

# 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

- Based on risks and projects
  - Internal and external audit observations
  - Significant nonconformances
  - CAPA and projects
  - Significant customer complaints
  - Adverse events and Recalls
  - Compliance History
  - Regulatory Trends (Regulatory Intelligence)
  - Benchmarking against industry trends on technologies

# Step 2: Risk Prioritization

- Based on results of gap analysis, identify high risk area, which need 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