



GMP Compliance Set-Up Services Action Items Action Items

GMP Compliance Strategy Development

- **Develop Customized Compliance Plan**
 - Draft a GMP compliance strategy tailored to the specific needs of the organization.
 - Define key compliance objectives and success criteria.
- **Create Implementation Roadmap**
 - Develop a timeline with milestones for achieving compliance.
 - Assign responsibilities and resources required for each phase of implementation.

Facility and Equipment Optimization

- **Facility Layout Review**
 - Evaluate existing facility layout and design for GMP compliance.
 - Provide recommendations for layout adjustments if necessary.
- **Equipment Validation and Calibration**
 - Review equipment validation protocols.
 - Develop and implement validation and calibration schedules.

Documentation and Record-Keeping

- **Draft and Review SOPs**
 - Develop Standard Operating Procedures (SOPs) for critical processes.
 - Review and update existing SOPs to ensure they meet GMP standards.
- **Establish Record-Keeping Systems**
 - Set up a documentation system for maintaining accurate and comprehensive records.
 - Implement procedures for routine documentation review and audits.

Training and Personnel Development

- **Develop Training Programs**
 - Create GMP training materials and programs for staff.
 - Schedule and conduct initial training sessions.
- **Implement Ongoing Training**
 - Establish a schedule for refresher training and updates on regulatory changes.
 - Monitor training effectiveness and adjust programs as needed.



Quality Management System (QMS) Implementation

- **Design and Implement QMS**
 - Develop a Quality Management System tailored to the organization's needs.
 - Integrate QMS with existing processes and systems.
- **Establish Quality Control Procedures**
 - Implement quality control procedures and testing protocols.
 - Monitor and adjust quality control processes based on performance data.

Regulatory Compliance Support

- **Prepare for FDA Inspections**
 - Assist in preparing documentation and procedures for FDA inspections.

Continuous Improvement and Monitoring

- **Implement Improvement Strategies**
 - Analyze audit results and industry trends to identify areas for improvement.
 - Implement continuous improvement initiatives based on audit findings and feedback.

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