Indian Society for Clinical Research

PHARMACOVIGILANCE COUNCIL announces 4th NATIONAL SYMPOSIUM

"Enhancing Pharmacovigilance Excellence in India: An Integrated Approach"

October 28, 2017 (Saturday) Timing: 8.00 am to 6.00 pm

Venue: Hotel Lemon Tree Premier, Plot No.2, Survey No.64, HITEC City, Hyderabad – 500 081, India

Objective:

To leverage India's status as a leader in the global pharmacovigilance domain for augmenting Indian pharmacovigilance standards by integrating the views of all the relevant stakeholders such as the pharmaceutical industry, CROs, pharmacovigilance service providers, investigators, clinicians, academia, the CDSCO and the PvPI.

Target Audience:

- Pharmaceutical Industry
- Contract Research Organizations
- Senior Medical Officers
- Government Agencies
- Non-profit Organizations/Associations
- Clinical Investigators & Health Care Professionals
- Academia

Who Should Attend?

Vice Presidents, Directors/CEOs, Heads, Managers/Leads of

- Pharmacovigilance Strategy
- Drug Safety/Risk Management
- Information and Clinical Data Management
- Clinical Research
- Research & Development
- Product Safety/Assurance Assessment
- Patient Safety, Outcomes Research & Data Analysis
- Epidemiology Project Management
- Regulatory Affairs and Compliance
- Sales & Marketing
- Biotech Manufacturers

Hurry!!!
Only for 100 Participants
Last date of registration:
27th October, 2017

Highlights of the Symposium: The symposium will provide different insights from key stakeholders such as Industry, HCPs, Regulators and Academia on current Pharmacovigilance requirements, upcoming changes in regulations, Global Pharmacovigilance Practices, and opportunities and challenges in effective management of Pharmacovigilance operations.

REGISTRATION DETAILS:

✓ **Delegate Fee** : Academia - Rs. 2500/- per person
ISCR Member - Rs. 4500/-per person (For Individual & Corporate Members – AMOs)
Non-Member- Rs. 5000/-per person
Group Registration (5 or more) – Rs. 2000 (Academia), Rs. 4000 (ISCR Member), Rs. 4500 (Non-Member)

Online Registration (Mandatory): http://www.iscr.org/events-registration/

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

Online Payment: **http://www.iscr.org/payment-events-workshops/**

For any query please contact on Email: info@iscr.org or call on - +91-8454827775

AGENDA

ISCR 4th National Pharmacovigilance Symposium

Hyderabad 28-Oct-2017

TIMING	TOPICS	SPEAKERS
08:00 am-9:00 am	**REGISTRATION**	
09:00 am-9:30 am **Inauguration**	**Welcome Address** **Chief Guest's Address** **Guest of Honor's Address**	**Dr J Vijay Venkatraman –** Chair, ISCR PV Council **Dr Chirag Trivedi –** President, ISCR **Dr P Usha Rani** – Core Training Panel Member, PvPI
Session 1: Global Pharmacovigilance and India		
09:30 am-10:05 am	Current EU Regulations, planned changes and their impact on India	**Mr John Barber –** Director, Head of Pharmacovigilance – European Operations, Dr Reddy's Laboratories UK
10:05 am-10:40am	Pharmacovigilance of Biosimilars – Around the World	**Dr S D Sinha –** Vice President & Head – Global Pharmacovigilance, Clinical Development & Medical Affairs, Hetero Drugs
10:40 am-11:00 am	**TEA BREAK**	
Session 2: Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products in India – Obligations & Challenges		
11:00am-12:30 pm	Moderator: • **Dr PS Karthik Babu**– Affiliate Pharmacovigilance Head, Sanofi Panelists: • MNC Representatives: **1. Dr Babita Kirodian** – Global Safety Manager, Amgen **2. Ms Indu Nambiar** – Senior Manager – Pharmacovigilance, Boehringer Ingelheim • Indian Companies' Representative: **Mr Surya Kiran Kadali** – Head, Global Pharmacovigilance, MSN Labs • Government Representative: **Mr Somnath Basu** – Assistant Drugs Controller (India), CDSCO (HQ)	
12:30 pm-12:45 pm	**Q & A**	
12:45 pm-01:45pm	**LUNCH**	
Session 3: Clinical Trial Pharmacovigilance		
01:45 pm- 02:20 pm	The Proper Use of Independent Expert Committees to Ensure Optimal and Accurate Safety Assessment	**Dr Jonathan Seltzer -** President - ACI Clinical, BalaCynwyd, PA & Director of Clinical Research at Lankenau Heart Institute, Wynnewood, PA, USA
02:20 pm-02:55 pm	Challenges in Real World Evidence Studies for Safety	**Dr Arun Bhatt –** Consultant - Clinical Research & Development
02:55 pm-03:30 pm	Safety evaluation in Clinical Studies: What is important to focus on?	**Dr Ramesh Jagannathan –** Director & Head, Clinical Development, Dr Reddy's Laboratories
03:30 pm-03:45pm	**TEA BREAK**	
Session 4: Technological Advancements in PV		
03:45 pm- 04:15 pm	Robotics in PV	**Mr Soumya Padhy –** Director & Regional Pharmacovigilance Head - Global Medical Services, Parexel
04:15 pm-04:45 pm	New Models of PV Databases – Changing Trends	**Mr Sriram Varma** – Director – Service Operations, Techsol
04:45 pm-05:15 pm	Social Media/Apps in PV	**Ms Aparna Mangari** - Group Head – Pharmacovigilance Systems Dev, Pharmacovigilance Systems, Novartis
05:15 pm-05:30pm	**Valedictory & Vote of Thanks – Ms Indu Nambiar,** Co-Chair, ISCR PV Council **National Anthem**	

For any query: Please write to info@iscr.org or call ISCR Secretariat on +91-8454827775.

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