



Uppsala
Monitoring
Centre

6th ISoP-UMC Training Course
24th – 26th of September 2018, Guayaquil - Ecuador
(Courtyard Marriott Guayaquil)

Pharmacovigilance concepts and tools in Latin America

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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 their safe and effective use. 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 UMC and ISoP and delivers theory and experiential learning of pharmacovigilance, including but not limited to management of individual case safety reports, signal detection and risk management and risk communication.

Target audience includes regulatory agencies, hospitals, universities as well as industry professionals. Lectures, working groups and panel discussions between regulators and industry will be the main training method.

At the end of the course, the participants are expected to have an overall understanding about the complexities of pharmacovigilance system, the good pharmacovigilance practices and risk management to promote product safety.



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Day 1 Monday 24 th , September 2018	
08:30	<i>Registration</i>
	Opening words and introduction <i>Chairpersons: Juan Carlos Galarza (Control Sanitario, Ecuador), Elki Sollenbring (UMC) and Sten Olsson (ISoP)</i>
09:00-09:15	Introduction of ISoP: History, vision and mission and programmes <i>By: Sten Olsson (President of ISoP)</i>
09:15-09:30	Introduction of the UMC: history, vision and mission and activities <i>By: Elki Sollenbring (UMC)</i>
Session	Individual case safety reports (ICSR) - a basic source in pharmacovigilance & spontaneous reporting systems (SRS) <i>Chairpersons: Margarita Galarza Figueroa (Control Sanitario, Ecuador) and Sten Olsson (ISoP)</i>
09:30-10:00	Improving reporting - developing a positive ADR reporting culture and ways to collect safety information <i>By: Elki Sollenbring (UMC)</i>
10:00-10:15	<i>Coffee Break</i>
10:15-11:00	Effective communication in pharmacovigilance <i>By: Alexandra Hoegberg (UMC)</i>
11:00-11:30	Managing ICSRs and safety data exchange in a global PV environment quality of ICSR <i>By: Elki Sollenbring (UMC)</i>
11:30-12:00	Individual case safety reports (ICSR): quality of ICSR <i>By: Elki Sollenbring (UMC)</i>
12:00-13:00	<i>Lunch</i>
Session	Signal detection & management <i>Chairpersons: Martina Vlkova (ISoP) and Gloria Giraldo (Health Canada)</i>
13:00-13:30	Logic of causality and single case assessment <i>By Monica Tarapués (UMC)</i>
13:30-14:30	Case assessment: workshop <i>By: Monica Tarapués (UMC)</i>
14:30-15:00	Signal detection <i>By: Monica Tarapués (UMC)</i>
15:00-15:15	<i>Coffee Break</i>
15:15-17:15	Signal detection -workshop <i>By: Monica Tarapués (UMC)</i>
17:15-17:45	Disproportionality and statistics (example) <i>By: Mariano Madurga (Pharmacovigilance Expert)</i>



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Day 2 | Tuesday 25th, September 2018

<i>Opening Day 2</i>	
Session	Pharmacovigilance documents and compliance monitoring <i>Chairpersons: Alexandra Hoegberg (UMC) and Martina Vlkova (ISoP)</i>
08:30-09:30	Pharmacovigilance indicators <i>By: Sten Olsson (ISoP)</i>
09:30-10:15	Pharmacovigilance inspections <i>By: Rosana Angélica Ramírez (National PV centre, Colombia)</i>
10:15-11:00	Risk Management Plans <i>By: Gloria Giraldo (Health Canada)</i>
11:00-11:15	<i>Coffee Break</i>
11:15-12:00	Periodic Safety Update Reports <i>By: Gloria Giraldo (Health Canada)</i>
Session	Assessment of risks and benefits <i>Chairpersons: Elki Sollenbring (UMC) and Patricia Acuña (Hospital Carlos Andrade Marín, Quito, Ecuador)</i>
12:00- 12:30	Pharmacovigilance Systems and Risk Management Systems <i>By: Martina Vlkova (ISoP)</i>
12:30-13:00	Comparative benefit-to-harm assessment <i>By: Mariano Madurga (Pharmacovigilance Expert)</i>
13:00-14:00	<i>Lunch</i>
14:00-14:30	Organizational management in pharmacovigilance and decision making <i>By: Martina Vlkova (ISoP)</i>
Session	Risk communication <i>Chairpersons: Monica Tarapués (UMC) and Mariano Madurga (Pharmacovigilance Expert)</i>
14:30-15:00	Risk communication <i>By: Alexandra Hoegberg (UMC)</i>
15:00-15:15	<i>Coffee Break</i>
15:15-16:00	Risk communication <i>By: Alexandra Hoegberg (UMC)</i>
16:00-17:30	Improving reporting - workshop <i>By: Elki Sollenbring and Alexandra Hoegberg (UMC)</i>



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Day 3 | Wednesday 26th, September 2018

	<i>Opening Day 3</i>
Session	The broader scope of PV: vaccines, biotherapeutics <i>Chairpersons: Alexandra Hoegberg (UMC) and Rosana Angélica Ramírez (National PV centre, Colombia)</i>
08:30-09:30	Pharmacovigilance on vaccines <i>By: Rebecca Chandler (UMC) (via video)</i>
09:30-10:15	Pharmacovigilance in Public Health Programs <i>By: Sten Olsson (ISoP)</i>
10:15-10:45	<i>Coffee Break</i>
10:45-11:30	Biotherapeutics: Pharmacovigilance challenges and considerations <i>By: Paola Fletscher (Amgen) (IPVG LATAM)</i>
Session	Harmonization of pharmacovigilance concepts and tools in Latin America <i>Chairpersons: Elki Sollenbring (UMC) and Sten Olsson (ISoP)</i>
11:30-12:00	How to implement pharmacovigilance in a hospital – practical experience <i>By: Patricia Acuña (Hospital Carlos Andrade Marín, Quito, Ecuador)</i>
12:00-12:30	The main differences between performing pharmacovigilance in a small national company and within a multinational company <i>By: Santiago Schiaffino (Boehringer Ingelheim)</i>
12:30-13:30	<i>Lunch</i>
13:30-14:15	Harmonization of pharmacovigilance concepts and tools in Latin America – how far are we? – regulators point of view <i>By: Rosana Angélica Ramírez (National PV centre, Colombia)</i>
14:15-14:45	Harmonization of pharmacovigilance concepts and tools in Latin America - industry point of view <i>By: Everardo Vazquez (Pfizer) (AMFV)</i>
14:45-16:15	Regulators meet industry: Roundtable discussion about common problems and solutions
16:15-16:45	Concluding remarks. Joint-statement from UMC and ISoP <i>By the Chairpersons and Presenters</i> <i>Distribution of course evaluation forms Collection of course evaluation</i> <i>Training Certificates collection</i>
17:00	<i>End of the training course</i>

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