



Indian Society for Clinical Research

Announces 2nd NATIONAL PHARMACOVIGILANCE SYMPOSIUM

“Leveraging India's Potential for the Advancement of Global Drug Safety”

September 25, 2015(Friday) Timing: 8.00 am to 6.00 pm

Venue: Goldfinch Hotel, # 32/3, Crescent Road, Off High Grounds, Race Course Road, Bengaluru – 560001

Objective:

Pharmacovigilance in India is growing rapidly and its development is making tremendous impacts in the Medical and Pharma sectors. This Symposium will bring together various Pharmaceutical and Regulatory Representations so as to address current issues and assist to gain greater understanding of new and existing Pharmacovigilance requirements. It will prove to be an important platform to discuss and share best practices to enhance the development of Pharmacovigilance in India and thus ensure safer medicinal products. It aims to share the contemporary opinions and valuable experiences through an interactive session by panel of esteemed speakers.

Target Audience:

- Pharmaceutical Industry
- Contract Research Organizations
- Healthcare Professionals
- Government Health Agencies
- Non-profit Organizations/ Associations
- Clinical Investigators & Research Staff
- Academia



Highlights: The symposium will provide different perspectives from key stakeholders such as Industry, Academia and Healthcare Professionals on current the Pharmacovigilance requirements, recent advances in regulations, Best Pharmacovigilance Practices, Opportunities and Challenges in effective management of outsourced Pharmacovigilance operations and so on.

“Leveraging India's Potential for the Advancement of Global Drug Safety” emphasizes on how the significance of Pharmacovigilance can be gauged by the fact that it has made huge advancements over the course of time and is continuing to effectively influence the pharmaceutical industry in India thus contributing to global drug safety.

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)
- ✓ **Register & Pay online** : www.iscr.org → LHS of the home page click on Forthcoming Events
for Online Registration & Payment -
(<http://www.iscr.org/View-Event-Public.aspx>)
- ✓ **Payment** : 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, Patel Estate, S.V. Road,
Jogeshwari (W), Mumbai – 400 102
For any query please contact on -Email: info@iscr.org Tel.:+91-22-66932440/2028
- ✓ **CME Credit Hours** : Medical Graduates/Postgraduates, please include your Medical Council Registration number and Medical Council name & address in the additional information section while you register online to claim 2 Credit Hours accredited by Karnataka Medical Council.

AGENDA

TIMING	TOPICS	SPEAKERS
08:00 am-9:00 am	REGISTRATION & BREAKFAST	
09:00 am-9:30 am	Welcome Address Chair's Address Inauguration	Dr. Anand Harugeri Organizing Committee, ISCR Pharmacovigilance Symposium Dr. J. Vijay Venkatraman - Chair, ISCR Pharmacovigilance Council Dr. Darshan Bhatt - Senior Consultant in Pharmacovigilance & Senior Pharmacovigilance Physician
Session 1: Pharmacovigilance in Clinical Trials and Post Marketing: India Perspective Moderator: J. Vijay Venkatraman		
09:30 am-09:50 am	PvPI: Towards an integrated Pharmacovigilance System	Dr.V.Kalaiselvan - Principal Scientific Officer, Pharmacovigilance Program of India (PvPI)
09:50 am-10:10am	Role of Pharmacoepidemiology in Post Marketing Pharmacovigilance	Dr. Padmini Devi D. - Assoc. Prof. Dept. of Pharmacology, St. John's Medical College, Bengaluru
10:10 am-10:30 am	Improving Clinical Trials Environment: Changes in SAE Regulations and Implementation	Dr. Renuka Munshi -Prof. & Head, Dept. of Pharmacology, T. N. Medical College & Nair Hospital, Mumbai
10:30 am-10:45 am	PANEL DISCUSSION	
10:45 am-11:00 am	TEA BREAK	
Session 2: Pharmacovigilance from Bench to Bed side Moderator: Dr. Anand Harugeri - Patient Safety & Regulatory Affairs Manager, AstraZeneca Pharma India Limited.		
11:00 am-11:20 am	Best Practices in Pharmacovigilance: An Overview	Dr. Viraj Suvarna -Medical Director, Boehringer-Ingelheim
11:20 am-11:50 am	Pharmacovigilance in Clinical Practice	Dr. Renuka Munshi
11:50 am-12:10 pm	Causality and Clinical Trial Related Injury Assessment	Dr.M.Ramesh -Prof.& Head, Dept. of Pharmacy Practice, JSS College of Pharmacy, JSS University, Mysore
12:10 pm-12:30 pm	Role of Professional Bodies in Promoting Pharmacovigilance in India	Dr. J. Vijay Venkatraman
12:30 pm-12:45 pm	PANEL DISCUSSION	
12:45pm-01:45pm	LUNCH & NETWORKING	
Session 3: Recent Advances in Global Pharmacovigilance Chairperson: Dr. Darshan Bhatt		
01:45 pm-02:05 pm	Transition from PSUR to PBRER	Dr. Karthik Babu - Affiliate Pharmacovigilance Head, India Region, Sanofi
02:05 pm-02:25 pm	Update on Pharmacovigilance Regulations: Asia Pacific, Middle East and Africa	Dr. Nipom Deka - Regional Pharmacovigilance Manager, Asia, Africa & Middle East, Abbott
02:25 pm-02:45 pm	A Brief Overview of Risk Evaluation and Mitigation Strategies for US FDA Compliance	Dr. Anand Harugeri
02:45 pm-03:05 pm	Safety Surveillance & Signal Management - The Sunrise Pharmacovigilance Segment in India	Mr. Mandar Kelkar - Sr. Manager Pharmacovigilance & Lead Safety Surveillance,Tata Consultancy Services, Mumbai
03:05 pm-03:30pm	PANEL DISCUSSION	
03:30 pm-03:45 pm	TEA BREAK	
Session 4: Pharmacovigilance Operations: Opportunities and Challenges Chairperson: Dr.Deepa Arora , Vice President - Pharmacovigilance & Global Head- Drug Safety & Risk Management, Lupin		
03:45 pm- 04:05 pm	Pharmacovigilance Audits and Inspections: Opportunities to Exhibit and Enhance Regulatory Compliance	Ms. Renuka Marwah - Lead Compliance Specialist Asia Pacific, Bristol-Myers Squibb
04:05 pm-04:25 pm	Pharmacovigilance Outsourcing and Effective Operation	Dr. Kumaresan Subramanyam -Senior Director, Quintiles
04:25 pm-04:45 pm	Capacity Building in the Emerging Pharmacovigilance Outsourcing Era	Dr. Ajoy Roy - Senior Medical Director & Regional Head of Global Medical Services in India, Parexel
04:45 pm-05:00 pm	PANEL DISCUSSION	
05:00 pm-05:30 pm	Vote of Thanks	Ms. Indu Nambiar -Co-Chair, ISCR Pharmacovigilance Council

For any query: Please write to info@iscr.org or call ISCR Secretariat on +91-22-66932028/2440

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