



Workshop on Good Clinical Practice (GCP) and Good Laboratory Practice (GLP)

March 11-12, 2025

Institute of Medical Sciences, Banaras Hindu University, Varanasi



DAY 1- Workshop on Good Clinical Practice (GCP)		
Timings: 08:30 AM to 06:00 PM		
Time	Topic	Speaker
08:30-09:00 AM	Registration Inauguration / Lamp lighting/ Saraswati Vandana Welcome Address	
09:00-09:45 AM	How to Write a Clinical Protocol/Scientific Paper	Prof. Bikash Medhi PGIMER, Chandigarh
09:45-10:30 AM	Overview of Good Clinical Practice (GCP)	Prof. Bikash Medhi PGIMER, Chandigarh
10:30-11:30 AM	New Drugs and Clinical Trials Rules, 2019 (India)	Prof. Bikash Medhi PGIMER, Chandigarh
11:30-12:15 PM	Informed consent process in Clinical Research	Prof. Kiran R.Giri , BHU, Varanasi
12:15-01:00 PM	Randomization-IVRS, eCRF, Sample size calculation, Data entry & result representation	Dr. Ajay Prakash, PGIMER Chandigarh
01:00-02:00 PM	Lunch	
02:00-02:45 PM	Clinical Study report preparation	Dr. Suyog Mehta, Sun Pharma
02:45-03:30 PM	Statistical Significance Vs Clinical Significance Basic Statistics	Dr. Ajay Prakash, PGIMER Chandigarh
03:30-04:00 PM	SAE reporting in Clinical trials and Compensation in clinical trials	Prof. Bikash Medhi PGIMER, Chandigarh
04:00-04:30 PM	Clinical trial Data management	Dr. Amay Mane Mumbai
04:30-05:50 M	Discussion	

Day 2- Workshop on Good Laboratory Practice (GLP)		
Timings: 09:00 AM to 05:00 PM		
Time	Topic	Speaker
09:00-09:30 AM	Registration	
09:30-10:00 AM	History and development of GLP: OECD, MAD, its current perspective	Prof. Bikash Medhi PGIMER, Chandigarh
10:00-10:45 AM	Introduction to Good Laboratory Practices (GLP)	Dr. Ekta Kapoor NGCMA, New Delhi
10:45-11:45 AM	Role of Test facility Management in GLP facility	Dr. Ajay Prakash PGIMER, Chandigarh
11:45-12:45 PM	Role of Quality Assurance in Review of Standard Operating Procedure (SOPs)	Prof. Bikash Medhi PGIMER, Chandigarh
12:45-01:30 PM	Role of study director and study protocols	Dr. Ajay Prakash PGIMER, Chandigarh
01:30-02:00 PM	Pre-Clinical/Non-Clinical Toxicity studies: Investigator New Drug Applications (IND)	Prof. Bikash Medhi PGIMER, Chandigarh
02:00-02:45 PM	Valedictory Function	



Prof S N Sankhwar,
Director,
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Prof. Gopal Nath
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Prof. Kiran R.Giri Professor & Head
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