

# Computerized Systems Validation Landscape – Strategy Definition

Zamann Pharma Support provides strategic guidance to clients in implementing Computerized Systems Validation (CSV) activities. We assist clients in creating a comprehensive strategy tailored to their specific needs and regulatory requirements, enabling them to effectively navigate the complexities of CSV implementation.

## Regulatory Compliance Assessment

Our team conducts a thorough review of relevant regulatory requirements, including FDA 21 CFR Part 11 and EU Annex 11, to ensure a comprehensive understanding of compliance obligations.

We meticulously analyze these regulations to identify specific requirements related to CSV activities, such as data integrity, electronic records, and electronic signatures. We assess the client's existing systems, processes, and documentation to determine their alignment with regulatory standards, identifying any areas of non-compliance or potential gaps that may require remediation.

## Strategy Development and Roadmap Creation

Collaborating closely with the client, we translate the findings from the regulatory compliance assessment into a customized CSV strategy tailored to their unique needs and organizational context. Our team develops a detailed roadmap that outlines the sequential steps, milestones, and timeline for CSV implementation, ensuring clarity and accountability throughout the process.

The strategy encompasses elements such as risk-based approaches, resource allocation, and quality assurance measures.

## Stakeholder Engagement

We engage with stakeholders across different departments and levels of the organization to foster understanding, alignment, and commitment to the CSV strategy.

Through interactive workshops and seminars, we educate stakeholders on CSV principles, methodologies, and best practices, empowering them with the knowledge and skills required for effective implementation.



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

**Contact:**  
[quality-services@zamann-pharma.com](mailto:quality-services@zamann-pharma.com)  
[www.zamann-pharma.com](http://www.zamann-pharma.com)