

3-Step How to Guide for Quality System Implementation

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Overview of Approach

- Step 1: Assess quality systems and identify gaps
- Step 2: Develop a comprehensive improvement plan
- Step 3: Execute the improvement plan
- Step 4: Implement process in e-system (if applicable)

Step 1: Assess quality systems

- Assess As-Is state of quality systems strategy
- Assess quality systems based on regulatory requirements, includes:
 - Quality Manual and Quality Policy
 - Global standards
 - Quality system procedures
 - QMR Presentations and metric
- Develop To Be state of Quality systems strategy
- Determine the gaps in strategy, procedures, and standards

Step 2: Develop comprehensive remediation plan

- Develop overall QMS implementation plan
- Develop an individual implementation plan
 - Develop a detailed plan for each system
 - Details of activities of each system including gaps, metrics, training, etc.
 - Timeline from start to finish

Step 3: Execute remediation plan

- Develop/Revise process maps (input from site QA)
- Revise the procedures
- Revise the forms
- Ensure that the appropriate metric is included in Quality Management Review
- Ensure that all the systems well-aligned with local and global procedures
- Review with site QA to finalize

Project Proposal

- Inputs:
 - Quality system documents
 - QMR presentations/minutes
- Outputs:
 - QMS improvement plan
 - Individual quality system blueprint
 - Individual quality system process maps
 - Quality system procedures and forms
- Completion time: Generally 3-12 months, depending on complexity and number of standards and procedures

