Drug Safety Research Unit

Global Pharmacovigilance Regulatory Requirements: What's new?

10 – 11 June 2020

Wednesday 10 June

0830 - 0900	**Registration for delegates**
0900 - 0915	**Introduction to the course**
0915 - 1000	**Impact of quality systems and PV system master file on pharmacovigilance inspection**
1000 - 1100	**Latin American regulations and their impact on pharmacovigilance processes: including Mexico, central America and the Caribbean**
1100 - 1115	**Coffee**
1115 - 1145	**Australia, New Zealand and the Middle East, an overview**
1145 - 1200	**Discussion**
1200 - 1300	**Managing pharmacovigilance activities within global licensing agreements**
1300 - 1345	**Lunch**
1345 - 1430	**Global considerations for periodic reports, benefit risk management and risk minimisation and the lifecycle implications**
1430 – 1515	**US FDA regulations for pharmacovigilance**
1515 - 1530	**Tea**

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1530 - 1600	**Russian Pharmacovigilance; is Russia moving in the same direction as Europe?**
1600 - 1645	**PV in Asia – Getting ready for the future**
1645 - 1730	**Interactive Question & Answer session**
1730	**End of day one**
1730 - 1815	**Students on the Postgraduate Programme in PV only**

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Thursday 11 June

0845 - 0900	**Registration**
0845 - 0900	**Postgraduate student voice meeting** Postgraduate students only
0900	**Start of day 2**
0900 - 1000	**Legal considerations for global compliance**
1000 - 1045	**Global PASS/ PAES implications**
1045 - 1100	**Coffee**
1100 - 1145	**Differences globally in the SmPC, USPI and CCDS**
1145 - 1230	**Implementation of clinical trials regulation (what you need to know)**
1230 - 1300	**Effects of Japanese regulations and guidances on EU compliance**
1300 - 1345	**Lunch**
1345 - 1430	**What's new with EU legislation and what you need to know**

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1430 - 1530	**African pharmacovigilance regulations and their impact on global pharmacovigilance processes**
1530 - 1545	**Tea**
1545 - 1630	**EU Pharmacovigilance Inspections: recent findings and new challenges**
1630 - 1700	**Summing up: the rest of the world**
1700	**Close of meeting**

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