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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Preliminary 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 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 Workshop Introduction**
9:00-09:15 09:15-09:30	**ISoP Overview： History, mission & vision, Plan of 2019** **UMC Overview：History, mission & vision, upcoming events**
Session 2	**Implementation of ICH Guidelines**
09:30-10:30	**ICH E2B implementation and structure of good quality case report**
10:30-11:00	*Tea Break*
11:00-11:45	**Updates on ICH E2C PSUR and ICH E2F DSUR**
11:45-12:30	**WHODrug and MedDRA terminologies and coding**
12:30-13:30	*Lunch*
Session 3	**Creating a good quality case report in China**
13:30-13:50	**How a quality process creates a good quality case report**
13:50-14:20	**Pharmacovigilance Practice and consideration in Shenzhen**
14:20-14:50	**Experience sharing—Shenzhen Hospital**
Session 4	**Safety Evaluation**
14:50-15:30	**Introduction to signal detection applied to logic of causality**
15:30-16:00	*Tea Break*
16:00-17:30	**Principles of Signal Detection – lecture and workshop**

Day 2 Saturday, 21 Sept 2019	
Session 5	**Risk management**
08:30-09:30	**Serious organ toxicity: Drug Induced Liver Injury (DILI) and renal injury**
09.30-09.55	**Risk management overview and China implementation example**

09.55-10.15	**Epidemiology study in effectiveness evaluation of additional risk minimisation measures (aRMM)**
Session 6	**Regulations about Enhanced Pharmacovigilance**
10.15-10:40	**China Regulations about safety monitoring in clinical trials**
10:40-11:10	*Tea break*
11:10- 11:50	**China Regulation about safety monitoring—post marketing** *-- Risk management planning and its execution*
11:50-12:30	**EMR for post-market surveillance** *-- China Hospital Pharmacovigilance System and China Sentinel Hospital Alliance Program (CHIPS) in China*
12:30-13:30	*Lunch*
13:30-15:30	**Case study (2 subgroups running simultaneously)**
15:00 -15:30	**Feedback from the case study**
15:30 -16 :00	*Tea Break*
Session 7	**ISoP Special Interest Groups and Closing**
16:00-17:00	**Updates from Herbal and Traditional medicines and Medication Errors Special Interest Groups**
17:00-17:15	**Closing Remarks**

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