



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Pharmacovigilance in the Western Pacific: Global approaches to risk-management of medicines.

**Training course – Programme
15th-16th March, 2018, Canberra, Australia**

Rydges Capital Hill Canberra
17 Canberra Avenue, Forrest ACT 2603

<https://www.rydges.com/accommodation/canberra-act/capital-hill-canberra/>

Day 1: Thursday 15th March

08:30 – 09:00 **Registration**

09:00 – 09:10 **Introduction to the course**
Mira Harrison-Woolrych (ISoP EC member) and Richard Hill (TGA)

Session 1: Current landscape and regulatory frameworks

Moderators: Mira Harrison-Woolrych (ISoP EC member) and Richard Hill (TGA)

09:10 – 09:45 **Globalisation of pharmacovigilance: current setting and predicted evolution**
Speaker: Sten Olsson (ISoP President)

09:45 – 10:25 **Pharmacovigilance in the Western Pacific region**
Speaker: Ian Boyd (Former ISoP Board Member)

10:25 – 10:55 **Coffee break**

10:55 – 11:30 **Current TGA Activities**
Speaker: Claire Behm (TGA)

11:30 – 12:05 **Pharmacovigilance in New Zealand: regulation and legislation**
Speaker: Chris James (Senior Pharmacovigilance Advisor, MedSafe)

12:05 – 12:30 **Panel discussion**

12:30 – 13:30 **Lunch break**

Session 2: Current issues in pharmacovigilance

Moderators: Sten Olsson (ISoP President) and Ian Boyd (Former ISoP Board Member)

13:30 – 14:10 **Raising awareness levels: findings from the EU SCOPE Joint Action Project**

Speaker: Phil Tregunno (ISoP Board member)

14:10 – 14:45 **Pharmacovigilance Inspections in Australia**

Speaker: Sarah May (TGA)

14:45 – 15:15 **Social media and mobile technologies**

Speaker: Phil Tregunno (ISoP Board member)

15:15 – 15:45 **Coffee break**

Session 3: Risk Management and early access schemes

Moderators: Mira Harrison-Woolrych (ISoP EC member) and John McEwen (Former ISoP Board Member)

15:45 – 16:15 **Risk management planning: the theory**

Speaker: Jan Petracek (ISoP Board member)

16:15 – 16:45 **Early access to medicines schemes: International perspective**

Speaker: Sten Olsson (ISoP President)

16:45 – 17:15 **Early access to medicines schemes: Local perspective**

Speaker: Adrian Bootes (Director of Prescription Medicines Authorisation Branch, TGA)

17:15 – 17:30 **Questions and Discussion**

17:30 **Closing Day 1**

Day 2 - Group 1: Friday 16th March

Session 4: How to apply international regulatory actions in a local context

Moderators: Jean-Christophe Delumeau (ISoP EC member), Elspeth Kay (TGA)

- 09:00 – 09:30** **Australia-specific considerations**
Speaker: Richard Hill (TGA)
- 09:30 – 10:00** **An industry perspective**
Speaker: Andreas Wortmann (Novartis)
- 10:00 – 10:30** **Workshop Applying international recommendation in a local setting a) Introducing the workshop**
Jean-Christophe Delumeau (ISoP EC member), Elspeth Kay (TGA)
- 10:30 – 11:00** **Coffee-break**
- 11:00 – 12:00** **Workshop: Applying international recommendation in a local setting b) Group exercise**
Facilitators: Jean-Christophe Delumeau (ISoP EC member), Elspeth Kay (TGA) and Andreas Wortmann (Novartis)
- 12:00 – 12:45** **Lunch break**

Session 5: Benefit-Risk Assessment and Clinical Considerations

Moderators: Mira Harrison-Woolrych (ISoP EC member) Jan Petracek (ISoP Board member)

- 12:45 – 13:30** **Key considerations in benefit-risk assessment**
Speaker: Jan Petracek (ISoP Board member)
- 13:30 – 14:15** **Workshop: Benefit-risk assessment**
Facilitators: Jan Petracek (ISoP Board member), Mira Harrison-Woolrych (ISoP EC member)
- 14:15 – 14:45** **Coffee break**
- 14:45 – 15:45** **Workshop: Benefit-risk assessment continued**
Facilitators: Jan Petracek (ISoP Board member), Mira Harrison-Woolrych (ISoP EC member)

Session 6 (Groups 1 and 2): Panel discussion

Moderators: Sten Olsson (ISoP President) and Richard Hill (TGA)

- 15:45 – 16:15** **Issues arising from workshop sessions**
- 16:15 – 16:30** **Closing remarks**

Day 2 - Group 2: Friday 16th March

Session 4: Benefit-Risk Assessment and Clinical Considerations

Moderators: Mira Harrison-Woolrych (ISoP EC member) Jan Petracek (ISoP Board member)

09:00 – 09:45 **Key considerations in benefit-risk assessment**

Speaker: Jan Petracek (ISoP Board member)

09:45 – 10:30 **Workshop: Benefit-risk assessment**

Facilitators: Jan Petracek (ISoP Board member), Mira Harrison-Woolrych (ISoP EC member)

10:30 – 11:00 **Coffee break**

11:00 – 12:00 **Workshop: Benefit-risk assessment continued**

Facilitators: Jan Petracek (ISoP Board member), Mira Harrison-Woolrych (ISoP EC member)

12:00 – 12:45 **Lunch break**

Session 5: How to apply international regulatory actions in a local context

Moderators: Jean-Christophe Delumeau (ISoP EC member), Elspeth Kay (TGA)

12:45 – 13:15 **Australia-specific considerations**

Speaker: Richard Hill (TGA)

13:15 – 13:45 **An industry perspective**

Speaker: Andreas Wortmann (Novartis)

13:45 – 14:15 **Workshop Applying international recommendation in a local setting a) Introducing the workshop (30)**

Jean-Christophe Delumeau (ISoP EC member), Elspeth Kay (TGA)

14:15 – 14:45 **Coffee-break**

14:45 – 15:45 **Workshop: Applying international recommendation in a local setting b) Group exercise (60)**

Facilitators: Jean-Christophe Delumeau (ISoP EC member), Elspeth Kay (TGA) and Andreas Wortmann (Novartis)

Session 6 (Groups 1 and 2): Panel discussion

Moderators: Sten Olsson (ISoP President) and Richard Hill (TGA)

15:45 – 16:15 **Issues arising from workshop sessions**

16:15 – 16:30 **Closing remarks**