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

Assuring and Advancing Quality in Clinical Research Education since 1965

Certificate Program in Conducting & Managing Bioequivalence & Bioavailability Studies

BA/BE studies are required by regulations to ensure therapeutic equivalence between a pharmaceutically equivalent test product and a reference product. BE studies are done for Early and late clinical trial formulations, Formulations used in clinical trial and stability studies, if different Clinical trial formulations and to-be-marketed drug product.This program covers types of BA/BE studies, need of BE studies-NCEs & Generic Drugs, Analysis, Managing & Reporting of BE studies.

Program Details : The program would cover

- Introduction
- Basics of Pharmacokinetics
- The concept of Bioavailability and Bioequivalence-Regulatory Terminology
- Regulatory aspects of BE studies
- Need of Bioequivalence Studies- NCEs & Generic Drugs
- Intellectual Property Rights & TRIPs agreement
- Generic Drugs,ANDA approval, Reference List of Drugs & Orange book
- Approaches to Bioequivalence studies
- Types of BA/BE studies
- Design and Conduct of Bioequivalence Studies
- Study personnel required for conduct of BE studies and their role and responsibility
- Facilities for conducting BA/BE studies (CRO checklist)
- Departments - Clinical, Bio-Analytical and Quality Assurance
- Managing BE Studies
- Measurement Methodology
- Analysis of BE Studies
- Food effect BE studies
- Biowaivers

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

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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 :

- Distinguish between bioequivalence and bioavailability
- Understanding the management and conduct of bioequivalence and bioavailability studies
- Understand how factors related to the dosage form and patient variables affect drug stability, dissolution capacity, and absorption properties
- Recognize problems that arise with bioequivalence and generic substitution
- Learn which critical patient and disease factors require special consideration
- Understand the process of approval of generic drugs in USA, Europe and India.