



INDIAN SOCIETY FOR CLINICAL RESEARCH
12th Annual ISCR Conference
Clinical Research Advancing the Frontiers of Health
Pre-Conference workshop:

How the New Pharmacovigilance Obligations for MAHs in India may be fulfilled

Date: 14-Feb-2019, Thursday Timing: 09:00 am – 4:45 pm

Venue: The EROS Hotel, S1, American Plaza, ITT Building, Nehru Place, New Delhi.

Agenda:

TIME	TOPIC
09:00 – 09:15	Welcome
09:15 – 10:15	Pharmacovigilance in India – An Industry Perspective
10:15 – 11:00	Regulations & Guidelines Governing Pharmacovigilance in India – A Step Forward
11:00 – 11:15	Tea Break
11:15 – 11:45	Pharmacovigilance System Master File (PvMF) – An Approach Towards System Creation & Implementation
11:45 – 12:15	Collection, Processing and Reporting of ICSRs – An Overview
12:15 – 12:45	Break-out session: Case studies on different types of ICSRs
12:45 – 13:30	Lunch
13:30 – 14:00	Periodic Safety Update Report – An Integral Part of Safety Management
14:00 – 14:30	Risk Management Plan Requirements: When and Why?
14:30 – 14:45	Break-out session: Quiz on PSUR & RMP
14:45 – 15:00	TEA BREAK
15:00 – 15:30	Implementing a Quality Management System at MAH Organisation
15:30 – 16:00	Pharmacovigilance Audits & Inspections – Requirements in India
16:00 – 16:30	Panel Discussion – Overcoming Challenges in Achieving PV Compliance
16:30 – 16:45	Wrap-up and Conclusion



- **Registration and Payment details:**
- **Online Registration:** (Mandatory for all including delegate/speakers/organizing committee/volunteers etc) –

<https://www.iscr.org/iscr-conference-2019/#workshop-online-registration>

- **Registration fees details:**

Students – Rs 1500/-
Academia – Rs 2000/-
ISCR Members – Rs 3000/-
Non-Members – Rs 3500/-

<https://www.iscr.org/iscr-conference-2019/#registration-fees-payment-details>

- **Payment details:**

Online Payment Link: <https://www.iscr.org/iscr-conference-2019/#online-offline-payment>

Offline 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, The Capital, 1802, 18th Floor, Plot No.C-70, ‘G’ Block, Bandra Kurla Complex, Bandra (E), Mumbai- 400051 –

For any query please feel free to write to info@iscr.org or call on **+91-8454827775**