DEVELOP YOUR SKILLS

IMPROVE YOUR CAREER

REALISE YOUR POTENTIAL

EXPAND YOUR KNOWLEDGE

Drug Safety Research Unit

Global Pharmacovigilance Regulatory Requirements: What's new?

Hybrid event: Novotel London West, Hammersmith and Online

14 - 15 June 2023

Wednesday 14 June

0830 – 0845 (BST)	**Registration** **Virtual meeting room open for online delegates to join**
0845 - 0900	**Introduction to the course**
0900 - 1000	**How to use PV system master file to deal with globalised requirements Presentation**
1000 - 1010	**Comfort break**
1010 - 1040	**How to use PV system master file to deal with globalised requirements Practical workshop**
1040 - 1130	**Implementation of clinical trials regulation (what you need to know)**
1130 - 1145	**Coffee break**
1145 - 1245	**Latin American regulations and their impact on pharmacovigilance processes: including Mexico, central America and the Caribbean**
1245 - 1330	**Lunch break**
1330 - 1415	**Global considerations for periodic reports, benefit risk management and risk minimisation and the lifecycle implications**
1415 - 1445	**Can automation help with complying with global regulations**

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

1445 - 1500	**Coffee break**
1500 - 1545	**Global PV inspection readiness**
1600 - 1645	**US FDA regulations for pharmacovigilance**
1645 – 1650	**Comfort break**
1650 - 1715	**Interactive Question & Answer session** Led by Shelley Gandhi
1715	**End of day one**
1720 - 1745	**Session for Postgraduate students only** Meet with the course leader for a discussion on the pre-course reading

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0830 – 0845 (BST)	**Registration** **Virtual meeting room open for online delegates to join**
0845	**Start of day 2**
0845 - 0915	**Australia, New Zealand and the Middle East, an overview**
0915 - 1000	**What's new with EU legislation and what you need to know**
1000 - 1010	**Coffee break**
1010 - 1055	**Differences globally in the SmPC, USPI and CCDS**
1055 - 1155	**Managing pharmacovigilance activities within global licensing agreements**
1155 - 1205	**Comfort break**
1205 - 1235	**Effects of Japanese regulations and guidance's on EU compliance**
1235 - 1315	**Lunch break**
1315 - 1415	**Legal considerations for global compliance**
1415 – 1425	**Comfort break**

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1425 - 1525	**African pharmacovigilance regulations and their impact on global pharmacovigilance processes**
1525 - 1540	**Coffee break**
1540 - 1625	**PV in Asia – Getting ready for the future**
1625 – 1630	**Comfort break**
1630 - 1715	**Global PASS/ PAES implications**
1715 - 1730	**Summing up: the rest of the world**
1730	**Close of meeting**

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