

3-Step How to Guide for Global Quality 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

- From all sites to be involved
 - Requirements of the global quality management systems
 - Internal and external audit findings and CAPA
 - FAR/BPDR/Recalls
 - Compliance history of sites
 - Inventory of quality systems and metric
 - Maturity state of quality systems
 - Emerging Regulatory Trends
 - Industry trends on innovations to enhance quality systems
 - Interview with key personnel to identify opportunities & challenges
 - Other data as identified by project sponsor

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, complexity and financial impact
- 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 processes and procedures for global function
 - Metric related to global functions
 - Interview with key personnel
- Output:
 - Risk Heat maps
 - Global Quality Plan
- Completion Time: 3-12 months based on the number of sites