Engineering Data Architectures for AI/ML Integration in Regulated Manufacturing

About

This study investigates the challenges and opportunities of integrating Artificial Intelligence (AI) and Machine Learning (ML) in regulated manufacturing sectors like pharmaceuticals and medical devices. Through 20 qualitative interviews with data architects, AI specialists, and compliance officers, the research identifies key barriers and proposes a conceptual framework for designing compliant, AI-driven data architectures.

Problem

Life science manufacturers are increasingly adopting AI/ML to improve production and compliance, but progress is slow. They face significant hurdles from fragmented data systems, legacy infrastructures, and data silos, which are compounded by complex and evolving regulatory requirements that create uncertainty around system validation and traceability.

Study Outcome

- Current data infrastructures in regulated manufacturing are highly fragmented, with data silos and legacy systems acting as the primary technical barriers to AI adoption.
- Evolving regulatory frameworks and uncertainty in how to validate AI systems create significant compliance challenges that slow down innovation.
- Experts agree that overcoming these barriers requires unified data architectures, embedded governance, enhanced security, and proactive regulatory operations (RegOps).
- The study proposes a conceptual framework for a validation-aware, layered data architecture that can bridge fragmented systems and support the entire AI/ML lifecycle in a compliant manner.

Keywords

AI adoption • data architecture • regulated manufacturing • life science • regulatory compliance • GxP • AI validation