Computerized System Validation
Audit Readiness – Strategy Definition

Zamann Pharma Support offers specialized consultancy designed to provide comprehensive services to develop necessary documentation, including SOPs, checklists, and workflows, in compliance with applicable regulations, focused on empowering clients with the knowledge and tools required to ensure the Audit Readiness regarding CSV

Regulatory Compliance Assessment

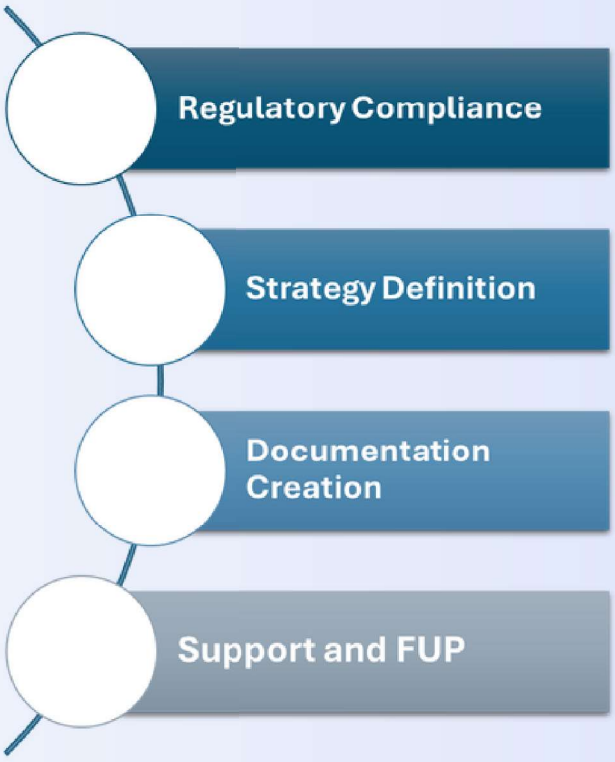
We conduct a detailed analysis of regulatory requirements related to CSV audits, including FDA 21 CFR Part 11 and Annex 11 of the EU GMP guidelines.
Our experts assess the regulatory landscape to identify key requirements and expectations for CSV audit readiness, ensuring alignment with industry standards.

Development of Audit Readiness Strategy

Collaborating closely with clients, we develop a tailored strategy outlining the objectives, scope, and methodologies for achieving CSV audit readiness.
We define the roles and responsibilities of stakeholders involved in the audit readiness process and establish timelines for implementation.

Documentation Framework Creation

Zamann assists in creating a comprehensive documentation framework to support CSV audit readiness efforts. We develop SOPs, checklists, and workflows detailing procedures for CSV system validation, maintenance, and documentation management, ensuring regulatory compliance and audit preparedness.



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

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