



# 2<sup>nd</sup> ISoP-UMC Training course

12-14 January 2015, Mysore (India)

JSS Hospital, Rajendra Centenary Auditorium (3<sup>rd</sup> Floor), Mahatma Gandhi Road, Mysore



## Risk Management through fostering Good Pharmacovigilance Practice in Emerging Markets

Course coordinator: Parthasarathi Gurumurthy, JSS University, Mysore

### PROGRAMME

Day 1 Monday January 12		Rajendra Centenary Auditorium	
Registration	8.30 - 9.00AM		
<i>Chairperson: B Suresh, Vice Chancellor, JSS University</i>			
Opening Meeting	9.00 - 9.15AM 9.15 - 9.30AM	Introduction about ISoP Introduction about UMC	<i>Hervé Le Louet (President of ISoP)</i> <i>Marie Lindquist (Director, UMC)</i>
Session 1: Keynote	9.30 - 10.15AM	History and importance of Pharmacovigilance	<i>YK Gupta (All India Institute of Medical Sciences)</i>
Coffee break	10.15 - 10.45AM		
Session 2: Trends in Pharmacovigilance	10.45 - 1.00PM	Current trends in Asia/Indian Pharmacovigilance: Industry, Academia and Regulatory Perspective	<i>Babita Kirodian (Bristol Myers Squibb, India)</i> <i>Parthasarathi Gurumurthy (JSS University Mysore)</i> <i>Anand Harugeri (AstraZeneca Pharma, India)</i>
	1.00 - 1.30PM	Panel Discussion	
Lunch	1.30 - 2.30PM		
<i>Chairperson: Yola Moride (ISoP EC Member)</i>			
Session 3: Spontaneous Reporting System and Quality	2.30 - 3.15PM	Spontaneous reporting systems	<i>Ian Boyd (ISoP EC Member)</i>
	3.15 - 4.00PM	Data management: Importance of high quality structured data in PV (incl coding of drugs and ADRs)	<i>Marie Lindquist (Director, UMC)</i>
Coffee break	4:00 - 4.15PM		
Session 4: Generics, Biosimilars, counterfeiting and quality defects	4.15 - 5.00PM	Counterfeiting and quality defects	<i>Surinder Singh (National Institute of Biologicals, India)</i>
	5.00 - 5.45PM	Pharmacovigilance of generics and biosimilars	<i>Hervé le Louet (President of ISoP)</i>
	5.45 - 6.15PM	Panel discussion	

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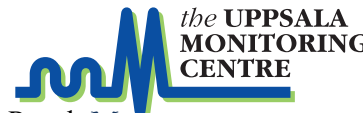
Day 2 Tuesday January 13		Rajendra Centenary Auditorium	
<i>Chairperson: Ralph Edwards (UMC)</i>			
Session 5: Wider scope of pharmacovigilance	9.00 - 9.45AM	Pharmacovigilance in special population: Children, pregnancy and lactation, and elderly	<i>Marco Tuccori (ISoP EC Member)</i>
	9.45 - 10.30AM	Medication errors and inadequate use	<i>Nilima Kshirsagar (Indian Council of Medical Research)</i>
<i>Coffee break</i>	10.30 - 11.00AM		
Session 6: Signal detection	11.00-11.45AM	Signal detection basics: definitions, sources and potentials	<i>Ian Boyd (ISoP EC Member)</i>
	11.45- 12.30PM	Signal detection by non statistical medical means	<i>Rebecca Chandler (UMC)</i>
<i>Lunch</i>	12.45 - 1.45PM		
<i>Chairperson: Marie Lindquist (Director, UMC)</i>			
Session 7: Signal detection	1.45 - 2.30PM	Disproportionality statistics for signal detection	<i>Andrew Bate (ISoP EC Member)</i>
	2.30 - 3.15PM	Recent developments in signal detection	<i>Andrew Bate (ISoP EC Member)</i>
<i>Coffee break</i>	3.30 - 4.00PM		
Session 8: Signal detection	4.00- 6.00PM	CIOMS insights and recommendations on Risk management, risk minimisation and some other PV areas	<i>Gunilla Sjölin Forsberg (ISoP EC Member)</i>
		Accessing spontaneous report databases for signal detection: an interactive session with Vigibase	<i>Parthasarathi Gurumurthy (JSS University Mysore) and Anders Viklund (UMC)</i>
		Hands on practice	
*This can be a prolong session as there is demo and exercises and may run past 6.00 pm. We will ask participants to bring own laptops for this exercise.			



# 2<sup>nd</sup> ISO P-UMC Training course

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Day 3 Wednesday 14 January		Rajendra Centenary Auditorium	
<i>Chairperson: Nilima Kshirsagar (Indian Council of Medical Research)</i>			
Session 9: Risk Management Introduction	9.00 - 9.45AM	Overview on risk management	<i>Brian Edwards (ISO P EC Member)</i>
	9.45 - 10.30AM	RMP: Regulations in Emerging markets	<i>Ian Boyd (ISO P EC Member)</i>
	10.30 - 11.00AM	Panel discussion	
<i>Coffee break</i>	11.00 - 11.30AM		
Session 10: Risk prevention and minimization	11.30-12.15PM	Methods of risk minimization	<i>Brian Edwards (ISO P EC Member)</i>
	12.15 - 1.00PM	Risk management planning and activities - CIOMS guidelines	<i>Yola Moride (ISO P EC Member)</i>
<i>Lunch</i>	1.00 - 2.00PM		
<i>Chairperson: Hervé le Louet (President of ISO P)</i>			
Session 11: Outcome of pharmacovigilance activities	2.00 - 2.45PM	Studies to measure effectiveness of risk minimization actions	<i>Yola Moride (ISO P EC Member)</i>
	2.45 - 3.30PM	Hypothesis testing safety studies and drug utilization studies: tools for risk management	<i>Yola Moride (ISO P EC Member)</i>
<i>Coffee break</i>	3.30 - 4.00PM		
Session 12: Risk Management and Communication	4.00 - 4.45PM	Balancing risk v/s benefits	<i>Ralph Edwards (UMC)</i>
	4.45 - 5.30PM	Methods of risk communication	<i>Ralph Edwards (UMC) and Marie Lindquist (Director, UMC)</i>
	5.30-6.00PM	Interactive panel discussion	
<i>Closing</i>	6.00 - 6.30		

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