

DEVELOP
YOUR SKILLS

IMPROVE YOUR
CAREER

REALISE YOUR
POTENTIAL

EXPAND YOUR
KNOWLEDGE



Drug Safety Research Unit

EU and UK Regulations & Guidelines in Pharmacovigilance

Novotel London West, Hammersmith

15 - 16 March 2023

Wednesday 15 March

0845 – 0900
(GMT)

Registration

0900 - 0915

Introduction to the meeting

0915 - 1015

Pharmacovigilance systems including PV System Master File

1015 - 1030

Discussion

1030 - 1040

Comfort break

1040 – 1140

Quality systems in pharmacovigilance

1140 – 1145

Comfort break

1145 - 1215

Changes to PV regulations in the UK after Brexit

1215 - 1315

Lunch break

1315 - 1415

ADR reporting requirements

1415 - 1420

Comfort break

1420 - 1520

Signal detection and signal investigation

1520 - 1530

Comfort break

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

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In the event of unforeseen circumstances, the DSRU
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1530 - 1630 **Periodic Safety Update Reports / Periodic Benefit Risk Evaluation Reports**

1630 - 1635 **Comfort break**

1635 - 1700 **Question and answer sessions**

1700 **End of day one**

1700 - 1730 **Postgraduate in Pharmacovigilance students only**
Presentations to be given by delegates attending this course as Postgraduate students to
Course Leader

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Thursday 16 March

0845 – 0900 (GMT)	Meeting room open
0900 - 0910	Introduction to day 2
0910 - 0945	Management and updating of new safety information
0945 - 0950	Comfort break
0950- 1050	Compliance and inspections – a UK regulator’s perspective
1050 - 1100	Comfort break
1100 - 1145	Role of EUQPPV and UKQPPV
1145 - 1150	Comfort break
1150 – 1230	Preparing for inspections
1230 - 1245	Discussion and questions
1245 - 1345	Lunch break
1345 - 1415	Licensing and outsourcing agreements including PV requirements for patient support programmes, market research and social media
1415 - 1420	Comfort break

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1420 - 1520 Risk management, post-marketing studies and effectiveness of risk minimisation

1520 - 1530 Comfort break

1530 - 1600 What makes a good PV system? Central organization, affiliate organization, audits and the rest

1600 - 1630 Question and answer session

1630 Close of meeting

1630 - 1645 **Postgraduate in Pharmacovigilance students only**
Student meeting to discuss any questions regarding the post-course assignment

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