

**STAYING CURRENT & IN CONTROL IN THE CONSTANTLY  
CHANGING GLOBAL REGULATORY PHARMACOVIGILANCE ENVIRONMENT**

Novotel London West Hotel, Hammersmith, London

**23 - 24 MAY 2012**

**Chair: Sidney Kahn**

**Programme – Wednesday 23 May**

- 0830 - 0900**      **Registration for delegates**
- 0900 - 0915**      **Evolving pharmacovigilance regulations – setting the scene**  
Sidney Kahn, Pharmacovigilance & Risk Management Inc
- 0915 - 1000**      **The EU pharmacovigilance package: summary of  
pharmacovigilance requirements**  
Vicki Edwards, Abbott Laboratories Ltd
- 1000 - 1100**      **The US perspective - how to satisfy the FDA**  
Barton Cobert, BLCMD Associates LLC
- 1100 - 1115**      **Coffee**
- 1115 - 1145**      **The role of the QPPV under the new legislation**  
Vicki Edwards, Abbott Laboratories Ltd
- 1145 - 1215**      **Effects of Japanese regulations and guidances on EU  
compliance**  
Jasna Rakic-Connors, AstraZeneca
- 1215 - 1245**      **Discussion on previous sessions**
- 1245 - 1330**      **Lunch**
- 1330 – 1400**      **Development Safety Update Reports**  
Brian Davis, Consultant in Clinical Trials
- 1400 – 1445**      **The quantum leap from PSUR to Benefit Risk evaluation**  
Val Simmons, Eli Lilly & Co
- 1445 - 1500**      **Tea**

**DSRU** EDUCATION & RESEARCH LIMITED

- 1500 - 1530**      **Impact of new Clinical Trial legislation and update on required legislation in the EU**  
Brian Davis, Consultant in Clinical Trials
- 1530 – 1615**      **FDA regulations, guidances and EU compliance**  
Sidney Kahn, Pharmacovigilance & Risk Management Inc
- 1615 - 1700**      **Benefit Risk management in pharmacovigilance**  
Saad Shakir, Drug Safety Research Unit
- 1700**              **Close of day 1**
- 1900**              **Complimentary evening dinner**

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**Chair: Vicki Edwards**

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- 0845 - 0900**      **Registration for delegates**
- 0900 - 0945**      **Impact of Quality Systems and PV system master file on  
pharmacovigilance inspection**  
Karen Pattenden, Gilead Sciences International Ltd
- 0945 - 1030**      **SmPC, USPI and CCDS as benefit-risk management tools**  
Anne Kehely, Eli Lilly & Co
- 1030 - 1045**      **Coffee**
- 1045 - 1130**      **A European regulatory perspective: Pharmacovigilance  
inspection coordination and the centralised procedure**  
Keith Wibley, VigiReg Consulting Ltd
- 1130 - 1215**      **Managing pharmacovigilance activities within global  
licensing agreements**  
Karen Pattenden, Gilead Sciences International Ltd
- 1215 - 1230**      **Discussion on previous sessions**
- 1230 - 1315**      **Lunch**
- 1315 - 1345**      **PV outsourcing – ensuring compliance in a globalised  
offshore operating environment**  
Sidney Kahn, Pharmacovigilance & Risk Management Inc
- 1345 - 1415**      **Organised data collection schemes and regulatory  
expectations**  
Vicki Edwards, Abbott Laboratories Ltd
- 1415 - 1515**      **Legal considerations for compliance**  
Yuung Yuung Yap, Johnson & Johnson Law Department Europe
- 1515 - 1530**      **Tea**

- 1530 - 1615**      **Post Authorisation Safety Studies / Post Authorisation Efficacy Studies**  
Marianne Keisu, Swedish Orphan Biovitrum AB
- 1615 - 1630**      **Discussion**
- 1630**              **Close of meeting**