

# 3-Step How to Guide for Site Quality Risk Assessment

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# Overview of Approach

- Step 1: Plan the risk assessment
- Step 2: Conduct the risk assessment
- Step 3: Develop the risk assessment report

# Step 1: Risk Assessment Planning

- Create an agenda
- Identify team
- Create timelines

# Step 2: Risk Assessment

- Conduct baseline (deep dive) risk assessment for quality systems
- Ensure in-depth evaluation of policies, procedures, programs, and practices for compliance with regulations
  - Quality systems
  - Laboratory controls
  - Facility and Engineering
  - Materials control
  - Manufacturing controls
  - Labeling and packaging
  - Data integrity (if applicable)

# Step 3: Develop the report

- List the risks
- Rank the risks
- Provide recommendations

# Project Proposal

- Input:
  - Documents
  - Production, warehouse and lab tours
- Output:
  - Risk assessment report
- Completion Time: 3-6 weeks