

3-Step How to Guide for Quality Strategic Planning

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Overview of Approach

- Step 1: Where Are We (As-Is Analysis)
- Step 2: Gap Analysis and Risk Ranking based on severity and complexity
- Step 3: Plan of Action

Step 1: “As Is” Data Collection

- Internal and external audit observations
- Significant nonconformances
- CAPA
- New business projects related to site transfer, validation, audit and quality agreements
- Significant customer complaints
- Adverse events and Recalls
- Compliance History
- Regulatory Trends (Regulatory Intelligence)
- Benchmarking against industry trends on innovation
- Interview with key personnel's to learn pain points



Step 2: Risk Prioritization

- Based on the results of gap analysis, identify high-risk area, which needs process improvement
- Perform the risk ranking based on risk and complexity
- Senior Management requires tangible and intangible benefit to financially approve the initiative.

Step 3: Developing Plan of Action

- Develop strategies to address gaps
- Develop short-term plans
- Develop long-term plans
- Assess organizational capacities and capabilities
- Develop initiatives
- Identify resources
- Realize tangible and intangible benefits

Project Proposal

- Input: Documents related to audits, trends, etc.
- Output: Risk heat maps and Strategic Quality Plan
- Completion Time: 3-6 months based on the size of the organization