

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

### **(Limited Scholarships Available)**

The objective of this program is to provide complete understanding of the Clinical Research and Regulatory Affairs in Pharma & Clinical Research process and to provide working knowledge to the students, which would enable them to work in the industry with minimal training.

In the first module we would provide a comprehensive practical knowledge to the clinical research processes, drug development process, regulatory affairs, essential documentation, roles and responsibilities, ethics, monitoring, conduct and management of trials and various other related issues.

In the second module extensive training on Pharma/ Clinical Research Regulatory Affairs is provided. This module is especially been designed for the students who would like to develop their career in the field of regulatory affairs. Upon completion of the module students would understand the concept of Regulatory Affairs in the field of pharmaceuticals, clinical research, patents & regulatory process; how the product is marketed in other countries, what are the legal requirements of regulatory bodies, procedure for the submission of common technical documents etc. After completion of the program, students would become reasonably well versed in regulations governing pharmaceutical and clinical research domain

<b>Mode</b>	:	Class Room – Weekend
<b>Eligibility</b>	:	MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharma, Graduate/Post Graduate Degree in Life Sciences, Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and hospitals.
<b>Methodology</b>	:	6 Months Weekend Classroom Contact Program; Printed Training Modules; Online E learning system
<b>Examination</b>	:	Classroom exams & Project work.
<b>Certificate</b>	:	Certificate would be awarded upon successful completion of the program. Program is certified & Accredited by the <b>Pharmaceutical Society of India</b> .
<b>Job Assistance</b>	:	Placement support would be provided to the successful classroom candidates.
<b>Fee Payment</b>	:	Fee Payable by Cash, Cheque / Bank draft in the name of ' <b>TENET HEALTH EDUTECH PVT. LTD.</b> ' payable at Delhi. Fee can also be deposited in company bank account. We also accept Credit/Debit Cards.
<b>Loan Facility</b>	:	HDFC Bank.
<b>Program Details</b>	:	The program would cover:

### **MODULE I**

- 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 II**

- 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

### **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 and Regulatory jobs.
- ❖ Become more familiar with roles/jobs as part of the study team.
- ❖ Basic concepts, importance of Regulatory Guidelines