

# Workshop on ‘Advances in GCP and regulatory applications’

- A preconference workshop on ‘*Advances in GCP and regulatory applications*’ will be conducted as part of the 15th Annual Conference of the Indian Society of Rational Pharmacotherapeutics (ISRPTCon 2023) hosted by Department of Pharmacology, Kasturba Medical College, Manipal.

Venue: Kasturba Medical College, Manipal

Date: 03-11-2023

Time: 9.00 am-5.30 pm

- Interested participants can register either for the workshop only or for the conference along with the workshop.
- Link for registration: <https://forms.gle/MqiCHbp9MwKC5FGy7>
- Link for conference website: <https://conference.manipal.edu/ISRPTCON2023/Home.aspx>

## Workshop details

Sl No.	Name of resource person	Topic	Time
1.	Dr. Shubhadeep Sinha KMC Adjunct Faculty, Senior VP & Medical Director, Hetero Labs, Hyderabad & Dr. Pankaj Thakur, PhD Hetero Labs, Hyderabad	Introduction To GCP, History of GCP & ICH	9.00 am to 9.30 am
2.	Dr. Pankaj Thakur, PhD General Manager, Clinical Development & Medical Affairs Hetero Labs, Hyderabad	Current GCP Updates	9.30 am to 9.50 am
3.	Dr. Satyajit Mohapatra, MD Prof Pharmacology & Director- Centre for Clinical Trials (CCTR), SRM Medical College, Chennai.	Investigator responsibilities in clinical trials	9.50 am to 10.15 am

<b>4.</b>	Dr. Shubhadeep Sinha, MD KMC Adjunct Faculty, Senior VP and Medical Director, Hetero Labs, Hyderabad	Sponsor Responsibilities in Clinical Trials	10.15 am to 10.45 am
<b>5.</b>	Prof Dr. Santanu Tripathi, MD, DM Dean, Netaji Subhash Medical College, Patna	Ethics Committee role in GCP and regulatory guidelines	10.45 am to 11.30 am
<b>6.</b>	Dr. Nalini Puran, MD,DM Zenrise Clinical Research Organisation Hyderabad	ICH E3 Clinical study report writing - Variations	11.30 am to 11.50 am
<b>7.</b>	Dr.Nitu Sinha, Ph.D Head- Pharmacovigilance Operations Dr. Reddy's Laboratories	Pharmacovigilance- in Clinical Trials- ICH-E2	11.50 am to 12.15 pm
<b>8.</b>	Sheejith Kakunath, Deputy GM, Lead- Clinical Trials (Biologics) Clinical Development and Medical Affairs ( CD& MA), Hetero Labs Limited	ICHE-8- General Considerations for clinical studies	12.15 pm To 1.00 pm
	LUNCH BREAK	1.00 pm To 1.30 pm	
<b>9.</b>	Ishani Banik, Associate Director, Data Management, Parexel	ICHE9- Statistics in Clinical Trials	1.30 pm To 2.30 pm
<b>10.</b>	Dr. Prabhakar Reddy, MD, DM Additional Professor- Clinical Pharmacology, Nizam's Institute of Medical Sciences (NIMS), Hyderabad	Special Population Studies and GCP (ICH E7)	2.30 pm To 2.50 pm
<b>11.</b>	Dr. Praveen Shetty, General Manager & Head Clinical Trials, Anthem Biopharma	ICHE-5 & Ethnic Factors in the Acceptability of Foreign Clinical Data	2.50 pm To 3.10 pm

<b>12.</b>	Dr. Ramesh Holla, Associate Professor, KMC Mangalore	ICHE4- Dose-Response Information to Support Drug Registration	3.10 pm To 3.30 pm
<b>13.</b>	Ms. Kajal Bhambani, Senior Director, Head- Regulatory- Biologics, Dr.Reddy's	ICH M4- Common Technical Document	3.30 pm to 4.10 pm
<b>14.</b>	Dr. Shubhadeep Sinha KMC Adjunct Faculty and Hetero Labs, Hyderabad	Closing Remarks and Summary	4.10 pm To 5.30 pm

### **Preconference Workshop registration fees**

<b>Delegate Category</b>	<b>Fees</b>
Postgraduate	₹ 1200
Faculty	₹ 2200

- Credit points will be awarded as per Karnataka Medical Council.
- For queries, please contact;  
Dr Shreya Hegde (7043328646) or Dr Smita Shenoy (9844559772)