Quality Management System Landscape – Strategy Definition

Our service is meticulously crafted to assist pharmaceutical organizations in establishing robust Quality Management Systems (QMS) aligned with international standards set forth by regulatory authorities like the FDA, EMA, and WHO. We specialize in creating all essential documentation elements necessary for a comprehensive QMS, including guides, policies, SOPs, and templates for activities execution

GAP Analysis and Needs Assessment

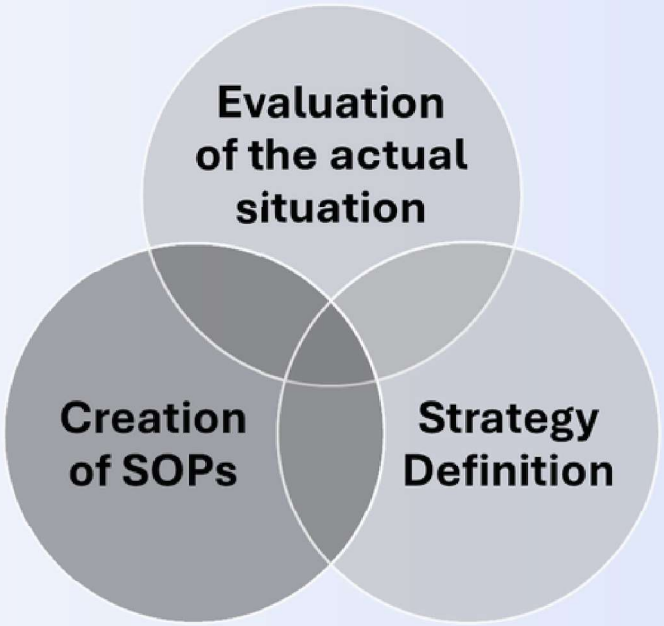
We conduct a thorough analysis of your organization's existing processes, identifying the necessities and deficiencies.

After this comprehensive assessment, we determine the specific requirements and objectives of your QMS implementation, ensuring alignment with regulatory standards.

SOPs Development and Documentation Creation

Our team of experienced consultants collaborates closely with your organization to develop customized Standard Operating Procedures (SOPs) created to your specific operational needs.to your specific operational needs.

We adhere to regulatory guidelines and best practices, ensuring that SOPs are comprehensive, clear, and compliant with FDA, EMA, and WHO requirements.



Documentation Review and Approval Process

We facilitate the review and approval process for all QMS documentation, engaging stakeholders across departments to ensure accuracy, consistency, and alignment with organizational objectives.

Our consultants provide guidance on establishing robust documentation control procedures, including version control, change management, and document lifecycle management.

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

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