



DSRU

Drug Safety Research Unit

REALISE YOUR
POTENTIAL

DEVELOP
YOUR SKILLS

IMPROVE
YOUR CAREER

EXPAND YOUR
KNOWLEDGE

EU and UK Regulations & Guidelines in Pharmacovigilance

Hybrid event: Novotel London West Hotel, London and Online | 12 - 13 March 2025

Wednesday 12 March 2025

0845 - 0900 (GMT) Registration / Meeting room open for delegates to join

0900 - 0915 Introduction to the meeting

0915 - 0945 Changes to PV regulations in the UK after Brexit

0945 - 0955 Comfort break

0955 - 1110 Pharmacovigilance systems including PV System Master File

1110 - 1125 Coffee/Tea break

1125 - 1225 Quality systems in pharmacovigilance

1225 - 1315 Lunch break

1315 - 1415 ADR reporting requirements

1415 - 1430 Coffee/Tea break

Book your place here: www.dsrु.org/education-training

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

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

Prog draft 1 WEB (R&G 25)

In the event of unforeseen circumstances, the DSRU reserves the right to alter the programme, speakers or venue.

1430 - 1530	Signal detection and signal investigation
1530 - 1540	Comfort break
1540 - 1640	Periodic Safety Update Reports / Periodic Benefit Risk Evaluation Reports
1640 - 1650	Question and answer sessions
1650	End of day one
1650 - 1800	Postgraduate in Pharmacovigilance students only Presentations to be given by delegates attending this course as Postgraduate students to the Course Leader.

Thursday 13 March 2025

0845 - 0900 (GMT)	Registration / Meeting room open
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0900 - 0910	Introduction to day 2
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0910 - 0945	Management and updating of new safety information
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0945 - 0950	Comfort break
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0950 - 1050	Compliance and inspections – a UK regulator’s perspective
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1050 - 1105	Coffee/Tea break
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1105 - 1150	Role of EUQPPV and UKQPPV
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1150 - 1200	Comfort break
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1200 - 1240	Preparing for inspections
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1240 - 1250	Discussion and questions
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1250 - 1345	Lunch break
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1345 - 1415	Licensing and outsourcing agreements including PV requirements for patient support programmes, market research and social media
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1415 - 1425	Comfort break
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1425 - 1525	Risk management, post-marketing studies and effectiveness of risk minimisation
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1525 - 1540	Coffee/Tea break
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1540 - 1610	What makes a good PV system? Central organization, affiliate organization, audits and the rest
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1610 - 1630	Question and answer session
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1630	Close of meeting
1630 - 1645	Postgraduate in Pharmacovigilance students only Student Voice meeting to discuss any questions regarding the post-course assignment or postgraduate programme in general.
