# 2nd ISoP UMC
# Pharmacovigilance Training course
## 12-14 January 2015
## Mysore - India

## Risk Management through fostering good pharmacovigilance practice in emerging markets

### The Event


The International society of Pharmacovigilance (ISoP) and the Uppsala Monitoring Centre (UMC) have a common interest to promote scientific research and practice through the mutual exchange of information on adverse events and , risks related to medicinal products. Both parties have come together to train people and build capacity in the area of Pharmacovigilance.

This second pharmacovigilance training program will be conducted with expertise from ISoP and UMC and designed for interdisciplinary groups to learn and work together in contributing to patient safety when medicines are used. The programme is focused on providing expert perspective and guidance on key elements of pharmacovigilance for the provision of risk management, with a focus on activities in emerging markets. This course provides solid practical foundations for those working in drug safety and updates for experienced staff. The course faculty consists of Asian and International experts in pharmacovigilance, representing government, academia, and industry. There will be ample opportunity to exchange views and ideas with international experts and fellow participants.

### The Organizers

ISoP is an international non-profit scientific organization, which aims to foster pharmacovigilance both scientifically and educationally, and enhance all aspects of the safe and proper use of medicines, in all countries (www.isoponline.org )

UMC is the WHO Collaborating Centre for International Drug Monitoring located in Uppsala, Sweden. The UMC is an independent foundation and a center for international service and scientific research in pharmacovigilance (www.who-umc.org)

### The Host

JSS University offers graduate, post-graduate and research programs in the field of Medical, Dental and Pharmaceutical Sciences. JSS Mahavidyapeetha, sponsoring society of JSS University is the largest education provider and employer in the region. In addition to being committed towards imparting high quality professional education, the university is also involved in creating applicable knowledge to support social and economic advancement (www.jssuni.edu.in).

# Program Schedule

## Monday, 12th January 2015

DAY 1

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| Registration 08:30 - 09:00 AM | | |
| OPENING MEETING | 09:00 - 09:15 AM | Introduction about ISOP |
| | 09:15 - 09:30 AM | Introduction about UMC |
| Session 1: Keynote | 09:30 - 10:15 AM | History and importance of Pharmacovigilance |
| Coffee Break 10:30 - 10:45 AM | | |
| Session 2 : Trends in Pharmacovigilance | 10:45 – 01:00 PM | Current trends in Asia/Indian Pharmacovigilance: Industry, Academia and Regulatory Perspective |
| | 01:00 – 01:30 PM | Panel Discussion |
| Lunch 01:30 - 02:30 PM | | |
| Session 3: Spontaneous Reporting System and Quality | 02:30 – 03:15 PM | Spontaneous reporting systems |
| | 03:15 – 04:00 PM | Data management: Importance of high quality structured data in PV (incl coding of drugs and ADRs) |
| Coffee Break 04:00 - 04:15 PM | | |
| Session 4: Generics, Biosimilars, counterfeiting and quality detects | 04:15 – 05:00 PM | Counterfeiting and quality defects |
| | 05:00 – 05:45 PM | Pharmacovigilance of generics and biosimilars |
| | 05:45 – 06:15 PM | Panel discussion |

## Tuesday, 13th January 2015

DAY 2

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| Session 5: Wider scope of pharmacovigilance | 09:00 - 09:45 AM | Pharmacovigilance in special population: Children, pregnancy and lactation, and elderly |
| | 09:45 - 10:30 AM | Medication errors and inadequate use |
| Coffee Break 10:30 - 11:00 AM | | |
| Session 6: Signal detection | 11:00 – 11:45 AM | Signal detection basics: definitions, sources and potentials |
| | 11:45 – 12:30 PM | Signal detection by non statistical medical means |
| Lunch 12:45 - 01:45 PM | | |
| Session 7: Signal detection | 01:45 – 02:30 PM | Disproportionality statistics for signal detection |
| | 02:30 – 03:15 PM | Recent developments in signal detection |
| Coffee Break 03:30 - 04:00 PM | | |
| Session 8: Signal detection | 04:00 – 05:30 PM | CIOMS insights and recommendations on risk management |
| | | Signal detection tools |
| | | Hands on practice |

## Wednesday, 14th January 2015

DAY 3

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| Session 9: Risk Management Introduction | 09:00 - 09:45 AM | Overview on risk management |
| | 09:45 - 10:30 AM | RMP: Regulations in Emerging markets |
| | 10:30 - 11:00 AM | Panel discussion |
| Coffee Break 11:00 - 11:30 AM | | |
| Session 10: Risk prevention and minimization | 11:30 – 12:15 PM | Methods of risk minimization |
| | 12:15 – 01:00 PM | Risk management planning and activities - CIOMS guidelines |
| Lunch 01:00 - 02:00 PM | | |
| Session 11: Outcome of pharmacovigilance activities | 02:00 – 02:45 PM | Studies to measure effectiveness of risk minimization actions |
| | 02:45 – 03:30 PM | Hypothesis testing safety studies and drug utilization studies: tools for risk management |
| Coffee Break 03:30 - 04:00 PM | | |
| Session 12: Risk Management and Communication | 04:00 – 04:45 PM | Balancing risk v/s benefits |
| | 04:45 – 05:30 PM | Methods of risk communication |
| | 05:30 – 06:00 PM | Interactive panel discussion |
| Closing | 06:00 – 06:30 PM | |

# Speakers

Pharmacovigilance experts from the ISoP, UMC, Pharmaceutical industries, reputed Universities, and academic institutions across the globe will lead the sessions.

**Marie Lindquist**
MSc, PhD, Hon FRCP, Director
Uppsala Monitoring Centre, Sweden

**Hervé Le Louet**
Professor in Clinical Pharmacology
President, ISoP
Co-opted member by the European Commission
of the Pharmacovigilance Risk Assessment Committee,

**Ian Boyd**
Pharmacovigilance Adviser,
Ian Boyd Consulting Service, Australia
Executive committee member
ISoP

**Marco Tuccori**
Pharmacovigilance Manager at
the Unit of Adverse Drug Reactions Monitoring
University Hospital of Pisa. Italy
Executive committee member

**Andrew Bate**
Senior Director, Quantitative Epidemiologist,
Pfizer Inc, UK
Chair, Education and Training Programme
ISoP

**Anders Viklund**
Subject Matter Expert
Search and Analysis tools
Uppsala Monitoring Centre, Sweden

**Ivor Ralph Edwards**
Senior Advisor,
Uppsala Monitoring Centre, Sweden

**Nilima Kshirsagar**
National Chair in clinical Pharmacology
Indian Council of Medical Research

**Yola Moride**
Professor, Department of Epidemiology,
University of Montreal, Canada
Vice President, ISOP

**Brian Edwards**
Principal Consultant at
NDA Regulatory Science Ltd, UK
Treasurer, ISoP

**Y K Gupta**
Professor and Head
Department of Pharmacology, AIIMS
National Scientific coordinator,
Pharmacovigilance Program of India

**Surinder Singh**
Director, National Institute of Biologicals

**G Parthasarathi**
Dean, Faculty of Pharmacy, JSS University, Mysore

**Gunilla Sjölin-Forsberg**
Secretary general, CIOMS
Executive committee member, ISoP

**Rebecca Chandler**
Uppsala Monitoring Centre, Sweden

**Anand Harugeri**
Patient Safety and Regulatory Affairs Manager,
AstraZeneca Pharma India Ltd.

# Registration

- 280 Euros for ISoP members
- 380 Euros for non members
- 180 Euros for emerging countries / students ISoP members
- 230 Euros for emerging countries / students non members

The cost includes lunch with drinks and coffee break, but does not include accommodation, dinner or travel.

**Payments**

Payment in Euro (payable to: International Society of Pharmacovigilance)
Bank transfers and Credit/Debit Card - PAYMENT ONLINE – **AMEX, VISA and MasterCard accepted http://www.isoponline.org/index-.php?page=isop-umc-training**

**Registration forms available from the ISoP Administration office**

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website: www.isoponline.org

# Who should attend?

- People working in drug safety and pharmacovigilance departments of CRO/Pharma Companies
- Medical, Dental, Pharmacy institutions and Pharm D students interested in the area of Pharmacovigilance and healthcare improvement
- Members of government or regulatory, Research institutions and NGOs involved in Public Health

# The venue

Rajendra Centenary Auditorium at JSS Hospital, JSS University, Mysore. City of Mysore lies in Southern part of India about185 km from Kempegowda International Airport (Bengaluru). Mysore city is also known as City of Palaces and retains a quaint charm that never fails to enchant. Mysore city is well connected by air, rail and road. Taxi and other public transport facilities are available.


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