



INDIAN SOCIETY FOR CLINICAL RESEARCH

Regulatory Council- South Chapter

in collaboration with

HCG Hospital, Bengaluru

presents

One-Day Workshop on “Good Clinical Practices”

15th November 2019 (Friday)

At

Auditorium, First Floor, Tower 5,

No 8, HCG Towers, P. Kalinga Rao Road, Sampangi Ram Nagar,

Bengaluru, Karnataka- 560020

Tel: 080 40206000

Agenda		
Time	Topic	Speaker
08:30 to 09:00	Registrations	
09:00 to 09:20	Introduction to ISCR	Dr. Gaurav Mathur Director, Regulatory Affairs RDS India, IQVIA
09:20 to 10:00	ICH GCP E6R2 – Overview and Highlights of Latest Revision	Ms. Mala Srivastava Co-founder & Managing Partner Nextvel Consulting LLP
10:00 to 10:15	TEA BREAK	
10:15 to 11:15	IRB – IECs (Responsibilities, Composition, Procedures and New Revisions)	Dr. Ananya Chakraborty Prof & HOD Pharmacology Vydehi Institute of Medical Sciences IEC Co-Chair, Manipal Hospital
11:15 to 12:15	Investigator (Qualifications, Responsibilities, Medical Oversight, Compliance, Informed Consent and New Revisions)	Mr. Sudip Sinha Senior Vice President, Clinical Operations Strand Life Sciences
12:15 to 13:15	Sponsor (Medical Expertise, Investigator Selection, Monitoring, Reporting, Compliance and New Revisions)	Mr. Tapankumar Shah Director, Clinical Operations Astrazeneca, India
13:15 to 14:15	LUNCH BREAK	
14:15 to 15:00	Safety Reporting and Compensation (Safety Data & Reporting Expectations, Process Flow, Compensation Calculation and Responsibilities of Stakeholders)	Ms. Swetha Khokale Independent Clinical Research Consultant
15:00 to 15:45	Essential Documents (Good Source Documentation and New Revisions)	Ms. Lakshmi Achuta Strategic Advisor in Quality and Compliance for Biotech and Pharmaceuticals
15:45 to 16:00	TEA BREAK	
16:00 to 16:45	Quality Assurance & Regulatory Audit Compliance	Ms. Mala Srivastava Co-founder & Managing Partner Nextvel Consulting LLP
16:45 – 17:15	Protocol and Investigator Brochure (Design, Considerations and Contents, ICD)	Dr. Harsha Dodihal Senior Director- Ichnos Sciences
17:15 to 17:30	Q&A and Vote of Thanks	

Registration and Payment details:

Registration fees:

Academia and students	Ethics Committee members and Clinical Research Coordinators	ISCR Member (For Individual & Corporate Members – AMOs)	Non-Member
Rs 500/-	Rs 1000/-	Rs 750/-	Rs 1000/-

Seat Limit - We have limited seats. Registration will close once the seat limit is reached.

All registered participants will get a “Certificate of Participation” from ISCR

Online registration - <http://www.iscr.org/events-registration/>

Online payment - <http://www.iscr.org/payment-events-workshops/>

Offline Payment - Cheque/DD payable at Mumbai should be made in favor of “Indian Society for Clinical Research” & mailed to us at ISCR Secretariat, c/o Pfizer Limited, The Capital 1802, 18th Floor, Plot No. C-70, ‘G’ Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400051

For any query, please feel free to write to info@iscr.org