



Indian Society for Clinical Research

Regulatory Council Announces a One-Day workshop

Favorable Regulatory Momentum for Future Clinical Research

Schedule:

Date	Time	Venue
3-Nov -17	8:30 am – 6:00 pm	Delhi – India International Centre

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	Organizing Committee
9:15 to 10:00 am	Sharing experiences- Challenges with SUGAM- industry Expectations by regulators- regulators	Ms.A Visala (Deputy Drug Controller, CDSCO)
10:00 to 10:45 am	Dialogue with EC members- empowerment, training, current practices	Dr. Sameer Bakhshi (AIIMS, New Delhi)
10:45 to 11:15 am	TEA BREAK	
11.15 to 11.45 am	Raising Quality- compliance standards in clinical research	Dr. Sita Naik (Apollo, New Delhi)
11.45 to 12.00 pm	Recent positive regulatory reforms	Video clip TBC
12.00 to 1.00 pm	Break out session: real-life challenging cases	Organizing team
1.00 to 1.45 pm	LUNCH BREAK	
1:45 to 2:15 pm	Investigators experiences- challenging protocols, study conduct, expected support	TBC
2:15 to 3.00 pm	Clinical research in newer areas- medical devices, vaccines, stem-cell	Kirti Arora (Associate Director – Boston Scientific) Dr. Roli Mathur (ICMR) (Tentative)
3.00 – 3:30 pm	TEA BREAK	

<p>3:30 to 5:30 pm</p>	<p>Panel Discussion:</p> <p>Forward momentum for clinical research</p> <p>Panelists from-</p> <ul style="list-style-type: none"> • Industry experts • Regulators • EC representatives • Investigator • SEC experts 	<p>Dr. V G Somani (Joint Drug Controller, CDSCO)</p> <p>Ms. A Visala (Deputy Drug Controller, CDSCO)</p> <p>Dr. Pooja Sharma (EC member, Medanta)</p> <p>Mr. Anirban RoyChowdhury (Senior Director – Clinical Operations, MSD)</p>
<p>5.30 – 5:45 pm</p>	<p>Wrap Up and Conclusions</p>	<p>Zonal organizing team</p>