



GMP Setup Services Action Items

Initial GMP Assessment

- **Action Item:** Conduct a comprehensive evaluation of current practices and facility.
- **Deliverable: GMP Readiness Assessment Report**—includes an evaluation of existing practices, identification of gaps, risks, and a tailored action plan for achieving GMP compliance.

GMP Documentation Development

- **Action Item:** Develop and customize GMP documentation, including Standard Operating Procedures (SOPs) and quality manuals.
- **Deliverable: Custom SOPs and Quality Manuals**—complete documentation that meets GMP standards, tailored to your specific operational needs.

Facility Design and Layout Optimization

- **Action Item:** Review and optimize facility design and layout to meet GMP requirements.
- **Deliverable: Facility Design Optimization Report**—detailed recommendations for layout improvements to ensure GMP compliance and operational efficiency.

Process Implementation and Optimization

- **Action Item:** Develop and implement manufacturing processes and controls in alignment with GMP standards.
- **Deliverable: Process Implementation Plan**—a detailed plan outlining optimized procedures, control systems, and recommended enhancements.

Equipment Qualification and Validation

- **Action Item:** Ensure all manufacturing equipment is qualified and validated for GMP compliance.
- **Deliverable: Equipment Qualification and Validation Reports**—documentation confirming that equipment meets GMP standards and performs as required.



Staff Training and Development

- **Action Item:** Provide training programs on GMP principles, procedures, and regulatory requirements for your staff.
- **Deliverable: Training Materials and Certification**—includes training presentations, manuals, and certificates of completion, along with detailed training records.

Internal Audit Preparation

- **Action Item:** Prepare your facility for internal GMP audits to ensure readiness for certification.
- **Deliverable: Internal Audit Report**—includes audit findings, compliance gaps, and recommendations for corrective actions.

Certification Application Support

- **Action Item:** Assist with the preparation and submission of GMP certification applications.
- **Deliverable: Completed Certification Application**—all necessary documentation and an **Audit Preparation Checklist** to address potential issues before the official audit.

Regulatory Compliance Guidance

- **Action Item:** Provide ongoing guidance to ensure continued GMP compliance and adaptation to regulatory changes.
- **Deliverable: Regulatory Compliance Updates and Guidance Reports**—includes information on new regulations and best practices to keep your operations compliant.

Post-Setup Support and Maintenance

- **Action Item:** Offer support and maintenance to ensure ongoing GMP compliance and resolve any emerging issues.
- **Deliverable: Post-Setup Support Plan**—includes periodic reviews, compliance checks, and corrective action plans to address any new challenges.

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