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SMi
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SMi presents its inaugural conference on...

Pharmacovigilance

Systems for Drug Development & Post-Marketing Surveillance

Monday 15th and Tuesday 16th March 2010
Crowne Plaza London - St. James

KEY SPEAKERS INCLUDE:

Andrew P. Marr
Director, Global e-Regulatory Development, Global Regulatory Operations
GlaxoSmithKline

Sian Ratcliffe
Senior Director, Safety and Risk Management Lead
Pfizer

Jacques Wodelet
Head of Quality Intelligence
Merck Serono

Leann Fieldstad
Global Head of Compliance
F. Hoffmann-La Roche

Dominique Brunier
Head of Pharmacovigilance and Quality, Europe
Novartis

Benoit Nauge
Senior Manager, Global Compliance Auditing
Amgen

Ceri Deveney
Director, Pharmacovigilance
MedImmune

KEY TOPICS:
- **Pharmacovigilance system design**
- **Post-marketing drug safety and risk management**
- **The future of pharmacovigilance in the EU**
- **Handling inspections by national health authorities**
- **Development of an internal audit strategy**

Conference highlights include presentations on inspections, risk management, the use of Independent Data Monitoring Committees and managing relationships with regulatory bodies

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PLUS A HALF DAY POST-CONFERENCE WORKSHOP

Wednesday 17th March 2010, Crowne Plaza London - St. James

Pharmacovigilance Inspections: a Practical Approach

Workshop leader: **Colin Knight**, Senior Partner, **TranScrip Partners**

8.30am – 12.30pm

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Pharmacovigilance

Day One | Monday 15th March 2010

www.smi-online.co.uk/

8.30 Registration & Coffee

9.00 **Chairman's opening remarks**
William C. Maier, Vice President, Epidemiology, Drug Safety and Risk Management, **Registrat-Mapi**

9.10 **OPTIMISING PHYSICIANS AND HEALTHCARE PROFESSIONALS IN GLOBAL PHARMACOVIGILANCE**
- A vital colleague accountable for the medical cohesiveness of ICSRs
- Providing clinical judgment to colleagues responsible for case processing activities
- Understanding the product profile and actively supporting safety teams
- Establishing a collaborative environment between safety operations, safety science and clinical science
- Safety physicians role in leading the risk management activities

Leann Fieldstad, Global Head of Compliance, **F. Hoffmann-La Roche**

9.50 **POST-MARKETING DRUG SAFETY AND RISK MANAGEMENT – THE NEW REALITY**
- Regulatory requirements and strategic considerations
- Signal generation – case investigation, trials, spontaneous events, databases, data mining
- Signal investigation – study designs and resources
- Comparison of methods used at different stages of drug development
- Risk management planning – US/EU regulations, tools and strategy

William C. Maier, Vice President, Epidemiology, Drug Safety and Risk Management, **Registrat-Mapi**

10.30 Morning Coffee

11.00 **THE ICH INDIVIDUAL CASE SAFETY REPORT SIGNIFICANT CHANGES AHEAD: WHY AND HOW?**
- Transition of the ICH standard from 'home-grown' to an international standard
- Rationale for the change - collaboration with HL7/ISO/CEN
- Changes anticipated and associated timelines

Andrew P. Marr, Director, Global e-Regulatory Development, Global Regulatory Operations, **GlaxoSmithKline**

11.40 **SAFETY SPECIFICATION AND RISK MANAGEMENT: THE ROLE OF THE RESEARCHER**
- How to develop safety specification and identify issues and missing information
- The role of drug utilisation studies to support risk management
- Pharmacoepidemiological studies
- Monitoring the effectiveness of risk management
- Case studies

Saad Shakir, Director, **The Drug Safety Research Unit**

12.20 Networking Lunch

1.50 **THE FUTURE OF PHARMACOVIGILANCE IN THE EU**
Key issues of European Commission proposal on pharmacovigilance
- The new Pharmacovigilance Risk Assessment Advisory Committee (PRAAC)
- New expedited reporting requirements
- New requirements on PSURs
- Summary of essential information

Elmar Kroth, Head of Pharmacovigilance, **German Medicines Manufacturers' Association**

2.30 **SUCCESSFUL PHARMACOVIGILANCE AND GCP INSPECTIONS**
- Inspections – what and why?
- Effective preparation before the inspection
- Logistics and planning – how to be ready
- During the inspection – how to survive and perform

Ceri Deveney, Director, Pharmacovigilance, **MedImmune**

3.10 Afternoon Tea

3.40 **INTERNAL AUDIT STRATEGY FOR PHARMACOVIGILANCE**
- How to define and maintain the audit universe
- The risk-based approach in practice
- Creating and validating the audit plan
- Implementing the audit plan

Benoit Nauge, Senior Manager, Global Compliance Auditing, **Amgen**

4.20 **DRUG SAFETY: A VIEW FROM A PHARMACOVIGILANCE REGIONAL CENTRE**
- Spontaneous reporting
- Signal follow-up
- Case/non-case approach
- Causality reasoning in pharmacovigilance

Alfonso Carvajal, Professor of Pharmacology, Institute of Pharmacoepidemiology, **University of Valladolid**

5.00 **Chairman's Closing Remarks and Close of Day One**

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Pharmacovigilance

Day Two | Tuesday 16th March 2010

8.30 Re-registration & Coffee

9.00 **Chairman's opening remarks**
Ralph Edwards, Medical Advisor, **Uppsala Monitoring Centre**

9.10 **PHARMACOVIGILANCE INSPECTIONS BY NATIONAL HEALTH AUTHORITIES**
- Challenges for the industry
- Organisation and key tasks
- Need for sustained readiness
- Inspection process and outcome

Dominique Brunier, Head of Pharmacovigilance and Quality, Europe **Novartis**

9.50 **DEVELOPING A PROACTIVE APPROACH TOWARD INSPECTIONS**
- Inspection objectives
- Visual thinking and process mapping
- Categories of individuals
- Inspection readiness
- Technical and financial aspects

Jacques Wodelet, Head of Quality Intelligence, **Merck Serono**

10.30 Morning Coffee

11.00 **QUALITY MANAGEMENT SYSTEMS IN PHARMACOVIGILANCE**
- What system should be in place to support pharmacovigilance legislation and guidelines?
- Essential features of a robust quality management system
- Quality oversight at both a global and local marketing affiliate level
- Internal audits of a pharmacovigilance system

Lucy Hampshire, Quality Consultant, **Eli Lilly**

11.40 **DRUG SAFETY IN THE CONTEXT OF CLINICAL TRIALS**
Independent Data Monitoring Committees and randomised trials in phase IV
- Importance of IDMC make-up and charter
- Roles of IDMCs in phases I/II/III
- Optimising IDMC reports
- Potential for low-cost large randomised drug safety trials in phase IV

Ian Ford, Director, **Robertson Centre for Biostatistics**

12.20 Networking Lunch

1.50 **CASE STUDY: THE DESIGN AND IMPLEMENTATION OF A PHARMACOVIGILANCE SYSTEM IN A MULITNATIONAL EUROPEAN COMPANY**
- Legal background
- Implementation of a pharmacovigilance system in a small European company
- Increasing efficiency in a standardised global pharmacovigilance process
- What worked well
- Opportunities for improvement

Petra Heyen, Vice President, Regulatory Affairs and PharmacoVigilance, **Therabel Pharma**

2.30 **OPTIMISING THE BENEFIT/RISK PROFILE WITH EFFECTIVE RISK MANAGEMENT PLANNING THROUGHOUT DRUG DEVELOPMENT**
- Risk prediction in early development
- Risk identification and mitigation in mid and late development
- Safety review/analysis plans
- Regulatory expectations and interactions, REMS and RMPs

Sian Ratcliffe, Senior Director, Safety and Risk Management Lead, **Pfizer**

3.10 Afternoon Tea

3.40 **FINDING THE WOOD AMONGST THE TREES – HOW TO EVALUATE A POTENTIAL SAFETY SIGNAL**
- Whether a signal is real or not
- Including the Bradford Hill Criteria
- Graphical representations of data
- Making a decision

Nicky Wallis, Medical Director, Oncology, **Pfizer**

4.20 **CIOMS VIII: SIGNALS AND BEYOND**
- Role of Council for Organisations of Medical Sciences
- Impending publication of CIOMS VIII
- Data-mining of longitudinal health care records
- Risks and benefits

Ralph Edwards, Medical Advisor, **Uppsala Monitoring Centre**

5.00 **Chairman's Closing Remarks and Close of Conference**

atively fax your registration to +44 (0)870 9090 712 or call +44 (0)870 9090 711

Who should attend this event?

All those responsible for pharmacovigilance in the following areas:
- Post-marketing
- Regulatory Affairs
- Risk Management
- Quality Assurance
- Compliance

Why you should attend:

- Hear the latest updates on pharmacovigilance systems in the industry
- Explore ways in which you can optimise your own pharmacovigilance activities
- Discuss the potential impact of impending regulatory changes
- Learn more about the relationship between drug safety and pharmacovigilance

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PHARMACEUTICAL FORWARD PLANNER

JANUARY 2010

18/19 Paediatric Clinical Trials
18/19 Models for Key Opinion Leader Management*
20/21 Pre-filled Syringes
27/28 Electronic Laboratory Notebooks

FEBRUARY 2010

01/02 Biomarkers Summit
03/04 Adaptive Designs in Clinical Drug Development
10/11 Parallel Trade
15/16 Stem Cells
22/23 Drug Design

MARCH 2010

10/11 Imaging in Oncology
15/16 Pharmacovigilance
17/18 Superbugs & Superdrugs
24/25 Accelerating Patient Recruitment in Clinical Trials

APRIL 2010

21/22 Asthma & COPD
21/22 Computer Systems Validation
26/27 High Throughput Screening
28/29 Controlled Release

MAY 2010

10/11 Generics, Supergenerics & Patient Strategies
17/18 Clinical Trial Logistics

JUNE 2010

07/08 Pain Therapeutics
14/15 KOL Europe*
17/18 Global Protein Summit
28/29 RNAi, siRNA & miRNA
28/29 Pharmaceutical Portfolio & Product Lifecycle Management

JULY 2010

05/06 Clinical Trials in Cancer
06/07 ADMET
12/13 In Vitro Diagnostics

* These conferences will take place in mainland Europe.

ABOUT THE SMI PHARMACEUTICAL TEAM

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

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HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 17th March 2010
8.30am – 12.30pm
Crowne Plaza London - St. James

Pharmacovigilance Inspections: a Practical Approach

In association with: TranScrip Partners

This is a practical workshop aimed at all personnel involved in PV inspections. It will cover the concept of inspection readiness not just for the PV department but for the entire company; before, during and after the inspection. Topics that will be covered include logistics, communication (both internal and external), document preparation and interview preparation. We will introduce handy tools and processes to aid inspection management.

Workshop Agenda:

- **Introduction to inspection readiness**
- **Tools for managing PV inspections**
- **Inspection do's and don'ts**
- **Interview preparation**

8.30	**Registration & Coffee**
9.00	**Introduction and ice-breaker**
9.30	**Preparing for the inspection**
10.30	**Coffee**
10.50	**Managing the inspection**
11.30	**Exercise**
12.00	**After the inspection**
12.20	**Questions**
12.30	**Close of Workshop**

About the Workshop Leader:

Colin Knight is a pharmacovigilance scientist with over 30 years of varied industry experience in different therapeutic areas including CNS, ophthalmology, wound-healing and pain. At AstraZeneca Colin was responsible for providing pharmacovigilance input into global study teams. More recently, he worked with a global team involved with the development of an in-house safety database. In addition, he has direct experience of converting legacy safety data from several coding dictionaries into the MedDRA dictionary. Colin has a special interest in Data Safety Monitoring Boards (DSMB) and has given external presentations on industry perspectives of DSMB at academic meetings.

PHARMACOVIGILANCE

Conference: Monday 15th and Tuesday 16th March 2010, Crowne Plaza London - St. James Workshops: Wednesday 17th March 2010, London

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