3rd National workshop

GOOD CLINICAL PRACTICE (GCP)

Every Thursday 7th, 14th, 21st & 28th March 2024, 3-4 PM (Online mode)

Organized by

NATIONAL ASSOCIATION OF PHARMACOLOGY AND THERAPEUTICS

in association with

Department of Pharmacology
All India Institute of Medical Sciences, Nagpur

Note: All medical doctors irrespective of specialty are eligible for this GCP workshop

About National GCP workshop

Good Clinical Practice (GCP) is a set of international ethical and scientific standards that govern the design, conduct, and reporting of clinical trials involving human subjects. GCP ensures that the rights, safety, and well-being of participants in clinical research are protected, and that the data collected is reliable and credible. It sets forth guidelines and principles that researchers, sponsors, and ethics committees must adhere to when conducting clinical research.

Every year, our esteemed association brings together hundreds of medical doctors and healthcare professionals for an enriching online experience dedicated to Good Clinical Practice. Designed to equip you with the knowledge and tools needed to excel in clinical research, our workshop has become a cornerstone event in the medical community



Join us at the annual National GCP Workshop, organized by the National Association of Pharmacology and Therapeutics, to gain valuable insights and training in this essential aspect of medical research

Key Highlights:

1. **Expert Faculty:** Learn from distinguished experts in the field of clinical research. Our faculty members bring a wealth of experience and knowledge to provide you with the most up-to-date insights.
2. **Comprehensive Curriculum:** Explore a comprehensive curriculum covering all aspects of Good Clinical Practice. From ethical considerations to data integrity and regulatory compliance, our workshop ensures that you are well-prepared to conduct and oversee clinical trials /clinical research effectively.
3. **Interactive Sessions:** Engage in interactive sessions, case studies, and group discussions that encourage active participation and collaborative learning. Get answers to your specific questions and real-world scenarios from our expert instructors.
4. **Online Convenience:** Access the workshop from the comfort of your home or office, eliminating the need for travel. Our user-friendly online platform ensures a seamless learning experience.
5. **Certification:** Upon successful completion of the workshop, participants receive a recognized certificate, demonstrating their commitment to ethical and high-quality clinical research.
6. **Networking Opportunities:** Connect with fellow medical professionals, researchers, and industry experts, fostering valuable relationships and collaborations in the field of clinical research.

Message



Dear Participants

I am honoured to extend my warmest welcome as the organizing chairman of the Good Clinical Practice (GCP) Workshop 2024, hosted by the National Association of Pharmacology and Therapeutics. Our workshop is scheduled to take place online every Thursday throughout the month of March 2024, specifically on the 7th, 14th, 21st, and 28th 3-4 PM in association with with AIIMS Nagpur.

The significance of GCP cannot be overstated in the realm of clinical and medical research. It represents the cornerstone of ethical conduct, scientific rigor, and quality standards in the execution of clinical trials and research studies. GCP is internationally recognized and accepted, facilitating the global harmonization of clinical research standards. It enables the collaboration of researchers, institutions, and pharmaceutical companies across borders. GCP is internationally recognized and accepted, facilitating the global harmonization of clinical research standards. It enables the collaboration of researchers, institutions, and pharmaceutical companies across borders.

Our GCP Workshop in March 2024 has been carefully crafted to provide you with comprehensive insights into GCP principles, practical applications, and the latest developments in the field. We have assembled a panel of distinguished experts who will guide you through these crucial aspects of clinical research.

I encourage each of you to actively engage in discussions, ask questions, and share your experiences. The collective knowledge exchange during this workshop will undoubtedly enhance your understanding of GCP and empower you to contribute to the advancement of clinical and medical research.

Best regards,

Dr. Nitha Gogtay
Organizing Chairman

Professor and Head
Department of Clinical Pharmacology
Seth G. S. Medical College and KEM Hospital, Mumbai



Dear Friends and researchers

We want to emphasize the significance of Good Clinical Practice (GCP), which stands as an international benchmark for ethical and scientific quality standards encompassing the entire spectrum of clinical trial activities. It encompasses the design, execution, monitoring, auditing, recording, analysis, and reporting of clinical trials. In line with the guidelines set forth by the Indian Council of Medical Research (ICMR), it is mandatory for all individuals involved in clinical trials or new drug development research to undergo basic training in clinical research, commonly referred to as GCP training or Good Clinical Practice training. This becomes even more crucial considering the numerous changes and amendments to clinical trial and new drug approval regulations in India in recent years.

We are delighted to announce that the National Association of Pharmacology and Therapeutics is hosting a national-level online GCP training workshop scheduled for March 2023. This workshop is being conducted in collaboration with AIIMS, Nagpur.

We extend a warm invitation to all of you to take advantage of this exceptional GCP training opportunity. Distinguished leaders in clinical research and renowned experts will provide insights and instruction on a wide array of important topics during this workshop.

For further information and registration details, please visit our website at www.nationalpharmacology.org.

Thank you for your attention and participation.

Dr. Ganesh Dakhale
Organizing Secretary

Professor and Head
Dean (Academics)
Department of Pharmacology
All India Institute of Medical Sciences. Nagpur

Event Schedule

GOOD CLINICAL PRACTICE (GCP)

NATIONAL WORKSHOP

Every Thursday March 2024

Thursday 7th March

Topic	Time
Overview of Indian GCP and ICH GCP	3:00–3:30 PM
Overview of Indian GCP and ICH GCP	3:30–4:00 PM

Thursday 14th March

Topic	Time
Clinical trial protocol, IB and Essential documents	3:00–3:30 PM
Informed consent process	3:30–4:00 PM

Thursday 21st March

Topic	Time
Ethics Committee Composition & responsibilities of iIndividual members	3:00–3:30 PM
National Ethical guideline for biomedical & health research involving human partipants ICMR 2017	3:30–4:00 PM

Thursday 28th March

Topic	Time
SAE and Compensation guidelines in India as per NDCT 2019	3:00–3:30 PM
Salient features of NDCT 2019	3:30–4:00 PM

Organizing team



PATRON

Dr. M. H. Rao

Director

All India Institute of Medical Sciences, Nagpur







ORGANIZING CHAIRMAN GCP 2024

Dr. Nitha Gogtay

Professor

Department of Clinical Pharmacology

Seth G. S. Medical College and

KEM Hospital , Mumbai

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Professor & Head

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All India Institute of Medical Sciences,

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Department of Pharmacology and Therapeutics

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Professor and Head

Department of Pharmacology

SMMH Govt. Medical College

Saharanpur, Uttar Pradesh

Thursday, 7th March, 2024

Topic

Overview of Indian GCP and ICH GCP

Time

3:00 PM-3:30 PM

RESOURCE PERSONS



Speaker

Dr. Mrunalini Kalikar

Associate Professor
Department of Pharmacology
Government Medical College ,Nagpur,Maharashtra



Moderator

Dr. Jacob Jesuran

Professor and Head
Department of Pharmacology
Believers Church Medical College Hospital
Thiruvalla,. Krerala

Topic

Responsibilities of Investigators, Sponsors and monitors

Time

3:30 PM-4:00 PM



Speaker

Dr. Rima Shah

Associate Professor and Head
All India India Institute of Medical Sciences
Rajkot Gujarat



Moderator

Dr. Avinash Turankar

Professor
Department of Pharmacology
Government Medical College, Nagpur, Maharashtra

Thursday, 14th March, 2024

Topic

Clinical trial protocol, IB and Essential documents

Time

3:00 PM-3:30 PM

RESOURCE PERSONS



Speaker

Dr. Seema Pai

Director Clinical Site Operations - India Cluster
Global Site & Study Operations
Clinical Development & Operations, GPD
Pfizer Limited, Mumbai, Maharshtra



Moderator

Dr. Deepak Langade

Professor & Head
Department Pharmacology
D Y Patil Medical College, Navi Mumbai

Topic

Informed consent process

Time

3:30 PM-4:00 PM



Speaker

Dr. Urmila Thatte

Professor Emeritus
Department of Clinical Pharmacology
Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra



Moderator

Dr. Prakash B. M .

Professor & Head
Department of Pharmacology
Andaman & Nicobar Islands Institute of Medical Sciences, (ANIIMS), Port Blair, Andaman & Nicobar Islands

Thursday, 21st March, 2024

Topic

Ethics Committee-Composition &
Individual responsibilities of members

Time

3:00 PM-3:30 PM

RESOURCE PERSONS



Speaker

Dr. Usharani Pingali

Professor and Head
Department of Clinical Pharmacology and Therapeutics
Nizams Institute of Medical Sciences, Hyderabad, Telangana



Moderator

Dr Lalit Kumar Gupta

Director-Professor
Department of Pharmacology
Lady Hardinge Medical College, New Delhi

Topic

National Ethical guideline for biomedical & health research involving human participants-ICMR 2017

Time

3:30 PM-4:00 PM



Speaker

Dr Nandini Kumar

Scientist E
Indian Council of Medical Research
New Delhi



Moderator

Dr . Mirza Shiraz Baig

Professor and Head
Department of Pharmacology
Govt. Medical College, Chhatrapati Sambhajinagar, Maharashtra

Thursday, 28th March, 2024

Topic

Salient features of NDCT rules 2019

Time

3:00 PM-3:30 PM

PERSONS



Speaker

Dr Savita Verma

Professor
Department of Pharmacology
Pt B D Sharma Post Graduate Institute of Medical Sciences,
Rohtak, Haryana



Moderator

Dr Ashok Shenoy

Professor
Department of Pharmacology
Kasturba Medical College
Mangalore, Karnataka

RESOURCE

Topic

SAE and Compensation guidelines in India
as per NDCT 2019

Time

3:30 PM-4:00 PM



Speaker

Dr. Mira K. Desai

Professor and Head
Department of Pharmacology
Nootan Medical College , Visnagar, Gujrat



Moderator

Dr. Balakrishan

Professor and Head
Department of Pharmacology
All India Institute of Medical Sciences, Bhopal , Madhya Pradesh

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Member Clinical Research Board
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Professor and Head
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Maharashtra



Member Clinical Research Board
Dr. Mrunalini Kalikar
Associate Professor
Government Medical College, Nagpur
Maharashtra.

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National Association of Pharmacology & Therapeutics

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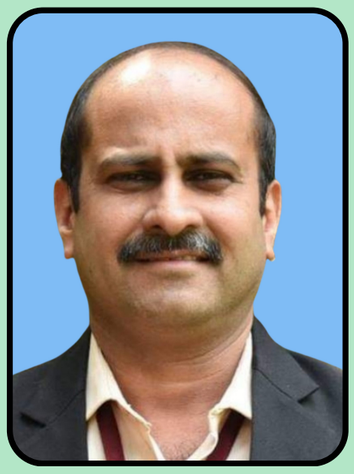
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GMC Dehradun
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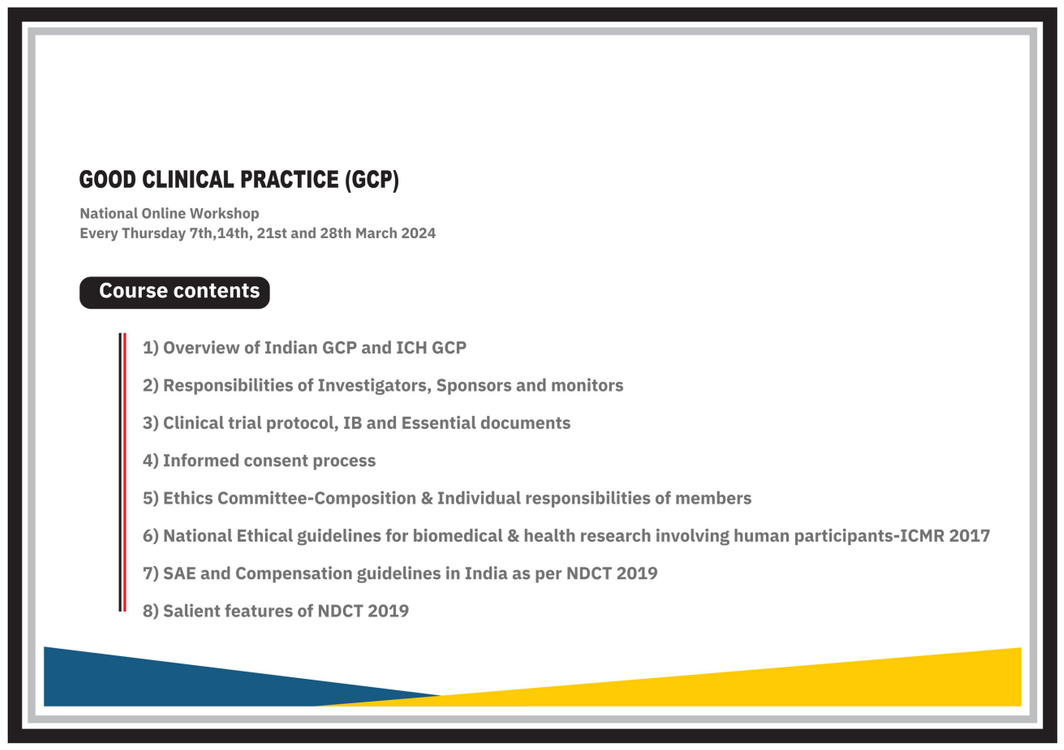
Dr. Hardik Nagar

Assistant Professor
Department of Pharmacology
Namo Medical Education and Research Institute
Silvassa, Diu, Daman and DNH

Online certificate



Front



Back

Registration fee details

Note:

- Only medical doctors with at least MBBS Degree are eligible to register.
- Registration number of MBBS/MD/MS mandatory to apply for registration.

CATEGORY	1st Feb to 15th Feb 2024	15th Feb to 29th Feb 2024
Post graduate students MD Pharmacology	750	900
Post graduate students other medical specialties	750	900
Faculty members/Post Graduate MD/MS doctors (any medical specialty)	900	1050
Life member/Student Member (National Association of Pharmacology & Therapeutics)	700	850

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IMPORTANT INSTRUCTIONS FOR PARTICIPANTS

- This GCP workshop is being organized exclusively for medical doctors with MBBS/MD/DNB/DM degree
- It is the responsibility of the applicant to check eligibility for workshop before applying as the fee is non refundable
- Resource material will be provided within 24hs. of each session on e-mail

HOW TO REGISTER

- Log on website www.nationalpharmacology.org and click on GCP page or click on the link provided in this document.
- Only online payment is applicable. (Cash/draft/cheques etc. not accepted)
- Choose your category for registration
- After submission of registration details the payable amount will be auto calculated and you will be directed to payment gateway.
- Save an image of fund transaction receipt with payment reference number and date/time of payment for future reference.
- Applicants will receive an SMS on their registered mobile and an e-mail within 24 hr after registration process is completed.
- All applicant shall get a link to join a WhatsApp group GCP 2024 on their e-mail 24 hrs prior to workshop
- Applicant will get a link to join the zoom on the email provided by him/her 24 hr prior to workshop
- **Please provide your e-mail that is linked with zoom account.**
- **You may not be able to log in if you provided an e-mail not linked with zoom account**

CERTIFICATES

- Only e-certificate will be delivered at the e-mail (linked with zoom account) provided by applicant after the successful completion of workshop.
- It is the responsibility of participants to carefully check the correctness of e-mail ID and WhatsApp number
- The delivery of certificate will start w.e.f.15th April and will be completed by 30th April 2024.
- All participants please note it may not be possible to resend the certificate if its or lost misplaced at your end.
- All queries related to e-certificates shall be entertained by 30th April 2024.

www.nationalpharmacology.org

NATIONAL ASSOCIATION OF PHARMACOLOGY AND THERAPEUTICS

Promoting Pharmacology and Therapeutics for a better tomorrow...

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