

CERTIFICATE FROM SPONSORING AUTHORITY (IF APPLICABLE)

Certified that the above applicant is employed in our organization and the information stated by him/her is verified and found correct. We therefore, sponsor him/her to attend the short term training organized at your institute

Date : Signature of Sponsoring Authority
Place : with Seal

HOW TO APPLY

The applicants are required to send completely filled in application form (photocopy may also be used) along with the registration fees so as to reach the coordinator on or before 19/09/2015

Address for Correspondence:

Coordinator – Centre for Continuing Education
A Block, Nirma University
Sarkhej-Gandhinagar Highway
Near Chharodi,
Ahmedabad 382 481, Gujarat
Phone: 02717 241911-15 ext. 314
Fax : 02717 241917

About Conducting Institute

Institute of Pharmacy is a constituent Nirma University. The future pharmacists will be required to function, communicate and work effectively in multidisciplinary teams. Institute of Pharmacy was established with a view to promote excellence in Pharmaceutical education and to prepare new generation to meet the challenges in the area of pharmaceutical industries, education, research and development as well as marketing. Institute of Pharmacy is poised to face global challenges of the pharmaceutical industry and education with the changed perspectives. It has modern, well-designed and very well equipped laboratories in addition to the spacious & ICT enabled classrooms and seminar hall.

Institute of Pharmacy has taken initiative and started M.Pharm. Program in Regulatory Affairs and Quality

Assurance to cater the need of Pharmaceutical Industry, which is facing the regulatory challenges globally. The department of Pharmaceutical Analysis deals with different fields including Pharmaceutical analysis, Regulatory affairs, Quality Assurance, Validation of Pharmaceutical Manufacturing units, forensic analysis, bio-equivalence studies and solid state analysis. Regulatory affairs impart knowledge on the regulatory requirements for approval of new drugs, drug products, medical devices, biological, biosimilar, in various regulated countries.

Research is facilitated by laboratories housing advanced instruments like Fourier Transform Infra-Red (FTIR), UV-Near IR Spectrophotometer, HPLC with PDA detector, GC, HPTLC, Raman Spectrophotometer, Super-critical fluid extraction chromatogram; to name a few.

About Centre For Continuing Education

Nirma University has established a Centre for Continuing Education with the following objectives:

- To provide Need based Continuing Education, Knowledge, Training etc. in various fields to all stakeholders.
- To assist working professionals in the industry in widening their knowledge base and in improving their skills.
- To arrange Workshops, Lectures, Seminars, Services, on requests.
- To identify employment potential areas and to conduct competency based skilled development programme.
- To conduct Vocational Training to meet the specific needs of industrial businesses.
- To conduct short duration and long duration programmes in Management, Engineering and Technology, Pharmacy, Science, Law and Architecture.
- To conduct Training Programme for Competitive Examinations.
- To coordinate the continuing education programme offered by various Institutes at the University level.



National Seminar on CTD: Technical & Regulatory Requirement

26/09/2015



Conducted By
Prof. Priti Mehta, HOD
Dr. Charmy Kothari, Asst. Prof.
Department of Pharmaceutical Analysis
Institute of Pharmacy
Nirma University

Organized By
Centre for Continuing Education
Nirma University

Website: www.nirmauni.ac.in
Tel: 02717 – 241911/12/13/14/15
Fax: 02717-241917

APPLICATION FORM

National Seminar on
CTD: Technical & Regulatory
Requirement

On 26/09/2015

1. Name Mr./Ms.....
2. Age years
3. Edu. Qualification.....
4. Designation
5. Organization
6. Internal/External.....
7. If Internal Student Specify Roll No
.....
8. Address
-
-
- Phone..... Fax.....
- Email.....
9. Experience (years) in relevant area
Academic:.....
Industry:.....
10. Demand Draft No..... Dated.....
Bank:-

Date : _____ Signature of Participant
Place : _____

FOR WHOM

Interested faculty members from Pharmacy colleges, other academic Institutes, UG/PG/Ph.D. students and Pharmaceutical Industry Person can fill up the attached application form and return it to the Coordinators.

COURSE REGISTRATION FEES

Fees	Types of Participants
Rs. 600	Nirma University Students
Rs. 800	External Students
Rs. 1100	External Faculty
Rs. 1300	Industry Person

Tea, lunch and course materials will be provided to all the participants. All other expenses are to be borne by the participants. Registration charges are non refundable. Participants are required to make their own arrangements for lodging, boarding and travelling. However, on request, the arrangement for accommodation can be made on chargeable basis.

Fees can be paid by Cash/Demand Draft/Local Cheque. Demand Draft / Cheque should be drawn in favor of “**Centre for Continuing Education, Nirma University**” payable at Ahmedabad

For further details, contact:

Dr. Charmy Kothari

Contact No (9898617612, 02717 241911 ext. 879)

Email: charmey.kothari@nirmauni.ac.in

OBJECTIVE OF THE PROGRAM

The program is intended for the regulatory Professional in the pharma regulatory field. The main objective of the program on CTD filing is to provide the interface between the pharmaceutical industry and drug regulatory authorities across the world. As per global regulatory authorities, the products to be marketed must meet all the regulatory expectations with regards to quality, safety and efficacy. Its purpose is to ensure the dossier submission requirement in form of CTD which can eliminate the need to reformat the information for submission to the different ICH regulatory authorities.

OUTLINE OF CONTENTS

- Common Technical Document (CTD) Overview
- CTD Requirements in US, EU, India and ASEAN
- Consequences faced during CTD filing
- Comparison of CTD with ACTD
- eCTD requirements and software used in eCTD

RESOURCE PERSONS

Scientific sessions will be conducted by experienced and renowned speakers from Pharmaceutical Industry and government regulatory body.

IMPORTANT DATES

Last date of registration : 19/09/2015

Confirmation of registration : 21/09/2015

By Email/Website