INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Risk Management and Regulatory Inspections

Training Course, 26th – 27th May 2011, Minsk, Belarus

Belarusian Medical Academy of Post-Graduate Education
3, Brovki str., build.3, 220013, Minsk, Belarus

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The programme will be held in the unique city of Minsk.

Risk management lies at the heart of modern pharmacovigilance and is now supported by a strong regulatory framework within the EU and elsewhere. This two day-seminar will be dedicated to the principles and practice of safety risk management, both from a company and a regulatory authority perspective, beginning with basic PV system requirements and covering risk identification, management and communication.

This course is targeted at all interested healthcare professionals and in particular industry and MAHs with a strong focus on practical examples and real-life solutions.

Day 1: Thursday 26th May 2011

Chairpersons: Deirdre McCarthy & Ulrich Hagemann

8.30 to 9.00 am **Registration**

9.00 - 9.10 am
Introduction Course objectives
Deirdre McCarthy, ISoP

9.10 - 9.50 am
Roles and responsibilities of the MAH for pharmacovigilance
Natália Kocánková, PharmaSwiss, Czech Republic

9.50 - 10.30 am
Principles of Risk Management
Emil Cochino. European Medicines Agency

10.30 - 11.00 am
Coffee-break

11.00 - 11.45 am
Patient reporting – impact on risk management?
Eugene van Puijenbroek, ISoP

11.45 - 12.30 pm
PV Planning and the EU-RMP
Ulrich Hagemann, ISoP

12.30 - 1.00 pm
Open Forum for Questions and Answers

Lunch

2.00 - 2.45 pm
Practical examples of risk minimization tools
Emil Cochino. European Medicines Agency

2.45 - 3.30 pm
Risk communication such as the Direct Healthcare Professional Communication
Ulrich Hagemann, ISoP

3.30 - 4.00 pm
Coffee-break

4.00 - 4.45 pm
The EU QPPV – roles and responsibilities in risk management and regulatory inspections
Deirdre McCarthy, ISoP

Final comments and Close of Day 1

Day 2: Friday 27th May 2011

Chairperson: Deirdre McCarthy & Jan Petracek

Welcome to Day 2

9.00 - 9.45 am
PSURs as a Risk Management Tool
Natália Kocánková, PharmaSwiss, Czech Republic

9.45 am – 11.00 am
Development Safety Update Reports and ICH E2F
Jan Petracek, European Pharminvent Services, Czech Republic

11.00 - 11.30 am
Coffee-break

11.30 am - 12.15 pm
Benefit-risk management across the product lifecycle
Jan Petracek, European Pharminvent Services, Czech Republic

12.15 - 1.00 pm
New EU Post-marketing PV legislation
Deirdre McCarthy, ISoP

Lunch

2.00 - 3.30 pm
Practical workshop on Risk Management Planning
Facilitator: *Jan Petracek, European Pharminvent Services,* Czech Republic

3.30 - 4.00 pm
Coffee-break

4.00 - 4.45 pm
How to survive Regulatory Inspections
Natália Kocánková, PharmaSwiss, Czech Republic
& Deirdre McCarthy, ISoP

4.45 - 5.00 pm
Closing remarks
Panel

The International Society of Pharmacovigilance gratefully acknowledges assistance from the Center for Examinations and Testing in Health Service of the Republic of Belarus as partner co-organizer