cliniminds™
Academy for Clinical Research Training & Management
An ISO 9001:2000 Certified Academy

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Post Graduate Diploma in Bio analytical Techniques

(Limited Scholarships Available)

Bio analysis plays most critical role in drug development and clinical research. Cliniminds is launching international level program for Bio analytical research professionals and to foster professional excellence in design and execution of Bio analytical research, thereby contributing to enhancing the clinical research culture in India.

During the course, we would emphasize towards the core Bio analytical processes like method Development, validation, & carrying the Bio analytical Studies successfully. Carrying all the steps successfully in highly regulated environment we also need to focused on the GLP regulatory requirements according to the latest guidelines like FDA, EMEA & ICH.

Regulatory requirement are always stringent towards quality which means they need high quality data with integrity. Bio studies should be carefully documented which should be good enough to reconstruct the study by regulatory or monitoring agencies.

This course has been designed to provide hands on training on quantification of drugs in biological matrix using sophisticated instruments like HPLC & LCMS/MS especially for the Bioequivalence & Bioavailability Studies. This programme has been developed to provide an in depth practical training to the students to enable them to become Research Scientist / Research Associates in Pharmaceutical/Clinical Research Industry and analytical laboratories to quantify drugs using sophisticated instruments like LCMS/MS.

Mode	**:**	Class Room
Duration	**:**	6 months (3 Months Class Room + 3 Months Paid Internship)
Classroom Location	**:**	Delhi
Eligibility	**:**	MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharma, Graduate/Post Graduate Degree in Chemistry, Life Sciences, Pharmacology, Pharmacy, Medical Laboratory, Biochemistry, Microbiology, Biotechnology.
Selection Criteria	**:**	Personal Interview
Methodology	**:**	3 Months class Room + 3 Months Hands on Training at Leading Global Clinical Research Organization
Internship	:	All students would get opportunity to get 3 months paid internship at the leading Clinical research company.
Examination	**:**	Classroom exams .
Faculty	:	Full time and part time leading experts from the bio analytical and clinical research industry.
Certificate	**:**	Upon successful completion students would receive two certifications : **1. Cliniminds Diploma – co certified by Pharmaceutical Society of India** **2. Internship Certificate from the leading global clinical research organisation**
Job Assistance	**:**	Placement support would be provided to the successful classroom candidates.
Fee	**:**	Rs .125,000 /-(Payable in two installments)

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.

Loan Facility : HDFC Bank.

Program Details : The program would cover the following topics:

- Introduction over Bioavailability and Bio equivalance
- Introduction: Bio analytical
- Introduction of Liquid Chromatography Mass spectrometry
- Bio analytical Method Development
- Bio analytical Method Validation
- Matrix factor
- Challenges of Incurred Sample Reanalysis
- Bio analytical Subject Samples
- Batch Acceptance Criteria
- GLP & GMP Guidelines
- Reference Standard Handling
- Standard Operating Procedure (SOP)
- Regulatory Aspect of Bio analytical Studies
- Documentation Involved during the Bio analysis
- Sample Processing Technique
- CFR Part 11 or electronic data handling(LIMS)

Course Objectives :

At the end of the programme, participants would have strong understanding of the following areas :

Bio analytical Techniques

- **Bio analytical Method Development and Method Validations using LCMSMS & HPLC**
- **Bio analytical Sample Analysis under regulated environment**
- **Using Bio analytical skills, one is highly acceptable in the Pharma Industry**

Bio analytical monitoring skills

- **Monitoring of BA / BE studies for USFDA, EMEA and Health Canada submissions**

Concept of Clinical Trials

- **Basics concepts of clinical trials and clear understanding of ICH GCP**