13th Annual Conference
Beyond New Regulations- Increasing Participation and Enhancing Patient Safety
January 24-25, 2020, Mumbai

Pre-Conference Workshop –
Pharmacovigilance (PV) Audits and Inspections: Pre Inspection readiness & effective Corrective And Preventive Action (CAPA) implementation
23-Jan-2020

Speakers Profile
Dr. PS Karthik Babu
Chair, PV Council- Indian Society for Clinical Research (ISCR)

- Multi country Safety Head – South Asia at Sanofi, Mumbai
- Responsible for the PV activities for all Sanofi entities in India, Bangladesh, Sri Lanka, Bhutan, Nepal & Maldives
- Lead the PV Task force in Organisation of Pharmaceutical Producers of India (OPPI)
- Represent South Asia in International PV Group in European Federation of Pharmaceutical Industries and Associations (EFPIA)
Gerald J. Dal Pan is the Director of the Office of Surveillance and Epidemiology (known then as the Office of Drug Safety) in November 2005. Before that, he was the Director of the Division of Surveillance, Research, and Communication Support in CDER's Office of Drug Safety, a position he held since December 2003.

He received his medical degree from Columbia University, and his Master's degree in clinical epidemiology from Johns Hopkins University. He is trained in internal medicine at the Hospital of the University of Pennsylvania, and in neurology at Johns Hopkins Hospital.

Dr. Dal Pan is board certified in internal medicine and neurology. He was an instructor in the Neurology Department at Johns Hopkins. He next worked for Guilford Pharmaceuticals in Baltimore, and then for HHI Clinical Research and Statistical Services in Hunt Valley, MD. He joined FDA in July 2000 as a medical officer in the Division of Anesthetic, Critical Care, and Addiction Drug Products.
Dr. Vishwas Sovani
Founder & Director, Pharmawisdom

- MD (Pharmacology), Mumbai University
- Diploma in Management, IIM Ahmedabad
- Over 35 yrs in pharma industry in medical department,
- Responsible for Clinical research, regulatory & medicomarketing and pharmacovigilance in companies like Sarabhai, Cipla, FDC, Cyanamid/Wyeth, Organon, in local and regional roles
- Was also Head of Pharma delivery in TCS BPO
- Retired as India Head for Revogenex
Dr. Chitra Bargaje  
**General Manager - Clinical Quality Assurance, Lupin Pharmaceuticals**

- MD (Ayurveda), ISO Lead Auditor, MRQA and life member of ISCR
- Started career in Academics in Clinical Pharmacology at KEM Hospital and then moved to corporate and worked with Pfizer, BMS in Clinical Research Quality Assurance
- GCP and PV Auditor with ADAMAS Consulting
- More than 15 years of experience in Clinical Research and Pharmacovigilance quality assurance
- Has conducted audits in more than 30 countries across Asia-pacific, Europe and America
- Hosted/prepared clients for health authority inspections in GCP and PV
- Authored and contributed for articles in ISCR and RQA journals
- Lead and conducted workshops in CAPA and PV
- Invited speaker for certificate courses in PV and GCP
Durga Phalke Mane
Associate Director, Quality Assurance - Cognizant Technology Solutions

➢ Durga Mane, M. Pharm (Quality Assurance) and MBA (Operations Management), is a Clinical Research professional with 19+ years of experience in Clinical Quality Assurance.

➢ She started as a trainer in a Pharmacy college and has worked with various CROs, and Pharma companies in different capacities. Her primary role has been designing of the quality set up, development of regulatory complaint systems, hosting client audits, regulatory inspections, employee trainings and she has been the quality expert on various electronic software applications.

➢ Durga has been instrumental in setting Quality assurance systems of two independent CRO facilities and has led many successful regulatory inspections like USFDA, MPA Sweden, Ministry of Health Turkey, Brazilian Regulatory authority, WHO, AFSSAPS and CAP.

➢ She has extensive experience of planning and conducting vendor and investigator site audits across various geographies and has participated as a speaker in various conferences. She has also conducted training for DCGI inspectors and has been an external auditor for National Coordination Center (NCC) and Pharmacovigilance Program of India (PVPI).

➢ Durga has been associated with Cognizant for more than 6 years in the Life Science Delivery Excellence team and is responsible for planning and managing global internal and external audits programs for LSDO.

➢ She continues to hope and push for simpler, more effective processes and documentation to ensure GXP compliance and rationale approach to understanding regulations.
Dr. Nirmal Shankar
PV Scientist, Global Patient Safety – AstraZeneca

- Dr Nirmal Kumar Shankar is a PV Scientist at AstraZeneca, Global Patient Safety.
- He has over 13 years of experience in patient safety and medical writing.
- He holds the Bachelor’s degree in Ayurvedic Medicine and Surgery (BAMS) and living in Bengaluru, Karnataka, India.
- He is responsible for strategic input or oversight for periodic reports, signal detection, risk management plans, surveillance activities, label updates, and health authority responses.
Dr. Babita Kirodian
Org Committee, PV Council- ISCR

- Dr. Babita Kirodian holds a Ph.D in Liposomal Drug Delivery System from Dept of Clinical Pharmacology, Seth GS Medical College & KEM hospital, Mumbai, under Dr.N.A.Kshrisagar.
- She has over 17 years of industry experience in MNCs like Amgen, Bristol Myers Squibb and Abbott.
- Currently, she is working as Global Safety Manager for Amgen India, responsible for India, Indonesia and Philippines.
- She was instrumental in setting up the PV council within Indian Society for Clinical Research (ISCR)
- Speaker at various national and international events
- Faculty for PV course
Dr. Jamal Baig  
M.Pharm, PhD in Pharmacology  
Global PV Country Leader, MSD Pharmaceuticals, Pvt Ltd  
Co-Chair, PV Council - ISCR

- Managing PV country operations in India, Pakistan, Sri Lanka, Nepal, Bhutan, Bangladesh.
- Team Leader, Pfizer Drug and Safety PV Process with Wipro Ltd.
- Lecturer NIPER, Govt of India
- Key role in setting up of an ADR monitoring centre, Kasturba Hospital, Manipal
- Key role in development of PV guidelines for MAH in India released by CDSCO-NCC-PvPI in Sep 2017
- Key role in development of NCC-PvPI, PV Program curriculum
- Invited faculty at NCC-PvPI both for AMCs and PV Program
- Speaker at various national and international PV events
- Interest: Patient Medication Counselling, Cardiovascular Pharmacology.