

3-Step How to Guide for Quality Control (QC) Program Implementation

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Overview of Approach

- Step 1: Assess QC programs 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 QC Programs

- Assess As-Is state of QC compliance strategy
- Assess QC programs based on regulatory requirements, includes:
 - Standards and procedures
 - Quality Control programs
 - Metrics for QC
- Develop To Be state of QC program strategy
- Determine the gaps in strategy, procedures, and standards

Step 2: Develop comprehensive remediation plan

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

Step 3: Execute remediation plan

- Develop process maps (input from site QC)
- Revise the procedures
- Revise the forms
- Develop/revise metric for quality and cycle time
- Ensure that an appropriate metric is included in Quality Management Review
- Ensure that all the programs are well-aligned
- Review with site QC to finalize

Project Proposal

- Inputs:
 - QC Program documents
 - QC metric
- Outputs:
 - Overall improvement plan
 - Individual program blueprints
 - Process maps
 - QC Programs and forms
- Completion time: Generally 3-6 months, number of standards, procedures, and programs