

# Quality Systems - Implementation and Improvements

Our service specializes in the implementation and enhancement of Quality Systems within the pharmaceutical market. We offer comprehensive landscape implementation and/or improvement for all quality activities, including Standard Operating Procedures (SOPs), batch record review, training programs, effective Change Control, and Deviation management, ensuring regulatory compliance and product quality

## Creation of the QMS Landscape

We assist in designing and implementing a comprehensive Quality Management System (QMS) tailored to your organization's needs, ensuring alignment with regulatory requirements and industry best practices. Additionally, we are able to implement the perfect Management Review process, considering the reality of your company.

## Quality GAP Assessment

Our consultants perform a comprehensive GAP Assessment of your Quality management practices, scrutinizing SOPs, processes, and systems. We meticulously compare these practices against regulatory standards from authorities like the FDA and EMA, identifying potential GAPs.

Based on our findings, we provide detailed reports outlining identified GAPs and deficiencies, along with actionable recommendations for improvement.

Our goal is to ensure that your Quality management system is robust, compliant, and continuously improving to meet the evolving regulatory landscape and industry standards.



QMS LANDSCAPE  
IMPLEMENTATION

QUALITY PROCESSES  
GAP ASSESSMENTS

AUDIT READINESS  
PROGRAM

## Audit Readiness Program and Mock Inspection

We offer a comprehensive Audit Readiness Program to prepare your organization for regulatory inspections, including training, GAP Assessments, documentation review, and mock inspections, to ensure readiness and compliance. Our Mock Inspection service simulates real regulatory inspections, providing valuable practice for your team, identifying potential gaps or deficiencies, and offering recommendations for improvement to ensure readiness for official inspections.

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

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