



## GMP Certification Action Items

### Initial Assessment

- **Action Item:** Conduct a comprehensive assessment of current manufacturing practices.
- **Deliverable: GMP Readiness Assessment Report** including an evaluation of existing practices, identification of gaps, and a strategic roadmap.

### Documentation Development

- **Action Item:** Develop and customize Standard Operating Procedures (SOPs) and quality manuals.
- **Deliverable: SOPs and Quality Manual Documentation** that meets GMP requirements, including procedures, responsibilities, and quality control measures.

### Process Optimization

- **Action Item:** Review and optimize manufacturing processes to align with GMP standards.
- **Deliverable: Process Improvement Plan** detailing recommended changes, new control systems, and enhancements to current practices.

### Staff Training

- **Action Item:** Provide training programs for staff on GMP principles, procedures, and compliance.
- **Deliverable: Training Materials and Attendance Records** including presentation slides, training manuals, and a list of trained employees.

### Internal Audits

- **Action Item:** Perform internal audits to prepare for GMP certification and ensure readiness.
- **Deliverable: Internal Audit Report** highlighting audit findings, areas of non-compliance, and corrective action recommendations.

### Certification Application Support

- **Action Item:** Assist with the GMP certification application process and prepare for certification audits.
- **Deliverable: Completed Certification Application** including all required documentation and **Audit Preparation Checklist** to address potential issues.



### Regulatory Compliance Updates

- **Action Item:** Monitor and update GMP documentation to reflect the latest regulatory changes.
- **Deliverable: Updated GMP Documentation** incorporating recent regulatory changes and compliance requirements.

### Corrective Actions

- **Action Item:** Develop and implement corrective action plans to address issues identified during audits.
- **Deliverable: Corrective Action Plan** including detailed steps for resolving issues, implementation timelines, and responsible parties.

### Post-Certification Support

- **Action Item:** Provide ongoing support to maintain GMP certification and address any emerging compliance issues.
- **Deliverable: Post-Certification Support Plan** including periodic reviews, compliance maintenance guidelines, and ongoing support services.

### Consultative Support

- **Action Item:** Offer expert consultancy on GMP-related matters and tailor solutions to specific operational challenges.
- **Deliverable: Consultation Report** outlining expert recommendations, best practices, and customized solutions to address unique business needs.

**To avail of our professional services kindly contact [hello@consultareinc.com](mailto:hello@consultareinc.com) or call 1-202-982-3002.**