Developing risk management capability: Maximising opportunities from global pharmacovigilance experience to ensure the safe and appropriate use of medicinal products

Training course – Preliminary Programme

25th-26th May, 2017, Bangkok, Thailand

Meeting venue: Mandarin Hotel Bangkok

Enquiries: ISoP Phone and Fax +44 (0)20 3256 0027
www.isoponline.org or administration@isoponline.org

This two day-course leverages the Pharmacovigilance expertise of ISoP and has been designed to help interdisciplinary groups to learn and work together in contributing to patient safety when medicines are used.

At the end of the course, the participants are expected to understand current local and international legislative frameworks, and how they are expected to develop over the coming years. Participants will gain an understanding of considerations when developing strategies to increase volumes of ADRs, and how they might be handled through different signal management systems.

The second part of the course will focus on risk management and minimization approaches. Participants will gain hands-on experience of development of Risk Management Plans (RMPs) and the conduct of Benefit-Risk assessments.

Day one will take the form of lectures with opportunity for discussion through questions and answers and panel discussion, while day two will focus on hands-on interactive tasks.
Day 1: Thursday 25th May 2017

08:30 – 09:00 Registration

09:00 – 09:10 Introduction to the course
Ian Wong (ISoP EC member) and Puree Anantachoti (Faculty of Pharmaceutical Sciences, Chulalongkorn University)

Session 1: Current landscape and regulatory frameworks
Moderators: Ian Wong (ISoP EC member) and Rungpetch Sakulbumrungsil (Dean of the Faculty of Pharmaceutical Sciences, Chulalongkorn University)

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

09:45 – 10:25 ASEAN progress and Thailand perspective
Speaker: Wimon Suwankesawong (Expert in Drug Standard, Thai FDA)

10:25 – 10:55 Coffee break

10:55 – 11:30 Advances in international legislation: what’s coming next?
Speaker: Ian Wong (ISoP EC member)

11:30 – 12:00 Panel discussion

12:00 – 13:00 Lunch break

Session 2: ADR Collection and signal detection
Moderators: Vittaya Kulsomboon (Faculty of Pharmaceutical Sciences, Chulalongkorn University) and Yaowares Oppamayun (Head of Health Product Vigilance Center, Thai FDA)

13:00 – 13:35 Raising awareness levels: findings from the EU SCOPE Joint Action Project
Speaker: Phil Tregunno (ISoP Board member)

13:35 – 14:10 Data sources for pharmacovigilance
Speaker: Ian Wong (ISoP EC member)

14:10 – 14:45 Signal detection and statistical approaches
Speaker: Phil Tregunno (ISoP Board member)

14:45 – 15:15 Panel discussion

15:15 – 15:45 Coffee break
Session 3: Risk Management and early access schemes
Moderators: lan Wong (ISoP EC member) and Tarnkamol Chanprapaph (Chief of Pre-Marketing Control Division, Bureau of Drug Control, Thai FDA)

15:45 – 16:15  Risk management planning: the theory
Speaker: Jan Petracek (ISoP Board member)

16:15 – 16:45  Early access to medicines schemes
Speaker: Sten Olsson (ISoP President)

16:45 – 17:15  Communicating Benefit and Risk: a patient centred approach
Speaker: Paula Alvarado (Head of Global Communications, Uppsala Monitoring Centre)

17:15 – 17:30  Panel discussion
Day 2 (Group 1): Friday 26th May 2017

Session 4: Risk Management Plan Preparation
Moderators: Jean-Christophe Delumeau (ISoP EC member), Chen Wen Wen (Taiwan Drug Relief Foundation), Andreas Wortmann (Novartis Pharmaceuticals Australia)

09:00 – 10:30 Development of a Risk Management Plan (RMP)
09:00 – 09:30 Risk Management Planning in Asia: requirements and practices
Speaker: Jean-Christophe Delumeau
09:30 – 10:00 The Australian-Specific Annex: Insights from the Authority and License Holder perspective
Speaker: Andreas Wortmann
10:30 – 10:30 Experience of the Taiwan risk management strategy: the regulatory point of view
Speaker: Chen Wen Wen
10:30 – 11:00 Coffee-break
11:00 – 12:00 Interactive panel discussion with the audience: Key considerations and Pitfalls when developing a RMP
Panelists: Jean-Christophe Delumeau, Chen Wen Wen, and Andreas Wortmann
12:00 – 12:45 Lunch break

Session 5: Benefit-Risk Assessment
Moderators: Mira Harrison-Woolrych (ISoP EC member) and Wimon Suwankesawong (Expert in Drug Standard, Thai FDA)

12:45 – 13:30 Key considerations in benefit-risk assessment
Speaker: Jan Petracek (ISoP Board member)
Facilitators: Jan Petracek (ISoP Board member), Liu Wei (Pfizer China)
14:15 – 14:45 Coffee break
14:45 – 15:45 Workshop: Benefit-risk assessment continued
Facilitators: Jan Petracek (ISoP Board member), Liu Wei (Pfizer China)

Session 6 (Groups 1 and 2): Panel discussion
Moderators: Sten Olsson (ISoP President) and Puree Anantachoti (Faculty of Pharmaceutical Sciences, Chulalongkorn University)

15:45 – 16:15 Issues arising from workshop sessions
16:15 – 16:30 Closing remarks
16:30 Close
Day 2 (Group 2): Friday 26th May 2017

Session 4: Benefit-Risk Assessment
Moderators: Mira Harrison-Woolrych (ISoP EC member), and Wimon Suwankesawong (Expert in Drug Standard, Thai FDA)

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), Liu Wei (Pfizer China)

10:30 – 11:00  Coffee break

11:00 – 12:00  Workshop: Benefit-risk assessment continued  
Facilitators: Jan Petracek (ISoP Board member), Liu Wei (Pfizer China)

12:00 – 12:45  Lunch break

Session 5: Risk Management Plan Preparation
Moderators: Jean-Christophe Delumeau (ISoP EC member), Chen Wen Wen (Taiwan Drug Relief Foundation), Andreas Wortmann (Novartis Pharmaceuticals Australia)

12:45 – 14.15 Development of a Risk Management Plan (RMP)

12:45 – 13.15 Risk Management Planning in Asia: requirements and practices  
Speaker: Jean-Christophe Delumeau

13:15 – 13.45 The Australian-Specific Annex: Insights from the Authority and License Holder perspective  
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