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ChatMD Quality Management System (QMS) Protocol and Procedure Plan

Introduction

The Quality Management System (QMS) for ChatMD is designed to ensure compliance with FDA Class 1 medical device regulations. The following components outline the specific protocols and procedures necessary to maintain compliance and ensure product quality. This plan will cover Design Controls, Document Controls, Purchasing Controls, Production and Process Controls, Corrective and Preventive Actions (CAPA), and Internal Audits.

1. Design Controls

Objective: Ensure that all design aspects of ChatMD meet specified requirements and are thoroughly documented.

Procedures:

1. **Design and Development Planning:**
    - Define design and development stages.
    - Identify responsibilities and authorities for each stage.
    - Establish design review checkpoints.
2. **Design Input:**
    - Document user needs and intended use.
    - Ensure inputs are measurable, testable, and unambiguous.
3. **Design Output:**
    - Document the final product specifications.
    - Ensure outputs meet input requirements and are suitable for verification and validation.
4. **Design Review:**
    - Conduct formal reviews at planned intervals.
    - Include representatives from all relevant functions.

5. **Design Verification:**
    - Confirm that design outputs meet design inputs.
    - Document verification activities and results.
6. **Design Validation:**
    - Ensure the final product meets user needs and intended uses.
    - Conduct validation under actual or simulated use conditions.
7. **Design Changes:**
    - Document all design changes.
    - Evaluate changes for potential impact on the product.

2. Document Controls

Objective: Ensure all documents are managed systematically to maintain accuracy, integrity, and accessibility.

Procedures:

1. **Document Approval and Issue:**
    - Establish a procedure for document creation, review, approval, and issue.
    - Ensure documents are approved by authorized personnel.
2. **Document Changes:**
    - Document all changes with a detailed history.
    - Ensure updated documents are reviewed and approved.
3. **Document Distribution:**
    - Control distribution to ensure relevant personnel have access to the latest versions.
    - Prevent unintended use of obsolete documents.
4. **Document Retention:**
    - Retain documents for a specified period in compliance with regulatory requirements.

- Ensure documents are stored in a secure and accessible manner.

3. Purchasing Controls

Objective: Ensure that all purchased products and services conform to specified requirements.

Procedures:

1. **Supplier Evaluation:**
    - Evaluate and select suppliers based on their ability to meet specified requirements.
    - Maintain a list of approved suppliers.
2. **Purchasing Data:**
    - Ensure purchasing documents clearly describe the product or service requirements.
    - Include specifications, acceptance criteria, and quality requirements.
3. **Verification of Purchased Products:**
    - Establish a process for inspecting and verifying purchased products.
    - Document verification activities and results.

4. Production and Process Controls

Objective: Ensure consistent product quality through documented and validated manufacturing processes.

Procedures:

1. **Process Validation:**
    - Validate processes to ensure consistent performance.
    - Document validation activities and results.
2. **Production Documentation:**
    - Maintain detailed records of manufacturing processes.

    - Include work instructions, equipment settings, and inspection criteria.
3. **Environmental Control:**
    - Control environmental conditions as necessary to ensure product quality.
    - Document environmental monitoring and control measures.
4. **Equipment Maintenance:**
    - Establish a schedule for routine maintenance and calibration of equipment.
    - Document maintenance activities and results.

5. Corrective and Preventive Actions (CAPA)

Objective: Identify and address issues to prevent recurrence and ensure continuous improvement.

Procedures:

1. **CAPA Process:**
    - Establish a process for identifying, documenting, and investigating issues.
    - Determine root causes and implement corrective actions.
2. **Preventive Actions:**
    - Identify potential issues and implement preventive measures.
    - Document preventive actions and monitor their effectiveness.
3. **Effectiveness Review:**
    - Regularly review the effectiveness of CAPA activities.
    - Document findings and take additional actions if necessary.

6. Internal Audits

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

Procedures:

1. **Audit Planning:**
    - Develop an internal audit schedule covering all QMS aspects.
    - Ensure audits are conducted by trained personnel.
2. **Audit Execution:**
    - Conduct audits according to the schedule.
    - Use checklists and document findings.
3. **Audit Reporting:**
    - Prepare audit reports summarizing findings and areas for improvement.
    - Distribute reports to relevant personnel.
4. **Corrective Actions:**
    - Implement corrective actions based on audit findings.
    - Document actions taken and review their effectiveness.