

Labware LIMS – System Validation (Implementation)

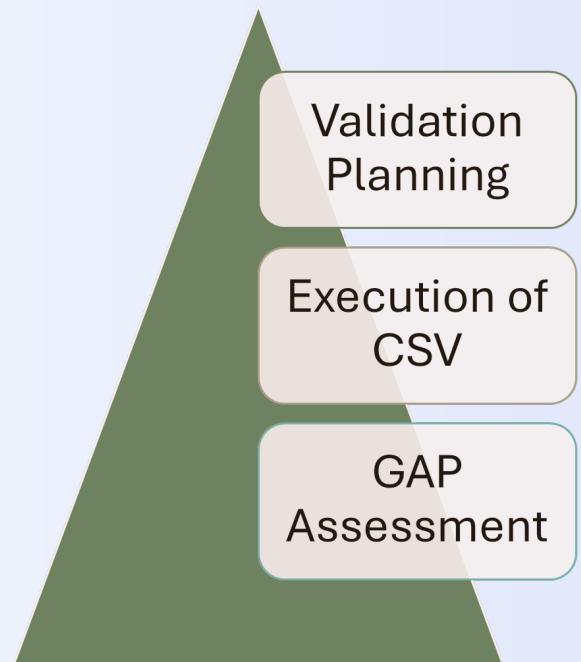
Zamann Pharma Support offers consultancy services in Labware LIMS – System Validation (Implementation), covering end-to-end Computer System Validation (CSV) services aligned with regulatory requirements (e.g., FDA, EMA) and GAMP5 guidelines. This included the creation of validation strategies, execution of qualification protocols, and documentation review to ensure the LIMS implementation complied with industry standards. The consultancy enabled the organization to achieve a validated system that ensured data integrity, reliability, and compliance

Validation Planning and Documentation Development

Development of a comprehensive Validation Master Plan (VMP) aligned with Labware LIMS necessities, including the validation deliverables, risk assessments, and a timeline aligned with regulatory expectations. Creation, review and approval of all required CSV documents (e.g., URS, FRS, IQ, OQ, PQ protocols).

Execution of Validation Protocols

Coordination and execution of Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) protocols to confirm that the Labware LIMS met design specifications, operated as intended, and supported the company’s business needs.



Regulatory Gap Assessment and Risk Mitigation

Performing a detailed GAP analysis to evaluate the system’s alignment with FDA 21 CFR Part 11, EU Annex 11, and other regulatory requirements, identifying compliance risks and providing specific recommendations to mitigate GAPs, ensuring robust data integrity and regulatory adherence.