

DEVELOP
YOUR SKILLS

IMPROVE YOUR
CAREER

REALISE YOUR
POTENTIAL

EXPAND YOUR
KNOWLEDGE



Drug Safety Research Unit

Pharmacovigilance Planning and Risk Management

Solent Hotel, Whiteley near Fareham

25 – 26 September 2019

Wednesday 25 September

0830 - 0900 **Registration for delegates**

0900 - 0905 **Welcome and introduction to the course**
Lesley Wise, Wise PV & Risk Management Ltd



0905 - 0950 **Risk management in pharmacovigilance – the background**
Miranda Davies, Drug Safety Research Unit



Learning objectives:

- To understand the origins and purposes of risk management plans; to discuss how they are used in practice and how risk management is continuing to develop

0950 - 1045 **Risk Management Planning: an industry perspective**
Muhammad Haris Shaikh, UK PV Services Provider Ltd

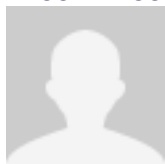


Learning objectives:

- To appreciate, 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.

1045 - 1100 **Coffee**

1100 - 1200 **Risk Management: a regulatory perspective**
Claire Corrigan, Medicines & Healthcare products Regulatory Agency (MHRA)



Learning 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

1200 - 1300 **Open forum discussion: With a case study about the interaction between industry, regulators and Risk Management**
Facilitator: Lesley Wise & Claire Corrigan

1300 - 1400 **Lunch**

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Contact us on EandT@dsru.org or 023 8040 8600

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1400 - 1500 **The life span of a risk management plan**
Bridget King, NDA Regulatory Science Ltd



1500 - 1515 **Tea**

1515 - 1600 **Development risk management plans: A case study in planning for the future**
Dr Lesley Wise, Wise PV & Risk Management Ltd

Learning objectives:

- To understand the strategic approach to risk management planning during drug development

1600 **Close of day one**

1600 - 1700 **Postgraduate candidates' presentations / discussion**
Facilitator: Lesley Wise

1700 **Complimentary networking drinks reception**

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0845 - 0900 **Registration**

0845 - 0900 **Student voice meeting**
Postgraduate students only

0900 - 0905 **Introduction to day 2**
Lesley Wise, Wise PV & Risk Management Ltd



0905 - 1015 **Studies for risk management - researcher's experience and handling challenges**
Prof Saad Shakir, Drug Safety Research Unit



1015 - 1030 **Coffee**

1030 - 1145 **Risk management plans: the design of post-marketing studies**
Presentation: Lesley Wise, Wise PV & Risk Management Ltd
Interactive session: Lesley Wise & Vicki Osborne



Learning objectives:

To understand the factors important in the design of PE studies used as tools to support RMPs and to introduce you to operational research standards that should be considered when conducting PE and PhV research

1145 - 1245 **An overview of risk minimisation and studying its effectiveness**
Prof Saad Shakir, Drug Safety Research Unit

Learning objectives:

- To be aware of 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.

1245 - 1345 **Lunch**

1345 - 1445 **Interactive session on defining and designing risk minimisation measures**
Facilitators: Lesley Wise & Vicki Osborne

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1445 - 1500 Tea

1500 - 1545 **Special cases in risk management**

Valerie Joynson, Medicines & Healthcare products Regulatory Agency (MHRA)



Learning objectives:

- To learn about issues specific to the risk management of vaccines and biologicals and medicines in children.
- To describe particular requirements for the risk management plan and further points to consider in the planning of pharmacovigilance measures.

1545 - 1615 **Question and Answer session**

Led by Lesley Wise

1615 **Close of meeting**

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