Current Good Manufacturing Practices (cGMP) Management System Software Services Action Items

Initial Consultation and Requirements Gathering

- Schedule a meeting with key stakeholders to discuss current processes and compliance needs.

- Collect existing documentation and workflows related to cGMP compliance.

- Prepare a requirements report outlining software needs and desired functionalities.

Custom Software Development

- Develop a project timeline for software development, including key milestones.

- Collaborate with your team to design the software architecture and user interface.

- Conduct regular check-ins to gather feedback during the development phase.

Quality Management Module Implementation

- Identify key quality processes to integrate into the software (e.g., CAPA, non-conformance).

- Develop functionalities for real-time tracking and reporting of quality metrics.

- Test the quality management features with end-users for usability and effectiveness.

Document Management System Setup

- Create a centralized repository for critical documentation (SOPs, batch records, etc.).

- Implement version control and automated workflow processes for document approvals.

- Train staff on how to upload, access, and manage documents within the system.

Training Management System Configuration

- Set up training modules for scheduling and tracking employee training sessions.

- Develop automated reminders and reporting features for training compliance.

- Conduct training sessions for HR and compliance teams on managing the training system.

Risk Management and Compliance Tracking Setup

- Integrate risk assessment tools into the software for ongoing monitoring.

- Create dashboards for real-time compliance tracking and reporting.

- Train staff on how to use these tools for risk identification and mitigation.

Supplier and Vendor Management Module Development

- Design evaluation criteria for supplier performance monitoring.

- Implement features for documenting supplier qualifications and audits.

- Train relevant staff on using the supplier management functionalities.

Internal Audit and Inspection Readiness Features

- Create templates and checklists for internal audits within the software.

- Develop features for documenting audit findings and tracking corrective actions.

- Conduct mock audits to test the software's audit management capabilities.

Data Analytics and Reporting Configuration

- Set up analytics tools for generating insights from operational data.

- Develop customizable reporting options to meet regulatory and internal requirements.

- Train staff on how to create and interpret reports from the software.

Ongoing Support and Maintenance

- Establish a schedule for regular software updates and enhancements.

- Set up a support ticketing system for troubleshooting and user assistance.

- Conduct periodic training sessions to ensure staff remains proficient with the software.

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