# Quality Management Systems
# Audit Readiness – Routine Support

**Zamann Pharma Support GmbH offers comprehensive Audit Readiness services customized to meet the stringent requirements of regulatory agencies such as the FDA and EMA. Our expert consultants ensure that pharmaceutical companies are well-prepared for audits, providing strategic guidance and support to achieve compliance and readiness**

## GAP Assessment and Remediation Planning

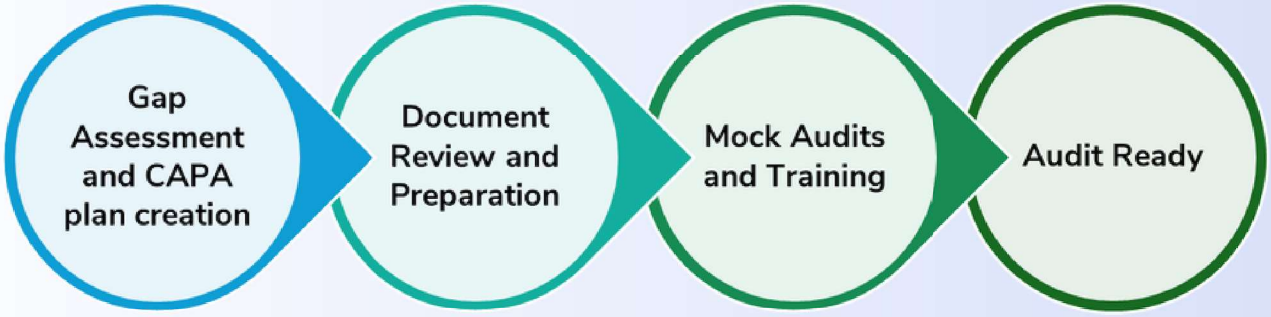
We conduct thorough gap analysis assessments to identify areas of non-compliance and potential vulnerabilities in existing systems and processes. Based on the findings, we develop tailored remediation plans, outlining corrective actions and strategies to address deficiencies and enhance compliance with regulatory standards.

## Documentation Review and Preparation

Our team assists clients in reviewing and organizing documentation to ensure completeness, accuracy, and accessibility for regulatory inspections. We provide guidance on the creation and maintenance of audit-ready documentation, including SOPs, validation reports, and quality records, to demonstrate compliance with FDA and EMA requirements.

## Mock Audit Simulations and Training

To simulate real-world audit scenarios, we conduct mock audit simulations designed to assess preparedness and identify areas for improvement. Our consultants facilitate mock audits, closely mirroring regulatory inspection processes, and provide feedback and training to key personnel to enhance their readiness and confidence during actual audits.

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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
www.zamann-pharma.com