Indian Society for Clinical Research
ISCR
Enhancing patient outcomes through clinical research

CELEBRATING 10 years

Mailing address:
ISCR Secretariat,
Indian Society for Clinical Research, C/o, Pfizer Limited,
The Capital, 1802, 18th Floor,
Plot No. C- 70, 'G' Block,
Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051

Website: www.iscr.org

Indian Society for Clinical Research

Announces

One-Day workshop on

"EVOLVING REGULATORY LANDSCAPE: OPPORTUNITIES & CHALLENGES"

Workshop Details:

04th Dec 2015 (Friday)
9:00 am – 5:30 pm
MAGNOLIA, India Habitat Centre,
Lodhi Road, New Delhi - 110003

Number of participants : 50

Target Audience:
Regulatory and Clinical Research Associates of Sponsors & CROs

This one day workshop is designed to present & clarify the evolving regulatory landscape especially over the last one year. Topics chosen for this workshop will make this interface useful and interesting for professionals with Clinical Research.

Workshop will provide an overview of the recent developments governing the process of filing, review and approval of Clinical Trial applications, including relevant recent updates. Workshop agenda is provided overleaf.

Online registration is compulsory:
Please visit http://www.iscr.org/events_MemberRegistration.aspx

Registration Fee:

For ISCR Members Rs 2500/-

For Non-Members Rs 3000/-

Mode of Payment: 1) Online 2) By Cheque/Demand Draft

Online Payment link: http://www.iscr.org/Events.aspx

Cheque/DD: Payable at Mumbai should be made in favor of **"Indian Society for Clinical Research"** and mailed to: ISCR Secretariat, Indian Society for Clinical Research, C/o, Pfizer Limited, The Capital, 1802, 18th Floor, Plot No. C- 70, 'G' Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051

For any assistance please write to info@iscr.org or call on +91-22- 6693 2028/2440

Workshop AGENDA

CELEBRATING 10 years

08:30 AM - Registration & Tea

0930 - 0945	Welcome Note	**ISCR Regulatory Council**
0945 -1045	Clinical trial applications: Recent changes in application, review and approval process	**Vikas Kumar Dhiman, Abbott**
	Tea Break	
1115 - 1145	Good documentation practices - Building a good application dossier	**Rahul Chauhan, Eli Lilly**
1145 - 1245	How to optimize clinical operations and regulatory affairs collaboration	**Dr. Chirag Trivedi Sanofi**
	Lunch Break	
1345 - 1415	Career Development – Learning from seniors	**Dr Shoibal Mukherjee**
1415 - 1515	Current Challenges faced by Industry: • Inspection • Regulations on Compensation • Subject Expert Committee review process	**Anirban Roychowdhury (MSD) Dr Shashwati Pramanik, (Amgen)**
	Tea Break	
1545 - 1700	**PANEL DISCUSSION** - "CDSCO 2020: Ideas and Vision Towards Building a Robust Regulatory Framework for Advancement Clinical Research in India " Panel members will include representatives from Health Authority, Industry /Sponsor/ CRO, Investigator	• **Dr. V.G. Somani, CDSCO** • **Dr. Shoibal Mukherjee** • **Dr. Chirag Trivedi, Sanofi** • **Dr. P.K. Julka, AIIMS** • **Moderator– Sneha Gupta, Sanofi**
1700 -1715	Wrap up and Conclusions	**ISCR Regulatory Council**