



## GMP Gap Assessment Action Items

### Project Kick-Off and Planning

- **Action Item:** Initiate the project with a kick-off meeting to define scope, objectives, and timelines.
- **Deliverable: Project Kick-Off Document**—includes project plan, timeline, scope of work, and stakeholder roles.

### Initial GMP Evaluation

- **Action Item:** Conduct a comprehensive evaluation of current GMP practices, processes, and documentation.
- **Deliverable: GMP Evaluation Report**—detailed findings on existing practices, compliance status, and identified gaps.

### Regulatory Compliance Analysis

- **Action Item:** Analyze current operations against relevant GMP standards and regulatory requirements.
- **Deliverable: Regulatory Compliance Report**—assessment of adherence to regulations, highlighting non-compliance areas.

### Facility and Equipment Review

- **Action Item:** Review the facility layout, design, and equipment for GMP compliance.
- **Deliverable: Facility and Equipment Gap Report**—findings and recommendations on facility and equipment compliance with GMP standards.

### Document and Record Examination

- **Action Item:** Evaluate existing documentation and records, such as SOPs, quality manuals, and training records.
- **Deliverable: Documentation Review Report**—analysis of documentation with recommendations for updates and improvements.

### Process and Procedure Assessment



- **Action Item:** Assess manufacturing processes and procedures for GMP compliance.
- **Deliverable: Process Assessment Report**—identification of process deficiencies and suggested corrective actions.

### Risk Assessment and Management

- **Action Item:** Perform a risk assessment to identify potential compliance risks and vulnerabilities.
- **Deliverable: Risk Assessment Report**—detailed analysis of risks with mitigation strategies and action plans.

### Training and Competency Evaluation

- **Action Item:** Review and assess the effectiveness of current staff training programs and competency levels.
- **Deliverable: Training and Competency Report**—evaluation of training programs with recommendations for enhancements.

### Internal Audit Review

- **Action Item:** Review past internal audit findings and evaluate the effectiveness of corrective actions taken.
- **Deliverable: Internal Audit Review Report**—summary of previous audit results with an assessment of corrective actions.

### Compliance Gap Identification

- **Action Item:** Identify and document specific gaps between current practices and GMP requirements.
- **Deliverable: Gap Identification Report**—detailed documentation of compliance gaps with a prioritized list of issues to address.

### Action Plan Development

- **Action Item:** Develop a comprehensive action plan to address identified gaps and achieve GMP compliance.
- **Deliverable: Corrective Action Plan**—strategic plan outlining necessary changes, timelines, and responsible parties for remediation.

### Review and Final Report



- **Action Item:** Review findings with stakeholders and present the final assessment report.
- **Deliverable: Final GMP Gap Assessment Report**—includes an executive summary, detailed findings, and the corrective action plan.

#### Follow-Up and Support

- **Action Item:** Provide support for implementing the corrective actions and conduct follow-up reviews as needed.
- **Deliverable: Follow-Up Support Plan**—ongoing support and periodic reviews to ensure implementation of corrective actions and continuous compliance.

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