3rd ISoP-UMC Training Course
7-9 September 2016, Lima – Peru

From case reports to benefit-harm assessment and risk communication

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Course Programme

Introduction

The International Society of Pharmacovigilance (ISoP) and the Uppsala Monitoring Centre (UMC) have a common interest to promote scientific research and practice through the mutual exchange of information on adverse events and risks related to medicinal products. It is one of the primary objectives of ISoP and UMC to offer appropriate education and training in pharmacovigilance and to intensify our activities in Latin America.

Aim

This three day-course, the first ISoP-UMC joint training in Latin America, is conducted with expertise from WHO-UMC and ISoP, and designed for interdisciplinary groups to learn and work together in contributing to patient safety when medicines are used. 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. Assessment of causality and the benefit-harm of medicinal products and communication are other important course contents that will align regulators and industry to promote product safety.

Lectures, working groups and panel discussions will be the main training method.

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Day 1 Wednesday, 7 September 2016	
08:30	*Registration*
	Chairpersons: Sten Olsson (UMC) and Hervé Le Louet (ISoP)
09:00-09:15 09:15-09:30	**Opening words and introduction** Introduction of ISoP: History, vision and mission and programmes *By Hervé Le Louet (President of ISoP)* Introduction of the UMC: history, vision and mission and activities *By: Sten Olsson (UMC)*
Session	**Individual case reports (ICSR) – a basic source in pharmacovigilance - & spontaneous reporting systems (SRS) – Part I** *Chairpersons: Sten Olsson (UMC) and Hervé Le Louet (ISoP)*
09:30-09:50	**The WHO Programme for International Drug Monitoring** *By: Elki Sollenbring (UMC)*
09:50-10:30	**Improving reporting – developing a positive ADR reporting culture and ways to collect ADR reports** *By: Elki Sollenbring (UMC)*
10:30-11:00	*Coffee Break*
Session	**Individual case reports (ICSR) – a basic source in pharmacovigilance - & spontaneous reporting systems (SRSs) – Part II** *Chairpersons: Hervé Le Louet (ISoP) and Dina Fernandez Valencia (DIGEMID, Peru)*
11:00-11:30	**Individual case reports (ICSR): reporters, content, validity, quality - how VigiGrade works** *By: Elki Sollenbring (UMC)*
11:30-12:30	**Managing ICSRs and data exchange in a global PV environment** *By: Elki Sollenbring and Sten Olsson (UMC)*
12:30-13:30	*Lunch*
Session	**Signal detection & management – Part I** *Chairpersons: Ulrich Hagemann (ISoP) and Elki Sollenbring (UMC)*
13:30-15:00	**Case assessment: certainty of diagnosis, seriousness and severity, causality, expectedness** *By Monica Tarapués (UMC)*
15:00-15:30	**Signals: definition and sources** *By Monica Tarapués (UMC)*
15:30-16:00	*Coffee Break*
16:00-18:00	**Signal detection – small data bases - workshop** *By Monica Tarapués (jointly UMC and ISoP)*

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Day 2 Thursday, 8 September 2016	
	Opening Day 2
Session	**Signal detection & management – Part 2** *Chairpersons: UMC (tbc) and Luis Alesso (ISoP)*
08:30-09:00	**Disproportionality and other observational analytic methods - overview and basic principles** *By: Cláudia Soares (GSK, Brazil)*
09:00-09:30	**Clinical assessment of signals – methods and examples** *By: Raquel Herrera Comoglio (Córdoba National University, Argentina)*
09:30-10:30	**Experiences with signal management – did signal contribute to early detection of risks and to early decision making?** Panel discussion (regulators and industry) Fernanda Simioni Gasparotti (ANVISA, Brazil) Giovanna Jimenez Fuentes (DIGEMID Peru) Romina Heredia (ANMAT, Argentina) tbc; Veronica Vergara (Instituto de Salud Pública de Chile) Claudia Soares (GSK Brazil) tbc
10:30-11:00	*Coffee Break*
Session	**Assessment of risks and benefits** *Chairpersons: National Centre (tbc) and UMC (tbc)*
11:00- 11:30	**Pharmacovigilance systems and Risk Management Systems** *By: Cláudia Soares (GSK, Brazil)*
11:30-12:00	**Comparative benefit-to-harm assessment** *By: Ulrich Hagemann (ISoP)*
12:00-12:30	**Organizational management in pharmacovigilance and decision making** *By: Kenneth Hartigan-Go (ISoP)*
12:30-13:30	*Lunch*
Session	**Risk communication** *Chairpersons: Paula Alvarado (UMC) and Ulrich Hagemann (ISoP)*
13:30-14:30	**Effective communication in pharmacovigilance** *By: Paula Alvarado (UMC)*
14:30-15:30	**Risk communication - part 1** *By: Paula Alvarado (UMC)*
15:30-16:00	*Coffee Break*
16:00-16:30	**Risk communication - part 2** *By: Paula Alvarado (UMC)*
16:30-17:15	**Meet the trainers** – informal discussion Concluding remarks

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Day 3 Friday, 9 September 2016	
Session	**The broader scope of PV: counterfeiting, medication errors, off-label use** *Chairpersons: National Centre (tbc) and Elki Sollenbring (UMC)*
08:30-09:00	**Counterfeiting: definition, scale and action** *By Luis Alesso (ISoP)*
09:00-09:30	**Medication errors: detection, assessment and preventability** *By Adalton Ribeiro (GVS-SP, Brazil)*
09:30-10:00	**Therapeutic failure – how to handle reports?** *By Claudia P Vaca Gonzales (Universidad Nacional de Colombia, Bogota, Colombia)*
10: 00–10:30	**Off-label use: an overview and how does it relate to medication errors** *By Ulrich Hagemann (ISoP)*
10:30-11:00	*Coffee Break*
11:00-11:30	**Safety monitoring of biotherapeutics – challenges and options** *By Claudia P Vaca Gonzales (Universidad Nacional de Colombia, Bogota, Colombia)*
Session	**Harmonization of pharmacovigilance concepts and tools in Latin America** *Chairpersons: National Centre (tbc) and Elki Sollenbring (UMC)*
11:30-12:00	**Pharmacovigilance in Public Health Programs** *By: Sten Olsson (UMC)*
12:00-12:30	**Pharmacovigilance indicators** *By: Sten Olsson (UMC)*
12:30-13:30	*Lunch*
13:30-14:15	**Harmonization of pharmacovigilance concepts and tools in Latin America – how far are we?** *By Veronica Vergara (Instituto de Salud Pública de Chile)*
14:15-15:30	**Pharmacovigilance capacity building on regional and national level** *By Kenneth Hartigan-Go (ISoP)*
15:30-16:00	**Regulators meet participants:** Roundtable discussion about common problems and solutions *Chairpersons: Kenneth Hartigan-Go (ISoP) and Ulrich Hagemann (ISoP)* Fernanda Simioni Gasparotti (ANVISA, Brazil) Romina Heredia (ANMAT, Argentina) Kelly Serrano Mestanza DIGEMID, Peru) Veronica Vergara *(Instituto de Salud Pública de Chile)*
16:00-16:30	*Coffee Break*
16:30-17:00	**Concluding remarks. Joint-statement from UMC and ISoP** *By the Chairpersons and Presenters* *Distribution and collection of course evaluation forms* *Training Certificates release*
17:00	*End of the meeting*

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