7th ISoP-UMC Training Course

20th – 21st of September 2019, Shenzhen– China

Pharmacovigilance systems in China: Moving to the next step

Venue: The University of Hong Kong - Shenzhen Hospital

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Programme (version 17 July 2019)

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. Since China formally joined ICH in June 2017, China pharmacovigilance regulations have significantly changed since 2018 moving forward with high standards and requirements for new PV systems and electronic data transmission (e.g. E2B R3). Those updated PV regulations cover PV activities from clinical trials to post- marketing surveillance. 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

This two day-course will be conducted with expertise drawn from UMC & ISoP as well as local organizations and is designed to address the practical and theoretical aspects of pharmacovigilance from clinical trials to post-marketing surveillance.

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 program will cover topics such as:

- ICH related topics such as E2B and its implementation as well as Periodic Safety Update Reports (PSUR) and Development Safety Update Reports (DSUR) submissions
- Terminologies used in pharmacovigilance: WHODrug and MedDRA
- Experience sharing about good quality case reports in China
- Safety evaluation and Risk management covering signal detection and serious organ toxicity
- Introduction to new Chinese Regulations and their application in clinical trials and post-market surveillance
- ISoP special interest groups with focus on Herbal and Traditional medicines and Medication Errors

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

This training is organized in the city of Shenzhen, Southeast China, in collaboration with the ISoP China chapter and Hong Kong University Shenzhen Hospital.

Day 1 Friday, 20 Sept 2019	
08:30	*Registration*
Session 1	**Opening and course Introduction** *Chairs: Brian Edwards (ISoP Board Member, Chapter Coordinator) and Xue Tang (Pfizer, ISoP China Chapter)*
9:00-09:15	**ISoP Overview: History, mission & vision, Plan of 2019** *Brian Edwards (ISoP Board Member, Chapter Coordinator)*
09:15-09:30	**UMC Overview: History, mission & vision, upcoming events** *Zhurong Liu (Uppsala Monitoring Centre)*
Session 2	**Implementation of ICH Guidelines** *Chairs: Brian Edwards (ISoP Board Member, Chapter Coordinator) and Xue Tang (Pfizer, ISoP China Chapter)*
09:30-10:30	**ICH E2B implementation and structure of good quality case report** *Phil Tregunno (ISoP Board Member, MHRA)*
10:30-11:00	*Tea Break*
11:00-11:45	**Updates on ICH E2C PSUR and ICH E2F DSUR** *Dawn Ren (Bayer, China)*
11:45-12:30	**WHODrug and MedDRA terminologies and coding** *Qun-Ying Yue (Uppsala Monitoring Centre)*
12:30-13:30	*Lunch*
Session 3	**Creating a good quality case report in China** *Chair: Pearl Pai (Hong Kong University Shenzhen Hospital)*
13:30-13:50	**How a quality process creates a good quality case report** *Brian Edwards (ISoP Board Member, Chapter Coordinator)*
13:50-14:20	**Pharmacovigilance Practice and consideration in Shenzhen** *Qiurong Mao (Shenzhen Institute of Pharmacovigilance and risk management) (invited)*
14:20-14:50	**Experience sharing—Shenzhen Hospital** *Pearl Pai (Hong Kong University Shenzhen Hospital)*
Session 4	**Safety Evaluation** *Chair: Li Zhang (ISoP China Chapter, Dongfang Hospital Affiliated to Beijing University of Chinese Medicine)*
14:50-15:30	**Introduction to signal detection applied to logic of causality** *Qun-Ying Yue (Uppsala Monitoring Centre) and Phil Tregunno (ISoP Board Member, MHRA)*

15:30-16:00	*Tea Break*
16:00-17:30	**Principles of Signal Detection – lecture and workshop** *Qun-Ying Yue (Uppsala Monitoring Centre) and Phil Tregunno (ISoP Board Member, MHRA)*

Day 2 Saturday, 21 Sept 2019	
Session 5	**Risk management** *Chairs: Lynn Zhou (ISoP China Chapter, Sanofi, China), and Jing Bao (Livzon Pharmaceutical Group Inc, China)*
08:30-09:00	**Serious organ toxicity: Drug Induced Liver Injury (DILI)** *Yiming Mao (Shanghai Renji Hospital, affiliated to Shanghai Jiao Tong University)*
09:00-09:30	**Serious organ toxicity: Renal injury** *Xing Min Qiu (Pfizer, China)*
09.30-09:55	**Risk Management overview and China implementation example** *Xing Min Qiu (Pfizer, China)*
09.55-10.15	**Epidemiology study in effectiveness evaluation of additional risk minimisation measures (aRMM)** *Juhaeri Juhaeri (Head of Epidemiology and Benefit Risk, Medical Evidence Generation, Sanofi, USA)*
Session 6	**Regulations about Enhanced Pharmacovigilance** *Chairs: Li Zhang (Dongfang Hospital Affiliated to Beijing University of Chinese Medicine) and Dawn Ren (Bayer, China)*
10.15-10:40	**China Regulations/Technical Requirement on safety monitoring in clinical trials** *NMPA CDE Expert*
10:40-11:10	*Tea break*
11:10- 11:50	**China Regulation on safety monitoring—post marketing** *-- Risk management planning and its execution* *NMPA CDE / CDR Expert*
11:50-12:30	**Electronic medical record (EMR) for post-market surveillance** -- China Hospital Pharmacovigilance System and China Sentinel Hospital Alliance Program (CHIPS) in China *NMPA CDR Expert*
12:30-13:30	*Lunch*
13:30-15:30	**Case study (2 subgroups running simultaneously)**

	Facilitators: Lynn Zhou and Dawn Ren
15:00 -15:30	**Feedback from the case study** *Dawn Ren, Brian Edwards and others*
15:30 -16 :00	*Tea Break*
Session 7	**ISoP Special Interest Groups (SIGs) and Closing** *Chair: Brian Edwards (ISoP Board Member, Chapter Coordinator)*
16:00-16:20	**Survey result of risk minimisation measures (RMM)** *Dawn Ren (Bayer, China)*
16:20-16:40	**Updates from Herbal and Traditional medicines SIG** *Li Zhang (ISoP China Chapter, Dongfang Hospital Affiliated to Beijing University of Chinese Medicine)*
16:40-17:00	**Updates from Medication Errors SIG** *Brian Edwards (ISoP Board Member, Chapter Coordinator)*
17:00-17:15	**Closing Remarks** *Brian Edwards (ISoP Board Member, Chapter Coordinator), Zhurong Liu (Uppsala Monitoring Centre), ISoP China Chapter and Hong Kong University Shenzhen Hospital.*

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