



Schedule



Fourth Asia Pacific Pharmacovigilance Training Course 29 January - 09 February 2018, Mysuru, India

Date	Time	Event
28/1/2018 Sunday	6:00 PM – 10:00 PM	JSS & UMC staff will meet the participants at Hotel Dawn Welcome Dinner at Hotel Royal Orchid Metropole Participants interview each other by using Agile method

Day 1

29/1/2018 - Monday

Time	Topic	Speaker
9:00 - 9:30 AM	Inaugural Event - Welcome and Lighting	G Parthasarathi JSS University, India
9:30 - 10:30 AM	Keynote Address: Quality and safe use of medicines: The role of Pharmacovigilance and Pharmacoepidemiology	Frank May The University of Queensland, Australia
10.30 - 11:00 AM	Tea Break	
11.00 - 11.15 AM	Introduction of participants – present each other with A4 size photos and details	Participants
11.15 - 12.00 PM	Pharmacovigilance - Global Scenario	Madhur Gupta World Health Organization Country Office, India
12.00 - 12.30 PM	Pharmacovigilance capacity building and organization on the regional and national level	G Parthasarathi JSS University, India
12:30 - 1:00 PM	UMC introduction and overview	Elki Sollenbring Uppsala Monitoring Centre, Sweden
1:00 - 2:00 PM	Lunch Break	
2:00 - 3:00 PM	Developing a positive ADR reporting culture - how to collect ADR information	Elki Sollenbring Uppsala Monitoring Centre, Sweden
3:00 - 3:30 PM	Tea Break	
3.30 - 4.30 PM	ADR reporting form - workshop	Elki Sollenbring Uppsala Monitoring Centre, Sweden



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Day 2

30/1/2018 - Tuesday

Time	Topics	Speaker
9:00 - 11:00 AM	Wider scope of Pharmacovigilance – with exercises <ul style="list-style-type: none">Medication Errors - role of Pharmacovigilance centres in the detection and management of medication errors	Zineb Sekkat Seba WHO Collaborating Centre of Rabat, Morocco
11:00 - 11:30 AM	Tea Break	
11:30 - 12:30 PM (Webinar)	Wider Scope of Pharmacovigilance <ul style="list-style-type: none">Substandard and falsified medical products - a global view from WHO	Michael Deats World Health Organization, Switzerland
12:30 - 01:30 PM	Lunch Break	
1:30 - 3:15 PM	Clinical diagnosis of ADRs	Birgitta Grundmark Uppsala Monitoring Centre, Sweden
3:15 - 3:45 PM	Tea Break	
3:45 - 4:30 PM	Adverse Drug Reactions & Adverse Drug Events - classification, mechanism, predisposing factors	Birgitta Grundmark Uppsala Monitoring Centre, Sweden
4:30 - 5:00 PM	Seriousness and severity of the ADR/AE Expectedness of the ADR/AE	Birgitta Grundmark Uppsala Monitoring Centre, Sweden



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Day 3

31/1/2018 – Wednesday

Time	Topics	Speaker
9:00 - 10:30 AM	Causality assessment of ADR/AE	M Ramesh and Team JSS University, India
10:30 - 11:00 AM	Tea Break	
11:00 - 1:00 PM	Hands on session on causality assessment of ADR/AE	M Ramesh and Team JSS University, India
1:00 - 2:00 PM	Lunch Break	
2:00 - 3:00 PM	Risk, risk perception and benefit-risk balance	Birgitta Grundmark Uppsala Monitoring Centre, Sweden
3:00 - 3:30 PM	Tea Break	
3:30 - 5:00 PM	Risk management – options and choices - case studies	Birgitta Grundmark Uppsala Monitoring Centre, Sweden



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Day 4

1/2/2018 - Thursday

Time	Topics	Speaker
9:00 - 10:30 AM	ICSR management tools + Vigiflow	Afifa Trad Uppsala Monitoring Centre, Sweden + PvPI Team
10:30 - 11:00 AM	Tea Break	
11:00 - 1:00 PM	Vigiflow - Hands-on session	Afifa Trad Uppsala Monitoring Centre, Sweden + PvPI Team
1:00 - 2:00 PM	Lunch Break	
2:00 - 3:00 PM	VigiLyze - Hands-on session	Afifa Trad Uppsala Monitoring Centre, Sweden + PvPI Team
3:00 - 3:30 PM	Tea Break	
3:30 - 5:00 PM	Establishing Pharmacovigilance centre in a hospital	M Ramesh JSS University, India



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Day 5

2/2/2018 - Friday

Time	Topics	Speaker
9:00 - 10:00 AM	WHO Drug Dictionary and ATC Coding WHO - ART and MedDRA	Anna Baumgarten Uppsala Monitoring Centre, Sweden
10:00 - 11:00AM	Pharmacovigilance in elderly	Alpana Mair The Scottish Government, UK
11:00 - 11:30 AM	Tea Break	
11:30 - 12:15 PM	Partnering with industry to enhance patient safety	Indu Nambiar Boehringer Ingelheim, India
12:15 - 1:15 PM	Medication without harm – Third global patient safety challenge	Alpana Mair The Scottish Government, UK
1:15 - 2:15 PM	Lunch Break	
2:15 - 5:15 PM	Visit to regional Pharmacovigilance center at JSS hospital	M Ramesh and Team JSS University, India
7:00 - 10:00 PM	Course Dinner at Silent Shores	

Day 6

3/2/2018 - Saturday

Time	Event
10:00 AM - 8:00 PM	Guided Tour at Mysuru

Day 7

4/2/2018 Sunday

Off



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Day 8

5/2/2018 - Monday

Time	Topics	Speaker
9:00 - 10:30 AM	Effective communications - workshop	<i>Lecture:</i> Paula Alvarado <i>Facilitators:</i> Federica Santoro and Thomas Rowsell Uppsala Monitoring Centre, Sweden
10:30 - 11:00 AM	Tea Break	
11:00 - 13:00 PM	Effective communications - workshop	<i>Lecture:</i> Paula Alvarado <i>Facilitators:</i> Federica Santoro, Gediminas Norgela and Thomas Rowsell Uppsala Monitoring Centre, Sweden
1:00 - 2:00 PM	Lunch Break	
2:00 - 3:15 PM	Principles for Pharmacovigilance systems at regulatory authorities and MAHs	Jayesh Pandit Bayer, Kenya
3:15 - 3:30 PM	Tea Break	
3:30 - 4:15 PM	Haemovigilance	Pallavi P JSS University, India
4:15 - 5:00 PM	Good Pharmacovigilance Practices - Risk Minimization Measures (RMM)	Jayesh Pandit Bayer, Kenya



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Day 9

6/2/2018 - Tuesday

Time	Topics	Speaker
9:00 -10:30 AM	Vaccine Pharmacovigilance - Introduction to vaccine Adverse Events Following Immunization (AEFI)	Jyoti Joshi Center for Disease Dynamics, Economics & Policy, India
10:30 - 11:00 AM	Tea Break	
11:00 - 11:30 AM	Causality assessment of AEFI	Juny Sebastian JSS University, India
11:30 - 1:00 PM	Causality assessment of AEFI - Hands-on session	Juny Sebastian JSS University, India
1:00 - 2:00 PM	Lunch Break	
2:00 - 3:00 PM	Benefit Risk Communications	<i>Lecture:</i> Paula Alvarado <i>Facilitators:</i> Federica Santoro and Thomas Rowsell Uppsala Monitoring Centre, Sweden
3:00 - 3:30 PM	Tea Break	
3:30 - 5:00 PM	Crisis management	<i>Lecture:</i> Paula Alvarado <i>Facilitators:</i> Federica Santoro and Thomas Rowsell Uppsala Monitoring Centre, Sweden



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Day 10

7/2/2018 - Wednesday

Time	Topics	Speaker
9:00 - 10:30 AM	Introduction to Pharmacoepidemiology and different study designs	Krishna Undela JSS University, India
10:30 - 11:00 AM	Tea Break	
11:00 - 12:00 PM	Important observational studies and their strengths and weaknesses	Krishna Undela JSS University, Mysuru
12:00 - 1:00 PM	Consumer reporting of ADRs	Eugene Puijenbroek Netherlands Pharmacovigilance Centre Lareb, The Netherlands
1:00 - 2:00 PM	Lunch Break	
2:00 - 3:00 PM	Signal Detection	Eugene Puijenbroek Netherlands Pharmacovigilance Centre Lareb, The Netherlands
3:00 - 3:30 PM	Tea Break	
3:30 - 5:00 PM	Signal Detection - Hands-on sessions	Eugene Puijenbroek Netherlands Pharmacovigilance Centre Lareb, The Netherlands Krishna Undela JSS University, India



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Day 11

8/2/2018 - Thursday

Time	Topics	Speaker
9:00 - 10:30 AM	How to integrate pharmacovigilance in Public Health Programme? <ul style="list-style-type: none">• HIV• Tuberculosis• Malaria	Sten Olsson Preseident ISoP, Sweden
10:30 - 11:00 AM	Tea Break	
11:00 - 12:00 PM	Pharmacovigilance methods	Anand B Harugeri IQVIA, India
12:00 - 1:00 PM	Active surveillance of Bedaquiline - Indian experience	V Kalaiselvan Pharmacovigilance Programme of India, India
1:00 - 2:00 PM	Lunch Break	
2:00 - 3:30 PM	Narrative writing in Pharmacovigilance with exercises	Manohar VS and Liya Bose IQVIA, India
03:30 - 03:45 PM	Tea Break	
03:45 - 4:30 PM	Quality Management System in Pharmacovigilance Programme - experience of and learnings from PvPI	V Kalaiselvan Pharmacovigilance Programme of India, India
04:30 - 5:15 PM	Patient safety initiatives in India - How Pharmacovigilance centers can contribute for better patient safety	Inder Prakash Ministry of Health and Family Welfare, Govt. of India



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Day 12

9/2/2018 - Friday

Time	Topics	Speaker
9:00 – 9:40 AM	Pharmacovigilance journey of Health Sciences Authority, Singapore	Adena Lim Health Sciences Authority, Singapore
9:45 - 10:30 AM	Source of funding in Pharmacovigilance	Sten Olsson Preseident ISOoP, Sweden Afifa Trad Uppsala Monitoring Centre, Sweden
10:30 – 11:00AM	Tea Break	
11:00 - 12:00 PM	Pharmacovigilance of traditional medicines	Nilima A Kshirsagar Indian Council of Medical Research, India
12:00 - 1:00 PM (Recorded message)	Future of Pharmacovigilance - Agile	Marie Lindquist Uppsala Monitoring Centre, Sweden
1:00- 2:00PM	Lunch Break	
2:00 - 3:00 PM	Working out a Pharmacovigilance plan for the respective countries/organization	Sten Olsson Preseident ISOoP, Sweden G Parthasarathi JSS University, India
3:00 - 3:30 PM	Tea Break	
3:30 - 4:30 PM	Presentations of Pharmacovigilance plans	Participants
4:30 - 5:00 PM	Feedback & Closing ceremony	G Parthasarathi JSS University, India