PHARMAELITE
Writing THE SUCCESSFUL STORIES

www.pharmaelite17.com

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ONLINE CERTIFICATION COURSES

- MARKETING MANAGEMENT
- INTELLECTUAL PROPERTY RIGHTS
- PHARMACOVIGILANCE
- CLINICAL RESEARCH

PHARMAELITE started as a YouTube channel on 17th August, 2017 led by Dharmesh Mehta (MS in Pharmaceutics from NIPER Hyderabad, NIPER AIR -66). It further begun with classroom coaching for GPAT/NIPER/PHARM MBA/MET On 27th May, 2018 at Thane, Mumbai. We at PHARMAELITE ensure quality education with one on one counselling, assuring students reach their aimed goals and turn their dreams into reality. Our faculty team comprises of GPAT toppers, who are presently students of ICT and NIPER, along with few Ph.D. We are a team driven by dedication, perseverance and hard-work.

EDUCATION PARTNER

Centrica Pharmakam
We Believe in Integrity

INDUSTRY PARTNER

Bio Re Inventors
New Identity of Innovation and Technology

VISION

To develop innovative thinking among students, skill development and smart work along with hard work and discipline

MISSION

To inspire, educate and help students turn their dreams into reality in every possible way. To create efficient pharmacist who can serve the society in the best possible manner

CLINICAL RESEARCH

process of taking a newly discovered compound or drug through regulatory approval to the point of marketing

4 Months
Fees 3000₹

Pay by Phone pe / Google pay onto 8692820106

Course Outline

The entire process of taking a newly discovered compound or drug through regulatory approval to the point of marketing. During the development, the new drug or the compound should adhere to high standards in the conduct, analysis and interpretation of preclinical and clinical studies for it smooth passage through the regulatory approval phase and eventually to marketing. The drug discovery and drug development process is designed to ensure that only those pharmaceuticals products that are both safe and effective are bought to the market.

Following are the few steps involved in drug discovery and development process:

- Target identification
- Target Validation
- Lead identification
- Lead optimization

Module 1

- Introduction to Clinical Trials
- Various Phases of Clinical Trials
- Methods of Post Marketing Surveillance
- The Role of Purchasers and Payers in the Clinical Research Enterprise

Module 2

- Good Clinical Practice ICH , GCP , Central drug standard control organization (CDSCO) guidelines
- Role and responsibilities of clinical trial personnel as per ICH GCP Key terms:
  - Sponsor
  - Investigators
  - Clinical research associate
  - Auditors
  - Contract research coordinators
  - Regulatory authority
- Abbreviated New Drug Application submission
- Principal and Practice of Clinical Research
- Safety monitoring in trials

Module 3

- Designing of clinical Study documents.
- Informed Consent process
- Composition and Responsibilities, procedures of IRB/IEC
- Challenges in the implementation of guidelines

Module 4

- Ethical Guidelines in Clinical Research
- Overview of regulatory environment in USA, Europe and India
- Data Management and its components

JOB OPPORTUNITIES

As on 14th April, 2021
No. of job openings in CLINICAL RESEARCH: 12,613 JOB OPENINGS for "ANY NO. OF EXPERIENCE EMPLOYEES TOGETHER": https://www.naukri.com/clinical-research-jobs

2297 JOBS FOR FRESHERS:
https://www.naukri.com/clinical-research-jobs?experience=0
Salary in the range of 2.5-5.0 Lacs per annum as per listings on Naukri.com

No. of students who has already enrolled for the course: 97