Important FDA update

world DrugSafety congress

AMERICAS 2009

21 - 24 April 2009, The Capital Hilton Hotel, Washington DC, United States

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Hear from

Dr Kasia Petchel
Vice President & Global Head
Drug Safety Centre
Roche

Dr Jose Vega
Vice President Global Safety
Amgen

Dr Michael Blum
Vice President, Medical
Pharmacovigilance,
Global Safety Surveillance
and Epidemiology
Wyeth Research

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

Plus representatives from:

Health Canada, FDA, MHRA, MPA and the Society of Japanese Pharmacopia

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

Safety assured

Addressing the key challenges for safety professionals worldwide

The future of drug safety

Consider fresh ideas from our industry leaders driving innovative drug safety strategic changes page 3 to 5 >>

Regulatory round table

Meet regulatory representatives providing insight into evolving global regulatory demands pages 4 and 5 >>

Don't just sit there!

Interactive & flexible agenda with unique networking opportunities, panel discussions, workshops and multiple presentation streams page 6 >>

Pre & post conference workshops:

21 April 2009 Pharmacovigilance Inspections

24 April 2009 Writing and implementing a successful risk management plan

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**

"Knowlegable presenters, experience based presentations, we could see the present and have a flavour of the future of pharmacovigilance"

Head of Pharmacovigilance, **Afssaps**

"Excellent speakers and program / content"

Medical Information & Safety Officer, **Wyeth**

Drug safety; the major consideration for the drug development community

Are you prepared for the unprecedented challenges in global drug safety?

The *World Drug Safety Congress Americas 2009* brings together top pharmaceutical, biotechnology and regulatory representatives in a forum that addresses all the key issues confronting the industry. The in-depth programme covers the detection, analysis and prevention of adverse drug reactions with case studies, industry experiences and global regulatory coverage of developments in the Americas, Europe and Asia. The varied agenda approaches the critical issues that affect the development and execution of drug safety operations, as some of the health industry's top representatives address how to make improvements within current practices and develop safety operations with innovative approaches and revolutionary ideas.

The meeting is set to bridge the gap between international regulatory bodies, industry and academia and will address how to drive pharmacovigilance operations forward into the 21st Century.

The key topics to be addressed;

- Today's international drug safety landscape
- Innovative look at the current drug safety challenges faced universally by the industry
- Global regulatory overview and update of all the key developments and how these are being integrated into safety operations
- The increasing complexities affecting the management of drug safety operations during a products lifecycle

Interact with industry experts in the interactive panel sessions

- Data management and electronic submissions
- Post-marketing safety surveillance techniques and operations
- Risk minimization and management strategies
- Experiences of outsourcing, co-development and partnership building to drive pharmacovigilance and drug safety operations
- Industry and regulatory view point of pharmacovigilance audits & inspections
- In-depth look at strategic clinical safety and the resulting limitations to pre-marketing safety testing

You will hear from industry experts including drug safety specialists from **Novartis, Roche, Pfizer, Eli Lilly, Wyeth, Takeda, Bayer, Bristol-Myers Squibb and Biogen Idec,** who will provide a summary of the best current practices and look at how we can drive safety operations forward. Regulatory representatives including **Health Canada, FDA, MHRA, MPA and the Society of Japanese Pharmacopia** will provide an update on recent international regulatory developments and offer their valued experiences to demonstrate how you can integrate these into your everyday business.

Industry sectors: pharmaceutical, biotech and CROs

8 REASONS

8 reasons why you should attend *World Drug Safety Congress Americas 2009:*

Packed agenda We have over 35 sessions confirmed so far, keep track on our website as this number looks set to grow

Pfizer, Wyeth, Roche, Eli Lilly, Amgen, Novartis, BMS Hear insights into the industry from our top notch speaker panel which includes some of the leading pharmaceutical and biotech representatives!

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

International regulatory experts! FDA, MHRA, Health Canada and MPA

Wide 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 workshops, focused networking sessions, panel discussions, multiple streams, breakfast briefing and a topical evening seminar Tailor the packed congress to meet your own information and networking needs

A proven track record Continued from our success in 2007 and 2008 this event promises to be bigger and better than ever

Extensive networking opportunities Plan and arrange meetings before the conference with 'Contact', take part in 'Speed Networking' to meet more people in less time and continue those conversations into the evening drinks reception

The Health Network difference

Health Network events create exciting places to...

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- meet and make contacts
- become inspired and reenergised

use your brain

A-list industry experts

Drug safety in China from the industry perspective

Dr Rebecca Wang, Head of Drug Safety, Global Pharma Development Center, **Roche China**

The role of epidemiology in pre-approval safety studies

Dr Songlin Xue, Vice President, Global Head, Clinical Epidemiology, **Novartis**

Clinical safety reporting in India

Dr Kamala Rai, Head of Clinical Development, **Novartis**

Pharmacoepidemiology in supporting product safety surveillance activities from a biotech perspective

Dr Sean Zhao, Executive Director Global Safety, **Amgen**

A systems - level solution: the reporting of adverse events and making spontaneous reporting work

Dr Michael Ibara, Head Pharmacovigilance Information Management, Worldwide Development, **Pfizer**

PV sponsor inspections, how to cope with the increasing requirements of the inspection process

Dr Peter Odenthal, Head Global R&D Quality Compliance Management, **Bayer**

Global safety issues in co-development and partnerships

Dr Ashraf Youssef, Associate Medical Director, Pharmacovigilance, **Takeda**

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 when required"
Group Safety Manager, **AstraZeneca**

Hear from the FDA, MHRA, Health Canada and MPA

Day One Wednesday 22 April 2009

GLOBAL DRUG SAFETY LANDSCAPE

8.00 **Registration & coffee**

8.30 **International drug safety landscape; an industry overview and update on recent developments**
- Overview of strategic and regulatory developments impacting drug safety
- How is the industry responding to changes?

Dr Kasia Petchel, Vice President & Global Head Drug Safety Centre, **Roche**

9.00 **Drug safety challenges: addressing the safety issues faced globally by the industry**
- Proactive, detection and assessment of safety signals
- Addressing increasing regulatory and public focus on safety
- Improving benefit-risk definition through a drug lifecycle
- Optimizing risk management planning pre and post-approval

Dr Jose Vega, Vice President Global Safety, **Amgen**

09.30 SPEED NETWORKING **and morning refreshments**

10.30 **Global safety issues in co-development and partnerships**
- Approaches affecting the multiple processes, agreements and models during co-development
- Streamlining perceptions and evaluations of safety signals across departments or regions

Dr Ashraf Youssef, Associate Medical Director, Pharmacovigilance, **Takeda**

11.00 **Assessing the potential benefit risk balance of a drug**
- Assessment of the need for a REMS program early in R&D
- Creating the benefit-risk profile of a drug based on the characteristics of the proposed population of use
- Evaluating minimization of REMS program burden to patients, physicians and other healthcare professionals

Edgar H. Adams, Executive Director, Epidemiology, **Covance Periapproval Services**

11.30 **USA: update of regulatory developments**
- REMS; post-approval studies and clinical trials

Arnold I Friede, FDA Law Attorney, Counsel, **McDermott Will & Emery LLP,** former Associate Chief Counsel, **FDA,** former Senior Corporate Counsel, **Pfizer**

11.45 **Europe: update of regulatory developments**
Dr Qun-Ying Yue, Senior Medical Assessor, **Medical Products Agency, Sweden**

12.00 **Asia: update of regulatory developments**
- Conditional Approval and EPPV systems in Japan
- New direction of safety regulation

Shigeki Tsuda, Executive Director and **Dr Osamu Doi,** Chief Executive, **Society of Japanese Pharmacopoeia**

12.15 **Global challenges faced by industry in addressing regulatory authority expectations how do we move forward?**
- Compliant reporting; rising volumes, varyied reporting requirements; increasing product complexity
- Detection, evaluation, management and communication of signals
- Global risk management plans: tailoring to local needs

Dr Michael Blum, Vice President, Medical Pharmacovigilance, Global Safety Surveillance and Epidemiology, **Wyeth Research**

12.30 PANEL SESSION **International regulatory round up**

1.00 **Lunch**

Stream 1: PRE-APPROVAL SAFETY STRATEGY

2.10 **The complexities in designing a thorough QT study**
Dr Charles Beasley, Chief Scientific Officer of Global Product Safety, **Eli Lilly**

2.40 **Pre-approval safety strategy for gastrointestinal products: from the regulators perspective**
Joyce Korvick, Deputy Director of Gastrointestinal Drugs, **FDA**

3.10 **Clinical safety reporting in India**
Dr Kamala Rai, Head-Clinical Development, **Novartis**

3.40 **The role of epidemiology in pre-approval safety studies**
Dr Songlin Xue, Vice President, Global Head, Clinical Epidemiology, **Novartis**

OR

Stream 2: POST-MARKETING SAFETY STRATEGY

2.10 **Improving the reporting of adverse events and making spontaneous reporting work; a new business model**
Dr Michael Ibara, Head Pharmacovigilance Information Management, Worldwide Development, **Pfizer**

2.40 **Developing and implementing risk evaluation mitigation strategies (REMS)**
Dr Robert Sharrar, Executive Director Epidemiology and Risk Management, **UBC**

3.10 **Pharmacoepidemiology in supporting product safety surveillance activities from a biotech perspective**
Dr Sean Zhao, Executive Director Global Safety, **Amgen**

3.40 **Prospective monitoring beyond spontaneous reporting**
Dr K. Arnold Chan, Senior Scientist, **i3 Drug Safety**

AFTERNOON PLENARY SESSION

4.10 **Afternoon refreshments**

4.40 **The evolving role of pharmacoepidemiology in risk management**
Dr Jingping Mo, Senior Director, Therapeutic Area Group Head Epidemiology, **Pfizer**

5.20 **Challenges of data and safety monitoring boards**
- Impact of DSMBs on regulatory commitment studies and study validity
- Pre-marketing vs. post-marketing studies; different roles and responsibilities for DSMBs

Yola Moride, Associate Professor, **Faculty of Pharmacy Université de Montréal** and immediate Past-President, **International Society of Pharmacoepidemiology (ISPE)**

5.50 **Drinks reception**

6.20 **Evening seminar hosted by BioSoteria: Recognizing and meeting the training needs of your drug safety and pharmacovigilance team with technology-based and other training solutions.** See page 6 for more information >>

Day Two Thursday 23 April 2009

8.00 **Breakfast seminar hosted by Covance Periapproval Services: Delegates will be invited to join in an engaging discussion with a distinguished panel of speakers for breakfast, giving you the opportunity to gain unique and important perspectives on key topics, and discover new and practical insights at what will be a thought provoking and informative session.** See page 6 for more information >>

9.05 **Opening remarks from the chair**
Dr Sabine Richter, Vice President, Safety & Risk Management, **PRA International**

9.15 **The next generation pharmacovigilance – an innovative model to enhance patient safety**
- From concept to reality - an innovative model affecting transformational changes to meet the increasingly challenging regulatory requirements
- Innovation and globalization of pharmacovigilance
- Safety launches
- Transparency in pharmacovigilance data and systems

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

09.45 **Assessment of stakeholders for risk mitigation strategies**
- Steps to identify specific characteristics of all stakeholders
- Assigning level of risk to each stakeholder
- Assigning severity of risk to each stakeholder

Mark Nelson Tyrrell, Director, Risk Management, **PRA International**

10.15 **Implementation and monitoring of a risk management plan**
- Implementation of a risk management plan: integration of pharmacovigilance and risk minimization activities
- Ongoing interaction between the safety organization and the business unit in order to be successful

Dr Robin Gellar, Director of Risk Management, **Baxter**

10.45 **Morning refreshments**

Stream 1: INSPECTIONS & AUDITS

11.15 **Pharmacovigilance sponsor inspections; how to cope with the increasing requirements of the inspection process**
Dr Peter Odenthal, Head Global R&D Quality Compliance Management, **Bayer**

11.45 **Industry experience of pharmacovigilance inspection, preparation, implementation and lessons learnt**
Dr Carmen Bozic, Vice President and Global Head of Drug Safety and Risk Management, **Biogen Idec**

12.15 **US based pharmacovigilance inspections: processes, common industry issues, lessons learnt**
Speaker to be confirmed

12.45 **Lunch**

OR

Stream 2: DATA MANAGEMENT & ELECTRONIC SUBMISSIONS

11.15 **Electronic safety data reporting from a regulators perspective: recent developments and moving forward**
Dr Shelley Ghandi, Strategic Development Coordinator, **MHRA (pending final confirmation)**

11.45 **Practical aspects of electronic safety data standards in pharmacovigilance**
Dr William Gregory, Senior Director, Safety & Risk Management, **Pfizer**

12.15 **The collection and analysis of adequate safety data to meet regulatory guidelines – an FDA perspective**
George Rochester, Lead Mathematical Statistician Quantitative Safety & Pharmacoepidemiology Office of Biostatistics, OTS, CDER, **FDA**

12.45 **Lunch**

AFTERNOON PLENARY SESSION

1.45 **How can we maximize the benefit and the minimize the risk of a drug? Recent developments:**
- Assessing the benefit and the risk from the pre-approval to post-authorization stage in a drug lifecycle

Dr Paul Coplan, Senior Director, Global Safety Surveillance and Epidemiology, **Wyeth**

REGIONAL OVERVIEW OF PHARMACOVIGILANCE OPERATIONS

2.15 **Overview of pharmacovigilance operations and regulatory requirements in Canada**
- Post-market surveillance program and activities
- Modernization of the regulatory framework supporting the post-market surveillance program

Lucye Galand, Scientific Assessment Unit, Marketed Pharmaceuticals & Medical Devices Bureau, **Health Canada**

2.45 **Overview of pharmacovigilance operations and regulatory requirements in South America**
- Specific requirements for working within the region
- Keeping up to date and adhering to regulatory guidelines

Katia Yamasaki, Pharmacovigilance Manager, **Stiefel Laboratories**

3.15 **Drug safety in China from the industry perspective**
- The rapidly evolving role of drug safety in China
- Clinical trial permit application (CTP), new drug approval application (NDA) and post-marketing safety surveillance
- Considerations for imported drugs with approval in the US and EU - China registration studies and phase III global study

Dr Rebecca Wang, Head of Drug Safety, Global Pharma Development Center, **Roche China**

3.45 **Update on the latest drug safety regulatory developments in Asia**
- Pharmacovigilance in Japan: MHLW-mandated safety update report vs. the ICH DSUR
- MHRA / EMEA inspections to Japanese drug companies and the resulting impact these have
- The increased number of spontaneous reports in countries like Korea and China; are safety reporting systems almost in place?

Mr Shinya Yamauchi, Operating Officer Pharmacovigilance Department, **Otsuka Pharmaceutical**

4.15 **Afternoon refreshments and close of conference**

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Pre & Post Conference Workshops

Pre-conference workshop

Tuesday 21 April 2009

Pharmacovigilance inspections

This workshop will consist of two half-day sessions, both highly interactive with attendees being encouraged to ask questions and share experiences.

09.30 **Registration and coffee**

10.00 **Morning session**
Attendees will be divided into small groups and provided with a real life pharmacovigilance inspection scenario. The attendees will then review and present their impression of the amount of preparedness necessary to resolve the issues involved in each scenario.

12.30 **Lunch**

1.30 **Afternoon session**
- Didactic presentations
- What can initiate a pharmacovigilance inspection?
- Where pharmacovigilance areas inspections will focus when they occur
- Pharmacovigilance preparedness training. What to do when an inspection occurs
- Both sessions will applicable to FDA and International inspections; EMEA, Japan

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 having worked with large and small pharmaceutical organizations in resolving pharmacovigilance issues. Mike served as a member of the PhRMA regulatory, safety and nomenclature subcommittees for the biologic industry and is a member of the Drug Information Association Clinical Safety and Pharmacovigilance Special Interest Community.

EVENING SEMINAR

Wednesday 22 April 2009

6:20 **Recognizing and meeting the training needs of your drug safety and pharmacovigilance team with technology-based and other training solutions.**
- Educational issues facing the drug safety community: standardized education, expanding the pool of qualified practitioners to meet growing demand
- How eLearning and other technology-based training strategies can meet training needs
- Clinical safety and pharmacovigilance training: evaluating appropriateness of delivery method, matching training need to time horizon, evaluating off-the-shelf training, and integrating external vendors/contractors in training

Facilitated by BioSoteria™ Drug Safety & Risk Management Specialists

Post-conference workshop

Friday 24 April 2009

Preparation and Implementation of effective risk management plans

This one day interactive workshop will provide an in-depth review of the situations where an RMP may be necessary and how to develop an RMP taking into account differences in global and local regulations and health care delivery.

09.30 **Registration and coffee**

10.00 **Background and overview of recent RM activities**
- Current approaches to risk assessment
- Assessing the need for a RMP
- Routine vs. risk minimization / REMS
- ICH E2E and Eudra Vol. 9A – contents of the safety specification and the pharmacovigilance plan
- FDA guidances (risk assessment and minimization)

13:00 **Lunch**

14:00 **Examples of risk management and risk minimization activities**
- Additional information gathering: registries, post-approval safety studies, sentinel sites
- Heightened surveillance
- Enhanced communication and prescriber education
- Access control
- Monitoring and assessment of effectiveness

15:30 **Group discussion and Q&A**

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.

BREAKFAST BRIEFING

Thursday 23 April 2009

8:00 **Breakfast seminar hosted by Covance Periapproval Services - Delegates will be invited to join in an engaging discussion with a distinguished panel of speakers for breakfast, giving you the opportunity to gain unique and important perspectives on key topics, and discover new and practical insights at what will be a thought provoking and informative session.**
Visit www.healthnetworkcommunications.com/2009/safetyusa for a full description.

Facilitated by COVANCE THE DEVELOPMENT SERVICES COMPANY

Becoming a sponsor or exhibitor

Record numbers of senior personnel from pharmacovigilance and drug safety have attended this event over the past two years in Europe. On the back of this success the event is being taken to the US where it has already been extremely well received.

World Drug Safety Congress Americas 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.

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?
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