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

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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 (Pain points)
  - New business projects related to site transfer, validation, audit, and quality agreements
  - Other data as identified by the project sponsor

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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, complexity and financial impact
- Senior Management requires tangible and intangible benefit to financially approve the initiative.

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Step 3: Developing Plan of Action

- Develop vision and strategies to address gaps related to development, manufacture, and distribution of products
- Develop short-term plans
- Develop long-term plans
- Assess organizational capacities and capabilities
- Develop initiatives
- Identify resources
- Realize tangible and intangible benefits
- Create a culture of sustainable compliance

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Project Proposal

- Input
  - Documents related processes and procedures for the 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

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