

Accelerate Computer System Validation with SmartVal

SmartVal, an AI-powered solution, accelerates computer system validation for life sciences organizations by streamlining compliance documentation, reducing manual effort, and lowering validation costs—while ensuring regulatory integrity.

Key Challenges



Rigorous Computer System Validation is critical to ensure product quality, patient safety, and data integrity.



Risk assessments during project initiation determine validation scope but are complex, time-consuming, and subjective.



Lack of a risk-based approach leads to over-validation, higher costs, and operational inefficiencies.



Manual, paper-based processes slow down validation and increase the risk of human error.

Solution Approach



LTIMindtree's SmartVal Solution

LLM-powered multi-agent architecture automates regulatory research, risk assessment, and document generation.



Determines GxP, SOX, and data privacy applicability using contextual insights and checklists.



Generates first-draft validation artifacts (Initial Risk Assessment, VMP, FRS) using industry-standard templates.



Built on Microsoft Azure OpenAI and Azure Foundry, with built-in safeguards for secure and responsible AI usage.

Business Benefits



Time Savings



Lower Costs



Accelerated Time to Market

Benefitted personas

- Validation Leads
- Quality Assurance Team
- Business & Program Owners