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 – Managed by Centre Point (TBC)**

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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: 11/01/2017

Day 1: Thursday 25th May 2017

08:30 – 09:00 **Registration**

09:00 – 09:10 **Introduction to the course**

Session 1: Current landscape and regulatory frameworks
Moderator: Ian Wong (ISoP EC member) + LOC

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: Secretary General, 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
Moderator: LOC

13:00 – 13:35 **Signal detection and statistical approaches**
Speaker: Phil Tregunno (ISoP Board member)

13:35 – 14:10 **Data sources for pharmacovigilance**
Speaker: Kenneth Hartigan-Go
*(*Asian Institute of Management, Philippines)

14:10 – 14:45 **Raising awareness levels: findings from the EU SCOPE Joint Action Project**
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
Moderator: Ian Wong + LOC

15:45 – 16:15 **Risk management planning: the theory**
*Speaker: Kenneth Hartigan-Go (*Asian Institute of Management, Philippines)

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 5: Risk Management Plan Preparation
Moderator: Jean-Christophe Delumeau (ISoP EC member) & Chen Wen Wen (Taiwan Drug Relief Foundation)

09:00 – 9:45	**Development of a Risk Management Plan (RMP)** *Speaker: Jean-Christophe Delumeau & Chen Wen Wen*
09:45 – 10:30	**Key considerations and common pitfalls** *Speaker: Jean-Christophe Delumeau & Chen Wen Wen*
10:30 – 11:00	**Coffee-break**
11:00 – 12:00	**Workshop: RMPs** *Facilitators: Jean-Christophe Delumeau & Chen Wen Wen*
12:00 – 12:45	**Lunch break**

Session 6: Benefit-Risk Assessment
Moderator: Mira Harrison-Woolrych (ISoP EC member)

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

Session 7 (Groups 1 and 2): Panel discussion
Moderator: Sten Olsson (ISoP President) + LOC

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 5: Benefit-Risk Assessment
Moderator: Mira Harrison-Woolrych (ISoP EC member)

09:00 – 09:45	**Key considerations in benefit-risk assessment** *Speaker: TBC*
09:45 – 10:30	**Workshop: Benefit risk assessment** *Facilitators: Jan Petracek (ISoP Board member) & TBC*
10:30 – 11:00	**Coffee break**
11:00 – 12:00	**Workshop: Benefit risk assessment continued** *Facilitators: Jan Petracek (ISoP Board member) & TBC*
12:00 – 12:45	**Lunch break**

Session 6: Risk Management Plan Preparation
Moderator: Jean-Christophe Delumeau (ISoP EC member) & Chen Wen Wen (Taiwan Drug Relief Foundation)

12:45 – 13.30	**Development of a Risk Management Plan (RMP)** *Speaker: Jean-Christophe Delumeau & Chen Wen Wen*
13:30 – 14:15	**Key considerations and common pitfalls** *Speaker: Jean-Christophe Delumeau & Chen Wen Wen*
14:15 – 14:45	**Coffee-break**
14:45 – 15:45	**Workshop: RMPs** *Facilitators: Jean-Christophe Delumeau & Chen Wen Wen*

Session 7 (Groups 1 and 2): Panel discussion
Moderator: Sten Olsson + LOC

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