



Department of Clinical Pharmacology  
Seth GS Medical College & KEM Hospital Mumbai  
In collaboration with Dept of Infectious Diseases,  
MUHS



## **WORKSHOP ON GOOD CLINICAL PRACTICE**

### **Organized by**

Department of Clinical Pharmacology  
Seth GS Medical College & KEM Hospital Mumbai  
In collaboration with Dept of Infectious Diseases,  
MUHS

### **ON**

On 14<sup>th</sup> and 15<sup>th</sup> December, 2021  
(Tuesday and Wednesday)

### **Time**

9:00 to 17:00Hrs

### **Venue**

JMLT, Ground Floor, College Building,  
Seth GSMC & KEM Hospital Mumbai 400012

### **Target audience**

faculty, super-specialty students and post-graduate students  
from clinical research and medical affairs

In person/ workshop with COVID appropriate behavior



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## ORGANIZING COMMITTEE

### Mentors

Dr Hemant Deshmukh (Dean)  
Dr Milind Nadkar (Academic Dean)

Mr Sanjay Deshmukh (Ast. Registrar, MUHS)  
Dr Urmila Thatte (Emeritus Professor)

### Organizing Chairperson

Dr Nithya Gogtay

### Scientific Chairpersons

Dr Mahesh Belhekar  
Dr Bhaskar Krishnamurthy

### Organizing Secretaries

Dr Vijaya Gunjal  
Sheetal Kudtarkar

### Finance Secretary

Mr. Surendra Gije

### Registration Committee

Mr. Mayur Shekokar  
Ms. Poorva Patil

### Logistics Committee

Mr. Navnath Chitalkar  
Ms. Vedika Wadkar



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## WELCOME NOTE

Dear Sir/Madam,  
Greetings!

The Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai and Department of Infectious diseases, Maharashtra University of Health Sciences [MUHS] are jointly organizing a two-day workshop on Good Clinical practice on **14th and 15th December, 2021 [Tuesday and Wednesday]** at **JMLT, Ground Floor, College Building, Seth GSMC & KEM Hospital, Mumbai-400012**. This will be an **in-person** workshop with COVID appropriate behavior and protocols in place. It gives us immense pleasure to invite you to participate in the two-day workshop.

Good Clinical Practice [GCP] has become integral part of the medical research and curriculum. Changes in Biomedical health research and its environment have been very rapid in recent times creating the urgent need to obtain and update knowledge on GCP and biomedical research and regulatory guidelines.

Since last year, COVID-19 pandemic has led to several challenges for the medical fraternity and the workshop had to be eventually postponed. Hence, the two-day scientific fest will now be organized through **in person mode** and is designed to cover the important topics like *principles and history of GCP, role of ethics committee/ investigators and sponsor, New Drugs and Clinical Trials [NDCT] Rules 2019, ethical issues in clinical trials, Indian Council of Medical Research [ICMR] national ethical guidelines 2017 along with interesting case studies and group activities* which can be incorporated with latest information to help biomedical research and improve health-care services. The event will comprise of plenary lectures by most eminent speakers in the field of biomedical research.

This workshop is funded by MUHS and will be awarded **FOUR credit points from Maharashtra Medical Council [MMC]** to the delegates. Registrations are restricted to **only first 50 delegates [first come first serve basis]**. The completely filled **registration form** (attached herewith) has to be sent to [iddmuhs@gmail.com](mailto:iddmuhs@gmail.com) and [muhsmumbai@gmail.com](mailto:muhsmumbai@gmail.com) on and before **3<sup>rd</sup> December 2021 till 17:00hrs**. The **registration fee is Rs. 1500/-** which has to be paid by online/ electronic transfer to following bank account.

Name	Registrar Maharashtra University of Health Sciences, Nashik
Account No	00641450000649
Bank Name	HDFC Bank Nashik
IFSC No	HDFC0000064

Please spread the word among your colleagues, residents and students.

We will look forward to welcoming you all.

**Dr. Nithya Gogtay**  
Organizing Chairperson  
Professor & Head, Department of Clinical Pharmacology,  
Seth GS Medical College and KEM Hospital, Mumbai.



# MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES, NASHIK

## DEPARTMENT OF INFECTIOUS DISEASE

Ward no 24, 2<sup>nd</sup> Floor, New Multi Story Building, Seth G.S. Medical

College and KEM Hospital, Parel, Mumbai – 400 012

Phone: 022-24142101/22655073/22655072

Email: [iddmuhs@gmail.com](mailto:iddmuhs@gmail.com)/[muhsmumbai@gmail.com](mailto:muhsmumbai@gmail.com) / Web: [www.muhs.ac.in](http://www.muhs.ac.in)

### Good Clinical Practice Workshop

#### REGISTRATION FORM

1. Name Participant :- .....  
(In Capital Letters) (As to be printed on the certificate)
2. Name of College/ Institution :- .....
3. Department :- .....
4. Address for Communication :- .....
5. Pin code :- .....
6. Phone No. (With area code) :- .....
7. State/Country :- .....
8. Mobile No. :- .....
9. Email :- .....
10. MMC Registration number :- .....

#### PAYMENT DETAILS

1. Registration Fee: Rs. 1500/- for per participant.
2. Registration fee paid :- .....  
Details
3. Payment Gateway :- .....  
(Copy attached)

SIGNATURE

- For online registration please sent mail to [idd@gmail.com](mailto:idd@gmail.com) and [muhsmumbai@gmail.com](mailto:muhsmumbai@gmail.com) on and before 3<sup>rd</sup> December 2021 till 5pm
- Kindly note: As per MMC guidelines no certificates will be issued to Delegate & Faculty who have attended the workshop but not signed the MMC attendance sheet

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Venue- JMLT, Ground Floor, College Building, Seth GSMC & KEM Hospital Mumbai 400012

**Workshop on Good Clinical Practice**  
**In person/ workshop with COVID appropriate behavior**

**Agenda**

**DAY1**

**Date: 14<sup>th</sup> December 2021, Tuesday**

<b>SN</b>	<b>Topic</b>	<b>Speaker</b>	<b>Time (24Hrs format)</b>
	Registration	-	08:30-09:00
	Pre-test	-	09:00-9:15
<b>1</b>	Introduction and History of GCP	Dr. Nithya Gogtay	09:30-10:30
	Inauguration	Dean Sir	10:30-11:00
<b>2</b>	Principles of ICH-GCP	Dr. Manju Sengar	11:00-12:00
<b>3</b>	Role of Ethics Committee	Dr. Sandeep Bavdekar	12:00- 13:00
	Lunch	-	13:00-14:00
<b>4</b>	Investigator's responsibility	Dr. Renuka Munshi	14:00-15:00
<b>5</b>	Role of Sponsor	Dr. Sanish Davis Dr. Mahesh Belhekar	15:00-16:00
	Feedback of day 1		16:00-16:30

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**DAY2**

**Date: 15<sup>th</sup> December 2021, Wednesday**

<b>SN</b>	<b>Topic</b>	<b>Speaker</b>	<b>Time (24Hrs format)</b>
	Registration	-	09:00-09:30
	Pre-test	-	09:30-9:45
<b>1</b>	New Drugs and Clinical Trial Rules [NDCT] 2019	Dr. Urmila Thatte	09:45-10:45
	Tea break	-	10:45-11:00
<b>2</b>	Ethical issues in Clinical trials [Case Studies]	Dr. Durga Gadgil	11:00-12:30
<b>3</b>	ICMR Guidelines 2017 with COVID perspectives	Dr. Nithya Gogtay Dr. Jeffrey Raj	12:30- 13:30
	Lunch	-	13:30-14:30
<b>4</b>	Informed Consent -demo/videos	Dr. Vijaya Gunjal	14:30-15:30
<b>5</b>	Group activity	Dr. Vijaya Gunjal	15:30-16:00
	Feedback of day 2 & post test	-	16:00-16:30
	Vote of thanks and certificate distribution	Dr. Mahesh Belhekar & Sheetal Kudtarkar	16:30-17:00