

## **ChatMD FDA Regulations Training and Competency Policy, Procedure, and Process**

**Objective:** Ensure that all personnel involved in the design, manufacture, and distribution of ChatMD are adequately trained and competent, in compliance with FDA regulations.

### **1. Policy Statement**

**Policy:** ChatMD shall implement a comprehensive training and competency program for all personnel involved in the design, manufacture, and distribution of the ChatMD medical device. This program will include regular training sessions on regulatory requirements, QMS procedures, and product-specific information, as well as regular competency assessments.

### **2. Procedure and Process**

#### **2.1 Training Programs**

##### **Step 1: Training Needs Assessment**

- **Identify Training Needs:**
  - Conduct a needs assessment to identify the required knowledge and skills for each role involved in the design, manufacture, and distribution of ChatMD.
  - Consider regulatory requirements, QMS procedures, and product-specific information.

##### **Step 2: Developing Training Programs**

- **Training Curriculum:**
  - Develop a comprehensive training curriculum covering:
    - FDA regulatory requirements
    - Quality Management System (QMS) procedures
    - Product-specific information for ChatMD
    - Safety protocols and best practices
- **Training Materials:**
  - Create training materials, including manuals, presentations, videos, and interactive modules.

##### **Step 3: Conducting Training Sessions**

- **Regular Training Sessions:**
  - Schedule regular training sessions for all personnel, including new hires and existing staff.
  - Utilize a variety of training methods (e.g., classroom training, online courses, hands-on workshops).
- **Trainer Qualifications**
  - Ensure trainers are qualified and knowledgeable in their respective areas.
- **Attendance Records:**
  - Maintain records of training attendance, including dates, participants, and topics covered.

## 2.2 Competency Assessments

### Step 1: Designing Competency Assessments

- **Assessment Criteria:**
  - Define clear criteria for assessing competency in regulatory requirements, QMS procedures, and product-specific knowledge.
  - Develop assessment tools, such as quizzes, practical exercises, and performance evaluations.

### Step 2: Conducting Competency Assessments

- **Regular Assessments:**
  - Schedule regular competency assessments for all personnel.
  - Include assessments as part of the onboarding process for new hires and periodically for existing staff.
- **Assessment Methods:**
  - Utilize a combination of written tests, practical demonstrations, and peer evaluations to assess competency.

### Step 3: Evaluating and Documenting Competency

- **Evaluation Process:**
  - Evaluate assessment results to determine if personnel meet the required competency levels.
  - Identify areas for improvement and provide additional training as needed.
- **Documentation:**
  - Maintain detailed records of competency assessments, including dates, participants, assessment methods, and results.

## 2.3 Continuous Improvement

### **Step 1: Monitoring and Reviewing Training Effectiveness**

- **Feedback Mechanisms:**
  - Collect feedback from trainees and trainers to evaluate the effectiveness of training programs.
  - Conduct post-training surveys and follow-up evaluations.
- **Review Process:**
  - Regularly review training programs and materials to ensure they remain current and effective.
  - Update training content based on regulatory changes, product updates, and feedback.

### **Step 2: Addressing Gaps and Enhancements**

- **Action Plans:**
  - Develop and implement action plans to address any identified gaps in training or competency.
  - Enhance training programs based on feedback and assessment results.
- **Continuous Learning:**
  - Foster a culture of continuous learning and improvement within the organization.
  - Encourage personnel to seek additional training and development opportunities.

### **Step 3: Compliance and Reporting**

- **Regulatory Compliance:**
  - Ensure training and competency programs comply with FDA regulations and industry standards.
  - Prepare for and facilitate regulatory audits and inspections.
- **Reporting:**
  - Provide regular reports on training and competency activities to senior management.
  - Include metrics on training participation, assessment results, and continuous improvement initiatives.

## **Conclusion**

By implementing this comprehensive policy, procedure, and process for training and competency, ChatMD ensures that all personnel involved in the design, manufacture, and distribution of ChatMD are adequately trained and competent. This

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approach not only ensures compliance with FDA regulations but also promotes a culture of continuous learning and improvement, ultimately enhancing the quality and safety of the ChatMD medical device. Regular monitoring, feedback, and updates to the training program will help maintain high standards of competency and performance across the organization.