

4-Step How to Guide for PAI Readiness

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Overview of Approach

- Step 1: PAI Readiness Planning
- Step 2: Conduct Risk Assessment
- Step 3: Develop an Action Plan to Remediate Risks
- Step 4: Prepare the Site for PAI

Step 1: PAI Readiness Planning

- Develop a PAI readiness plan based on product and regulatory agency
- Develop approach and tools to be used for risk assessment
- Develop approach and tools to be used for site readiness for inspection

Step 2: Conduct Risk Assessment

- Conduct risk assessment in the following area
 - Readiness for commercial manufacturing
 - Conformance to application
 - Data integrity

Step 3: Develop Action Plan to Remediate Risks

- Develop strategies to address gaps
- Identify resources
- Track progress in regular meetings

Step 4: Prepare the Site for PAI

- PAI Team
- Documents requirement
- Facility requirement
- Personnel requirement
- Training requirement
- Mock PAI

Project Proposal

- Inputs:
 - Production, warehouse and lab tours
 - Study reports and documents
 - Submission draft
 - Dedicated site QA staff
- Outputs
 - Risk assessment reports
 - Remediation plan
 - Site readiness plan
- Completion time: 6-8 months