7th ISoP-UMC Training Course

11th – 12th of November 2019, Guangzhou– China

Pharmacovigilance systems in China: Moving to the next step

Venue: DoubleTree Hilton Guangzhou

Meeting room: Panorama (4th Floor)

Programme

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 risk minimisation measures, 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 Guangzhou, Southeast China, in collaboration with the ISoP China chapter and Hong Kong University Shenzhen Hospital.

Day 1 Monday, 11 November 2019	Panorama/4th Floor
08:30	*Registration*
Session 1	**Opening and course Introduction** *Chairs: EDWARDS Brian (ISoP Board Member, Chapter Coordinator, 2016-2019) and ZHOU Ling Yun (ISoP China Chapter, Sanofi, China)*
9:00-09:15	**ISoP Overview: History, mission & vision, Plan of 2019** *EDWARDS Brian (ISoP Board Member, Chapter Coordinator, 2016-2019)*
09:15-09:30	**UMC Overview: History, mission & vision, upcoming events** *LIU Zhu Rong (Uppsala Monitoring Centre, Sweden)*
Session 2	**Implementation of ICH Guidelines** *Chairs: EDWARDS Brian (ISoP Board Member, Chapter Coordinator, 2016-2019) and ZHOU Ling Yun (ISoP China Chapter, Sanofi, China)*
09:30-10:30	**ICH E2B implementation and structure of good quality case report** *TREGUNNO Phil (ISoP Board Member, 2016-2019, MHRA)*
10:30-11:00	*Tea Break*
11:00-11:45	**Updates on ICH E2C (PSUR) and ICH E2F (DSUR) guidelines** *REN Shu Guang (Bayer, China)*
11:45-12:30	**WHODrug and MedDRA terminologies and coding** *YUE QunYing (Uppsala Monitoring Centre, Sweden)*
12:30-13:30	*Lunch*
Session 3	**Creating a good quality case report in China** *Chair: HUI Christopher K M (Hong Kong University)*
13:30-13:50	**How a quality process creates a good quality case report** *EDWARDS Brian (ISoP Board Member, Chapter Coordinator, 2016-2019)*
13:50-14:20	**Pharmacovigilance Practice and consideration in Shenzhen** *MAO QiuRong (Shenzhen Institute of Pharmacovigilance and risk management)*
14:20-14:50	**Experience sharing—Shenzhen Hospital** *HUI Christopher K M (Hong Kong University)*
Session 4	**Safety Evaluation** *Chair: ZHANG Li (ISoP Board member 2019-2022, China Chapter and Dongfang Hospital Affiliated to Beijing University of Chinese Medicine)*
14:50-15:30	**Introduction to signal detection applied to logic of causality**

	YUE QunYing (Uppsala Monitoring Centre, Sweden) and TREGUNNO Phil (ISoP Board Member, 2016-2019, MHRA)
15:30-16:00	*Tea Break*
16:00-17:30	**Principles of Signal Detection – lecture and workshop** *YUE QunYing (Uppsala Monitoring Centre, Sweden) and TREGUNNO Phil (ISoP Board Member, 2016-2019, MHRA)*

Day 2 Tuesday, 12 November 2019	Panorama/4th Floor
Session 5	**Risk management** *Chairs: ZHOU Ling Yun (ISoP China Chapter, Sanofi, China), and BAO Jing (Livzon Pharmaceutical Group Inc)*
08:30-09:00	**Overview of drug life-cycle risk management** *REN Shu Guang (Bayer, China)*
09:00-09:30	**Serious organ toxicity: Severe cutaneous adverse reactions** *QIU Xing Min (Pfizer, China)*
09:30-09:55	**Risk Management overview and industry experience sharing** *QIU Xing Min (Pfizer, China)*
09:55-10.15	**Epidemiology studies for the evaluation of the effectiveness of additional risk minimisation measures (aRMM)** *LIU Shu Sen (Sanofi, China)*
10:15-10:45	*Tea break*
Session 6	**Regulations about Enhanced Pharmacovigilance** *Chairs: ZHANG Li (ISoP Board member 2019-2022, China Chapter and Dongfang Hospital Affiliated to Beijing University of Chinese Medicine) and REN Shu Guang (Bayer, China)*
10.45-11:30	**China Regulations/Technical Requirement on safety monitoring in clinical trials** *WANG Hai Xue (NMPA CDE Expert)*
11:30- 12:10	**Electronic medical record (EMR) for post-market surveillance** -- China Hospital Pharmacovigilance System (CHPS) and China Sentinel Hospital Alliance Program in China *SONG Hai Bo (NMPA CDR Expert)*
12:10-12:30	**Panel discussion**
12:30-13:30	*Lunch*
13:30-15:30	**Case study (2 subgroups running simultaneously)**

	Facilitators: ZHOU Ling Yun, DELUMEAU Jean-Christophe and REN Shu Guang
15:00 -15:30	**Feedback from the case study** *ZHOU Ling Yun, DELUMEAU Jean-Christophe and REN Shu Guang*
15:30-16 :00	*Tea Break*
Session 7	**ISoP Special Interest Groups (SIGs) and Closing** *Chair: EDWARDS Brian (ISoP Board Member, Chapter Coordinator, 2016-2019)*
16:00-16:20	**Result of a survey conducted by the SIG on risk minimisation methods in Asian Countries** *DELUMEAU Jean-Christophe (ISoP EC member, Bayer, Singapore)*
16:20-16:40	**Updates from Herbal and Traditional medicines SIG** *ZHANG Li (ISoP Board member 2019-2022, China Chapter and Dongfang Hospital Affiliated to Beijing University of Chinese Medicine)*
16:40-17:00	**Updates from Medication Errors SIG** *EDWARDS Brian (ISoP Board Member, Chapter Coordinator, 2016-2019)*
17:00-17:15	**Closing Remarks** *EDWARDS Brian (ISoP Board Member, Chapter Coordinator, 2016-2019), LIU Zhu Rong (Uppsala Monitoring Centre, Sweden), ISoP China Chapter and Hong Kong University Shenzhen Hospital.*

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7th ISoP-UMC training course has been awarded 3 CME credits by the Guangdong Province Continuing Education.