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Internal Audits Protocol and Procedures for ChatMD SaMD

Objective: Regularly audit processes to ensure compliance and identify areas for improvement.

Audit Planning

1. Develop an Internal Audit Schedule:

- **Step 1:** Identify all aspects of the Quality Management System (QMS) that require auditing, including design controls, document controls, purchasing controls, production and process controls, CAPA, and other regulatory requirements.
- **Step 2:** Create an annual audit schedule covering all QMS aspects. Ensure the schedule includes both planned and unplanned audits.
- **Step 3:** Assign specific dates and durations for each audit, ensuring a balanced distribution throughout the year.

2. Assign Trained Personnel:

- **Step 1:** Identify and assign qualified personnel to conduct the audits. Auditors should be independent of the areas being audited to ensure objectivity.
- **Step 2:** Provide training for auditors on audit techniques, QMS requirements, and FDA regulations. Maintain training records for all auditors.

Audit Execution

1. Preparation:

- **Step 1:** Develop audit checklists based on QMS requirements and specific processes or areas to be audited.
- **Step 2:** Review previous audit reports, CAPA records, and any other relevant documents to understand past issues and current focus areas.

2. Conducting the Audit:

- **Step 1:** Initiate the audit with an opening meeting with relevant personnel to explain the audit scope, objectives, and procedures.
- **Step 2:** Perform the audit according to the checklist, interviewing personnel, observing processes, and reviewing documentation.

- **Step 3:** Document all findings, including any non-conformances, observations, and opportunities for improvement. Gather objective evidence to support findings.

3. Closing Meeting:

- **Step 1:** Conduct a closing meeting to present preliminary findings to the relevant personnel.
- **Step 2:** Discuss any non-conformances, observations, and opportunities for improvement, and allow personnel to provide additional information or clarification.

Audit Reporting

1. Prepare Audit Reports:

- **Step 1:** Compile all audit findings into a comprehensive audit report. Include sections on the audit scope, objectives, methodology, findings, and conclusions.
- **Step 2:** Summarize non-conformances, observations, and opportunities for improvement. Include evidence and references to specific QMS requirements.

2. Distribute Reports:

- **Step 1:** Distribute the audit report to relevant personnel, including management and process owners.
- **Step 2:** Ensure that all recipients acknowledge receipt and understanding of the report contents.

Corrective Actions

1. Develop Corrective Action Plans:

- **Step 1:** For each non-conformance identified, develop a corrective action plan. Include root cause analysis, actions to be taken, responsible personnel, and deadlines.
- **Step 2:** Review and approve the corrective action plan by management or a designated authority.

2. Implementation:

- **Step 1:** Implement corrective actions according to the approved plan. Ensure that responsible personnel are informed and have the necessary resources.
- **Step 2:** Document all actions taken, including dates and responsible individuals.

3. Effectiveness Review:

- **Step 1:** Monitor the effectiveness of corrective actions over a specified period. Verify that the actions have resolved the issues and prevented recurrence.
- **Step 2:** Conduct follow-up audits or reviews as necessary to ensure compliance.
- **Step 3:** Document the results of the effectiveness review and any additional actions required.