



Indian Society for Clinical Research

Regulatory Council Announces a One-Day workshop

Favorable Regulatory Momentum for Future Clinical Research

Schedule:

Date	Time	Venue
18-Nov -17 (Saturday)	8:30 am – 5:30 pm	Bangalore – Goldfinch Hotel, 32/3, Crescent Road, High Grounds, Off Race Course Road, Bengaluru - 560 001

INTRODUCTION: This one day workshop designed to present & clarify the evolving regulatory landscape especially over the last one year. Topics mentioned in this draft flyer will make this interface useful and interesting for professionals with Clinical Research.

SCOPE: To provide an overview of the recent developments governing the process of filing, review and approval of Clinical Trial applications, including relevant recent updates.

TARGET AUDIENCE: Regulatory & Clinical Research Associates of Sponsors & CROs, Pharmacy and Clinical Research students

AGENDA		
Time	Topic	Speaker
8:30 to 9:00 am	Registration & Tea	
9:00 to 9:15 am	Welcome & Introduction to ISCR	Gaurav Mathur (IQVIA)- ISCR Regulatory Council Member (South Zone)
9:15 to 10:00 am	Presentation 1: Raising Quality-compliance standards in clinical research	Ms. Mala Srivastava – Nextvel Consulting
10:00 to 10:50 am	Clinical research in newer areas: <ul style="list-style-type: none"> Presentation 2: Medical Devices Presentation 3: Stem Cells 	Dr. Jayasheel Gangaiah - Alcon Dr. Umesh Baikunje – Baikunje Consulting
10:50 to 11:15 am	TEA BREAK	
11.15 to 11.45am	Presentation 4: Recent positive regulatory reforms	Gaurav Mathur (IQVIA) Expert Q&A: Ms. Annam Visala (Dy. Drugs Controller, CDSCO)
11.45 to 12.15 pm	Presentation 5: Dialogue with EC members: Empowerment, Training, Current practices	Mrs. Manjulika Vaz (SJRI) Dr. Raghavendra Rao (HCG) Dr. Jayanthi (Victoria Hospital) Moderator- Mala Srivastava (Nextvel)
12.15 to 1.00 pm	Break-Out Session: Real-life challenging cases	South Zone Organizing Team (Thanuja Naidu/Gaurav Mathur/Rajani Menon)
1.00 to 1.45 pm	LUNCH BREAK	

1:45 to 3:15 pm	<p>Panel Discussion:</p> <p><i>Forward momentum for clinical research</i></p> <p>Panelists from-</p> <ul style="list-style-type: none"> • Industry experts • Regulators • EC representatives • Investigators • SEC experts 	<p>Regulator – Ms. Annam Visala (DDC, CDSCO)</p> <p>Investigator – Dr. Raveendra Kodur (Victoria Hospital)</p> <p>EC Member – Dr. Jayanthi (Victoria Hospital)</p> <p>EC Member – Ms. Manjulika Vaz (SJRI)</p> <p>Academia – Dr. Denis Xavier (SJMC & SJRI)</p> <p>Industry – Dr. Ramesh Jagannathan (Dr. Reddy's)</p> <p>Moderator – Gaurav Mathur (IQVIA)</p>
3.15 – 3:45 pm	TEA BREAK	
3:45 – 4:30 pm	<p>Dialogue: Investigator Experiences - challenging protocols, Inspections, Expected support</p>	<p>Investigator – Dr. Raveendra Kodur (Victoria Hospital)</p> <p>Moderator – Mala Shrivastava</p>
4:30 – 5:15 pm	<p>Presentation 6: SUGAM – Process, Challenges, Industry Expectations by Regulators</p>	<p>Gaurav Mathur (IQVIA)</p> <p>Expert Q&A: Ms. Annam Visala (Dy. DC, CDSCO)</p>
5.15 – 5:45 pm	Wrap Up and Conclusions	Zonal Organizing Team