

**ONE WEEK ONLINE TRAINING COURSE
ON
GOOD CLINICAL PRACTICES (GCP)**

(March 17th - 23rd , 2025)

Organized By
**Resilient Foundation For Academic Innovation &
Scientific Research, New Delhi**
(Registered with NITI Aayog, Govt. of India)

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About Resilient Foundation :

Resilient Foundation for Academic Innovation & Scientific Research, New Delhi is a not-for-profit organization registered under section 8 of the companies' act 2013, India. The organization is established having primary aim to promote academic & research activities through knowledge sharing, innovation, skill development and capacity building in various sectors like academia, industry and government for betterment of society. For more details please visit <https://theresilientfoundation.org/>

About the Training Course:

Good Clinical Practices (GCP) refer to a set of ethical and scientific quality standards for designing, recording and reporting trials that involve the participation of human subjects. GCP guidelines define the responsibilities of sponsors, investigators, and ethics committees in conducting clinical research. These guidelines are essential to maintaining the rights, safety, and well-being of clinical trial participants and ensuring the validity and reliability of clinical trial data. Everyone involved in the conduct of clinical research must be competent to perform their tasks, qualified by education, training and experience. **It is now essential for all PG students and teaching faculties as per recent NMC Guidelines.**

Objective of the Training Course:

An understanding of GCP is prerequisite for anyone carrying out, or involved in, clinical research and clinical trials.

Members of ethics committees, institutional review boards (IRBs), or research ethics boards (REBs) who review and approve clinical trial protocols should have a solid understanding of GCP principles. GCP training helps them evaluate the ethical aspects of proposed trials, ensuring participant rights, safety, and welfare. **ICMR guideline also states that the members of IRB and Independent Ethics Committee (IEC) should have GCP training.**

The expected outcome of the Training Course:

This course will help :

- To Empower clinicians and researchers about basics of GCP and aware about current regulation and guidelines in India for Clinical Trials
- To describe the roles and responsibilities of IRB/ IEC, sponsors, investigators and monitors
- To understand the key components of GCP including informed consent research protocol
- To ensure the data management and quality assurance policies and practices involved in clinical research

THE COURSE CONTENT

Day	Topics Covered	Date & time
Day-1	<ul style="list-style-type: none"> ▪ Introduction to GCP ▪ Guidelines in India and WHO GCP ▪ Consequences of GCP non-compliance 	Date: 17 th March , 2025 Time: 06:30 PM-08:30 PM
Day-2	<ul style="list-style-type: none"> ▪ Roles and Responsibilities: Sponsor, Investigator and Ethics committee ▪ Informed Consent process 	Date: 18 th March , 2025 Time: 06:30 PM-08:30 PM
Day-3	<ul style="list-style-type: none"> ▪ Development of Research protocol 	Date: 19 th March , 2025 Time: 06:30 PM-08:30 PM
Day-4	<ul style="list-style-type: none"> ▪ Confidentiality and Privacy ▪ Documentation and Record Keeping 	Date: 20 th March , 2025 Time: 06:30 PM-08:30 PM
Day-5	<ul style="list-style-type: none"> ▪ Role of Bioethics in Research 	Date: 21 st March, 2025 Time: 06:30 PM-08:30 PM
Day-6	<ul style="list-style-type: none"> ▪ Safety and Adverse Events, Monitoring of clinical trial participants 	Date: 22 nd March, 2025 Time: 06:30 PM-08:30 PM
Day-7	Role of Regulatory Bodies	Date: 23 rd March, 2025 Time: 06:30 PM-08:30 PM

Methodology

- Online live classes by eminent experts from reputed organizations of the country
- Participatory discussion with Q&A
- Demonstrations
- Recordings of the all sessions will be provided to all registered participants

Nature of Participants

Pharma / Medical / Biotech / Life Sciences / Cosmetics / Homeopathy / Ayurveda / health supplements, alternate healthcare and other life sciences professionals and students.

Duration & Time

- One Week (17 -23 March,2025)
- Timing (02 Hours): 06:30 PM– 08.30 PM

Registration Process:

1. Registration Fee for all participants = **Rs. 600/-**

Registration Link

<https://theresilientfoundation.org/current-events/>

Note: After registration, you will get confirmation on your registered email from organizers in which link for joining official what's app group will be shared.

Training Rule

Highlights of the Training Course:

1. Registered participants will get e-certificates
2. Video recording of all sessions will be provided to all registered participants.
3. Workshop by Subject Experts from reputed Institute & Universities
4. Workshop will be on the Zoom meeting platform.

For further queries, please mail us at : info@resilientfoundation.in
or call at +91-8840112492.

Last Date of Registration: 17th March, 2025 (Till 4:00 PM)

About Resource Persons

1..Dr. Ravinder Singh, is medical graduate with doctorate training in public health. He is looking after the areas of mental health, disability, rehabilitation and assistive technologies at ICMR Headquarters (Department of Health Research, Ministry of Health & Family Welfare, Government of India), New Delhi. He completed his Ph.D. (Public Health) on Adolescent Stress from Jawaharlal Nehru University in 2013. He has experience of more than two decades in health research.

2 .Dr. Ashoo Grover is Currently working as Scientist 'F' (Medical) Deputy Director General Senior Grade at ICMR She promoted a Special programme for Medical Colleges for Research Methodology Courses, Establishment of Multidisciplinary Research Units in Govt. medical colleges, Model rural Health Research Units in 25 States in India, mechanisms for Health Technology Assessment at DHR, MOHFW. She has experience of more than two decades in research. She is editor of many national and international journals.

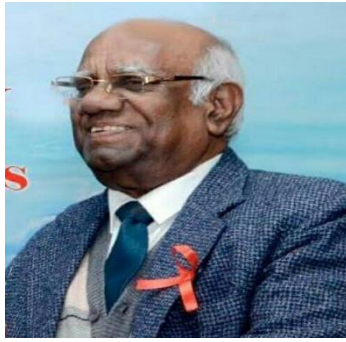
3..Dr. Gayatri Vishwakarma is an experienced Biostatistician having 14+ years of post-PhD work experience in academics and research. Dr. Gayatri is currently working as Principal Scientist, ZYDUS LIFESCIENCES LTD, Zydus Research Centre, Gujrat. She worked as Biostatistician with Department of Research at Rajiv Gandhi Cancer Institute, New Delhi. She worked as Visiting Scientist at University of Texas Health Science Center, Tyler TX, USA. She also worked as Monitoring & Evaluation Specialist in Woodward Charitable Foundation, Ethiopia. She has got PhD in Statistics from Jabalpur University and post-doctoral training at University of Saskatchewan, Canada. .

4. Prof (Dr) Sunil Raina is the Professor & Head, Department of Community Medicine at Dr. RP Government Medical College, Tanda (Himachal Pradesh), India. He is also the Director of the Centre for Advancing Tobacco Control in Himachal Pradesh (CATCH) and adjunct Professor for Manipal Academy of Higher Education (MAHE), Karnataka, India and Father Muller Research Centre, Mangalore. He is co-faculty at New England Complex Systems Institute (NECSI) Dr. Raina was a member Government of India panel on High Altitude Medicine and expert member C- 20 panel of G-20 Summit which was chaired by India in the year 2023. He is expert advisor to the Indian Council of Medical Research (ICMR)-Centre for Non Communicable diseases Kolkata, India and Member Scientific Advisory Committee, National Institute of Implementation Research (ICMR-NIIRNCD), Government of India.

5. Dr Kanica Kaushal is an accomplished medical professional with expertise in public health and is currently working as an Associate Professor, Department of Clinical Research and Epidemiology at Institute of Liver and Biliary Sciences (ILBS), New Delhi. She has worked at prestigious institutions and gained recognition from national and international organizations. Dr Kanica has spearheaded innovative public health projects at the ILBS, New Delhi, and is actively involved in implementing national guidelines for Non-Alcoholic Fatty Liver Disease (NAFLD) in India. She is also dedicated to creating awareness and challenging stigma related to Hepatitis B through various campaigns like EMPATHY (Empowering People Against Hepatitis) (<https://theempathycampaign.com/>), WOMB (Winning Over Mothers with Hepatitis B) and regarding Fatty Liver through nationwide initiatives like SMiES (Stronger India through a Million Health Educated Students) and IMELD (Indian Metabolic and Liver Diseases).



Organising Team of the Training Course



Patron

Prof. (Dr.) Padam Singh
Former Additional Director
General
Indian Council of Medical
Research (ICMR), New Delhi

Co - Patrons



Dr. Ashoo Grover
Senior Scientist
ICMR, New Delhi



Dr. Smita Asthana
Senior Scientist
ICMR- NICPR, Noida



Prof. Karan P. Singh
School of Medicine, University of
Texas, USA



Dr. Ravinder Singh
Senior Scientist
ICMR, New Delhi

Training Coordinators



Dr. Harlokesh Narayan Yadav
Additional Professor
Dept. of Pharmacology
AIIMS, , New Delhi
(Convenor)



Dr. Sushil Kumar Shukla
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Dr. Neha Singh
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Dr. D.K. Yadav
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