cliniminds™
Institute of Health Sciences Training & Management
An ISO 9001:2008 Certified Academy

Assuring and Advancing Quality in Clinical Research Education since 1965

Advanced Post Graduate Diploma in Clinical Research & Regulatory Affairs in Pharma

Regulatory professionals are the primary communication link between the company and global regulatory agencies such as USFDA (United States Food and Drug Administration) and European Union of Drug Regulatory Affairs (EUDRA).

The pharmaceutical, biotechnology and medical device research and development industries are among the most highly regulated industries globally. As pharmaceutical sector is growing rapidly, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. Pharmaceutical industry, being one of the highly regulated industries, is in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner.

Program Details **:** The program would cover

Module – 1

- Clinical Research Introduction
- Principles of Pharmacology & Drug Discovery & Development
- Roles & Responsibilities of Key Stakeholders
- Preparations & Planning for Clinical Trials
- Essential Documentation in Clinical Research & Regulatory Submissions
- Clinical Trials Project Planning & Management
- Study Start Up Process
- Clinical Monitoring Essentials
- Compliance, Auditing & Quality Control in Clinical Research
- Overview of Clinical Data Management and Pharmacovigilance

Module-2

- Introduction to Regulatory Affairs
- Global Regulatory Environment
- Pharma Regulations Practices & Procedures
- Import and Export of Drugs in Global Pharmaceutical Industry
- Common Technical Document
- Good Manufacturing Practice
- Quality Assurance and Regulation
- Regulatory Aspects in Pharmacovigilance
- Regulations Governing Clinical Trials & New Drugs
- Global Drug Policy
- Orphan Drugs
- TRIPS and Pharma Industry

- IPR Management
- Patent Application

Mode : Online/Distance Learning

Duration : 6 Months

Eligibility : MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharms, Graduate/Post Graduate Degree in Life Sciences, Mathematics, Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and Hospitals.

Methodology : Printed Training Modules; Online e-learning System

Examination : Online MCQs

Certificate : Certificate would be awarded upon successful completion of the program. Program is Certified & Accredited by the **Pharmaceutical Society of India.**

Accreditation : Accreditation would be awarded upon successful completion of the program. Program is Certified & Accredited by **Accreditation Council for Clinical Research Education**, **US.**

Job Assistance : Placement support would be provided to the successful candidates. CVs of successful candidates would be forwarded to relevant organization.

Fee payment : Fee Payable by Cash, Cheque/Bank draft in the name of **"TENET HEALTH EDUTECH PVT LTD."** Payable at Delhi Fee can also be deposited in company bank account. We also accept Credit/Debit Cards.

International Payments : Through Debit/Credit cards using Paypal or wire payment through banks

Course Objectives

- To provide a comprehensive introduction to the clinical research process.
- Learn the skills, knowledge and competencies of a candidate for the Clinical Research jobs.
- Become more familiar with roles/jobs as part of the study team.
- Concepts and importance of Drug Regulatory Guidelines
- Learn the skills, knowledge and competencies of a candidate for the drug regulatory jobs.
- Become more familiar with roles/jobs as part of the regulatory affairs team.
- Understanding of all drug development, marketing and post marketing regulatory issues.