INTERNATIONAL CONFERENCE

ADVANCEMENTS IN DRUG REGULATORY AFFAIRS: PHARMACEUTICAL INDUSTRY-ACADEMIA PERSPECTIVE (ADRA-2022)

26th-30th SEPTEMBER 2022

CHITKARA COLLEGE OF PHARMACY, CHITKARA UNIVERSITY, RAJPURA, PUNJAB, INDIA

OBJECTIVE

The ADRA-2022 International Conference aims to provide ample opportunities to learn fundamental as well as recent advancements in the field of pharmaceutical regulatory affairs. The eminent resource persons from premium organizations will be sharing their expertise to enrich the knowledge and skills of the participants.

The highlight of the conference would encompass:

1. Documentation and general principles involved in regulatory writing and submission to USFDA, EU and CDSCO.
2. Understanding the stages of regulatory filing
3. Know- how on filing and strategy in eCTD/QbD paradigms
4. Regulations and legislation for medical devices
5. Total Quality Management concept
6. Thesis Writing in DRA and outcome of the thesis
7. Intellectual property rights
8. Regulatory requirements for cosmetics
9. cGMP, ICH, GCP, GLP, WHO- guidelines
10. Ethical conduct and regulatory approval of Clinical Research.

ABOUT THE INSTITUTE

Chitkara College of Pharmacy was started in 2005 by the Chitkara Education Trust, Chandigarh, under the guidance of renowned academicians Dr. Ashok Chitkara and Dr. Madhu Chitkara. Chitkara University is located at Jhansla, Rajpura, Punjab and the campus has several institutions including Pharmacy, Engineering and Technology, Planning and Architecture, Education, Hospitality Management, Business School. The different institutes have relevant accreditations including National Councils, ISO and NAAC. The campus is hosting Graduation and Post Graduation courses in Pharmacy, Electrical Engineering, Computer Science and Engineering, Electronics and Communication Engineering and Mechanical Engineering, Architecture, Education, Management, Media and Health Sciences. Chitkara College of Pharmacy has courses B. Pharm, M. Pharm, Pharmacy Practice, Pharm D, Pharm D (PB) and Ph.D approved by AICTE, PCI & UGC. The institute has highly qualified faculty, well equipped laboratories, high speed internet facility and a very well equipped library. Chitkara College of Pharmacy has comprehensive research portfolios with more than 168 patents, 1235 publications, 317 PG thesis and Ph.D program, thus making it a premier center for higher education in Pharmaceutical Sciences.

Chitkara College of Pharmacy stands in top 50 Pharma institutions since 2016 till 2022 by the Ministry of Human Resource Development-NIRF ranking by bagging 20thposition in 2022. Parameters for the ranking included learning resources, research & collaborative performance, graduation outcome, outreach & inclusivity, and perception.

WHO THIS CONFERENCE IS FOR

- Pharmacy faculty members
- B.Pharm, M.Pharm, Pharm D students
- PhD, Research scholars
- Pharmaceutical industry expert
- Anyone who wants to make a career in Drug Regulatory Affairs.

The ADRA-2022 International Conference has been designed keeping in mind the zest and vigour in Pharma faculty and students to know and get trained in pharmaceutical regulatory affairs.

OUTCOMES

- Basic understanding and terminologies related to Drug Regulatory Affairs (DRA)
- Understand the role of a Regulatory Affairs Professional in Pharmaceutical industry, & career options in RA
- Navigation through historical background of US Drug Law and Regulations, and The USFDA regulations
- Major Agencies for drug regulations in USA, EU& other Countries
- Drug approval process in USA, New drug development-Preclinical Steps, IND, NDA, ANDA, Hatch-Waxman Act, etc
- Common Technical Document (CTD), Modules, ACTD Vs ICH-CTD
- Electronic Common Technical Document (eCTD), eCTD technical components, eCTD submissions, Paper CTD Vs eCTD, Various eCTD softwares
- Good Manufacturing Practices (GMP) and Current Good Manufacturing Practices (cGMP)
- Clinical Research and regulations
- Biologics License Application (BLA)
- Discover how to navigate important websites including ICH Guidelines to find more relevant information
- Professional reputation building and career success enhancement through proper understanding of Drug Regulatory Affairs and related concepts

CHIEF PATRONS

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Prof. (Dr.) Madhu Chitkara

Pro-Chancellor | Chitkara University, Punjab

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Dean, Chitkara College of Pharmacy
Chitkara University, Punjab

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Controlling & Licensing Authority and Deputy Drugs Controller, Head of Office, New Delhi

Prof. Bhupinder Singh Bhoop

Em. Professor and Ex-Chairperson & Dean, UIPS, Panjab University, Chandigarh

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Joint Commissioner – State Drugs Controller, FDA Punjab

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MD, Biogenetic Healthcare

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ABSTRACT SUBMISSION AND REGISTRATION

The participants of ADRA-2022 International Conference can present their work as e poster / e presentation. It should be complete with the subheadings - Title, Author's name, Affiliation, Address with email i.d and phone number. The TITLE should be written in capitals. Name of authors should start with full name followed by surname. List not more than 5 authors. Underline/Highlight the name of presenting author and mark with asterix. The main body of the abstract should not exceed 250 words and must be prepared in a standard format with clearly outlined. Type in single space with font Times New Roman and letter size 12 in the Abstract.

Selected papers will be published in "Journal of Pharmaceutical Technology, Research and Management" Author guidelines and other details could be accessed from www.jptrm.chitkara.edu.in

Abstracts can be submitted online to; workshopccp@chitkara.edu.in

Deadline for registration and abstract submission: 20th September, 2022

Registration & Payment Link:

https://paym.chitkara.edu.in/pharmaceutical-industry-academia-perspective/

3 best e-poster presentations will get certificate of Merit

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International Conference on

"ADVANCEMENTS IN DRUG REGULATORY AFFAIRS: PHARMACEUTICAL INDUSTRY- ACADEMIA PERSPECTIVE (ADRA-2022)"

from 26-30th September 2022

The primary objective of International Conference on "Advancements in Drug Regulatory Affairs: Pharmaceutical Industry- Academia Perspective (ADRA-2022)" is to provide in-depth knowledge and understanding of concept of generic drug and innovator, total quality management, drug discovery and development, regulatory strategy, approval process of all regulatory filings in various countries, filing process of IND, NDA and ANDA, etc., US registration for foreign drugs, Europe IMPD, marketing authorization application (MAA), Centralized procedure, bioequivalence and drug product assessment-in vivo, Manufacturing and Controls (CMC) and their regulatory importance, Submission of global documents (CTD/eCTD), Filing process in India-IND, NDA, Clinical trials (Schedule Y) etc.

Outcomes

- Basic understanding and terminologies related to Drug Regulatory Affairs
- Improved understanding of the role of a Regulatory Affairs Professional in Pharmaceutical industry, & career options in RA
- Furtherance of know-how of major agencies for drug regulations in USA, EU& other Countries
- Knowledge about drug approval process in USA, New drug development-Preclinical Steps,
  IND, NDA, ANDA, Hatch-Waxman Act, etc
- Professional reputation building and career success enhancement through
  proper understanding of Drug Regulatory Affairs and related concepts

Professor (Dr) Archana Mantri, Vice Chancellor, Chitkara University, Punjab, addressing the audience during the inauguration


Professor (Dr) Thakur Gurjeet Singh felicitating Professor Bhupinder Singh Bhoop (Chief Guest)

Dr Praveen Topale, Panacea Biotech, Punjab, delivering his keynote talk


Professor (Dr) Harish Dureja, MDU, Rohtak, delivering the talk to the gathering

Mr Sanjeev Garg, Joint Commissioner (Drugs) - State Drugs Controller, FDA Punjab, (Guest of Honour) addressing the audience

7. News (if any)