

PHARMACOVIGILANCE PLANNING AND RISK MANAGEMENT

1 - 2 December 2011

Solent Hotel, Whiteley, near Fareham

Programme – Thursday 1 December 2011

- 0830 - 0900** **Registration for delegates**
- 0900 - 0915** **Introduction to the course**
Prof Saad Shakir, Director, DSRU
- 0915 - 1015** **Risk Management – the background**
Prof Patrick Waller, Consultant & Honorary Professor, London School of Hygiene & Tropical Medicine
Objectives: To explain the origins and purposes of risk management plans; to discuss how they are used in practice and to outline how risk management is continuing to develop
- 1015 – 1115** **Risk Management – Regulatory perspective**
Dr Suzie Seabroke, Pharmacoepidemiologist, MHRA
Objectives: To outline the different sections of the risk management plan; to discuss the information to be included for each section; to discuss current experience of assessing risk management plans from a regulator's perspective
- 1115 - 1130** **Coffee**
- 1130 - 1230** **Risk Management Plans; not only planning – a perspective from industry**
Dr Glyn Belcher, PV Consultancy Ltd
Objectives: To describe from a company point of view the production and approval of a risk management plan and factors to be considered in implementation of the plan. To discuss updating of risk management plans and reporting of effectiveness of enhanced risk minimisation activities.
- 1230 - 1315** **Developmental Risk Management Plans – The challenges**
Dr Jasna Rakic-Connor, AstraZeneca
- 1315 - 1400** **Lunch**
- 1400 - 1500** **Open forum discussion**
With a case study about the interaction between industry, regulators and Risk Management
Facilitators: Dr Glyn Belcher and Dr Suzie Seabroke
- 1500 - 1600** **Risk Management of OTC medicines**
Dr Margaret Watson, Senior Research Fellow, University of Aberdeen

Objectives: To provide an overview of over-the-counter (OTC) medicines and risk and discuss risk management processes associated with these medicines

1600 - 1615

Tea

1615 - 1715

Discussion with case studies

Facilitators: Prof Saad Shakir and Dr Glyn Belcher

1715

Close of day 1

1900

Evening dinner

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| 0900 - 0915 | Registration for delegates |
| 0915 - 1030 | Researchers' contributions to Risk Management with examples and case studies
Prof Saad Shakir, Director, DSRU |
| 1030 - 1045 | Coffee |
| 1045 – 1130 | Risk Management Plans and the design of post-marketing studies
Dr Deborah Layton, Principal Research Fellow, DSRU
Objectives: To explore the factors important in the design of PE studies used as tools to support RMPs and to introduce delegates to operational research standards that should be considered when conducting PE and PhV research |
| 1130 - 1300 | Case studies on how to design studies for Risk Management
Facilitator: Prof Saad Shakir |
| 1300 - 1400 | Lunch |
| 1400 - 1500 | Methods for Risk Management
Prof Patrick Waller, Consultant & Honorary Professor, London School of Hygiene & Tropical Medicine
Objectives: To review the principal methods available to manage risks associated with medicines and to provide a framework for discussing how these can be better utilised and/or improved. |
| 1500 - 1515 | Tea |
| 1515 - 1645 | Case studies of methods for Risk Management
Facilitators: Prof Saad Shakir and Prof Patrick Waller |
| 1645 | Close of meeting |