# Post Graduate Diploma in Drug Regulatory Affairs

**Program accredited by Accreditation Council for Clinical Research Education, USA**

**100% Past Placement Track Record | Industry Accredited Program | Specialization | Job Oriented**

**Best Clinical Research & Health Sciences Business Management Institute in India – 2011, 2012, 2013, 2014 & 2015**

**Certified & Accredited by ACCRE, US & Pharmaceutical Society of India**

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**

- Introduction to Regulatory Affairs
- Pharma Regulations Practices and Procedure
- Global Pharmaceutical Industry Scenario
- Indian Pharmaceutical Industry
- Global Regulatory Environment
- Regulations Governing Clinical Trials and New Drugs
- Schedule Y
- Regulatory Inspections in Clinical Research (FDA, EMEA, UK and Indian)
- Future of Regulatory Compliance
- Orphan Drugs

**Module-2**

- Import and Export of Drugs
- Good Manufacturing Practice
- Quality Assurance and Regulations
- Global Drug Policies
- Regulation in Pharmaceutical Devices
- Test
- TRIPPs and Pharma Industry
- Intellectual Property Right Management
- Patents
- Pharmacovigilance (Introduction, global reporting requirements)

**Mode** : Online/Distance Learning

**Duration:** 6 Months

Assuring and Advancing Quality in Clinical Research Education since 1965

**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**

- 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.
- Basic concepts, importance of Regulatory Guidelines.

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 **Disclaimer -** This course brochure is for the purpose of creating an awareness about the program and career options. The exact information on course structure would be given to you at the time of orientation and may vary from this brochure.