Indian Society for Clinical Research
Regulatory Council
Announces a One-Day workshop

REFORMATIONS AND FUTURE READINESS:
CLINICAL TRIAL REGULATIONS

Schedule:

22-Dec-16	8:30 am – 6:00 pm	**Delhi - India Habitat Centre, Lodhi Road, Near Airforce Bal Bharati School, New Delhi, Delhi 110003, India**

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 Note	Rahul Chauhan, Head- Regulatory and Medical Affairs, South Asia , Reckitt Benckiser
9:15 to 10:00 am	2016 Regulations changes /updates	Vikas Dhiman, Senior Manager, Regulatory Affairs, Policy & Intelligence, ABBOTT
10:00 to 11:00 am	CT online submissions	Ms. Rubina Bose, - DDC, New Drugs, CDSCO (Invited)
11:00 to 11:30 am	**TEA BREAK**	
11:30 to 12:30 pm	**Mirror Talk** Best Practice in SEC meetings –View from Regulator, SEC expert, Industry expert	Regulatory – Ms.Rubina Bose, - DDC, New Drugs, CDSCO SEC Panelist - Dr. Sameer Bakshi- Deptt. of Medical Oncology, AIIMS, Delhi Industry – Dr. Chirag Trivedi- Director, CSU, Sanofi India
12:30 to 1:00 pm	Revised EC Roles and Responsibilities	Prof. N.K Ganguly- Advisor, Translational Health Science and Technology Institute
1:00 to 1:45 pm	**LUNCH BREAK**	
1:45 to 2:00 pm	Video clip of international stakeholders perspective	Video Clip
2:00 to 3:00 pm	Break out session: Regulatory feasibility of a new CT protocol in today's context	Leaders- Dr.Ritika Bajaj Assoc. Dir., Global Clinical Trial Operations, MSD & Sneha Gupta- Manager Regulatory Affairs, CSU, Sanofi India Facilitators: Rahul Chauhan, Vikas Dhiman & Anirban Roy Chowdhury- Sr. Dir . Global Clinical Trial Operations, MSD

3.15 – 3:30 pm	**TEA BREAK**	
3:30 to 5:30 pm	Panel Discussion: Regulation Changes and future readiness: Representatives from- • Industry • Regulatory • EC • Investigator • SEC	Regulators: Dr. V.G Somani Jt, Drugs Controller, CDSCO & Ms. Rubina Bose- DDC, CDSCO Industry –Anirban Roy Chowdhary & Dr. Chirag Trivedi Regulator- EC – Dr. Pooja Sharma Investigator- Dr. D.C Doval (Invited) SEC – Dr. Y.K Gupta (Invited) Moderator: Sneha Gupta
5.30 – 5:45 pm	Wrap Up and Conclusions	Lipi Chakhaiyar- Sr. Manager-Regulatory Affairs, Eli Lilly and Company

Registration details:

No. of Participants: 50
Delegate Fee:
For ISCR Members – Rs 3000/-
For Non-Members – Rs 3500/-
Academia/Students – Rs.1500/-

Mode of Payment: 1) Online 2) Cheque/DD

Online registration (compulsory): - http://www.iscr.org/events-registration/
Online Payment link: http://www.iscr.org/payment-events-workshops/
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 Centre, TheCapital,1802,18thFloor, PlotNo.C-70, 'G'Block,BandraKurlaComplex, Bandra (E), Mumbai- 400051

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