

# 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