

CHITKARA COLLEGE OF PHARMACY  
CHITKARA UNIVERSITY, PUNJAB

CHITKARA  
UNIVERSITY



INTERNATIONAL  
E-WORKSHOP ON



# GOOD CLINICAL PRACTICES & HEALTH ECONOMICS

Theme: “Updates on New Clinical Trial Regulation,  
Trends in HEOR & Global Challenges”



Collaborator

Indian Pharmaceutical Association (IPA) | APTI Punjab Branch  
Integrated Association of Medical Basic & Social Scientists  
Amulya Herbs | Operant Pharmacy Federation



Online Platform: CISCO WebEx | 7<sup>th</sup> -11<sup>th</sup> December, 2020

# OBJECTIVE OF INTERNATIONAL WORKSHOP ON GOOD CLINICAL PRACTICE & HEOR:

Good Clinical Practice (GCP) is an international ethical and quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials, that provides assurance that the Rights, safety and well-being of human research participants are well protected. Data and reported results are credible and accurate

## **The Workshop aims to achieve following objectives**

- To seek cognizance towards principles of GCP, roles and responsibilities of various stakeholder involved in a clinical research/trial
- To understand current ethical and regulatory requirements for conducting clinical research/trial in India
- To be aware of the national ethical guidelines for biomedical and health research involving human participants by ICMR and national ethical guidelines for biomedical research involving children by ICMR
- To understand various requirements for seeking accreditation/registration of ethics committees
- To enable the participants to understand that by seeking compliance to GCP they can give public an assurance that the rights, safety and well-being of human participants are well protected and the data from the study results are credible and accurate.
- This workshop will cover basic methods of health economics, key evaluation issues and how to critically appraise health economic research

The workshop sessions will be conducted and addressed by eminent experts actively engaged in the various fields of pharmacy and medical education and profession and attended by the various stakeholders. In the wake of an expanding Pharma and Health care industry, demand for trained pharmacy professional is on the rise. They would be required in larger numbers for work related to the discovery, design, development, manufacture, quality and in clinical practice of medicines to ensure the quality, safety and efficiency of medicinal products, cost effectiveness, so as to achieve optimal therapeutic outcomes and quality of life for patients in clinical setting and health care delivery. This workshop will allow budding pharmacy professionals to assume a more active role in optimizing the outcomes for medication therapies by providing more sophisticated levels of pharmaceutical care. The training necessary to provide clinical services in the india encompasses changes in the education of Practicing clinicians, Faculty members and pharmacists as well as pharmacy technicians.

# 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. (Mrs.) Madhu Chitkara. Chitkara Educational group campus is located at Jhansla, Rajpura and the campus has institutions including Chitkara College of Pharmacy, Chitkara Institute of Engineering and Technology, Chitkara School of Planning and Architecture, Chitkara School of Education, Chitkara School Hospitality Management, Chitkara Business School. The different institutes have relevant accreditations including National Councils, ISO and NAAC. The campus is hosting degree and Post degree level 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 and affiliated to Chitkara University, Punjab. The institute has highly qualified faculty, well equipped laboratories, high speed internet facility and a very well equipped library. The college has comprehensive research portfolios with more than 54 patents, 430 publications, 210 PG thesis and Ph.D Program going for making it a premier centre for higher education in Pharmaceutical Sciences. CCP is continuously ranked by MHRD NIRF in Top 50 Pharma Institutions since 2016 (Presently 38<sup>th</sup>).



## PROGRAM DETAILS:

Theme: **“Updates on New Clinical Trial Regulations, Trends in HEOR & Global Challenges”**

Date: **7<sup>th</sup> December to 11<sup>th</sup> December, 2020**

Who should attend?

The programme is designed to understand the recent advancements in Clinical Research as well as Health Economics & Outcome Research.

- Practicing clinicians, Faculty members and PG from Nursing/Pharmacy/Medical/Dental Institution
- Research scholars in Biomedical Sciences, Pharmaceutical Sciences and Pharmacy Practice
- Hospital/Health care administrators
- Faculty from Indigenous system of medicine, personnel like CRCs, Monitors, Auditors, etc.
- Industry/Institution/Academia

Number of participants: **Three Hundred [300]**

Registration: **200 INR** for Students, **300 INR** for faculty, **400 INR** for Industry personnel.

Note: Please make correspondence on [workshopccp@chitkara.edu.in](mailto:workshopccp@chitkara.edu.in)

Registration url: <http://paym.chitkara.edu.in/good-clinical-practices-and-health-economics>

Admin url: <https://paym.chitkara.edu.in/gcphe-list.php>

## ORGANIZING COMMITTEE

### PATRONS

**Professor (Dr.) Ashok Chitkara**

Chancellor | Chitkara University, Punjab

**Professor (Dr.) Madhu Chitkara**

Pro-Chancellor | Chitkara University, Punjab

## CONVENER & CHAIRMAN

**Professor (Dr.) Sandeep Arora**

Dean | Chitkara College of Pharmacy | Chitkara University, Punjab

## ORGANIZING SECRETARY

**Dr. Thakur Gurjeet Singh**

Associate Professor & Head | Department of Pharmacology

Chitkara College of Pharmacy | Chitkara University, Punjab

## CO-ORGANIZING SECRETARY

**Dr. Abhimanyu Prashar** (Faculty Advisor, ISPOR Student Chapter, Chitkara University, India), **Dr. Ravinder Singh Jaura**

## EVENT COORDINATORS

**Dr. Suman Baishnab, Dr. Nidhi Garg, Dr. Monika Rani, Ms. Rupinder Kaur**

## CORE COMMITTEE MEMBERS

Dr. Rajni Bala, Dr. Inderbir Singh, Dr. Reecha Madan, Dr. Sonia Dhiman, Dr. Amarjot Kaur, Dr. Manju Nagpal, Dr. Manjinder Singh, Dr. Rakesh Kumar, Dr. Anju Goel, Dr. Ritchu Babbar, Dr. Madhukar Garg, Dr. Poonam Arora, Dr. Balraj Saini, Dr. Neelam Sharma, Dr. Rajwinder Kaur, Dr. Varinder Singh, Ms. Pratibha Sharma, Ms. Heena Khan, Ms. Malkeet Kaur, Mr. Omkar Bedi, Dr. Amit Kumar, Dr. Manish Kumar, Ms. Sonia Sethi, Ms. Vandana, Dr. Amit Kumar, Dr. Madhukar Garg, Dr. Rakesh Kumar, Mr. Onkar Bedi, Dr. Sumit Sharma, Dr. Tapan Behl, Ms. Rashmi Arora, Dr. Amit Kumar, Dr. Deepinder Singh, Dr. Arun Dhiman, Dr. Deepika Rana, Ms. Janita Chander, Ms. Loveleen Kaur, Ms. Shareen Singh

## ISPOR STUDENT CHAPTER OFFICERS

**Mr. Nikhil Garg** (President, ISPOR Student Chapter, Chitkara University, India)  
**Ms. Ashi Manan, Ms. Heena Khan**

## Topics to be Covered

- Importance of Research Methodology
- Evidence Based Medicine; Systemic Literature Review & Meta-Analysis
- Epidemiology & Epidemiological Study Methods
- Introduction to Biostatistics & Hands-on with SPSS
- Statistical Analysis Using SPSS
- Techniques for Data Interpretation
- Importance of Case-Reports in Drug-Safety Research
- PVPI and Indian Scenario
- Role of PVPI in governing the reporting of Adverse Events
- The basics of designing clinical Trials
- Research Study design in clinical trials
- Clinical Trial Documentation, Audits and Inspections
- Data Analysis & R as open source for teaching
- Budget Development Considerations for Clinical Research Sites
- Clinical Data Management with overview on Post Clinical Phases
- Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions
- Pharmacovigilance, Data collection practices and role of drug safety officers in Clinical research
- Targeted Clinical investigations and Vaccine safety surveillance



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**REGISTRATION FORM**

**Title:** Dr./ Mr./ Ms.

**Name:** \_\_\_\_\_ **Designation:** \_\_\_\_\_

**Department:** \_\_\_\_\_

**Organization:** \_\_\_\_\_

**Contact No.:** \_\_\_\_\_ **Email ID:** \_\_\_\_\_

**Address for Correspondence** \_\_\_\_\_

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**Pin Code:** \_\_\_\_\_ **State:** \_\_\_\_\_

**Registration Category (Please tick)**

**Faculty Member**

**Student**

**Industry Personnel**

**Signature of Participant**