3rd annual event

# world DrugSafety congress EUROPE 2009

15 – 18 September 2009, The Bloomsbury Hotel, London, United Kingdom

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## Hear from

**Dr Amrit Ray**
Vice President, Medical Safety - Global Medical Affairs & Pharmacovigilance
**Bristol-Myers Squibb**

**Dr Salvador García de Quevedo Pérez**
Director European Operations - Global Patient Safety
**Eli Lilly**

**Dr Martin Huber**
Vice President Global Pharmacovigilance and Deputy Chief Medical Officer
**Schering-Plough**

**Prof Philippe Van der Auwera**
Global Head of Safety Risk Management and EU-QPPV
**F-Hoffman La Roche**

**Plus representatives from the MHRA, China's SFDA and Afssaps**

More highlights Page 3 >>
Full programme Page 4 - 6 >>

## Safety assured

## Addressing the key challenges for safety professionals worldwide

### The future of global drug safety
Learn from the thought leaders innovating safety strategy pages 4 and 5>>

### Regulatory round up
Let our regulatory representatives provide you with an insight into the evolving global regulatory environment pages 4 and 5>>

### Don't just sit there!
Interactive & flexible agenda with unique networking opportunities, panel discussions, workshops and multiple presentation streams, pages 4 - 6>>

### Pre & post conference workshops:

**15 September 2009** Making the most of pharmacovigilance inspections

**18 September 2009** Data management and data handling issues for drug safety

All details page 6 >>



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See page 8

> "The presentations and flow of topics was very thorough"
>
> Development Drug Safety Manager, **Norgine**

> "Knowledgeable presenters, experience based presentations, we could see the present and have a flavour of the future of pharmacovigilance"
>
> Head of Pharmacovigilance Inspections, **Afssaps**

> "Excellent speakers and programme / content"
>
> Medical Information & Safety Officer, **Wyeth**

# Drug safety is the major consideration for the drug development community; how prepared are you for the unprecedented challenges?

The 3rd annual *World Drug Safety Congress Europe* is the premier event for safety and pharmacovigilance professionals. The programme hits the perfect balance between high quality scientific content, strategy-led presentations and solutions-based discussions on the most pertinent issues impacting drug safety. It is a must-attend event for those striving for excellence within their pharmacovogilance operations. With four-days worth of specialised sessions developed through in-depth market research with drug safety professionals, the *World Drug Safety Congress Europe 2009* will deliver the safety solutions that ensure safe and effective medicines make it to market - and stay there.

**Safety is a vital element of today's development and post marketing environment, are you making the right safety decisions throughout your product's lifecycle?**

Today's climate has provided pharmaceutical and biotech drug manufacturers with unprecedented challenges. These include greater media interest and an increasing consumer awareness of safety issues. This has resulted in heightened concerns about the safety of marketed drugs and demands from regulators and patient groups that the industry must improve its safety record.

**The *World Drug Safety Congress Europe 2009* is a must-attend event for safety professionals searching for the solutions to these universal safety challenges.**

The congress provides a forum for discussion where top pharmaceutical, biotech and regulatory representatives can address the key challenges and issues faced by the industry. The programme is varied and in-depth and tackles the early detection, thorough analysis and interpretation of adverse drug events. The congress also offers you as a delegate the opportunity to examine how you can develop and deliver a compliant pharmacovigilance and risk management strategy - fundamental in ensuring the long term success of a drug.

The comprehensive agenda comprises of case studies, industry view points, panel sessions, delegate-led discussions and regulatory coverage of global developments.

**The key topics to be addressed are:**

- International drug safety landscape
- Drug safety challenges faced universally
- Global regulatory update
- Integrating regulatory changes into safety operations
- Management of drug safety operations
- Data management
- Electronic submissions
- Post-marketing safety surveillance
- Risk management strategies
- Outsourcing, co-development and partnerships in drug safety
- Pharmacovigilance audits & inspections
- Strategic clinical safety
- Signal detection
- Eudravigilance
- European focused pharmacovigilance
- Benefit / risk analysis

## Industry sectors: pharmaceutical, biotech and CROs

# 8 REASONS

## 8 reasons why you should attend *World Drug Safety Congress Europe 2009*

**Comprehensive agenda**
We have over 20 hours of in-depth sessions, keep track on our website as this number looks set to grow

**Pfizer, Wyeth, Roche, Eli Lilly, Amgen, Novartis, BMS**
Hear industry insights from our top-notch speaker panel which includes top pharmaceutical and biotech representatives!

**Quality content!**
We listen to you and your peers to ensure our programme confronts the topics you want to hear...**and no sales pitches!**

**Regulatory experts!**
Including representatives from **the MHRA, China's SFDA and Afssaps**

**Extensive global reach**
We have industry and regulatory representatives from Europe, America and Asia to give a much needed view of international safety operations

**Pre and post conference** multi speaker workshop days, focused networking sessions, panel discussions, multiple streams and delegate led discussions. **Tailor the packed congress to meet your own information and networking needs**

**Proven track record!** Continuing and evolving from the success of 2007 and 2008 in Europe and America, this event promises to be bigger and better than ever

**Extensive networking opportunities**
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## A-list industry executives

Pharmacovigilance inspections: the OTC experience

**Tracy Crooks,** Head of Pharmacovigilance, **Reckitt Benckiser**

How to develop a drug safety unit in emerging countries

**Dr Daniel Ciriano,** Medical Director, **Roche Argentina**

Pre-approval clinical risk management planning: from molecule to patient. Are we there yet?

**Dr Ayman Ayoub,** Director and Safety Risk Management Lead, Safety and Risk Management, **Pfizer**

PSURs within an evolving approach to Pharmacovigilance

**Dr Enrica Alteri,** Head Medical Safety Group, Global Drug Safety, **Merck-Serono**

Common inspection challenges and industry response: regulators perspective

**Dr Magda Daudin,** Head of Pharmacovigilance Inspections, **Afssaps**

Industry perspective: maintaining pace with the regulators and the evolving industry safety strategies to meet regulatory developments

**Dr Rudi Scheerlinck,** Director Global Medical Safety & Risk Management, **UCB**

Epidemiologic approaches throughout the development lifecycle

**Dr Robert Reynolds,** Vice President, Epidemiology Safety and Risk Management, **Pfizer**

**Your event contact is**
**Karen Williams +44 (0) 207 608 7056**
**kwilliams@healthnetworkcommunications.com**

> "Interesting topics and speakers"
>
> Head of Pharmacovigilance Europe & Regions, **Bayer Schering Pharma**

> "Good – broad range of drug safety topics with depth of discussion"
>
> Group Safety Manager, **AstraZeneca**

**Regulatory update: hear from the MHRA, China's SFDA and Afssaps**

## Day One Wednesday 16 September 2009

**08.00** **Registration & coffee**

### GLOBAL DRUG SAFETY LANDSCAPE

**09.00** **Opening remarks from chairperson**

**09.15** **Next generation pharmacovigilance - finding solutions to the challenges of drug safety**

KEY NOTE

- Critical importance of pharmacovigilance and risk management in successful drug development
- New opportunities for high performance
- Cutting-edge examples of innovation
- New globalisation of pharmacovigilance standards

**Dr Amrit Ray,** Vice President Medical Safety - Global Medical Affairs and Pharmacovigilance, **Bristol-Myers Squibb**

**09.45** **Global safety harmonisation initiatives - International drug safety landscape, an industry overview and update**

KEY NOTE

- Overall objective of the increasing regulatory legislation is to improve patient safety, though details vary substantially between authorities
- Challenges: ensuring global approach to patient safety while complying with local regulations

**Dr Martin Huber,** Vice President Global Pharmacovigilance, Deputy Chief Medical Officer, **Schering-Plough**

**10.15** SPEED NETWORKING **and morning refreshments**

**11.00** **European pharmacovigilance legislation: what does the future hold?**

- Current situation with an ever evolving Volume 9A
- Potential impact of ICH E2F
- EU Commission pharmacovigilance package proposals: high level considerations

**Dr Vicki Edwards,** QPPV, Senior Director European Pharmacovigilance, Global Medical Services, **Abbott Laboratories**

**11.30** **New US pharmacovigilance and risk management**

- FDA post marketing commitments continue to substantially change, spurred on by drug withdrawals and Congressional attention
- FDAAA 2007
- Risk Evaluation and Mitigation Strategy
- Guidance, examples and precedents

**Gerald Faich,** Senior Vice President Epidemiology and Risk Management, **UBC**

**12.00** **Industry perspective: maintaining pace with the regulators and the evolving industry safety strategies to meet regulatory developments**

- Industry response to evolving regulatory framework for European and international drug safety

**Dr Rudi Scheerlinck,** Director Global Medical Safety & Risk Management, **UCB**

**12.30** **Lunch**

### Stream 1: CLINICAL SAFETY STRATEGY

**1.25** **Opening remarks from chair**

**1.30** **Pre-approval clinical risk management planning: from molecule to patients; are we there yet?**
**Dr Ayman Ayoub,** Safety and Risk Management Lead, **Pfizer**

**2.00** **Safety quality risk management in clinical trials**
**Dr Genevieve Lapeyre,** Head of Quality Risk Management Safety, **F. Hoffmann-La Roche**

**2.30** **Management of safety information from clinical trials**
**Dr Nicky Wallis,** Medical Director Oncology, **Pfizer Worldwide Development**

**3.00** **Effective early stage signal detection and management**
**Glyn Belcher,** Vice President, Drug Safety and Risk Management, **Biogen Idec**

**3.30** **Afternoon refreshments**

**4.00** **Integrated risk management throughout the lifecycle: supporting a systematic multidisciplinary benefit/risk approach**

- Safety risk management challenges for pharmaceutical development and commercialisation
- Solutions: organisational, process, methodological and technology considerations
- Proactive safety signal handling, systematic benefit/risk assessment and communicating safety to the public in a society expecting transparency

**Dr Philippe Van der Auwera,** Global Head of Safety Risk Management, EU-QPPV, **F Hoffmann-La Roche**

**4.30** **Benefit/risk assessments: challenges on the road to a more quantitative approach**

- Concepts for benefit/risk assessment
- Requirements for quantity and quality of data from clinical development
- Implication for planning of clinical development and for post-marketing studies

**Dr Jürgen Kübler,** Global Head Integrated Safety & Health Economics Biostatistics, **Novartis**

**5.00** **Epidemiologic approaches throughout the development lifecycle**

- Developments in the use of de novo and electronic database study designs
- How can observational methods be used to provide additional scientific evidence about the safety of medicines?

**Dr Robert Reynolds,** Executive Director, Epidemiology Safety and Risk Management, **Pfizer**

**5.30** **Evening drinks reception**

OR

### Stream 2: POST MARKETING SAFETY STRATEGY

**1.25** **Opening remarks from chair:**
**Dr Sabine Richter,** Vice President, Safety and Risk Management, **PRA International**

**1.30** **Signal management – prioritising, tracking and managing signals**
**Bill Blackwell,** Director Lincoln Safety Group, **Phase Forward**

**2.00** **Evolving PSURs within an evolving approach to Pharmacovigilance**
**Dr Enrica Alteri,** Head Medical Safety Group, Global Drug Safety, **Merck-Serono**

**2.30** **Post-marketing safety surveillance design: choices and implementation**
**Mark Nelson Tyrrell,** Director Risk Management, **PRA International**

**3.00** **Risk management strategies for post authorisation drug safety**
**Dr Ennis H Lee,** Vice President, QPPV Pharma Benefit Risk Management, **Janssen Cilag**

## Day Two Thursday 17 September 2009

**8.00** **Registration & coffee**

**9.00** **Opening remarks from the chairperson**

**9.05** PANEL SESSION **Pharmacovigilance inspections: common industry challenges and the resulting solutions**

**Dr Magda Daudin,** Head of Pharmacovigilance Inspections, **Afssaps**
**Tracy Crooks,** Head of Pharmacovigilance, **Reckitt Benckiser**
**Dr Luis-Felipe Graterol,** Head Drug Surveillance Group Pharma, **Bayer**
**Patricia Bocciarelli,** International Pharmacovigilance Expert Clinical Quality & Compliance, **Sanofi-Aventis**

**9.45** **Pharmacovigilance quality assurance**
- PVQA as a corporate competitive advantage
- Application of quality risk management principles for ensuring an effective pharmacovigilance audit programme
- Creation of PVQA indicators for monitoring status of quality and future auditing needs

**Salvatore Curti,** Global Head Clinical Safety & Pharmacovigilance QA, **UCB**

**10.15** **Morning refreshments**

### SAFETY DATA MANAGEMENT

**10.45** **Eudravigilance: current status of implementation, training programme, upcoming changes and challenges**
- Present status of the system and recent changes
- Upcoming changes including E2B revision, Eudravigilance access policy and public consultation on the proposed changes to the pharmaceutical legislation

**Calin Lungu,** Chief Executive Officer, **Drug Development Consulting Services S.A**

**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

**Dr Andrew Marr,** Topic Leader, **EFPIA**

**11.30** **Electronic-submissions and the associated quality issues**
- Progress with the electronic exchange of adverse drug reaction data between industry and regulators
- Common problems faced by regulators when handling electronic reports

**Mick Foy,** Manager Signal Management Group, Vigilance and Risk Management of Medicines, **MHRA**

**12.00** **Electronic SAE reporting (site2sponsor) in studies using EDC**
- Why integrate SAE reporting into the EDC suite?
- Advantages for sites and for data management
- Architectural options
- Description of an implementation project

**Dr Uwe Barlage,** Project Leader for EDC, **Bayer Vital GmbH**

**12.30** **Lunch**

### DRUG SAFETY IN THE EMERGING MARKETS

**1.30** **Drug safety in Eastern Europe: what's new?**
- Exploring the existing environment and regulatory background to this region with focus on the possibilities given by running safety operations in Eastern Europe

**Monica Rusu,** Director Pharmacovigilance, **Solvay Pharmaceuticals**

**2.00** **How to develop a drug safety unit in emerging countries – South America focus**
- The challenge of post-marketing surveillance in the developing world
- How to interact with regulatory authorities
- Training doctors and pharmacist in safety reporting
- How can drug safety be incorporated into everyday work at the affiliate?

**Dr Daniel Ciriano,** Medical Director, **Roche Argentina**

**2.30** **Drug safety in the emerging markets – China focus**

**Dr Chen Yixin,** Director of Division ADR Monitoring, Center for Drug Reevaluation, **SFDA China**

**3.00** **Afternoon refreshments**

**3.30** **Safety considerations specific to biological products**
- Drug safety in rare genetic diseases
- Review of safety monitoring systems
- Signal detection and analysis, working with small patient numbers in a global environment
- Safety of protein therapies

**Dr Wytske Kingma,** Senior Vice President and Global Head Pharmacovigilance and Medical Information, **Genzyme**

**4.00** **How to organise a pharmacovigilance department at affiliate level, new ways of PV training**
- What activities to deal with
- Inspections: a challenge or a disaster?
- Internal and external training, how to become effective

**Dr Livia Stankovics,** Affliate Head of Pharmacovigilance & Regulatory Medical Affairs, **Sanofi-Aventis**

**4.30** KEY NOTE **What does the future hold for the drug safety industry? Emerging trends and directional analysis**
- Is harmonisation a dream?
- How is the access to large databases (i.e. electronic health dossier) going to influence our understanding of benefit/risk?
- How, what and when to communicate benefit/risk?

**Dr Salvador Garcia de Quevedo Perez,** Director European Operations, Global Patient Safety, **Eli Lilly**

*Hear from drug safety thought leaders*

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# Pre and post-conference workshops

## Tuesday 15 September 2009

### Making the most of pharmacovigilance inspections: a comprehensive guide to preparation, conduct and post-inspection activities

Pharmacovigilance inspections are often seen as a regulatory necessity to be endured rather than enjoyed! However, they can and should be seen as a positive experience and an opportunity to assess your pharmacovigilance system. This multi-speaker seminar day includes presentations by key speakers representing the pharmaceutical industry (prescription and over the counter medicines) and European regulatory authorities. An interactive workshop is included within the program and provides a hands-on session focused on post-inspection activities. The day ends with a panel discussion involving the expert speakers and offers an opportunity to raise your questions.

The day is chaired and the workshop facilitated by two experienced pharmacovigilance consultants, Elaine Clark (Meerkat Alliance Ltd) and Lesley Deane (Lesley Deane Consultancy Ltd)

**AGENDA**

**9.30** **Coffee and registration**

**10.00** **Overview and introduction to safety inspections and audits**
**Chairperson Elaine Clark,** Founder, **Meerkat Alliance Ltd**

**10.10** **Pharmacovigilance inspections in the UK: industry perspective**
**Dr Luis-Felipe Graterol,** Head Drug Surveillance Group Pharma, **Bayer Healthcare**

**10.50** **Morning refreshments**

**11.10** **Pharmacovigilance inspections in the UK: regulatory perspective**
**Joanne Harper,** Pharmacovigilance Inspector, **MHRA**

**11.50** **Common inspection challenges and industry response: regulators perspective**
**Dr Magda Daudin,** Head of Pharmacovigilance Inspections, **Afssaps**

**12.30** **Lunch**

**1.30** **Pharmacovigilance inspections: the OTC experience**
**Tracy Crooks,** Head of Pharmacovigilance, **Reckitt Benckiser**

**2.10** **Pharmacovigilance inspections outside Europe with a focus on FDA and other inspectorate**
**Patricia Bocciarelli,** International Pharmacovigilance Expert - Clinical Quality & Compliance, **Sanofi-Aventis**

**2.50** **Afternoon refreshments**

**3.00** **Hands on interactive session**

**4.00** PANEL SESSION **Panel discussion with contributions from the day's speakers and meeting close**

## Friday 18 September 2009

### Data management and data handling issues for drug safety

This roundtable will focus on a spectrum of topics associated with safety data management in this interactive one day workshop. A number of industry speakers will provide experience led presentations and participate in a Q&A session.

**9.00** **Coffee and registration**

**9.30** **Overview and introduction to safety data management**

**10.00** **E submissions for clinical safety and pharmacovigilance on the global platform**
- What are the international requirements for electronic submissions with a regional focus on Europe, USA and Asia? This session will focus on the regulatory requirements for electronic submissions in the pharmacovigilance system including likely developments of the near future

**11.00** **Signal data management, analysis & reports**
- This session will focus on the overall data handling once a signal is detected from the different perspectives from large and small pharmaceutical manufacturers

**11.30** **Morning refreshments**

**12.00** **Safety coding**
- This session will focus on the processing and coding of adverse events and effects in pharmacovigilance dictionaries

**1.00** **Lunch**

**2.00** **Data management at the clinical level**
- Overview of the regulatory and practical requirements for the industry when undertaking data management during clinical safety stages

**2.30** **Data management at the post marketing stage**
- Overview of the regulatory and practical requirements for the industry when undertaking data management once a drug has gained authorisation and is being marketed

**3.00** **Group discussion, Q&A session and meeting close**

**Confirmed participants to date include**
**Guy Pawson,** Director of E-Submissions, **Genentech**

### The venue

The Bloomsbury Hotel, London
Tucked between bustling Tottenham Court Road, gregarious Covent Garden and creative Clerkenwell, Bloomsbury is an enclave of calm contemplation and bookish reserve, right at the heart of the London metropolis.

# Becoming a sponsor or exhibitor

***A record number of senior personnel from pharmacovigilance have attended this event over the past two years in Europe and the US, and is the leading strategic drug safety event in the life sciences calendar.***

*World Drug Safety Congress Europe* is where people come to look for advice, guidance and support to the key challenges they face. As a CRO or technology provider with solutions to offer, this conference represents an exceptional opportunity to develop new business relationships while continuing to build on existing partnerships.

### Questions to determine your involvement

- Do you offer services and solutions that support the challenges faced in drug safety?
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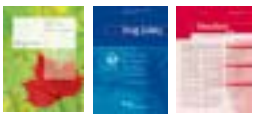

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