

# **Health care and Pharmaceutical**

## **(CMDCP) CERTIFIED MEDICAL DEVICE COMPLIANCE PROFESSIONAL™**

### **Curriculum**

#### **Program Outline :**

#### **Module 1: Fundamentals of (CMDCP) Certified Medical Device Compliance Professional™**

- 1. Regulatory Knowledge:** Comprehensive understanding of FDA and international regulatory requirements for medical devices.
- 2. Quality Management Systems:** Implementing and maintaining quality management systems to ensure compliance with regulatory standards.
- 3. Documentation and Record Keeping:** Ensuring accurate and complete documentation of all manufacturing processes and quality control measures.
- 4. Facility and Equipment Design:** Designing and maintaining facilities and equipment to meet regulatory requirements and prevent contamination.
- 5. Employee Training and Competency:** Ensuring that all employees are trained and competent in medical device compliance practices and procedures.

## **Module 2: Advanced (CMDCP) Certified Medical Device Compliance Professional™**

- 1. Regulatory Compliance Expertise:** Demonstrates advanced knowledge of global medical device regulations, including FDA (21 CFR Part 820), EU MDR, and ISO 13485 standards.
- 2. Product Lifecycle Management:** Focuses on compliance across the entire medical device lifecycle, from design and development to post market surveillance.
- 3. Risk and Quality Management:** Trains professionals in identifying, mitigating, and managing risks, as well as ensuring robust quality management systems (QMS).
- 4. Career Advancement:** Prepares individuals for roles such as Regulatory Affairs Specialist, Compliance Officer, and Quality Assurance Manager in the medical device industry.
- 5. Ongoing Certification Requirements:** Encourages continuing education to stay updated on evolving regulations, standards, and industry best practices.

## **Module 3: Practical Applications**

- 1. Patient Care and Management Medication Therapy Management (MTM):** Pharmacists optimize medication regimens to improve therapeutic outcomes and reduce adverse effects.

## **2. Clinical Practice**

**Patient Counseling:** Educating patients on proper medication use, potential side effects, and lifestyle modifications to enhance health outcomes.

## **3. Pharmaceutical Research and Development**

**Drug Discovery and Development:** Conducting research to discover new medications and develop existing ones

## **4. Healthcare Technology and Innovation**

**Telemedicine:** Using telehealth platforms to provide remote consultations, follow-ups, and health monitoring

## **Module 4: Capstone Project**

### **1. Impact of Telemedicine on Patient Outcomes**

Analyze the effectiveness of telemedicine in improving patient outcomes, especially for chronic disease management .

### **2. Pharmaceutical Waste Management**

Develop strategies to reduce pharmaceutical waste and its environmental impact.

### **3. Medication Adherence in Elderly Patients**

Investigate factors affecting medication adherence among elderly patients and develop interventions to improve adherence.

### **4. Implementation of an Electronic Health Records (EHR) System**

Assess the challenges and benefits of implementing an EHR system in a healthcare facility

## **ELECTIVE MODULES**

**1. Advanced Pharmacology:** Deep dive into the mechanisms of

action, side effects, and interactions of various drugs.

**2. Clinical Research Methods:** Learn about designing and conducting clinical trials, data analysis, and ethical considerations.

**3. Health Informatics:** Study the use of information technology in healthcare, including electronic health records and data management.

**4. Global Health:** Explore health issues and solutions in a global context, including international health policies and practices

### Websites:

- <https://chools.in/>
- <https://ramaqchools.com/>
- <https://www.choolsgroup.com/>