Commission, 2023).
- **Data Integrity Management:** Enforce strict data management protocols to maintain accuracy, consistency, and regulatory compliance.
- **Structured Change Management:** Clearly document and validate every system modification to ensure continuous compliance.
- **Stakeholder Training:** Educate users to interpret AI decisions correctly and respond to issues swiftly.
- **Consistent Monitoring & Review:** Employ continuous monitoring and periodic re-validation to ensure sustained compliance.

ARCONDIS – YOUR TRUSTED PARTNER IN VALIDATED AI

At Arcondis, we believe in combining leading AI technology with meticulous validation practices. Our GxP Lifecycle Automation Service is specifically designed to meet the demanding requirements of the life sciences industry. By orchestrating intelligent, automated workflows, we ensure your AI solutions deliver safe, transparent, and compliant outcomes.

Advantages of Partnering with Arcondis:

- **Streamlined Efficiency:** Reduce validation timelines and effort significantly through automated processes.
- **Comprehensive Regulatory Compliance:** Seamlessly align with global standards including FDA 21 CFR Part 11, EU Annex 11, ISO 13485, and ISO 27001 (FDA, 2023; European Commission, 2023; ISO, 2023).
- **Flexible Scalability:** Support from small, targeted deployments to enterprise-wide solutions (Arcondis, 2025).
- **Proactive Risk Management:** Benefit from continuous risk assessment and proactive monitoring capabilities (Arcondis, 2025).

SECURING THE FUTURE OF AI IN HEALTHCARE

The transformative power of AI in healthcare depends on our ability to ensure responsible development and strict validation. Don't wait for a crisis to highlight the need for validation. Prioritise validation now to safeguard patient safety, enhance clinical outcomes, and drive sustainable innovation.

To discuss how to secure and validate your AI solutions comprehensively, contact us.

References:

1. Arcondis (2025) GxP Lifecycle Automation Service. Basel: Arcondis Group.
2. European Commission (2023) Proposal for a Regulation Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act). Brussels: European Commission.
3. FDA (2023) Good Machine Learning Practice for Medical Device Development: Guiding Principles. Silver Spring: Food and Drug Administration.
4. ISO (2023) ISO 27001: Information Security Management. Geneva: International Organisation for Standardisation

About the author

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Claudio D'Antonoli is the Global Head of GxP Lifecycle Automation at Arcondis. With over 17 years of experience in compliance, quality, and security, Claudio helps organisations successfully manage regulatory challenges. He combines knowledge of new technologies with a clear understanding of regulations, helping businesses adopt innovations safely, ethically, and confidently as regulations evolve.

About Arcondis

Arcondis is a global professional services company exclusively focused on the life sciences and healthcare sector. Owned by a Foundation and committed to healthcare improvement, we accelerate value creation for our clients in R&D, Manufacturing & Supply Chain, Marketing, Sales & Services, to ultimately benefit patients.

Our solutions and services include Digitalisation, Data, IT & Infrastructure; Product Lifecycle Management; Industry Compliance & Managed Services and People & Culture. As an independent solutions and Managed Service provider, we have the flexibility to prioritise our clients' best interests without being constrained by exclusive partnerships. We follow an outcomes-based approach – from strategy to hands-on delivery and beyond.

With a well-established reputation built over two decades, we have earned the trust of leading companies in Pharma, MedTech, Healthcare and Start-ups. Headquartered in Switzerland, we employ more than 250 specialists and professionals, with offices in North America, Europe and APAC.

We make healthcare better, globally!

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