Indian Society for Clinical Research

Regulatory Council
Announces a One-Day workshop

Favorable Regulatory Momentum for Future Clinical Research

Schedule:

Date	Time	Venue
11 Nov 2017, Saturday	8:30 am – 6:00 pm	Mumbai – Dr. Jivraj Mehta Lecture Theatre (MLT) , Seth GS Medical College & KEM Hospital, Mumbai

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, Ethics Committee members, Investigators site associates

Agenda		
Time	Topic	Speaker
08:30 to 09:00 am	Registration & Tea	
09:00 to 09:15 am	Welcome	
09:15 to 10:15 am	Investigators Experiences and Challenges	**Dr NithyaGogtay** (Prof Clinical Pharmacology, KEM Hospital) **Dr VyankateshShivane** (Diabetologist)
10:15 to 10:45 am	Compliance Standards in Clinical Research- Raising the Quality Bar-Ethics Committee	**Dr Urmila Thatte**(Prof & Head Department of Clinical Pharmacology, Seth G S Medical College & KEM Hospital) **Moderator:Shehnaz Vakharia** (Managing Director ADAMAS Clinical Quality Consulting Pvt Ltd)
10:45 to 11:00 am	TEA BREAK	
11:00 to 11:30 am	Recent Regulatory Reforms	**CDSCO official**
11:30 to 12:30 pm	Case Study Quiz or breakout	**Organizing Committee**
12:30 to 13:30 pm	LUNCH BREAK	
13:30 to 14:30 pm	New frontiers in Clinical Research: Medical Devices, Vaccines	**Medical Device: Indira Narayan Murthy** (Associate Director, Regulatory Quality Compliance India and SE Asia, Abbott Healthcare Pvt Ltd) **Vaccines:Dr Prasad Kulkarni**(Medical Director, Serum Institute of India)
14:30 to 15:30 pm	e-governance and digitalization impact! SUGAM initiative by CDSCO Sharing experiences-Industry and Regulators	**Regulator: CDSCO official** **Industry:Dr Gaurav Mathur** (Director GRA and Head Asia Pacific Quintiles)
15:30 to 15:45 pm	TEA BREAK	
15:45 to 17:15 pm	Panel Discussion Forward momentum for clinical research: • Regulators • SEC • EC • Investigator • Sponsor	**Regulator**: **CDSCO official** **SEC**: **Dr Banavali** (Head Medical Oncology, Tata Memorial Hospital) **EC**:**Dr Urmila Thatte**(Prof & Head Department of Clinical Pharmacology, Seth G S Medical College & KEM Hospital) I**nvestigator**:**Dr NithyaGogtay** (Prof Clinical Pharmacology, KEM Hospital) **Sponsor**: **Dr Suresh Menon** (Chief Scientific Officer, Novartis) **Moderator:AmitaBhave** (Head Regulatory Affairs, Novartis)
17:15 to 17:30 pm	Wrap-up and Conclusions	Zonal Organizing Team