2-19-25

ChatMD Risk Management Protocol and Procedure

Objective: Implement a risk management process according to ISO 14971 to ensure compliance with FDA requirements for ChatMD.

1. Risk Management Protocol

1.1 Scope:

- This protocol covers the risk management activities for ChatMD to identify, evaluate, control, and monitor risks associated with the product throughout its lifecycle.

1.2 Responsibilities:

- **Risk Management Team:** Designated team responsible for overseeing and implementing the risk management process.
- **Product Development Team:** Collaborates with the Risk Management Team to integrate risk management into product development and lifecycle processes.

2. Risk Management Procedure

2.1 Risk Analysis

2.1.1 Hazard Identification:

- **Step 1:** Identify potential hazards associated with ChatMD. Consider all foreseeable use scenarios, including misuses
- **Step 2:** Document identified hazards in a Hazard Identification Worksheet.

2.1.2 Risk Assessment:

- **Step 1:** Assess the severity of each identified hazard. Use a risk matrix or qualitative assessment to categorize severity levels (e.g., minor, moderate, major).
- **Step 2:** Assess the likelihood of occurrence for each hazard. Consider factors such as frequency of exposure and control measures in place.
- **Step 3:** Calculate the initial risk level (risk = severity × likelihood).

2.2 Risk Evaluation

2.2.1 Risk Acceptability:

- **Step 1:** Determine if the calculated risks are acceptable based on predefined criteria (e.g., regulatory requirements, company policies).
- **Step 2:** Document the rationale for risk acceptability decisions.

2.3 Risk Control

2.3.1 Risk Mitigation Measures:

- **Step 1:** Develop and prioritize risk mitigation measures based on the assessed risks.
- **Step 2:** Implement control measures to reduce risks to an acceptable level. Consider engineering controls, warnings, labeling, and user instructions.

2.3.2 Verification of Risk Control Measures:

- **Step 1:** Verify the effectiveness of implemented risk control measures through testing, validation, or simulation.
- **Step 2:** Document verification activities and results.

2.4 Risk Monitoring

2.4.1 Ongoing Risk Review:

- **Step 1:** Establish procedures for ongoing monitoring and review of identified risks throughout the product lifecycle.
- **Step 2:** Conduct periodic reviews of risk management activities to ensure effectiveness and relevance.
- **Step 3:** Update risk assessments as new information becomes available, or changes occur in product design or use.

2.4.2 Risk Communication:

- **Step 1:** Communicate identified risks and risk management strategies to relevant stakeholders, including internal teams and regulatory authorities as necessary.
- **Step 2:** Document risk communication activities and maintain records.

3. Documentation and Records

3.1 Risk Management File:

- Maintain a Risk Management File that includes:
    - Hazard Identification Worksheet

    - Risk Assessment Reports
    - Risk Control Measures Documentation
    - Risk Acceptability Determinations
    - Records of Risk Monitoring and Reviews

3.2 Review and Update:

- **Step 1:** Review and update the Risk Management File as needed throughout the product lifecycle.
- **Step 2:** Ensure that all changes and updates are documented and approved by the Risk Management Team.

4. Training and Implementation

4.1 Training:

- Provide training to relevant personnel on the risk management process, including hazard identification, risk assessment techniques, and risk control measures.

4.2 Implementation:

- Implement the risk management process across all phases of product development and lifecycle management.

5. Continuous Improvement

5.1 Evaluation and Improvement:

- Continuously evaluate the effectiveness of the risk management process.
- Identify opportunities for improvement based on feedback, audits, and new regulatory requirements.

5.2 Documentation of Improvements:

- Document all improvements made to the risk management process and associated procedures.