Current Good Manufacturing Practices (cGMP) Set-Up Service Action Items

Initial Consultation and Needs Assessment

- Schedule an initial consultation meeting with key stakeholders.
- Gather existing documentation and processes for review.
- Prepare a needs assessment report identifying specific compliance requirements.

Development of cGMP Framework

- Draft a customized cGMP compliance framework based on the assessment findings.
- Outline key components, including quality management and SOP development.
- Review the framework with stakeholders for feedback and approval.

Standard Operating Procedures (SOPs) Creation

- Identify critical processes requiring SOPs.
- Draft SOPs in collaboration with subject matter experts.
- Review and finalize SOPs with input from relevant departments.

Training and Capacity Building

- Develop a training program tailored to different staff roles.
- Schedule training sessions (on-site and/or virtual).
- Create training materials and assessments to gauge understanding.

Quality Management System (QMS) Implementation

- Assess current quality systems and identify gaps.
- Design a QMS that incorporates risk management and continuous improvement.
- Document the QMS and ensure it is accessible to all staff.

Documentation and Record Management Setup

- Develop a document control procedure, including versioning and approval processes.
- Establish a centralized electronic document management system.
- Train staff on proper documentation practices and record-keeping.

Internal Audit Preparation

- Create a checklist for internal audits based on cGMP requirements.
- Schedule internal audits and assign audit teams.
- Conduct mock audits and compile feedback for improvement.

Supplier and Vendor Qualification

- Develop criteria for supplier and vendor qualification.
- Create a process for ongoing monitoring and evaluation of suppliers.
- Conduct audits of key suppliers to ensure compliance with cGMP standards.

Ongoing Compliance Monitoring and Support

- Set up a schedule for regular compliance reviews and updates.
- Establish communication channels for ongoing support and guidance.
- Monitor regulatory changes and adjust compliance strategies as needed.

Final Compliance Review and Certification

- Conduct a thorough review of the entire cGMP set-up.
- Identify any remaining gaps or areas for improvement.
- Prepare and issue a certification of compliance readiness to stakeholders.