

Certificate Program in Clinical Trial Regulations & GCP in Europe & U.K.

This course has been designed for clinical research professionals and those working with them involved in carrying out clinical trials. Primarily, it is for the following disciplines:

- ❖ Clinical research operations
- ❖ Quality Assurance Auditors
- ❖ Regulatory affairs
- ❖ Clinical trial supply
- ❖ Site Personnel
- ❖ CRO personnel
- ❖ Medical Writers
- ❖ Drug Development department
- ❖ All personnel who need to understand the impact of the EU Clinical Trials Directive

Mode	:	Distance/Online Learning
Duration	:	Six months
Eligibility	:	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.
Methodology	:	Printed Training Modules; Online Learning System; Workshops.
Examination	:	Online MCQs, Exercises & Project work.
Certificate	:	Certificate would be awarded upon successful completion of the program. Program is certified & Accredited by the Pharmaceutical Society of India.
Job Assistance	:	Placement support would be provided to the successful classroom candidates. CVs of successful candidates would be forwarded to CROs Hospitals and Pharmaceutical companies and Interviews would be organized. Limited placement support would also be provide to Distance/Online Learning students.
Fee	:	Distance/Online : 7,500/- (INR) , 200 (\$).
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.
Program Details	:	This course focuses on understanding the requirements of the EU Clinical Trial Directive, GCP and GMP directives, marketing authorization process in EU, UK, Germany and France:

Key topics discussed

- ❖ Background and History of Clinical Research Legislation in Europe : The current regulatory situation in relation to clinical trials in the EU.
- ❖ Eudralex Vol 10 - Clinical Trials: content, authorization procedure, Inspections, Pharmacovigilance, EC submission and approval, monitoring etc.
- ❖ The Clinical Trials Directive (2001/20/EC) : Content, integration of GCP and GMP, role of Qualifies person, Inspection procedure.
- ❖ The GCP Directive (2005/28/EC) :
- ❖ The GMP Directive (2003/94/EC) : GMP requirements for IMP and NIMP, certifications, QP role and responsibilities, GMP certificate.

- ❖ The Paediatric Regulations (1901/2006 and 1902/2006): Recent developments and amendments done, pediatric plan, role of pediatric committee.
- ❖ European Guidelines: ICH-GCP, Roles and responsibilities of Sponsor, Investigator, EC. Important tenets of GCP.
- ❖ MHRA guidelines on Clinical Trials: Organization, framework, Clinical trial application process, Inspection procedure, communication flow between EMEA and MHRA
- ❖ Authorization procedure in Germany and France: Procedure to apply for obtaining market authorization in Germany and France

Course Objectives

- ❖ Upon completion of this course students will have a thorough knowledge of the EU Clinical Trial Directive requirements. This will give latest information regarding the interpretation and enforcement of EU regulations and impact of directives on regulations. Also, it will enlighten students about authorization procedure in EMEA, UK, Germany and France.