4th annual event

# world DrugSafety congress

EUROPE 2010

14 – 17 September 2010, Millennium Gloucester Hotel, London, United Kingdom

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## Hear from

**Dr Susan Graver**
Group Director - Global Pharmacovigilance and Epidemiology
**Bristol-Myers Squibb**

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

**Dr Beverley Forsythe**
Principal Safety Physician R&D, Clinical Development, Patient Safety
**AstraZeneca**

**Dr Larry Johnson**
Executive Director, Global Safety
Head of Therapeutic Area Safety
**Amgen**

**Plus representatives from the MHRA, Afssaps and other key regulatory agencies**

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

## Safety assured

## Addressing the key challenges for safety professionals worldwide

### Hear from the experts shaping the drug safety industry

Engage with the thought leaders innovating safety strategy and driving the industry forward
Learn more about the speaker line up on page 3>>

### Regulatory round up

Get a much needed insight into global regulatory developments and what they mean to you
See the full conference agenda on pages 4 and 5 >>

### Don't just sit there!

Make the conference meet your needs with the interactive & flexible agenda that has unique networking opportunities, panel discussions, Q&A, workshops and multiple streams
For conference workshop information see page 6>>

**Pre & post conference workshops:**

**14 September 2010** Observational studies in post-approval safety: benefits and challenges

**17 September 2000** Designing and implementing an effective risk management system

All details page 6 >>

**Part of the leading international *World Drug Safety Congress* series**

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See page 8

# Where leading experts meet to address the industry's unprecedented safety challenges

The *World Drug Safety Congress Europe 2010* is now in its fourth year and is established as the leading strategic safety event for pharmaceutical professionals worldwide. It targets the major challenges of the industry head on with fresh insight and works to find the much needed solutions to help strengthen global pharmacovigilance.

Drug safety is a critical function within the pharmaceutical industry today, and is having greater prominence throughout the entire lifecycle of a product. The industry is under more scrutiny than ever before as it faces greater media interest and ever increasing consumer awareness as well as growing demands from regulators and patient groups to improve its safety record. The right proactive safety strategy promises to aid R&D efficiency; strengthen risk management; improve risk communication effectiveness; improve patient trust and ease regulatory pressure for the full product lifecycle. Hear fresh considerations as to how this can be achieved at the *World Drug Safety Congress Europe 2010*.

## Top speakers

*The World Drug Safety Congress Europe 2010* boasts an excellent speaker line up – including **Abbott, Amgen, Biogen Idec, Boehringer Ingelheim, BMS, GSK Biologics, Eisai, MHRA, Novartis, Novo Nordisk, Pfizer, Roche, Sandoz** and **UCB** – who better than the industry's leading experts to take us through the ongoing changes and help up prepare for tomorrows safety needs?

## Great networking

There are lots of interesting networking activities, letting you interact with your fellow delegates in a relaxed way, meeting new faces, building on existing contacts and starting those conversations about the issues affecting you.

## Excellent content

The in depth agenda has been developed from industry research – which includes your feedback, surveys and one-on-one interviews – to ensure it's focused on the exact areas of importance and interest to you.


"Good presentations with knowledgeable speakers"

Head of Pharmacovigilance and Safety Iinspections, **Afssaps**

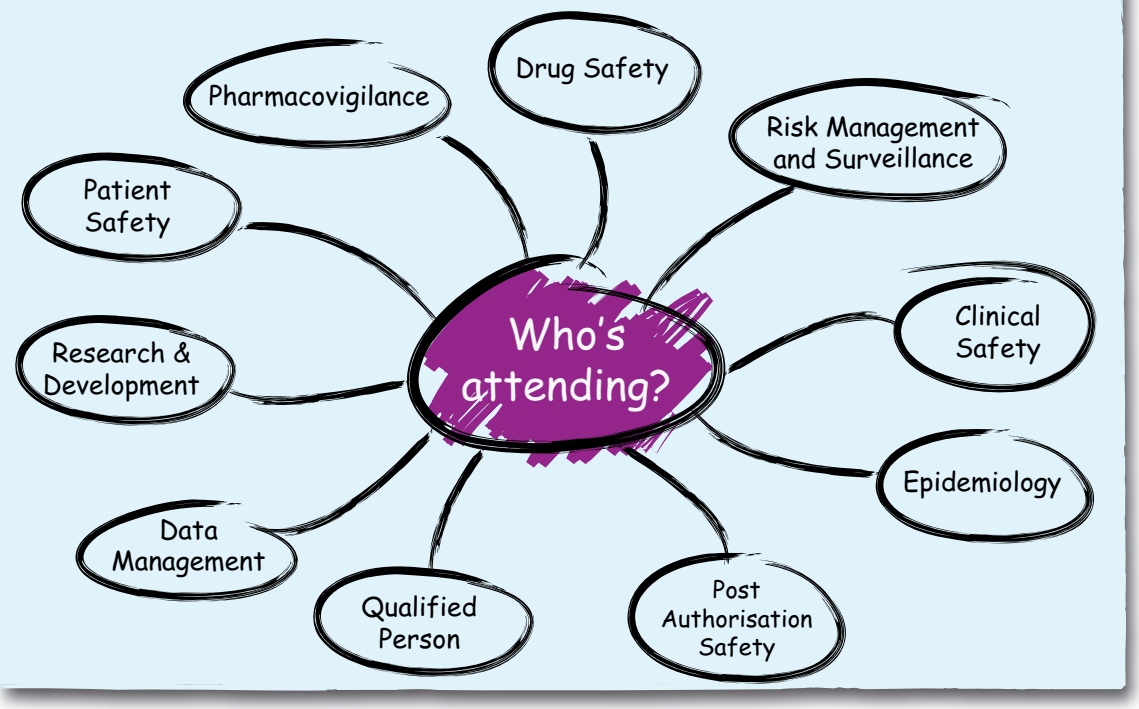
"Excellent line up of speakers … great networking too"

Associate Director, Drug Safety, **Gilead Sciences**

"Thank you for a great congress!"

Associate Director Pharmacovigilance, **Wyeth Europa**

## Industry sectors: pharmaceutical, biotech and CROs



# 8 REASONS

## 8 reasons why you should attend *World Drug Safety Congress Europe 2010*

**First rate speaker panel** Including Amgen, Biogen Idec, Boehringer Ingelheim, GSK Biologics, Eisai, MHRA, Novartis, Novo Nordisk, Pfizer, Roche, UCB and many more

**Over 75% new speakers** New industry insights and fresh perspectives

**Packed agenda** 30 sessions, multiple streams, panel sessions and workshop options. Tailor the congress to meet your own information and networking needs

**Proven track record!** Following the successes of 2007, 2008 and 2009 in Europe and America, this event promises to be bigger and better than ever

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

**Extensive networking opportunities** Make contact, plan who to meet and arrange meetings prior to the conference, take part in multiple networking sessions, continue and build those relationships following the event

**More case studies** Hear the good, bad and ugly real world experiences from the industry and utilise these to strengthen your own safety strategy

**Quality content** Addressing the key topics that you have asked to hear

## The Health Network difference

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- meet and make contacts
- become inspired and reenergised

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## A-list industry executives

European pharmacovigilance legislation: what does the future hold?

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

How to strengthen pharmacovigilance: a present-time strategic approach

**Doris I Stenver,** Chief Medical Officer, **Danish Medicines Agency**

Regulatory update on drug safety in Asia

**Stewart Geary,** Deputy Director, Corporate Regulatory Compliance and Quality Assurance Headquarters, **Eisai**

REMS legislation, guidance and practical experiences

**Dr Craig Hartford,** Executive Director, SRM/RMS Primary Care BU, **Pfizer**

How to collaborate as a QPPV with the EU affiliates

**Dr Ute Hoeffner,** EU QPPV, **Novartis Consumer Health GmbH**

Pharmacovigilance in the local affiliates: the regional PV management concept

**Dr Monica Rusu,** Director Pharmacovigilance, **Abbott Products GmbH**

The evolving role of social media and web based AE reporting in pharmacovigilance; is it the future?

**Michael Ibara,** Head of Pharmacovigilance Information Management, **Pfizer**

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

> "Excellent, the quality of the speakers and expertise was really high"
>
> Group Head – Global Drug Safety, **Merck-Serono**

> "Great selection of speakers & presentations, very informative, good spread of views from industry and agency – I really enjoyed the meeting!"
>
> Head of Pharmacovigilance, **Reckitt Benckiser**

**Hear from key regulatory agencies**

## Day One Wednesday 15 September 2010

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

### KEYNOTE GLOBAL DRUG SAFETY LANDSCAPE

**9.00** **Chairperson's opening remarks**

**9.15** **How to strengthen pharmacovigilance: a present-time strategic approach**
- Societal trends significantly impacting pharmacovigilance
- Interrelations between national and EU agencies

**Doris I Stenver,** Chief Medical Officer, **Danish Medicines Agency**

**9.45** **USA regulatory developments from a safety perspective**
- Impact of FDAAA on pharmacovigilance
- Post-marketing safety commitments
- REMS implications for postmarketing studies

**Dr Larry Johnson,** Executive Director, Global Safety Head of Therapeutic Area Safety, **Amgen**

**10.15** **Regulatory update on drug safety in Asia**
- Developments in drug safety focusing on Japan, China, Taiwan, Korea and India
- Risk Management Plans in Asia
- Safety reporting requirements in Asia

**Dr Stewart Geary,** Deputy Director, Corporate Regulatory Compliance and Quality Assurance Headquarters, **Eisai Japan**

**10.45** SPEED NETWORKING **and morning refreshments**

### Stream 1: PRE CLINICAL & CLINICAL SAFETY STRATEGY

**11.40** **Opening remarks from Sabine Richter,** Vice President, Safety and Risk Management, **PRA International**

**11.45** **Safety signal detection and assessment: key benefits of interactive graphical data exploration**
**Dr Michael Merz,** Preclinical Safety, Translational Sciences Head Safety Networks, **Novartis**

**12.15** **The benefits of early phase drug safety management**
**Dr Jonathan Deutsch,** Safety Science Leader, Director Pharma Development Safety, Licensing and Early Development, **Hoffmann-La Roche**

**12.45** **Optimising safety data collection and analysis in the premarketing setting**
**Pascale Pellet,** Project Leader, Medical Safety Operations, Drug Safety & Epidemiology, **Novartis Pharmaceuticals AG**

**1.15** **Lunch**

**2.15** **Clinical safety data reporting criteria**
**Dr Adrian Hsing,** Senior Director Clinical Data Management, **Gilead**

**2.45** **The clinical regulatory environment: meeting the challenge of global compliance**
**Angelika Schneider,** Director of Drug Safety Centre, Europe, Asia-Pacific, **PRA International**

**3.15** **Analysis of clinical trial safety data**
**Dr Glyn Belcher,** Vice President Drug Safety and Risk Management, **Biogen Idec**

**3.45** **Afternoon refreshments**

**4.15** **Strategic and operational transition between pre and post-authorisation safety in the EU**
**Dr Veronique Basch,** Executive Director, Safety Europe, **UBC**

### PHARMACOVIGILANCE INSPECTIONS

**4.45** **Compliance and inspections pharmacovigilance: an industry perspective**
**Dr Noha Kassem,** Head of Quality for Pharmacovigilance in Europe, Middle East and Asia Pacific, **Eli Lilly**

**5.15** **The regulator's view: standard inspection processes, common industry challenges, hints and tips**
**Emmanuelle Pines,** Pharmacovigilance Inspector, **Afssaps**

**OR**

### Stream 2: SAFETY DATA MANAGEMENT

**11.40** **Opening remarks from Kostas Kidos,** Vice President Product Strategy, Pharmacovigilance & Risk Management, **Oracle Health Sciences Global Business Unit**

**11.45** **Safety data management: quality of data**
**Dieter Konrad,** Senior Consultant Medical Information Systems, **Boehringer Ingelheim**

**12.15** **Challenges faced by signal management systems - what do you need to have in place?**
**Shelley Ghandi,** Unit Manager-Signal Management Group, Vigilance & Risk Management of Medicines, **MHRA**

**12.45** **Pharmacoepidemiology with a vaccine: a case study of RotaTeq**
**John Seeger,** Chief Scientist, **i3 Drug Safety**

**1.15** **Lunch**

**2.15** **Overcome challenges in pharmacovigilance quality assurance concerning safety documentation: data driven auditing strategies**
**Celestina Arrigo,** Senior Director, Pharmacovigilance & Affiliate Quality Services, **UCB**

**2.45** **Signal characterization and evaluation: methods and best practices for prioritisation, analysis and documentation of safety signals**
**Robbert van Manen,** Senior Consultant, **Phase Forward Lincoln Safety Group**

**3.15** **The changing landscape of PV: comprehensive risk management as a key prerequisite for product stewardship**
**Kostas Kidos,** Vice President Product Strategy, Pharmacovigilance & Risk Management, **Oracle Health Sciences Global Business Unit**

**3.45** **Afternoon refreshments**

### POST MARKETING SAFETY STRATEGY

**4.15** **Observational pharmacovigilance and the Sentinel/EU-ADR projects**
**Dr James Higginson,** Safety Surveillance Adviser, **Novo Nordisk**

**4.45** **REMS legislation, guidance and practical experiences**
**Dr Craig Hartford,** Executive Director, SRM/RMS Primary Care BU, **Pfizer**

**5.15** **The DSUR: where do we stand?**
**Dr Phil Eichorn,** Senior Director, Worldwide Safety Strategy, **Pfizer**

**5.45** **Evening drinks reception Join your peers and relax after a busy conference day**

# Day Two Thursday 16 September 2010

## EUROPEAN SAFETY LEGISLATION

**9.00 Chairperson's opening remarks**

**9.05 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**

**9.35 How to collaborate as a QPPV with the EU affiliates**
- Gaining oversight: SOPs / training, ICSR / PSUR submission and KPI data
- Exchange of information: emerging safety concerns, HA requests and changes In legislation
- Delegating responsibilities: relationship local country drug safety responsible / QPPV PVAs

**Dr Ute Hoeffner,** EU QPPV, **Novartis Consumer Health GmbH**

## RISK MANAGEMENT

**10.05 Supporting comparative benefit/risk decision making by patients and their treating physician**
- Current official information (labels & others) are proven to be inefficient and internet has become the main source of information mainly through private unofficial sites
- Comparative benefit/risk assessment in pharma and Health Authorities: forward thinking
- How to communicate effectively to patients and physicians

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

**10.35 Morning refreshments**

## SIGNAL DETECTION AND REPORTING

**11.00 Meeting the regulatory requirements and recent developments for signal detection and AE reporting**
- Current regulations pertaining to AE reporting
- Ensuring your safety operations are aligned with regulatory requirements

**Dr Beverley Forsythe,** Principal Safety Physician R&D, Clinical Development, Patient Safety, **AstraZeneca**

**11.30 Managing and processing detected signals**
- Strategies to enhance signal management: data entry, review, analysis and reporting

**Dr Irina Bogatyreva,** Global Safety Physician, Associate Director Global Clinical Safety & Pharmacovigilance, **UCB**

## DRUG SAFETY BEST PRACTICE

**12.00 New era of safety risk planning**
- Changing regulatory landscape
- Initiatives undertaken by health authorities
- Pharma infrastructure required to meet the challenge
- The future of safety risk management

**Dr Susan Graver,** Group Director Quality Standards and Training, Global Pharmacovigilance and Epidemiology, **Bristol-Myers Squibb**

**12.30 Pharmacovigilance in the local affiliates: the regional PV management concept**
- Particularities of different PV systems and requirements in countries worldwide
- Management of de-centralised PV activties
- Monitoring and maintaining compliance

**Dr Monica Rusu,** Director Pharmacovigilance, **Abbott Products GmbH**

**1.00 Lunch**

**2.00 The evolving role of social media and web based AE reporting in pharmacovigilance; is it the future?**
- Pharma's current use of social media
- How can social media be successfully incorporated into a drug safety strategy and what are the challenges?

**Michael Ibara,** Head of Pharmacovigilance Information Management, **Pfizer**

**2.30 AS03 adjuvanted vaccines: safety perspective**
- AS03 Mechanism of action
- AS03 Safety data

**Dr Fernanda Tavares Da Silva,** Senior Manager Safety, **GSK Biologics**

**3.00 Understanding the needs for a proactive pharmacovigilance in a global environment**
- Adaptive pharmacovigilance strategy to increasing regulatory demands
- Using technology to optimize effectiveness
- Challenges and solution from a small company perspective

**Dr Camelia Dumitrescu,** Senior Director, Drug Safety Physician, **Actelion Pharmaceuticals US**

**3.30 Differences in pharmacovigilance activities and responsibilities between originator and generic companies**
- Are there differences at all and if so in which areas?
- The safety challenges faced by generics and biosimilar medicines

**Dr Gernot Schreiber,** Head Global Pharmacovigilance & Clinical Safety and EU Qualified Person for Pharmacovigilance, **Sandoz International GmbH**

**4.30 Close of conference and afternoon refreshments**

*Hear from drug safety thought leaders*

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### The venue

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# Pre and post-conference workshops

## Tuesday 14 September 2010

### Observational Studies in Post-Approval Safety: Benefits and Challenges

This workshop will explore critical issues associated with prospective observational research as the basis for post-approval safety and other assessments. Discussions will address strategic planning, study design, statistical methods, concerns, risk management, epidemiology, and operational planning. There will be an interactive group exercise highlighting the multiple perspectives essential for effective post-approval observational study design and operational implementation.

**8.30** **Registration & coffee**

**9.00** **Introduction**

**9.15** **Overview of prospective observational research for post-approval safety**
- Benefits and challenges

**9.45** **Effective research design for assessing post-approval safety**

**10.30** **Regulatory perspective: The importance of well-designed observational studies**

**11.15** **Morning refreshments**

**11.30** **Pharma perspective**
- Addressing safety and other critical post-approval considerations

**12.15** **Statistical issues in observational research**
- What can we say?

**12.30** **The use of technology in observational research**

**1.15** **Lunch**

**2.00** **Panel discussion and questions**

**3.00** **Afternoon refeshments**

**3.15** **Interactive exercise: Designing and operationally planning a post-approval study**

**5.00** **Closing discussion**

**Your workshop leader**

**Jeff Trotter,** Executive Vice President - Phase IV Development, **PharmaNet**
Jeff Trotter has enjoyed a varied career in the healthcare industry spanning the past 25 years. As an entrepreneur, researcher, consultant, and industry leader, Jeff has been a pioneer in the evolving health economics and outcomes research community. Jeff recently joined PharmaNet Development Group and provides leadership for the company's Phase IV operations and its global expansion. Jeff is the author of a popular on-going industry survey on observational research.

**Confirmed contributors to date include:**
**Dr Amy Sing,** Associate Group Director-Post Marketing, **Genentech**
**Patrick Chassaigne,** Director, Late Phase Solutions, **Medidata**

## Friday 17 September 2010

### Designing and implementing an effective risk management system

A risk management system is a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products. This interactive workshop will provide an in-depth review of the steps, stages, challenges involved and factors to be considered in designing and implementing an effective risk management system.

**08.30** **Registration and coffee**

**09.00** **Risk Management Plans overview**
- What are RMP's?
- International regulatory requirements: including EU, USA, Japan, Canada

**11.00** **Morning refreshments**

**11.15** **Designing and implementing an effective EU RMP for a new active substance**
- RMP is a multifunctional document – who should be involved?
- Generating and assessing safety data
- Risks, potential risks and missing information

**12.15** **Lunch**

**1.15** **Designing and implementing an effective EU RMP for a marketed product – significant change in marketing authorisation or new safety concern?**
- Multiple indications, significant off label use and combination products

**2.15** **Afternoon refreshments**

**2.30** **The role of epidemiology**
- Epidemiology of disease indication, important co-morbidities and AEs
- Additional information gathering

**3.15** **Methods for risk minimisation**
- Enhanced communication and education
- Access control
- Monitoring and assessing effectiveness

**3.45** **Group discussion, Q&A, and wrap up**

**Your workshop leader**

**Dr Joy Chukwujindu,** Director, **Crown Drug Safety & Crown Consultants**
Dr Joy has spent over 20 years in the pharmaceutical industry in a variety of pharmacoepidemiology, pharmacovigilance and safety risk management roles within pharmaceutical companies and CROs. Crown Consultants provides drug safety services to pharmaceutical companies, one-to-one mentoring and small group training.

**Confirmed contributors to date include:**
**Dr Nadia Foskett,** Global Head of Epidemiology for CNS, Global PDB Epidemiology-PRO, **Roche Products**

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The *World Drug Safety Congress Europe* is now in its fourth year! It is widely recognised as Europe's leading strategic drug safety event and after the excellent feedback from 2009 we expect the conference to grow this year. Position yourself 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.

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