5th ISoP-UMC Training Course

11th – 12th of January 2018, Shenyang– China

(Venue: Hilton DoubleTree)

Pharmacovigilance training: from surveillance to inspections

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Preliminary Programme (version 08 Nov)

Introduction

The International Society of Pharmacovigilance (ISoP) and the Uppsala Monitoring Centre (UMC) have a common aim to explore the benefits and risks of medicinal products and to promote and enhance the safe and effective use of medicines. It is one of the primary objectives of ISoP and UMC to offer appropriate education and training in pharmacovigilance and to collaboratively intensify their activities in China. As China has formally joined ICH in June 2017, it is a great opportunity to seek views from global PV experts and learn from their experience about harmonization of safety reporting requirements and pharmacovigilance systems, to optimize the benefit risk ratio of medicinal products for Chinese patients and beyond.

Aim

How does harmonization of active surveillance and signal detection evaluated by PV inspection lead to better safety governance?

This two day-course will be conducted with expertise drawn from UMC & ISoP as well as local organisations and is designed to address the practical and theoretical aspects of pharmacovigilance.
Part of the training will also address the methodologies of intensive safety monitoring and post-authorisation safety studies using case studies as well as good practices for pharmacovigilance inspections to promote best practice.

The target audience includes regulatory agencies, hospitals, universities as well as

industry professionals in all areas of pharmacovigilance and those staff members in related functions, such as clinical trials, medical information, regulatory affairs, and audits.
Training will be delivered through lectures, working groups and panel discussions.

The programme will cover topics such as:
•Individual case safety reports and Spontaneous Reporting Systems
•Signal detection and management
•Logical application of causality
•PV inspection
•Risk communication
•Intensive safety monitoring programs

The main lectures will be delivered in English with simultaneous translation.

This training is organized in the city of Shenyang, Northeast China, in collaboration with the ISoP China chapter.

Day 1 Thursday 11th, January 2018	
08:30	*Registration*
	Chairpersons: Prof. Yang, Yue (Shenyang Pharmaceutical University (SPU)), Brian Edwards (Board Member and Chapters coordinator of ISoP)
09:00-09:15 09:15-09:30	**Opening words and introduction** Introduction of ISoP: History, vision and mission and programmes *Brian Edwards (Board Member and Chapters coordinator of ISoP)* Introduction of the UMC: history, vision and mission and activities *By: Pia Caduff (UMC Chief Medical Officer)*
Session	**Individual case safety reports (ICSR) – sources of safety data & spontaneous reporting systems (SRSs)**
09:30-10:30	**Data management and exchange in a global PV environment** *By: Helena Wilmar (UMC Pharmacovigilance Officer)*
10:30-11:00	*Coffee Break*
Session	**Signal detection & management** *Chairpersons: Prof. Yang, Yue (Shenyang Pharmaceutical University (SPU)), Brian Edwards (Board Member and Chapters coordinator of ISoP)*
11:00-12:00	**Logic of causality** *By: Pia Caduff (UMC Chief Medical Officer)*
12:00-13:00	**Principles of Signal detection** *By: Pia Caduff (UMC Chief Medical Officer)*
13:00-14:00	*Lunch*
Session	**PV Inspection** *Chairpersons: Zhou Lynn (Sanofi China & ISoP China chapter), Tang Xue (Pfizer & ISoP China chapter)*
13:30-14:30	**PV inspection in China** *By: CDR CFDA (TBD- invited)*
14:30-15:15	**PV inspection regulation in EU/US** *By: Brian Edwards (Board Member and Chapters coordinator of ISoP)*
15:15-15:45	Coffee Break
15:45-16:15	**Industry Experience in PV inspection (global & local)** By: *Zhang Yi Jing (Hellen Zhang) (Bayer China) (invited)*
16:30-17:30	**Communication of drug related risks** *By: Pia Caduff (UMC Chief Medical Officer)*

Day 2 Friday 12th, January 2018	
Session	**Intensive monitoring, introduction of relevant regulations** *Chairpersons: Zhou Lynn (Sanofi China & ISoP China chapter), TBD*
08:30-09:15	**Introduction of relevant regulation from EU/US on PASS studies** *By: Brian Edwards (Board Member and Chapters coordinator of ISoP)*
09:15-10:00	**China regulation on intensive monitoring** *By: CDR CFDA (TBD- invited)*
10:00-10:30	**Regulations from Japan/Korea on EPPV** *By: Prof. Yang, Yue (Shenyang Pharmaceutical University (SPU))*
10:30- 11:00	*Coffee Break*
Session	**Intensive monitoring-- methodology and case study** *Chairpersons: Pia Caduff (UMC Chief Medical Officer), Tang Xue (Pfizer China & ISoP China chapter)*
11:00- 11:45	**Example of a PASS** *By: Brian Edwards (Board Member and Chapters coordinator of ISoP)*
11:45-12:30	**Example of Traditional Chinese Medicines as a case study of intensive monitoring in China** *By: Zhang Li (Dongfang Hospital Affiliated to Beijing University of Chinese Medicine & ISoP China Chapter)*
12:30-13:30	*Lunch*
13:30-16:00	**Case study (2 subgroups running simultaneously, chemical product, biosimilar, rare disease)** *Facilitators: Brian Edwards (Board Member and Chapters coordinator of ISoP), Pia Caduff (UMC Chief Medical Officer), and Prof. Yang (Shenyang Pharmaceutical University (SPU))*
16:00-16:30	*Coffee Break*
	Conclusion
16:30-17:00	**Highlight from the case study**
17:00-17:15	**Closing Remarks** *By: ISoP + UMC + Prof. Yang*

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