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# world DrugSafety congress

AMERICAS 2010

20 - 23 April 2010, The Westin Grand, Washington DC, United States

## Hear from



**Dr Martin Huber**

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



**Dr Jose Vega**

Vice President Global Safety  
**Amgen**



**Dr Philippe Van der Auwera**

Global Head of Safety Risk  
Management, EU-QPPV  
**F Hoffmann-La Roche**



**Dr Valerie Perentesis**

Executive Director,  
Operations & External Affairs,  
Global Pharmacovigilance and  
Epidemiology  
**Bristol-Myers Squibb**

## Plus the FDA!

More highlights Page 3 >>  
Full programme Pages 4 - 5 >>

## Safety assured



## Addressing the key challenges for safety professionals worldwide

**Drug safety strategy update** including a global regulatory round up, pre and post marketing safety strategy, risk management, data management, inspections, drug safety infrastructure considerations and much more [pages 4 & 5 >>](#)

**Meet the experts shaping the drug safety environment** including global regulators, industry-leading experts and thought leaders [page 3 >>](#)

**Don't just sit there!** Interactive & flexible agenda, unique networking opportunities, panel discussions, Q&A, workshops and multiple streams [page 6 >>](#)

### Pre & post conference workshops:

**20 April 2010** Designing and implementing a computerized pharmacovigilance database system

**23 April 2010** Effective risk management for a sound safety strategy

All details [page 6 >>](#)

Speaker line up – more details	<a href="#">page 3</a>
Full conference programme	<a href="#">pages 4 – 5</a>
Pre and post workshops	<a href="#">page 6</a>
All booking offers & options	<a href="#">back page</a>

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delivery and  
interaction”

Director Global  
Pharmacovigilance,  
**Bayer Healthcare**

“The speakers  
were good,  
with excellent  
presentations  
and useful  
information”

Director of Drug  
Safety Management,  
**Shanghai Roche**

“Excellent –  
The best PV  
programme  
this year”

Senior Director,  
Safety & Risk  
Management,  
**Pfizer**

## How prepared are you for the current unprecedented drug safety challenges?

The annual *World Drug Safety Congress Americas 2010* is back, following an impressive launch in 2009, and it promises to be even bigger and better than before.

Safety is a critical element for the entire lifecycle of a drug. The right safety strategy promises to aid R&D efficiency; strengthen risk management functions; ease the pressure of meeting regulatory demands; address post marketing safety requirements and improve safety communication & patient trust. This congress provides the perfect platform for you to examine how you can make and fulfil the right safety strategy; a fundamental decision to ensuring the long term success of a drug.

### What you asked from us:

- ☒ Huge speaker panel of top industry speakers
- ☒ High level speaker seniority
- ☒ Regulatory experts
- ☒ Strategy led content
- ☒ Plentiful panel discussions
- ☒ In-depth case studies
- ☒ Extensive networking opportunities
- ☒ Solutions-based discussions

### Real experiences from the industry's best

Safety in special populations adds another significant challenge to the drug development process. Using the example of pediatrics, **how have Roche established a successful strategy** to meet regional regulations and ensure risk minimization?

Preparation is well underway for the exponential rise in adverse events expected as the use of H1N1 vaccine rises. **MedImmune discuss how their risk management strategy has been developed** and what the specific drug safety considerations for vaccine products are.

The industry is under enormous strain in the face of increasing regulatory pressure and public focus on safety. How can we move to a more proactive system and strive to overcome the challenges faced daily? **Amgen's Dr Jose Vega brings his unique experience to bear on these critical issues.**

Maintaining pace with the continuously evolving regulatory environment is a time and resource consuming process. **The FDA, Japan's PMDA and global industry representatives explore the most recent regulatory updates** and how to adapt to the changing requirements.

### The key topics to be addressed;

- Global drug safety environment
- Challenges in today's drug safety industry
- International regulatory round up
- Safety data management
- Post-marketing safety strategy
- Clinical safety strategy
- Risk management and minimization strategies
- Pharmacovigilance inspections processes
- The complete safety lifecycle of a drug from early development through to post authorization
- The evolving relationship between social media and drug safety
- Pharmacoevidemiology
- Drug safety in special populations
- Training and infrastructure requirements for drug safety operations

## Industry sectors: pharmaceutical, biotech and CROs



## 8 REASONS


### Why you should attend World Drug Safety Congress Americas 2010:

- 1. Fully packed agenda** Over 30 sessions, multiple streams and workshop options for you to tailor the congress to meet your own information and networking needs
- 2. Top notch speaker panel** Including Amgen, Astellas, Baxter, Bayer, BMS, Genzyme, Medimmune, Novartis, Otsuka, Pfizer, Roche, Schering-Plough, Wyeth and many more
- 3. Quality content** Confronting the topics you want and need to hear
- 4. Over 80% new speakers** New insights and fresh industry strategies
- 5. Wide global reach** We have industry and regulatory representatives from Europe, America and Asia to give a much needed view of international safety operations
- 6. A proven track record** Following an exceptional launch in 2009, this event promises to be bigger and better than ever
- 7. More case studies** Hear the good, the bad and the ugly experiences from the industry's best and utilize them to strengthen your own drug safety strategy
- 8. Extensive networking** Plan who to meet prior to the conference with the 'contact' system, take part in 'speed networking' to meet more people in less time and continue those conversations into the complimentary evening drinks reception

### The Health Network difference

Health Network events create exciting places to...

- interact and grow knowledge
- meet and make contacts
- become inspired and reenergised

use your brain 

## A-list industry experts



Risk management throughout a product's lifecycle: integrated safety business

**Mariette Boerstoeel-Streefland**, Chief Safety Officer, Vice President Global Drug Safety Forest Research Institute, **Forest Laboratories**



Leveraging technology to facilitate an efficient SAE reporting process

**Adrian Hsing**, Senior Director Clinical Data Management, **Gilead Sciences, Inc.**



Driving pharmacovigilance and epidemiology forward: innovation, harmonization and globalization

**Andrew Bate**, Director, Quantitative Epidemiologist, Safety & Risk management, **Pfizer**



Special considerations of safety in oncology patients: elderly patients

**Wei Dong**, Global Head of Epidemiology for Oncology, **Genentech**



Implementation and monitoring of a risk management plan

**Robin Geller**, Director of Risk Management Global Pharmacovigilance, **Baxter Healthcare Corporation**



Optimizing physicians and healthcare professionals in global pharmacovigilance

**Leann Fieldstad**, Global Head Compliance, PDS, **Hoffmann-La Roche**



Managing learning in the pharmacovigilance and compliance environment

**Nancy Grey**, Director, Safety and Risk Management, **Pfizer**



Challenges in developing an efficient, effective AE monitoring system; one small to midsize company's experience

**Eleanor Segal**, Vice President, Medical Safety Officer, **Actelion Pharmaceuticals**



The role of observational epidemiology studies in drug safety evaluation: oncology therapeutic area

**Jerzy Tyczynski**, Director Global Surveillance & Pharmacoepidemiology Global Medical Services GPRMS, **Abbott Laboratories**

Your event contact is **Karen Williams**  
+44 (0) 207 608 7056

kwilliams@  
healthnetworkcommunications.com

“Thank you for a nice meeting.... I met many new people and learned a lot from different perspectives”

Senior Medical Assessor, **Medical Products Agency, Sweden**

“Well presented talks which had the audience interested and engaged”

Head Pharmacovigilance Information Management, Worldwide Development, **Pfizer**

**Exceptional speaker faculty: hear from over 30 of the industry's best**

## Day One Wednesday 21 April 2010

8.00 Registration &amp; coffee

9.00 Opening remarks from the chair

9.10 Proactive drug safety management: successfully meeting the growing global expectations



- Continuous assessment, proactive management and transparent communication of drug risks
- Addressing increasing regulatory and public focus on drug safety
- Enhanced central role of safety scientists in clinical drug development
- Optimizing risk management and risk mitigation

Dr José Vega, Vice President Global Safety, Amgen

9.40 Drug safety considerations for vaccine products

- How has the risk management strategy been developed for the expected exponential rise in AE reports following the increased H1N1 jab use?

Sean Darcy, Director Product Safety, MedImmune

10.10 followed by morning refreshments

## GLOBAL REGULATORY ROUND UP

11.00 Drug safety regulatory developments in the USA

- An update on FDAAA, e-reporting, REMS and the Sentinel Initiative

George Rochester, Acting Director, Division of Biometrics VII, Quantitative Safety and Pharmacoepidemiology Group, FDA

11.20 Drug safety regulatory developments in Europe

- A focus on CIOMS, AE and periodic reporting, RMP, Volume 9a, Eurdravigilance, DSURs and the role of the QPPV

Dominique Delattre, Senior Director Pharmacovigilance and Risk Management Europe, Sanofi Pasteur MSD

11.40 Drug safety regulatory developments in Japan

- Regulations for clinical trials, drug safety reporting and EPPV

Dr Junko Sato, Director for Risk Management, Office of Safety II, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

12.00 Drug safety in Asia

- Regional differences for drug safety in Asia including Korea, Taiwan, China and Japan
- Inspection readiness in Asia with consideration of Volume 9a
- Challenges for DSUR preparation

Shinya Yamauchi, Operating Officer Pharmacovigilance Department, Otsuka Pharmaceuticals

12.20 Further discussion on the global drug safety landscape

In addition to the morning's speakers:

Susan Boynton, Executive Director, Therapeutic Area Head,

Global Regulatory Affairs &amp; Safety, Amgen

Mathias Hukkelhoven, Senior Vice President and Head of

Portfolio Stewardship Board, Novartis

Lourdes Frau, Vice-President and Head, Global Patient Safety, Vertex Pharmaceuticals

12.50 Lunch

STREAM 1:  
RISK MANAGEMENT STRATEGY

1.50 Opening remarks from the chair

Dr Sabine Richter, Vice President Safety &amp; Risk Management, PRA International

2.00 Risk management throughout a product's lifecycle: integrated safety business

Dr Mariette Boerstoel-Streefland, Chief Safety Officer, Vice President Global Drug Safety, Forest Research Institute, Forest Laboratories

2.30 Elements to ensure safe use: a practical guide to FDA REMS components

Mark Nelson Tyrrell, Director, Risk Management, PRA International

3.00 Implementation and monitoring of a risk management plan

Robin Geller, Director of Risk Management Global Pharmacovigilance, Baxter Healthcare Corporation

3.30 Afternoon refreshments

## SAFETY DATA MANAGEMENT

4.00 Data mining to risk management plan: the safety signal sojourn at Genzyme

Meg Richards, Director, Global Patient Safety &amp; Risk Management, Genzyme

4.30 Leveraging technology to facilitate an efficient SAE reporting process

Adrian Hsing, Senior Director Clinical Data Management, Gilead Sciences

5.00 Scope and context for product safety assessment planning

- Potential ways to address drug safety from FDA initiatives
- Quantitative Safety Analysis Plan (QSAP)
- Observational Medical Outcomes Partnership
- New idea for conducting larger, simpler, randomized treatment trials

George Rochester, Acting Director, Division of Biometrics VII, Quantitative Safety and Pharmacoepidemiology Group, FDA

OR

STREAM 2:  
POST MARKETING SAFETY STRATEGY

1.50 Opening remarks from the chair

2.00 Post-marketing signal detection: the role of medical evaluation

Anthony Lassiter, Senior Medical Director, Product Safety and Pharmacovigilance, Astellas Pharma

2.30 Improving post marketing safety NOW: a case study and plan for the future

Michael Ibara, Head of Pharmacovigilance Information Management, Pfizer

3.00 Optimizing physicians and healthcare professionals in global pharmacovigilance

Leann Fieldstad, Global Head Compliance, PDS, Hoffmann-La Roche

3.30 Afternoon refreshments

4.00 Post marketing safety risk management strategies including developing and implementing REMS

United Biosource Corporation

4.30 The use of epidemiology in drug safety strategy

Billy Holden, Head, Risk Benefit Management and Pharmacoepidemiology Pharmacovigilance and Public Health, Vertex Pharmaceuticals

5.30 Drinks reception: join your peers and relax after a busy conference day. To sponsor the drinks reception contact Roope Ghosh on +44 (0) 207 608 7137

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## Day Two Thursday 22 April 2010

## 8.00 Registration &amp; coffee

## 9.00 Opening remarks from the Chair

**Dr Wytse Kingma**, Senior Vice President and Global Head Patient Safety and Risk Management, **Genzyme**

## 9.10 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 Valerie Perentesis**, Executive Director, Operations & External Affairs, Global Pharmacovigilance and Epidemiology, **Bristol-Myers Squibb**

## 9.40 Web based AE reporting; is it the future?

- Pharma's current use of social media
- How can social media be incorporated into a drug's safety strategy and what are the challenges?

**John Mack**, Editor & Publisher, **Pharma Marketing News**

## 10.10 Pharmacovigilance inspections; preparation, implementation and lessons learnt

- Development of a quality management system approach within pharmacovigilance
- Pre-inspection readiness and logistics
- Recommendations for activities during the inspection

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

## 10.40 Morning refreshments

## DRUG SAFETY INFRASTRUCTURE REQUIREMENTS

## 11.10 Challenges in developing an efficient, effective AE monitoring system: one small to midsize company's experience

- Defining your company's needs
- Productive strategies to enhance AE collection: data entry, review, analysis and reporting
- Tips from experience at a company that grew from small to midsize in 10 years

**Eleanor Segal**, Vice President, Medical Safety Officer, **Actelion Pharmaceuticals**

## 11.40 Managing learning in the pharmacovigilance and compliance environment

- Building technical and soft skills curricula
- Training's role in regulatory inspections
- eLearning's impact in compliance training
- Developing customized training through role based scenario's

**Nancy Grey**, Director, Safety and Risk Management, **Pfizer**

## 12.10 The role of observational epidemiology studies in drug safety evaluation: oncology therapeutic area

- How epidemiology contributes to both pre and post-marketing safety evaluation
- Sources of data for observational studies in oncology
- Using population-based cancer registries data in drug safety evaluation: what needs to be done to effectively utilize this type of data?

**Jerzy Tyczynski**, Director Global Surveillance & Pharmacoeconomics Global Medical Services GPRMS, **Abbott Laboratories**

## 12.40 Lunch

## 1.30 Driving pharmacovigilance and epidemiology forward: innovation, harmonization and globalization



- Provide an overview of recent progress in signal detection in EHRs and claims data
- CIOMS VIII working party: harmonization in signal detection
- FNIH's OMOP public private partnership between FDA and industry
- Recent global initiatives and the future impact on safety operations

**Andrew Bate**, Director, Quantitative Epidemiologist, Safety & Risk management, **Pfizer**

## 2.00 Benefit-risk: lessons learned from systematic implementation during phase III development

- Various qualitative and quantitative approaches to benefit / risk
- Advantages of a more explicit and disciplined critical analysis of the data
- Quantitative investigations of decision-making on benefit / risk attributes by patients, prescribers and care-givers

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

## DRUG SAFETY FOR SPECIAL POPULATIONS

## 2.30 Specific safety &amp; pharmacovigilance in children: one more challenge in drug development

- Specific pediatric requirements in EU and US
- EMEA guideline on pediatric pharmacovigilance
- Preclinical and clinical pediatric safety considerations
- PIP (Pediatric Investigation Plan) and pediatric risk minimization

**Klaus Rose**, Head Pediatrics, Medical Science, **Roche**

## 3.00 Special considerations of safety in oncology patients: elderly patients

- Understanding disease epidemiology among cancer patients pertaining to their advanced age, high co-morbidities and complex healthcare systems
- Opportunities and challenges of this special population

**Wei Dong**, Global Head of Epidemiology for Oncology, **Genentech**

## 3.30 Close of conference and afternoon refreshments



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## Pre & post conference workshops

### Pre-conference workshop

Tuesday 20 April 2010

#### Designing and implementing a computerized pharmacovigilance database system

This workshop will provide an overview of the current global regulatory environment for adverse event reporting, the challenges of building an efficient adverse event database system for processing the signals and how it can affect your overall safety strategies. This is an interactive workshop session, featuring plenty of presenter, attendee interface and discussion.

#### Overview

- 8.30 Registration & coffee**
- 9.00 Review of adverse event reporting history and regulations for investigational and licensed products**
  - History and rationale
  - Drugs, biologics and devices
  - Impact of CIOMS and ICH
- 11.00 Morning refreshments**
- 11.15 US and international regulations**
  - USA regulations - 300 series, 600 series, 800 series
  - EMEA regulations – Clinical Trial Directive, Vol. 9a
  - ROW regulations
  - QA impact
- 12.15 Lunch**
- 1.15 Design, implementation and validation of computerized adverse event database systems**
  - Budgets, money and manpower
  - User requirements
  - System requirements
- 3.00 Afternoon refreshments**
- 3.15 Validation**
  - Installation qualification
  - Operational qualification
  - Production qualification
  - Go live

#### Your workshop leader

**Mike Bloh**, Founder, **Drug Safety Net LLC**

Mike is a consultant to the pharmaceutical industry with over 12 years of pharmacovigilance and risk management experience. He has worked with large and small pharmaceutical organizations in resolving pharmacovigilance issues. Mike served as a member of the PhARMA regulatory, safety and nomenclature subcommittees for the biologic industry. He currently is a member of the Drug Information Association Clinical Safety and Pharmacovigilance Special Interest Community. In that role he serves on the international core committee and is communication coordinator.

### Post-conference workshop

Friday 23 April 2010

#### Effective risk management for a sound safety strategy

This one day interactive workshop will provide an in-depth review of risk management and the role it plays throughout the entire life cycle of a drug. The day will address both the local and global regulatory environment and considerations for risk management strategies as well as providing interesting examples or risk management and minimization activities.

#### Overview

- 08.30 Registration and coffee**
- 09.00 Background and overview of recent RM activities**
  - Current approaches to risk assessment
  - Assessing the need for a RMP
  - "Routine" (most products) vs. risk minimization / REMS (selected products)
- 11.00 Morning refreshments**
- 11.15 Global regulatory environment**
  - ICH E2E and Eudra Vol. 9A – contents of the safety specification and the pharmacovigilance plan
  - FDA guidances (risk assessment and minimization)
  - General considerations for developing risk management and risk mitigation plans
- 12.15 Lunch**
- 1.15 Examples of risk management and risk minimization activities**
  - Additional information gathering – e.g. registries, post-approval safety studies, sentinel sites
  - Heightened surveillance
  - Enhanced communication – patients, prescribers
- 2.15 Afternoon refreshments**
- 2.30 Further examples**
  - Enhanced prescriber education
  - Access control
  - Monitoring and assessment of effectiveness
- 3.15 Group discussion, Q&A, and wrap-up**

#### Your workshop leader

**Dr Sidney Kahn**, Founder & President, **Pharmacovigilance & Risk Management Inc.**

Sidney is the Founder and President of Pharmacovigilance & Risk Management, Inc. (www.pvrm.com) providing independent expert advice on all aspects of pharmacovigilance and risk assessment and mitigation to pharmaceutical companies and industry support organizations worldwide.

# Becoming a sponsor or exhibitor

The *World Drug Safety Congress Americas* is now in its 2nd year! The inaugural event in April of 2009 was an unprecedented success with a record number of attendees and strong sponsor presence. After the excellent feedback from both sponsors and delegates alike, we expect the conference to grow in 2010. 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.

## Questions to determine your involvement

- Do you offer services and solutions that support the challenges faced in drug safety?
- Could you benefit from introductions to and time with decision makers in drug safety?

- Are you actively looking for new leads and clients to work with from the drug safety community?

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# world DrugSafety congress

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<b>2 day conference</b> 21 - 22 March 2010	\$1790	\$1990	\$2090	\$2190	<input type="checkbox"/>	

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