4th ISoP-UMC Training Course
4th – 6th of September 2017, Panama City – Panama

Pharmacovigilance concepts and tools in Latin America

Enquiries: ISoP Phone and Fax +44 (0) 20 3256 0027
www.isoponline.org administration@isoponline.org

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 Latin America.

Aim

This three day-course is conducted with expertise from WHO-UMC and ISoP and is designed to address the practical and theoretical aspects of pharmacovigilance. Part of the training will address the safety monitoring of biotherapeutics and vaccines, and the problem of antibiotic resistance.
Target audience include 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, technical product complaints, medical information, sales and marketing, regulatory affairs, legal affairs and audits.
At the end of the course, the participants are expected to understand the complexities of pharmacovigilance and to use various sources of information about risks and appropriate tools to advance better detection, monitoring, reporting and prevention to promote product safety.
Lectures, working groups and panel discussions between regulators and industry will be the main training method.

4th ISoP-UMC Training course

Day 1 Monday 4th, September 2017	
08:30	*Registration*
09:00-09:15	**Opening words and introduction** Introduction of ISoP: History, vision and mission and programme
09:15-09:30	Introduction of the UMC: history, vision and mission and activities
Session	**Individual case safety reports (ICSR) – a basic source in pharmacovigilance - & spontaneous reporting systems (SRS) – Part I**
09:30-09:50	**The WHO Programme for International Drug Monitoring**
09:50-10:30	**Improving reporting – developing a positive ADR reporting culture and ways to collect safety information**
10:30-11:00	*Coffee Break*
Session	**Individual case safety reports (ICSR) – sources of safety data & spontaneous reporting systems (SRSs) – Part II**
11:00-11:30	**Individual case safety reports (ICSR): quality of ICSR**
11:30-12:30	**Managing ICSRs and safety data exchange in a global PV environment**
12:30-13:30	*Lunch*
Session	**Signal detection & management – Part I**
13:30-15:00	**Case assessment: certainty of diagnosis, seriousness and severity, causality, expectedness**
15:00-15:30	**Signals: definition and sources**
15:30-15:45	Coffee Break
15:45-18:00	**Signal detection – small databases - workshop**

4th ISoP-UMC Training course

Day 2 Tuesday 5th, September 2017	
	Opening Day 2
Session	**Signal detection & management – Part 2**
08:30-10:00	**Experiences with signal management – did signal contribute to early detection of risks and to early decision making?** Panel discussion (regulators and industry)
10:00-10:30	**Disproportionality and statistics (overview)**
10:30-11:00	*Coffee Break*
Session	**Assessment of risks and benefits**
11:00- 11:30	**Pharmacovigilance systems and Risk Management Systems**
11:30-12:00	**Comparative benefit-to-harm assessment**
12:00-12:30	**Organizational management in pharmacovigilance and decision making**
12:30-13:30	*Lunch*
13:30-14:30	**Antibiotic resistance –Updates from REACT**
Session	**Risk communication**
14:30-15:30	**Effective communication in pharmacovigilance**
15:30-15:45	*Coffee Break*
15:45-17:00	**Risk communication**

4th ISoP-UMC Training course

Day 3 Wednesday 6th, September 2017	
Session	**The broader scope of PV: vaccines, biotherapeutics**
08:30-09:30	**Pharmacovigilance on vaccines**
09:30-10:30	**Safety monitoring of biotherapeutics - challenges and options**
10:30-11:00	*Coffee Break*
Session	**Harmonization of pharmacovigilance concepts and tools in Latin America**
11: 00–11:45	**Pharmacovigilance in Public Health Programs**
11:45-12:30	**Pharmacovigilance indicators (PAHO)**
12:30-13:30	*Lunch*
13:30-14:15	**Harmonization of pharmacovigilance concepts and tools in Latin America – how far are we?**
14:15-16:15	**Regulators meet industry:** Roundtable discussion about common problems and solutions
16:15-16:30	*Coffee Break*
16:30-17:00	**Concluding remarks. Joint-statement from UMC and ISoP**. *By the Chairpersons and Presenters* *Distribution of course evaluation forms* *Collection of course evaluation* *Training Certificates collection*
17:00	*End of the meeting*

Contacts	*e-mail*	*Cell phone and SMS*
Sophie Spence	administration@isoponline.org	+44 777 306 2841
The International Society of Pharmacovigilance		*www.isoponline.org*