Early Bird Registration

2nd Pharmacovigilance 2016

"Ensuring Drug Safety, Ensuring Life"

14th & 15th June 2016 , Strand Palace Hotel, London, UK

Key Speakers:

- ✓ Paul Dolin, Head of Pharmacoepidemiology, **Takeda Pharmaceuticals**
- ✓ Sandip Chaudhari, Senior Director and Clinical Safety and Risk Management, **Pfizer**
- ✓ Dr. Katrin Freund, Project Excellence Manager (Social Media) Drug Safety & Epidemiology, **Novartis Pharma GmbH**
- ✓ Dr. Heike Schoepper, Head Global Drug Safety Regions, **Merck Serono**
- ✓ Dr. Eszter Teleki, Group Director Regulatory Procedure Management and Operation & Regulatory Policy, **Bristol-Myers Squibb**
- ✓ Karina Corware, Associate Safety Risk Lead(ASRL), Safety Surveillance & Risk Management, **Pfizer**
- ✓ Jean Kilgour-Christie, , Director, Deputy EU QPPV Global Pharmacovigilance, **Takeda**
- ✓ Dr. Ruxandra Rogosca, Global Pharmacovigilance Manager, **Omega Pharma**
- ✓ Bawan A. Ahmed, Senior Pharmaceutical Assessor, **Kurdistan Regional Government-Iraq**
- ✓ Dr. Chetan Shatapathy, Director, **Sanjeevani Pharma**
- ✓ Jackie Roberts, Director - Regulatory, PHV and Medical, **Actavis**
- ✓ Robert L Bencher, Director, **Myriad-RBM, Inc.**
- ✓ John Parkinson, Consultant Expert, **Healthcare Data (Former Director CPRD, MHRA)**
- ✓ Sophie Molle, IPM Private Sector – Senior Manager, **World Customs Organization**
- ✓ Professor Saad Shakir, Director, **Drug Safety Research Unit**
- ✓ Sally Shorthose, Partner, UK, **Bird & Bird**
- ✓ Stefan Marcus, Research Strategist, **Creation Healthcare**

Exhibitors

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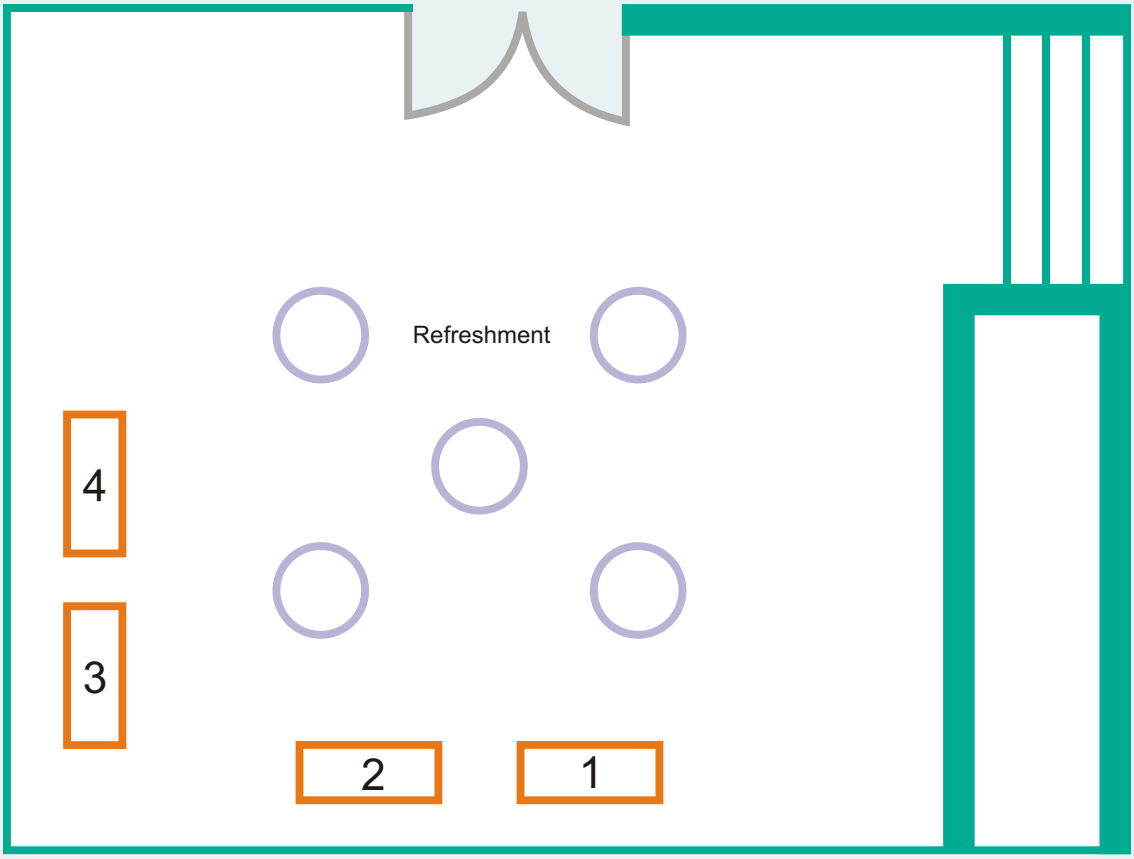
Exhibitors- Floor Plan

Strand Palace Hotel, London

372 Strand, London, WC2R 0JJ



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This year's forum is the place to gain the latest information

- Current regulatory trends in Inspections of the Signal Detection, Post-Authorisation Safety Studies(Pass) And Internal Audit.
- Use of social media in Pharmacovigilance.
- Incorporating Data Mining Technology in Spontaneous Reporting System.
- Strategic Pharmacovigilance pre and post product life cycle.
- Contemporary Regulatory scenario across Europe.
- Outsourcing Pharmacovigilance.

Attendees

VPs, Directors, Heads, Managers, Consultants of:

- Pharmacovigilance
- Pharmacoepidemiology
- Pharmacogenomics,
- Drug/Product Safety
- Drug Development
- Information & Clinical Data Management
- Clinical Pharmacology
- Clinical Safety
- Risk Management
- Quality Assurance
- Patient Safety
- Signal Detection
- Outcomes Research
- Regulatory Affairs &Compliance

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Day One

14th June 2016

08:30 Networking Coffee and Registration

09:00 Chairperson's opening remarks:

✓ **Paul Dolin, Head of Pharmacoepidemiology, Takeda Pharmaceuticals**

09:10 Pharmacovigilance and Drug Safety- Global market overview

09:40 Outsourcing Pharmacovigilance

10:10 **Sponsor Highlight**

10:30 Networking Coffee

11:00 Connection between pharmaceutics and adverse reactions to medications

✓ **Bawan A. Ahmed, Senior Pharmaceutical Assessor, Kurdistan Regional Government-Iraq**

11:30 Post approval signal management

✓ **Karina Corware, Senior Manager, Associate Safety Risk Lead in Safety Surveillance and Risk Management in World Wide Safety Strategy, Pfizer**

12:00 The Utilisation of Biomarkers to Assess Drug Induced Liability

- What testing strategies are being implemented to ensure safe and effective therapies?
- How are biological tools helping reduce attrition rates?
- When will the government bodies require additional testing methods to be implemented?
- Who will pay for these tests and how will they be deployed in clinical practice?

✓ **Robert L Bencher, Director, Myriad-RBM, Inc.**

12:30 Networking Lunch

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13:30 Pharmacovigilance compliance: Considerations of a local affiliate through mergers and acquisitions

✓ **Jackie Roberts, Director – Regulatory, PHV and Medical, Actavis**

14:00 **Sponsor Highlight**

14:20 Current regulatory trends in inspections of Signal Detection, Post-Authorisation Safety Studies (PASS) and internal PV audit:

- Best practice in Signal Detection – mind the gap
- 3rd anniversary of Module VIII (PASS) - impact on companies
- Efficient and effective internal PV audits – be prepared

✓ **Dr. Heike Schoepper, Head Global Drug Safety Regions, Merck Serono**

14:50 Networking Tea

15:20 Effective Patient Safety through Drug Safety

✓ **Dr. Ruxandra Rogosca, Global Pharmacovigilance Manager, Omega Pharma**

15:50 **Panel Discussion:** Pharmacovigilance- Future vision, goals and challenges

✓ **Moderator: Dr. Eszter Teleki, Group Director Regulatory Procedure Management and Operation & Regulatory Policy, Bristol-Myers Squibb**

✓ **Dr. Chetan Shatapathy, Director, Sanjeevani Pharma**

✓ **Dr. Heike Schoepper, Head Global Drug Safety Regions, Merck Serono**

16:30 Chairperson's closing remarks

16:40 Networking Drinks

17:40 End of Day One

Day Two

15th June 2016

08:30 Networking Coffee and Registration

09:00 Chairperson's opening remarks

✓ **Stefan Marcus, Research Strategist, Creation Healthcare**

09:10 Signal Detection Activation

✓ **Sandip Chaudhari, Senior Director and Clinical Safety and Risk Management, Pfizer**

09:40 Safety Data Exchange Agreement (SDEA)

10:10 **Sponsor Highlight**

10:30 Networking Coffee

11:00 A Researcher's perspective of Risk Management Planning

- Fulfilling the need for innovation.
- Understanding the local health services in practice.
- Study design considerations.
- Real-life case examples.

✓ **Prof Saad Shakir, Director, Drug Safety Research Unit**

11:30 Assessing different tools for Risk Management and Risk Minimisation

12:00 The WCO: anti-counterfeiting program and the use of technologies

- The IPM platform: a gateway of information and actionable resources
- IPR trainings and interception operations with customs
- Interoperability of track&trace and authentication technologies for customs agents

✓ **Sophie Molle , IPM Private Sector – Senior Manager, World Customs Organization**

12:20 Networking Lunch

13:20 Social Media: Chances and Challenges for Pharmacovigilance

- Social media networks/platforms: New fields for the pharmaceutical industry
- How to manage AE reporting of information from the digital world
- Using Social Media for collecting AE information

✓ **Dr. Katrin Freund, Project Excellence Manager (Social Media) Drug Safety & Epidemiology, Novartis Pharma GmbH**

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13:50 2nd Care Pharmacovigilance- Drugs and Devices

- Secondary Care- need for Pharmacoepi/vigilance
- Access to secondary care data
- Cardiovascular drugs and devices

✓ **John Parkinson, Consultant Expert, Healthcare Data (Former Director CPRD, MHRA)**

14:20 Case Study- Applying data mining techniques to big observational data for pharmacovigilance

- Provide an introduction to clustering/classification for observational data such as The Health Improvement Network (THIN) database.
- Present our work on signalling ADR risk factors using THIN and discuss what we learned during this work.
- Present a novel framework for identifying candidate ADR risk factors and discuss how such techniques could be used for stratified medicine.
- Discuss potential future applications of state of the art data mining techniques for pharmacovigilance.

14:50 Networking Tea

15:20 Contemporary Regulatory scenario across Europe

✓ **Sally Shorthose, Partner UK, Bird & Bird**

15:50 Chairperson's closing remarks

16:00 End of Conference

HOW TO REGISTER

Online:
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Please use the discount voucher code to avail extra £50 off online registration.

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Early Bird Registration (1st March – 1st May 2016) **£750 + Vat**

Standard Registration (From 2nd May 2016) **£950 + Vat**

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