cliniminds™
Institute of Health Sciences Training & Management
AN ISO 9001:2015 Certified Academy

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ACCRE
Assuring and Advancing Quality in Clinical Research Education since 1965

Post Graduate Diploma in Clinical Research for Medical Devices

Medical devices industry is over US$336 billion industry and growing at the rapid pace. This course is designed to introduce the fundamental concepts and regulatory requirements of clinical trials with medical devices. Clinical trials studies for medical devices are an integral part of the pre-market approval process. Demonstrating the effectiveness and safety of new medical devices is a critical part of the devices development process and require significant resources to accomplish. This program offers an opportunity for the medical professionals, pharmacists, chemists, nurses, biologists, biomedical engineers, professionals in drug and devices companies to gain detailed understanding of the regulatory process, monitoring and other clinical trial issues related to medical devices as well as the global regulatory framework as it related to the new medical device market.

Program Details : The program would cover

Module I

Introduction and regulatory process for medical devices

- Definition and extent of definition of medical devices
- Life process of Medical devices
- Classification
- Regulatory in various countries

Module II

Principles of clinical research in medical devices

- Differences between clinical research in medical devices and drugs
- Investigational plan
- Implementation
- Conducting and Management of clinical study
- Clinical event and their management

Module III

Special Considerations

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.

www.cliniminds.com
Mobile: +91-9910068241; +91 9560665441; +91-9810068241; Email: info@cliniminds.com

India | Canada | US | UK | Saudi Arabia | Philippines |

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Methodology : Online Training Modules; Online 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.**

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.

Internationl Payments : Through Debit/Credit cards using Paypal or wire payment through banks

Course Objective :

- Upon completion of this course, students should be able to recognize need and requisites of medical devices related to clinical research and should be able to frame a clinical study
- Understanding definition, classification and life span of medical devices
- Understanding regulatory process and market approval process in various countries and understanding responsibilities of clinical research
- Understanding how device trial from drug trial
- Understanding special considerations related to devices trials designing, conduction, event management etc
  Understanding trial design, documentation drafting and implementation
- Knowing major 25 clinical devices and clinical research specific information

Technology & Knowledge Partners

AB-Cube More than softwares | TARA | ADVERA HEALTH ANALYTICS | CLINEVO Technologies | Think i | CRQA Clinical Regulatory Quality Assurance

Cliniminds, Unit of Tenet Health Edutech Pvt. Ltd.
NOIDA ONE 602, Tower B Plot B8, Sector 62,NOIDA 201309,UP

www.cliniminds.com
Mobile: +91-9910068241; +91 9560665441; +91-9810068241; Email: info@cliniminds.com
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