

CENTRE FOR ADVANCEMENT IN HEALTH SCIENCES

Post Graduate Diploma in Clinico-Regulatory & Patents – PGDCRP

Program Overview

The boundaries of drug research are affected by a variety of factors, including medical needs of patients, capabilities of drug development technology, environment for research, global business & financial trends, turbulent marketplace transitions, and stunning advances in research and development capabilities.

Considering this complex and challenging environment in pharmaceutical industry, Center For Advancement in Health Sciences has designed a 6 months “composite” course in Clinical trials, Regulatory Affairs and Patents that not only offers academic training but also provides practical experience in the areas related to: *Drug development, Design, conduct and evaluation of clinical trials, Domestic as well as international regulatory submissions, Intellectual Property Rights.*

We believe that many of the challenges faced by the pharmaceutical industry, and many of the lessons learned by this industry in addressing them, have relevance to a broad range of individuals and institutions in the biomedical and healthcare communities. This program is intended to cater to working professionals as well as students seeking to make a career in R & D, medical services, clinical research, regulatory affairs, exports, and Patents.

Objectives and Outcomes

To develop understanding and competencies of Clinical Research, Regulatory Affairs and Patents in Pharmaceutical Industry. Upon successful completion of this program, a graduate with a PGDCRP is able to have a good knowledge and understanding of:

- Clinical Research:
 - Fundamentals of Clinical Research
 - Conduct of Clinical Research
 - Design of Clinical Trials
 - Good Clinical Practices
 - Management of Clinical Trials

- Regulatory Structure:
 - Indian Regulatory Structure - present and future
 - US Food and Drug Administration (FDA)
 - European Agency for the evaluation of Medicinal Products (EMA)
 - Investigational new drug applications (IND)
 - New Drug Applications (NDA)
 - Common Technical Document
 - International Committee on Harmonization (ICH)

➤ Patents and Trademarks:

- World Trade Organization (WTO)
- General Agreement on Tariffs and Trade (GATT)
- Intellectual Property Rights (IPR)
- Trade-Related Aspects of Intellectual Property Rights (TRIPS)
- Impact of IPR on Pharmaceutical business

The program utilizes a broad-based, multidisciplinary approach to the learning experience and consists of lecturers, seminars, workshops, industry visits related to nine main topics as follows:

Modes of sharing the knowledge

We believe in sharing and exchanging the knowledge and experiences, this essentially means that the course will be conducted in a seminar style with the key person from top pharma, biotech, and government assuming the role of a facilitator. The students are expected to read the materials given before sessions so that they will be ready for discussions and presentations in class. The traditional Lecture / tutorial style will not be used. Students prepared to put in some amount of effort will find this course a stimulating and challenging experience.

Evaluation Procedure & Eligibility

Continuous classroom evaluation by Faculty / Program Co-coordinator. Module related assignments will form part of the course. There shall be a qualifying examination for award of the Certificate.

Attendance

Failure to attend a minimum of 75 percent of the sessions will result in the participants not being allowed to complete the program.

Eligibility

Graduates and post graduates students (MD, MBBS, M.Pharm, B. Pharm., B.Sc., M.Sc.), Research students and professionals can apply.

Duration and Course Commencement

6 months, with classes being held on Sundays. New batch begins every September, & March.

Venue and Time

Classes shall be conducted on Sundays from 10 am-4 Pm at G-12, Ground Floor, Ramnarain Ruia College, Matunga (East), Mumbai, 400019

Admission Process

The selection procedure will include an interview in the Institute premises. There are total 50 seats for this course.

Fee Structure and Payment Terms

Fees Rs. 25,000/- The fee includes tuition fees, supply of reading material, workshops, and Industry visits. Full fees are payable at the time of admission. Fees should be paid by a demand draft payable at Mumbai in favor of "Centre For Advancement In Health Sciences".

Contact

Feel free to contact Rajshree - +919860697268, Dr. Vaidehi on +919820345616

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Please fill in all the details.
All entries should be made in CAPITALS.

For Office Use Only :

Application Number: _____

Application received on: _____

Enrolment number: _____

Paste your self
Attested
Photograph here

- Full name of the Candidate: _____
- Date of Birth: _____ Email: _____
- Telephone Residence: _____ Mobile: _____
- Address for Correspondence: _____

- Academic Qualifications (After 10 + 2)

Examination Passed	University / College	Year	Class / Percentage

Payment Details: Demand Draft No. _____ Date: _____

Drawn on (Bank) _____ for Rs. Twenty five thousand only /- (Bank draft must be drawn in favour of “**Centre For Advancement In Health Sciences**” payable at Mumbai. Candidate should write his/her name and address on the back of the demand draft)

Signature of the candidate: _____ Date: _____

Enclosures: Demand Draft, 2 Photographs, Photocopy of last examination passed / degrees obtained

(Photocopy of this form can be used.)