INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

New EU Post-licensing Legislation and Benefit-Risk Management

Training Courses, 11th - 12th June 2012

Berlin, Germany

Hotel H10berlin ku'damm
Joachimstalerstraße 31 – 32, D 10719 Berlin, Germany

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

This advanced two day-seminar will cover in detail the amendments to the EU Post-marketing legislation effective July 2012 which represent the greatest change in medicines legislation in the last ten years. A number of presentations will also be devoted to new developments in benefit-risk management practice.

This course is targeted at regulators, scientists and industry, with a strong focus on practical examples and real-life solutions.

Day 1: Monday 11 June 2012

Chairperson: Deirdre McCarthy

8.30 to 9.00 am Registration

9.00 – 9.15 am
Introduction to course 1 - Course objectives
Deirdre McCarthy, ISoP

9.15 – 10.00 am
Overview and rationale behind the changes
Deirdre McCarthy, ISoP

10.00 – 10.45 am
Industry perspectives: challenges for Marketing Authorisation Holders Part 1
Barbara Sickmüller, Bundesverband der Pharmazeutischen Industrie e.V. (BPI)

10.45 – 11.15 am
Coffee-break

11.15 – 12.15
Regulatory authority perspective
including New Community procedures: assessment of PSURs, PASS, referrals
Doris Stenver, Danish Medicines Agency

12.15 to 1.00 pm
Overview of the Good PV-Practice modules: the successor of Volume 9A
Priya Bahri, EMA

Lunch
1.00 – 2.00 pm

2.00 – 2.45 pm
Quality Management and the new Good PV Practice Guidance
Priya Bahri, EMA

2.45 – 3.10 pm
Industry perspectives: challenges for Marketing Authorisation Holders Part II
EVMPD updates
Barbara Sickmüller, Bundesverband der Pharmazeutischen Industrie e.V. (BPI)

3.10 to 3.30 pm
The role of the EU QPPV
Priya Bahri, EMA

3.30 – 4.00 pm
Coffee break

4.00 – 4.45 pm
The role of the new PRAC
Ulrich Hagemann, ISoP

4.45 – 5.00
Closing remarks

Day 2: Tuesday 12 June 2012

Welcome to day 2

8.45 – 9.30 am
Introduction to Benefit- and Risk Management and Methodology
Jan Petracek, PharmInvent, Czech Republic

9.30 – 10.15 am
RMP: Safety specification
Elliot Brown, ISoP

10.15 – 11.00 am
Efficacy and effectiveness specification
Jan Petracek, PharmInvent, Czech Republic

11.00 – 11.30 am
Coffee-break

11.30 – 12.15 am
Efficacy and effectiveness follow-up plan
Nicholas Moore, ISoP

12.15 – 1.00 pm
The pharmacovigilance plans
Elliot Brown, ISoP

Lunch
1.00 – 2.00 pm

2.00 – 2.45 pm
Risk Minimisation
Jan Petracek, PharmInvent, Czech Republic

2.45 – 3.30
Benefit optimisation
Jan Petracek, PharmInvent, Czech Republic

3.30 – 4.00
Coffee break

4.00 – 4.45 pm
Outline of benefit- and risk management activities – submissions to Regulatory Agencies
Jan Petracek, PharmInvent, Czech Republic

4.45 – 5.00 pm
Closing remarks