2-19-25

ChatMD Complaint Handling Policy, Procedure, and Process

Objective: Ensure a systematic approach for handling complaints related to the ChatMD medical device to comply with FDA regulations, ensure patient safety, and continually improve product quality.

1. Policy Statement

Policy: ChatMD shall implement and maintain a robust complaint-handling system ensuring that all complaints are logged, investigated, reported, and resolved in compliance with FDA regulations and Medical Device Reporting (MDR) requirements.

2. Procedure and Process

2.1 Complaint Logging

Step 1: Receiving Complaints

- **Channels for Receiving Complaints:**
  - Email: trust@chatrx.md
  - Online submission form on ChatRx's website

Step 2: Documenting Complaints

- **Complaint Logging Form:**
  - Date and time of the complaint
  - Complainant's contact information
  - Detailed description of the issue
  - ChatMD devise version/model affected
  - Initial assessment of the complaint severity
- **Complaint Management System (CMS):**
  - Enter all complaint details into the CMS for tracking and management.

2.2 Investigation

Step 1: Initial Review

- **Complaint Triage:**

    - Categorize complaints based on severity (e.g., minor, moderate, major).
    - Assign priority levels to complaints for timely investigation.

Step 2: Investigation Process

- **Assign Investigators:**
    - Designate qualified personnel to investigate the complaint.
    - Include experts from relevant departments (e.g., engineering, quality assurance).
- **Investigation Steps:**
    - Collect additional information from the complainant if necessary.
    - Analyze the reported issue and reproduce the problem if possible.
    - Review device history records and previous similar complaints.
    - Determine the root cause of the issue.
- **Documentation:**
    - Document all investigation steps, findings, and evidence in the CMS.

2.3 Reporting

Step 1: Determining Reporting Requirements

- **MDR Assessment:**
    - Evaluate if the complaint meets criteria for Medical Device Reporting to the FDA.
    - Serious complaints involving death, serious injury, or malfunction must be reported.

Step 2: Reporting to FDA

- **Report Submission:**
    - Prepare MDR reports using FDA's eMDR system.
    - Include all relevant details such as device identification, event description, and investigation findings.
- **Reporting Timeline:**
    - Submit MDR reports within the required timeframe (e.g., 5 days for serious injury or death).

2.4 Resolution

Step 1: Implementing Corrective Actions

- **CAPA (Corrective and Preventive Action):**
    - Develop a CAPA plan based on investigation findings.

    - Implement corrective actions to address the root cause of the complaint.
    - Preventive actions to avoid the recurrence of the issue.
- **Communication:**
    - Inform the complainant about the resolution steps taken.
    - Update internal teams on corrective actions implemented.

Step 2: Monitoring and Verification

- **Effectiveness Check:**
    - Monitor the effectiveness of corrective actions.
    - Verify if the issue has been resolved and no recurrence is observed.
- **Documentation:**
    - Record all corrective and preventive actions in the CMS.
    - Update complaint records to reflect the resolution status.