INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

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 in on risk management and minimization approaches. Participants will gain hand 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.

Version: 15/05/2017

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: Ian 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)*
13:30 – 14:15	**Workshop: Benefit-risk assessment** *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)

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