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**

Book your place here: https://www.dsru.org/education-training/
Contact us on EandT@dsru.org or 023 8040 8600

Prog draft 8 WEB (RMP 19)
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at
www.dsru.org

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**

Book your place here: https://www.dsru.org/education-training/
Contact us on EandT@dsru.org or 023 8040 8600

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

Thursday 26 September

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

Book your place here: https://www.dsru.org/education-training/
Contact us on EandT@dsru.org or 023 8040 8600

Prog draft 8 WEB (RMP 19)
In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

Browse our full range of courses at
www.dsru.org

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**

Book your place here: https://www.dsru.org/education-training/
Contact us on EandT@dsru.org or 023 8040 8600