Computerized System Validation
Audit Readiness – GAP Assessment

Consultancy focused on evaluation of existing CSV processes, to identify potential GAPs between applied regulations (e.g.: FDA and EMA) and current practices. Our services ensures compliance for future Audits by assessing the background and execution records of the validation process

Regulatory Compliance Review

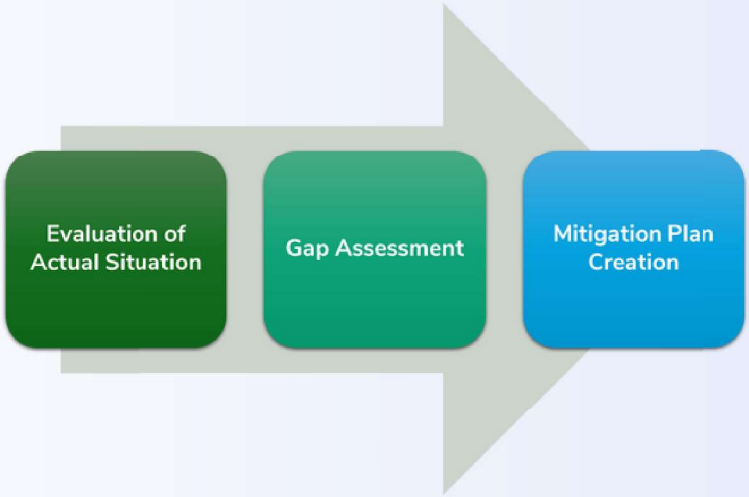
We conduct a comprehensive review of FDA and EMA regulations pertaining to computerized system validation, identifying specific requirements and expectations.
Our experts assess the existing validation process against regulatory standards to pinpoint areas of non-compliance or potential gaps.

GAP Analysis and Documentation Review

Zamann performs a detailed GAP analysis to compare the current state of the validation process with regulatory requirements.
We review existing documentation, procedures, and quality records related to computerized system validation to identify discrepancies or deficiencies in compliance.

Recommendations and Action Plan Development

Based on the findings from the GAP assessment, we provide actionable recommendations and develop a strategic action plan to address identified gaps.
We collaborate closely with clients to prioritize corrective actions, implement process improvements, and enhance compliance with regulatory standards for future audits.



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- Quality Consulting and Risk Management
- Qualification and Validation
- Personnel Qualification
- Customer-specific provision of QMS

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