Good Clinical Practice (GCP)

Workshop – 5 Hours Online Program

Organized by:

Physician Research Foundation (PRF),
API West Bengal Branch

Under the Aegis of:

Association of Physicians of India (API),
West Bengal Branch

Program Overview:

The Good Clinical Practice (GCP) workshop is designed to provide a comprehensive overview of GCP guidelines, ensuring participants understand the ethical and scientific quality standards necessary for conducting clinical research. This workshop is aimed at clinical investigators who are currently involved or planning to engage in clinical research. The program will cover core GCP principles, roles and responsibilities of the investigators, and essential documentation for ensuring compliance with regulatory standards.

Save the Date

25th MARCH 2025

01:30 PM
06:30 PM

Platform: Online

Target Audience:

Clinical Investigators, Researchers, Physicians

Registration Fees:

- API Members: Registration is Complimentary but mandatory
- Non-API Members: Rs 1000/-

Click Here to Register

Workshop Agenda:

Welcome Address and Context Setting:

1. Dr. Jyotirmoy Pal, President API
2. Dr A Muruganathan, Director, PRF
3. Dr. Partha Sarkar , Chairman, API WB
4. Dr. Uttam Paul, Chairman, PRF - API WB
5. Dr. Ashish K Saha, Secretary, API WB
6. Dr Nandini Kumar, President, FERCI

Lecture 1: Introduction to Good Clinical Practice (GCP) and Its Importance

Time: 02:00 pm - 02:30 pm

Speaker: Dr. Shambo Samrat Samajdar

✧ Overview of GCP guidelines and their significance in clinical trials.
✧ Understanding the ethical framework for research on human subjects.
✧ Importance of adhering to GCP standards for quality and compliance.

Lecture 2: Investigator Responsibilities and Roles in Clinical Research

Time: 02:30 pm - 03:00 pm

Speaker: Dr. Sucheta Kurundkar

✧ Key responsibilities of investigators.
✧ Ensuring safety and well-being of study participants.
✧ Managing the clinical trial team effectively.

Lecture 3: Informed Consent Process: Best Practices and Documentation

Time: 03:00 – 03:30 PM

Speaker: Dr. Pradeep Narayan

✧ Essentials of obtaining informed consent from study participants.
✧ Legal and ethical considerations.
✧ Case studies on common challenges and solutions.

Lecture 4: Sponsor's Role and Responsibility in Clinical Trials

Time: 03:30 – 04:00 PM

Speaker: Dr Sujoy Ghosh

✧ Overview of the sponsor's role in initiating, designing, and funding clinical trials.
✧ Ensuring adherence to GCP and regulatory requirements throughout the study.
✧ Collaboration with investigators, ethics committees, and regulatory agencies.
✧ Strategies for effective sponsor–investigator communication and oversight.

Lecture 5: Managing Adverse Events and Safety Reporting in Clinical Trials

Time: 04:00 – 04:30 PM

Speaker: Dr. Avijit Hazra

✧ Defining adverse events (AEs) and serious adverse events (SAEs).
✧ Guidelines for AE and SAE reporting.
✧ Handling unanticipated risks and ensuring participant safety.

Lecture 6: Data Integrity and Monitoring in Clinical Trials

Time: 04:30 – 05:00 PM

Speaker: Dr. Sandhiya Selvarajan

✧ Importance of data integrity and best practices for accurate data collection.
✧ Role of monitoring, auditing, and quality assurance in maintaining trial standards.
✧ Tools for monitoring clinical trial sites and documentation.

Lecture 7: Essential Documents for Clinical Trials and Regulatory Compliance

Time: 05:00 – 05:30 PM

Speaker: Dr. Santanu K Tripathi

✧ Overview of essential documentation (protocol, CRFs, IB, etc.).
✧ Preparing and maintaining accurate study documentation.
✧ Audits and inspections: How to prepare and comply.

Lecture 8: Open House Q & A

Time: 05:30 – 06:30 PM

Moderator: Dr Nandini Chatterjee

Panelists:

Dr. Santanu Tripathi, Dr. Sujoy Ghosh, Dr. Avijit Hazra, Dr. Pradeep Narayan

✧ Open discussion for participants to address any concerns and clarify doubts.
✧ Concluding thoughts on GCP and its application in daily clinical practice.

Lecture 9: How to register ethics committee

Time: 06:30 – 07:00 PM

Speaker: Dr. Indranil Chakrabarty

Closing Remark: Dr Asish K Saha, General Secretary, API WB

➢ PRE and POST test will be conducted

API Members: no registration fees **Non-API Members: Rs 1000/-**

Certificate of Participation

➢ A digital certificate will be provided to participants upon successful completion of the workshop. (After participating in both pre and post test)

For any queries, please contact

➢ We look forward to your participation and contribution to advancing clinical research practices!

Digital Partner

CLINNET

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Click Here to Register