



Principles of Risk Management

ISoP 2010 post conference Training course
Accra, Ghana

7th November 2010 (8.00 am-3.30 pm)

Venue: La Palm Beach Hotel

The tutorial will be held in the colourful and vibrant city of Accra, Ghana.

Risk management lies at the heart of modern pharmacovigilance and is now supported by a strong regulatory framework within the EU and elsewhere. This one-day tutorial will be dedicated to ensuring participants have a robust understanding of today's risk management theory and practice.

Objectives:

- Understand the principles of risk management planning
- Be aware of available methods
- Understand the practical aspects and implications
- Consider the feasibility of risk management outside the ICH regions

Chairpersons: Ms Deirdre McCarthy, Dr Elliot Brown, Prof Saad Shakir

7.30 to 8.00 am Registration

8.00 - 8.10 am

Introduction Course objectives

Elliot Brown, ISoP/Elliot Brown Consulting Ltd, UK

8.10 – 8.40 am

Global risk management guidelines – ICH, FDA, EU

Deirdre McCarthy, ISoP/Quintiles Ireland

8.40 – 9.10 am

Risk Management in the EU

Elliot Brown, ISoP/Elliot Brown Consulting Ltd, UK

9.10 – 9.40 am

Risk Management in the US

Deirdre McCarthy, ISoP/Quintiles Ireland



9.40 – 10.00 am

Tools for Risk Management

Saad Shakir, DSRU, UK

10.00 – 10.30 am

Coffee-break

10.30 – 11.00 am

Tools for Risk Management - continued

Saad Shakir, DSRU, UK

11.00 – 11.30

Risk communication

*Jayesh Pandit, Dept of Pharmacovigilance, Pharmacy and Poisons Board,
Ministry of Health, Kenya*

11.30 - 12 pm

Does your risk management approach work?

Saad Shakir, DSRU, UK

Lunch

Delegates will be given material in their delegates pack to review over lunch in preparation for the workshops

1.00 – 2.00 pm

The African approach to risk management

*Oppel Greeff, School of Medicine, University of Pretoria, South Africa
Delese Mimi Darko, Food and Drugs Board, Ghana*

2.00 – 3.00 pm

Risk Management Planning Workshop (2 case studies for students to work through)

Elliot Brown, Saad Shakir, Oppel Greeff, Jayesh Pandit

3.00 - 3.30

Closing Remarks

Panel

Coffee