



INTERNATIONAL **S**OCIETY OF **P**HARMACOVIGILANCE

**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

Session 1: Current landscape and regulatory frameworks

09:10 – 09:45 Globalisation of pharmacovigilance: current setting and predicted evolution

09:45 – 10:25 Pharmacovigilance in the Western Pacific region

10:25 – 10:55 Coffee break

10:55 – 11:30 Current TGA Activities

11:30 – 12:05 Pharmacovigilance in New Zealand: regulation and legislation

12:05 – 12:30 Panel discussion

12:30 – 13:30 Lunch break & Chapter Meeting

Session 2: Current issues in pharmacovigilance

- 13:30 – 14:05** **Raising awareness levels: findings from the EU SCOPE Joint Action Project**
- 14:10 – 14:45** **Pharmacovigilance Inspections in Australia**
- 14:10 – 14:45** **Social media and mobile technologies**
- 15:15 – 15:45** **Coffee break**

Session 3: Risk Management and early access schemes

- 15:45 – 16:15** **Risk management planning: the theory**
- 16:15 – 17:00** **Early access to medicines schemes**
- 17:00 – 17:30** **Communicating Benefit and Risk: a patient centred approach**
- 17:30 – 17:45** **Panel discussion**
- 17:45** **Closing Day 1**

Day 2 - Group 1: Friday 16th March

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

- 09:00 – 09:30** **Australia specific considerations**
- 09:30 – 10:00** **An industry perspective**
- 10:00 – 10:30** **Workshop: Applying international recommendation in a local setting**
- 10:30 – 11:00** **Coffee-break**
- 11:00 – 12:00** **Workshop: Applying international recommendation in a local setting continued**
- 12:00 – 12:45** **Lunch break**

Session 5: Benefit-Risk Assessment and Clinical Considerations

- 12:45 – 13:30** **Key considerations in benefit-risk assessment**
- 13:30 – 14:15** **Workshop: Benefit-risk assessment**
- 14:15 – 14:45** **Coffee break**
- 14:45 – 15:45** **Workshop: Benefit-risk assessment continued**

Session 6 (Groups 1 and 2): Panel discussion

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

Day 2 - Group 2: Friday 16th March

DN: reverse day 1 for group 2 once finalised