DSRU
Drug Safety Research Unit

REALISE YOUR POTENTIAL
DEVELOP YOUR SKILLS
IMPROVE YOUR CAREER
EXPAND YOUR KNOWLEDGE

# Global Pharmacovigilance Regulatory Requirements: What's new?

**Online Training | 26 - 27June 2024 | Chairperson & Course Leader: Shelley Ghandi**

## Wednesday 26 June 2024

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| **0830 - 0845 (BST)** | **Meeting room open for delegates to join** |
| **0845 - 0900**  | **Introduction to the course**<br>Shelley Gandhi, NDA Regulatory Science Ltd |
| **0900 - 1000**  | **How to use PV system master file to deal with globalised requirements (Presentation)**<br>Patricia Harding, Eli Lilly and Company Ltd |
| **1000 - 1005** | **Comfort break** |
| **1005 - 1035** | **How to use PV system master file to deal with globalised requirements (Practical workshop)**<br>Patricia Harding, Eli Lilly and Company Ltd |
| **1035 - 1045** | **Comfort break** |
| **1045 - 1135** | **Implementation of clinical trials regulation (what you need to know)**<br>Speaker invited |
| **1135 - 1140** | **Comfort break** |
| **1140 - 1240**  | **Latin American regulations and their impact on pharmacovigilance processes: including Mexico, central America and the Caribbean**<br>Pedro Lima, Sanofi |

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| **1240 - 1330** | **Lunch break** |
| **1330 - 1415**  | **Global considerations for periodic reports, benefit risk management and risk minimisation and the lifecycle implications**<br>Bridget King, BJK Pharma Consulting Ltd |
| **1415 - 1420** | **Comfort break** |
| **1420 - 1505**  | **What's new with EU legislation and what you need to know**<br>Nicholas Rees, Amicus Therapeutics |
| **1505 - 1515** | **Comfort break** |
| **1515 - 1600** | **US FDA regulations for pharmacovigilance**<br>Bethany Van Veen, Perspective Pharmacovigilance |
| **1600 - 1605** | **Comfort break** |
| **1605 - 1705**  | **African pharmacovigilance regulations and their impact on global pharmacovigilance processes**<br>Alex Dodoo, University of Ghana Medical School |
| **1705 - 1715** | **Interactive Question & Answer session**<br>Led by Shelley Gandhi |
| **1715** | **End of day one** |
| **1715 - 1745** | **Postgraduate in Pharmacovigilance students only**<br>Meet with the course leader for a discussion on the pre-course reading |

## Thursday 27 June 2024

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| **0830 - 0845 (BST)** | **Meeting room open** |
| **0845** | **Start of day 2** |
| **0845 - 0915**  | **Australia, New Zealand and the Middle East, an overview**<br>Andrew Bond, CSL |
| **0915 - 0920** | **Comfort break** |
| **0920 - 1020** | **Managing pharmacovigilance activities within global licensing agreements**<br>Andrew Bond, CSL |
| **1020 - 1030** | **Comfort break** |
| **1030 - 1115**  | **Differences globally in the SmPC, USPI and CCDS**<br>Ashwin Shahir, Eli Lilly & Co |
| **1115 - 1120** | **Comfort break** |
| **1120 - 1210**  | **Global PASS/ PAES implications**<br>Prof Saad Shakir, Drug Safety Research Unit |
| **1210 - 1220** | **Comfort break** |
| **1220 - 1250**  | **Effects of Japanese regulations and guidance's on EU compliance**<br>Fabio de Gregorio, Shionogi Europe |
| **1250 - 1345** | **Lunch break** |
| **1345 - 1430**  | **Global PV inspection readiness**<br>Raj Bhogal, Jazz Pharma |
| **1430 - 1435** | **Comfort break** |

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| **1435 - 1535**  | **Legal considerations for global compliance**<br>Lincoln Tsang, Ropes & Gray LLP |
| **1535 - 1545** | **Comfort break** |
| **1545 - 1630** | **PV in Asia – Getting ready for the future**<br>Speaker invited |
| **1630 - 1645**  | **Summing up: the rest of the world**<br>Shelley Gandhi, NDA Regulatory Science Ltd |
| **1645** | **Close of meeting** |
| **1645 - 1700** | **Postgraduate in Pharmacovigilance students only**<br>Student meeting to discuss any questions regarding the post-course assignment |