2-19-25

ChatMD Post-Market Surveillance Policy, Procedure, and Process

Objective: Ensure continuous monitoring of ChatMD's performance in the market to comply with FDA regulations, ensure patient safety, and facilitate ongoing product improvement.

1. Policy Statement

Policy: ChatMD shall implement a comprehensive post-market surveillance (PMS) system for ChatMD, ensuring timely adverse event reporting, effective field actions, and systematic collection and analysis of customer feedback to comply with FDA regulations and promote product safety and improvement.

2. Procedure and Process

2.1 Adverse Event Reporting

Step 1: Identifying Adverse Events

- **Monitoring Channels:**
  - Customer service reports
  - Online feedback forms
  - Social media monitoring
  - Direct communications (emails, phone calls)

Step 2: Assessing Adverse Events

- **Initial Assessment:**
  - Determine if the reported issue qualifies as an adverse event based on FDA criteria.
  - Categorize the event based on severity (e.g., minor, moderate, serious).

Step 3: Reporting Adverse Events to FDA

- **MDR Reporting:**
  - For serious adverse events involving death, serious injury, or significant malfunction, prepare and submit Medical Device Reports (MDRs) using FDA's eMDR system.
  - Include detailed information such as device identification, event description, and initial assessment.

- **Reporting Timeline:**
  - Submit MDR reports within the required timeframe (e.g., 30 calendar days for standard events, 5 working days for critical events).

2.2 Field Actions

Step 1: Determining the Need for Field Actions

- **Risk Assessment:**
  - Evaluate the severity and potential impact of identified issues or adverse events.
  - Determine if a field action (e.g., recall, safety notice) is necessary to protect patient safety.

Step 2: Planning and Implementing Field Actions

- **Recall Strategy:**
  - Develop a detailed recall plan, including scope, affected units, and corrective actions.
  - Notify affected customers, healthcare providers, and distributors promptly.
- **Implementation:**
  - Execute the recall plan, ensuring the safe and efficient removal or correction of affected ChatRx units.
  - Provide clear instructions and support to users during the recall process.

Step 3: Reporting Field Actions to FDA

- **Recall Reporting:**
  - Submit recall notifications to the FDA, including details of the issue, affected units, and corrective actions.
  - Provide periodic updates to the FDA on the progress and completion of the recall.

2.3 Customer Feedback

Step 1: Collecting Customer Feedback

- **Feedback Channels:**
  - Online surveys and feedback forms
  - Customer service interactions
  - Focus groups and user interviews
  - Social media and review platforms

Step 2: Analyzing Customer Feedback

- **Data Analysis:**
  - Aggregate and analyze feedback data to identify common themes, issues, and areas for improvement.
  - Use qualitative and quantitative methods to assess feedback trends.

Step 3: Implementing Improvements Based on Feedback

- **Action Plan:**
  - Develop action plans based on feedback analysis to address identified issues and enhance product performance.
  - Prioritize improvements based on impact and feasibility.
- **Feedback Loop:**
  - Communicate changes and improvements to customers to demonstrate responsiveness and commitment to product quality.

2.4 Monitoring and Continuous Improvement

Step 1: Ongoing Monitoring

- **Regular Reviews:**
  - Conduct regular reviews of post-market surveillance data, including adverse event reports, field actions, and customer feedback.
  - Monitor key performance indicators (KPIs) related to product safety and performance.

Step 2: Continuous Improvement

- **Process Enhancement:**
  - Continuously refine and improve the PMS process based on monitoring results and regulatory updates.
  - Implement best practices and innovative solutions to enhance post-market surveillance effectiveness.
- **Documentation:**
  - Maintain comprehensive records of all PMS activities, including adverse event reports, field actions, feedback analysis, and process improvements.
  - Ensure documentation is readily accessible for regulatory audits and reviews.

3.0 Post Market Compliance Procedure & Process

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For ChatMD, a medical device that falls under FDA Class I designation, the implementation of FDA Class I exemptions involves several key considerations and compliance steps. FDA Class I devices are typically low-risk devices subject to general controls. Many Class I devices are exempt from premarket notification (510(k)) and certain other regulatory requirements, but manufacturers must still comply with the applicable general controls. Here's how to implement these exemptions and ensure compliance:

1. **Understand the Scope of Exemptions**

- **Premarket Notification (510(k)) Exemption**: ChatMD qualifies as a Class I exempt device, it does not require a 510(k) submission.
- **Quality System (QS) Exemption**: Certain Class I devices are partially exempt from specific Quality System Regulations (QSR), but records, complaint handling, and general device requirements still apply.

2. **Comply with General Controls**

General controls apply to all devices, including exempt ones. For ChatMD, ensure adherence to:

- **Establishment Registration**: Register your establishment with the FDA and list the device.
    - Registered 12-8-24 with FDA
    - CHATMD
      328 S Michigan St Plymouth, IN 46563 UNITED STATES

    - Registration Number: 3032847781
    - Owner Operator Number: 10091612

- **Labeling Requirements**: Ensure labels are compliant with the FDA's labeling regulations, including proper branding, intended use, and any cautionary statements.
- **Medical Device Reporting (MDR)**: Implement systems for reporting adverse events as per the FDA's MDR requirements.
- **Device Listing**: Provide accurate information about the ChatMD device in the FDA's device listing database.

3. **Implement Quality System Practices**

Even if exempt from certain QSR requirements, ChatMD must:

- Maintain records of design and production.
- Ensure robust processes for complaint management and corrective actions.
- Conduct internal audits

4. **Maintain Design Controls**

While design controls may not be fully required, they are considered best practices for software-driven devices like ChatMD Implementation includes:

- Validation and verification of software.
- Ensuring the device meets its intended use and operates safely and effectively.

5. **Conduct Annual Device Registration**

Pay the **FDA Annual Establishment Registration Fee** and ensure timely renewal of registration and device listing.

6. **Monitor Regulatory Changes**

Stay informed about changes in FDA regulations or guidance documents that might affect the exemption status of ChatMD or impose additional compliance requirements.