Good Clinical Practice (GCP)

ESIC Medical College, Faridabad

August 10 - 11, 2017

OBJECTIVE

To enable basic awareness and understanding of GCP by the participants, so that they can ensure compliance and give public an assurance that the rights, safety and well-being of human subjects involved in research are well protected.

TARGET PARTICIPANTS:

Investigators, Ethics Committee Members, Clinical trial or research team members, Nurses. Any one working in the area of clinical trial or research or aspires to work in this area.

REGISTRATION:

Applicant will be considered on a first come first serve basis.

Registration Fees (For External Candidates)	
Fee	Rs. 2000
GST @ 18%	Rs. 360/-
Total	Rs. 2,360/-

Please apply in the prescribed application format available on the website:

Link for Registration

http://cdsaindia.in/node/202

Limited Seats 50

EXPECTED OUTCOME

- Indian regulations that govern human research
- Protection of rights, safety and well-being of humans participating in research
- Quality, reliability and integrity of data
- Standards & guidelines for the conduct of clinical research
- Understand the simple formula, Good Clinical Practice = Ethics + Quality Data
- Identify 'right' from 'wrong' approaches

9.5 CME Credit hours

Contact Information

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Good Clinical Practice

ESIC Medical College & Hospital, Faridabad
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Program Agenda
August 10, 2017

Time	Title (Learning Objectives)	Presenter
09:00 – 09:30	Registration	**Ms. Neha Mishra**, Training Coordinator, CDSA
09:30 – 10:00	• Welcome Address • Keynote Address • Course Introduction & Overview • Vote of Thanks	• **Dr. Asim Das** Dean, ESIC Medical College b, Faridabad • **Dr. Shinjini Bhatnagar** Dean, Clinical Research, THSTI • **Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA • **Dr. Ranabir Pal** Professor & Chair (Head) of Community Medicine, ESIC Medical College, Faridabad
10:00 – 10:30	**Group Photograph & Networking Tea**	
10:30 – 11:15	Overview of GCP • What is GCP? Why GCP? • Principles of ICH GCP • Addendum (R2)	**Dr. Pawandeep Kaur Dhawan** Associate Medical Director, CDSA
11:15 – 12:45	Ethical Considerations • EC Functioning • Informed Consent Process • Confidentiality and Privacy • Vulnerable Population	**Dr. Nandini K. Kumar** Former Deputy Director General (Sr. Grade), ICMR, Dr. TMA Pai Endowment Chair, Manipal University; Adjunct Faculty, CDSA
12:45 – 13:30	Current Regulations & Guidelines in India for Clinical Trials	**Shri. A. B. Ramteke** Former Joint Drugs Controller (India), CDSCO, HQ, New Delhi; Consultant, Regulatory Affairs, CDSA
13:30 – 14:15	**Lunch Break**	
14:15 – 15:00	Clinical Trial Documents	**Dr. Pawandeep Kaur Dhawan** Associate Medical Director, CDSA
15:00 – 15:45	Roles and Responsibilities of Sponsor and Institution	**Mr. Anirban Roy Chowdhury** Senior Director, Global Clinical Trial Operations, MSD Pharmaceuticals (Merck).
15:45 – 16:00	**Tea/Coffee Break**	
16:00 – 16:45	Roles and Responsibilities of an Investigator	**Dr. Ranabir Pal** Professor & Chair (Head) of Community Medicine, ESIC Medical College & Hospital, Faridabad
16:45 – 17:45	Exercises: Role play, case studies	All Faculty
>17:45	Open Forum for Q & A	

August 11, 2017 (Day 02)

Time	Title (Learning Objectives)	Presenter
09:00 – 09:30	Recap	Participants
09:30 – 10:15	Roles and Responsibilities of Monitor	**Dr. Monika Bahl** Director Clinical Portfolio Management, CDSA
10:15 – 10:30	**Tea/Coffee Break**	
10:30 – 11:15	Record Keeping and Data Handling	**Dr. Monika Bahl** Director Clinical Portfolio Management, CDSA
11:15 – 12:00	Quality Assurance	**Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA
12:00 – 12:45	GCP: Special Concerns	**Dr. N. R. Biswas** Director & Vice Chancellor, IGIMS, Patna; Chairperson, IEC, ESIC Medical College & Hospital, Faridabad
12:45 – 13:30	**Lunch Break**	
13:30 – 15:30	Exercises: Quiz, Individual exercise, Case studies	All Faculty
	Tea/Coffee Break	
15:30 – 16:30	Exit Assessment	
>16:30	Open Forum for Q & A and Feedback Distribution of Certificates	

Happy Learning!!