Pharmacovigilance is now more necessary than ever. With the sharp increase in product recalls and litigation cases in recent years, the need to scrutinise a drugs activity and effect from pre- to post-development has become of paramount importance.
Pharmacovigilance
Day One | Monday 14th March 2011

www.smi-online.co.uk/2011pharmacovigilance.asp • Alternative URL

Rule 1: Registration and coffee
Rule 2: Chairman’s opening remarks
Peter Schiemann, Global Head of Quality Risk Management, Hoffmann-La Roche

Rules and Regulations

2.00 Periodic safety reporting during clinical development and the DSUR
• Purpose and rationale for periodic reporting during clinical development
• Current regulations for periodic reporting during clinical development
• The US IND Annual Report, European Annual Safety Report and Japanese 6-monthly Periodic Report During Development
• ICH E2F and the DSUR
• The challenges for preparing the DSUR
Stewart Geary, Vice President, Deputy Director, Corporate Regulatory Compliance and Quality Assurance Headquarters, Eisai

2.40 Pharmacovigilance inspections involving the MHRA and FDA
• Keeping up with challenging new regulations to ensure compliance
• Effectively implementing new legislation
• Aspiring towards global harmonisation
Patricia Bocciarelli, International Pharmacovigilance Expert Clinical Quality & Compliance, Sanofi-Aventis

3.50 Panel Discussion
"The impact of new legislation on pharmacovigilance activities and the harmonisation of new regulations – An International Perspective"
Stewart Geary, Vice President, Deputy Director, Eisai
Mariska Kooijmans-Coutinho, Vice President Drug Safety and Risk Management, and QPPV, Biogen Idec
Vijay Annapareddy, Senior Pharmacovigilance Specialist, Sanofi-Aventis

4.30 Recent changes to the pharmacovigilance legislation
• Impact of new legislation
• Development safety update reports (ICH E2F)
• New rules on Pharmacovigilance enabling patients and health professionals to work more effectively together
• An increased level of transparency of safety information.
Vijay Annapareddy, Senior Pharmacovigilance Specialist, Sanofi-Aventis

5.10 Chairman’s closing remarks and close of day one

Who should attend:
Delegates at our last year’s Pharmacovigilance conference came from a wide range of Euro-centric locations, and represented a diverse range of current opinions regarding the current drug safety practices. Whilst stimulating debates arose amongst some of the largest international pharmaceutical organisations.

Delegate Breakdown

[Chart showing delegate breakdown by region]

Supported by

[Logos of supporting organizations]
### RISK MANAGEMENT AND SAFETY

#### 9.10 Drug safety in early phase oncology trials - Case studies
- A non-commercial sponsor’s perspective
- Early phase oncology trials in patients
- Recurring themes in case studies:
  - Underlying illness vs. Disease progression vs. Safety signals
  - Dealing with independent expert reviews (IMP quality issue with an impact on safety)
- Internal decision making processes and communication
  
  **Catarina Macedo, Pharmacovigilance Manager, Cancer Research UK**

#### 9.50 Optimizing the clinical safety contribution to the management of manufacturing quality issues
- Approach for medical assessments for product complaints possibly impacting patient’s safety
- Challenges for clinical safety
- Organizational structure to allow high quality medical assessments
- Monitoring the safety database for events which may result from product defects

  **Barbara Donner, Global Head of Safety Science Business Support, Hoffmann-La Roche**

#### 10.30 Risk management – What are we learning?
- Relationship between safety specification and risk management
- Developing strategies to answer relevant questions
- Managing the stakeholders

  **Saad Shakir, Director, Drug Safety Research Unit (DSRU)**

#### 11.40 Managing benefit/risk for mature medicines: A case study
- Mature products’ BR can be challenged after decades on the market
- External researches generating new data and hypotheses
- Poor quality data in house: Case data from spontaneous reporting and ‘historic’ dossiers
- Lack of expertise - Need to reach out to experts in the disease area
- Limited awareness of the needs for continued support of these products in a development organisation
- Resource constraints while health authority expectations and demands are growing

  **Katja Kusche, Global Head of Safety Science for Mature Product, Hoffmann-La Roche**

#### 12.20 Adverse event(s) reporting from a non-clinical safety perspective
- Relationship between safety specification and risk management
- What constitutes the necessity to report Adverse Events / Serious Adverse Events (SAE) / Adverse Drug Reactions (ADR) clinically
- Non-clinical safety assessment in support of clinical safety
- Traditional endpoints in non-clinical safety testing

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#### POST-MARKETING ACTIVITIES

#### 2.00 Pharmacovigilance in promotion: Necessity or argument?
- The legal and deontological requirements for safety info in informational/promotional materials for HCPs (including timelines)
- The challenges of wording and presentation
- The role of the OPVP and the legal responsible for material review: How far do they have to go?
- The DDLs and risk management activities integrated in promotion
- The reaction of European customers (HCP, patients, etc) to safety information

  **Michele Sangelhoer, Medical Information & Pharmacovigilance Manager, Eli Lilly**

#### 3.50 Management of safety data from related research activities
- Registration of clinical activities in a company tracking database
- Minimum requirements for safety data collection
- Vendor contract and the program protocol/description (if applicable) will contain the applicable safety language
- Vendor safety training

  **Heide Cunning, Director, Safety Operations, Ortho-McNeil Janssen (A Johnson and Johnson Company)**

#### 4.30 Improved pharmacovigilance reporting system for effective drug safety management
- The benefits of an adequate IT solution to drug safety management
- The importance of implementing a standardised data management system
- Regulatory requirements

  **Ronald Meyboom, Medical Adviser, World Health Organisation (WHO)**

#### 5.10 Chairman’s closing remarks and close of conference

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### Who should attend:
- Executive Directors, Vice Presidents, Directors, Heads, Managers, Team Leaders of:
  - Patient Recruitment
  - Pharmacovigilance
  - Pharmacoepidemiology
  - Pharmacogenomics
  - Drug/Product Safety
  - Drug Development
  - Clinical Pharmacology
  - Information and Clinical Data Management
  - Clinical Safety
  - PSUR
  - Risk Management
  - Research & Development
  - Quality Assurance

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Want to know how you can get involved? Interested in promoting your pharmaceutical services to this market? Contact Margaret Mugema, SMi Marketing on +44 (0)20 7827 6072, or email: mmugema@smi-online.co.uk
Overview of Workshop
Developing and maintaining an effective system for the monitoring of clinical trial status and activities in affiliate and outsourced organisations is essential. This runs especially true when the number of affiliates and their external partners can number in the hundreds. The aim of this briefing is to address the importance of working with your affiliates in order to ensure optimal pharmacovigilance, and to ensure that processes are in place to enable an oversight by central functions and the EUQPPV. The format of the workshop will be presented as an interactive experience with ideas exchanged, and opportunities will be presented and strategies outlined for overcoming challenges faced when developing Pharmacovigilance activities.

Programme will include:
- Facts and case studies of key Roche affiliates
- Why not knowing what is going on with global affiliates is a vulnerability to the company
- Effective risk management and mitigation

Agenda
8.30 Registration and coffee
8.50 Welcome and introductions
9.00 Introduction into the topic
9.30 Presentation of the Roche initiative to optimise PV in affiliates
10.00 Discussion: The interaction between global safety departments and safety affiliate organisations
10.30 Morning coffee
11.00 Role and responsibility of Local Safety Responsible (LSR)
11.30 Exercise/brain storming session
  - Local study activities - Ways to maintain central oversight
  - Cross functional collaboration at the affiliate - How to link to global drug safety
  - Local risk management activities and related assessments
12.30 Wrap up with summary and questions
13.00 Close of workshop

For more information and updates visit the conference website at [www.smi-online.co.uk/2011pharmacovigilance.asp](http://www.smi-online.co.uk/2011pharmacovigilance.asp)

About the Workshop Leader:
Katja Kusche, MD PhD is an Anaesthesiologist by training with 7 years hospital experience and 13 years in the Pharma industry working on Drug safety. She spent her first 3 years on the affiliate level (HMR Germany), and since 2000 has worked at the Roche Global Safety Risk Management division. Katja is currently the Global Head Mature of Products in Safety Science at Hoffmann-La Roche.
SMi have been involved in the pharmaceutical industry since 1993 and have developed a series of informative and niche events, covering the latest issues and developments surrounding the industry. Events bring together senior industry professionals and serving companies who have a focus on being at the forefront of developments in this area. SMi aim to generate informed and topical discussion through the medium of both conferences and executive briefings. Our pharmaceutical events are research-based and content driven with regular contact with major industry personnel and cover a wide range of industry sectors. For more information, please visit www.smi-online.co.uk/pharma.asp

December 2010
01/02 Cold Chain Distribution

January 2011
17/18 Pharmaceutical Microbiology
19/20 Pre-Filled Syringes
24/25 Paediatric Clinical Trials
26/27 Social Media for Pharmaceuticals
31/01 Biomarkers Summit

February 2011
02/03 Adaptive Designs in Clinical Drug Development
07/08 Pharmaceutical Parallel Trade
21/22 Advances and Progress in Drug Design
23/24 Stem Cells

March 2011
07/08 Imaging in Cancer Drug Development
14/15 Pharmacovigilance
16/17 Superbugs & Superdrugs
23/24 Accelerating patient recruitment & Retention in Clinical Trials
30/31 Controlled Release

April 2011
13/14 Asthma & COPD

May 2011
11/12 Generics, Supergenerics and Patent Strategies
16/17 Clinical Trial Logistics

June 2011
01/02 Pain Therapeutics
27/28 Nanotechnology
27/28 RNAi
29/30 Pharmaceutical Portfolio & Product Lifecycle Management
29/30 KOL Europe (Munich, Germany)

July 2011
06/07 BioBanking
06/07 ADMET
11/12 Freeze Drying
18/19 Clinical Trial Logistics Asia (Singapore)
20/21 Pre-Filled Syringes Asia (Singapore)

All conferences take place in central London, UK – unless indicated otherwise in brackets

ABOUT THE SMI PHARMACEUTICAL TEAM
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PHARMACOVIGILANCE
Conference: Monday 14th & Tuesday 15th March 2011, Cophthorne Tara Hotel, London, UK
Workshop: Wednesday 16th March 2011, London

4 WAYS TO REGISTER
www.smi-online.co.uk/2011pharmacovigilance.asp

FAX your booking form to +44 (0) 870 9090 712
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DELEGATE DETAILS

Please complete fully and clearly in capital letters. Please photocopy for additional delegates.

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Surname:
Job Title:
Department/Division:
Company/Organisation:
Email:
Address:
Post/Zip Code:
Country:
Town/City:
Signature: Date:
I agree to be bound by SMi’s Terms and Conditions of Booking.

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Payment must be made to SMi Group Ltd, and received before the event, by one of the following methods quoting reference 107 and the delegate’s name. Bookings made within 7 days of the event require payment on booking. CD ROMs will not be dispatched until payment has been received.

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