

Health care and Pharmaceutical
(GRACP) GLOBAL REGULATORY AFFAIRS
COMPLIANCE PROFESSIONAL™
Curriculum

Program Outline :

Module 1: Fundamentals of (GRACP) Global Regulatory Affairs Compliance Professional™

- 1.Global Regulatory Knowledge:** Comprehensive understanding of international regulatory frameworks, including FDA, EMA, and other major regulatory agencies.
- 2.Regulatory Strategy:** Developing and implementing regulatory strategies to ensure compliance and market access for pharmaceuticals and medical devices globally.
- 3.Regulatory Documentation:** Preparing and submitting regulatory documents, such as INDs, NDAs, and MAs, to regulatory authorities worldwide.
- 4.Compliance Monitoring:** Ensuring ongoing compliance with regulatory requirements and standards across different regions.
- 5.Risk Management:** Identifying and mitigating regulatory risks to avoid delays and ensure successful product launches.

Module 2: Advanced (GRACP) Global Regulatory Affairs Compliance Professional™

- 1. Global Regulatory Expertise:** Demonstrates advanced knowledge of international regulatory frameworks, including FDA, EMA, MHRA, ICH, and WHO guidelines, for managing regulatory affairs across multiple regions.
- 2. Compliance Leadership:** Focuses on ensuring products meet regulatory requirements throughout their lifecycle, from development to post-market surveillance.
- 3. Strategic Oversight:** Trains professionals in creating regulatory strategies, managing submissions, and addressing global compliance challenges for pharmaceuticals, medical devices, and biologics.
- 4. Career Advancement:** Prepares for high-level roles such as Global Regulatory Affairs Manager, Compliance Director, or Regulatory Consultant in multinational organizations.
- 5. Continuing Certification:** Requires periodic recertification and ongoing professional development to stay updated on evolving global regulations and industry standards.

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/>