

DEVELOP
YOUR SKILLS

IMPROVE YOUR
CAREER

REALISE YOUR
POTENTIAL

EXPAND YOUR
KNOWLEDGE



Drug Safety Research Unit

EU Regulations & Guidelines in Pharmacovigilance

25 – 26 March 2020

Wednesday 25 March

0830 - 0900 **Registration for delegates**

0900 - 0915 **Introduction to the meeting**

0915 – 1015 **Pharmacovigilance systems including PV System Master File**

1015 - 1030 **Discussion**

1030 - 1045 **Coffee**

1045 - 1115 **Licensing and outsourcing agreements**

1115 – 1215 **Quality systems in pharmacovigilance**

1215 - 1315 **Lunch**

1315 – 1415 **ADR reporting requirements**

1415 - 1515 **Signal detection and signal investigation**

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

Prog draft 2 WEB (RG20)
In the event of unforeseen circumstances, the DSRU
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1515 - 1530 Tea

1530 - 1630 Periodic Safety Update Reports / Periodic Benefit Risk Evaluation Reports

1630 - 1700 Question and answer sessions

1700 End of day one

1700 - 1745 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 26 March

0900 - 0910 Registration

0900 - 0910 **Postgraduate in Pharmacovigilance students only**
Student meeting

0910 - 0915 Introduction to day 2

0915 - 1000 Role of QPPV

1000 - 1100 Compliance and inspections

1100 - 1115 Coffee

1115 - 1200 Preparing for inspections

1200 – 1245 Management and updating of new safety information

1245 - 1345 Lunch

1345 – 1445 Risk management, post-marketing studies and effectiveness of risk minimisation

1445 - 1500 Tea

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1500 - 1530 **What difference does Brexit make?**

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**

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