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2nd Drug Safety Asia

Fortifying Safety with Quality Data

17–18 February 2009 | Traders Hotel, Singapore

Featuring a Stellar Line-up of International Speakers



Dr. Songlin Xue, Vice President and Head Global Clinical Epidemiology, Integrated Medical Safety, **Novartis Pharmaceuticals Corporation, USA**



Dr. Arlene Amor, Director – Regional Head, BRM Asia Pacific, **Johnson & Johnson, Australia**



Isobel Reid, Director, Asia Pacific Pharmacovigilance & Medical Information, **Bristol-Myers Squibb, Australia**



Dr. Krishna Bahadursingh, Senior Global Pharmacovigilance & Medical Advisor, Safety Management Department, Corporate Regulatory Affairs & Quality Assurance HQ, **Eisai Co Ltd, Japan**



Dr. Sushrut Bhatt, Pharmacovigilance & Quality Standards, Medical Writing, **GlaxoSmithKline Pharmaceuticals Ltd, India**



Dr. Akhilesh Sharma, Vice President – Medical Services, **Glenmark Pharmaceuticals Ltd, India**

Event Highlights

- The **ONLY** Drug Safety forum in Asia
- An expert panel of industry speakers to share their knowledge, experiences and success stories
- 4 days of in-depth coverage of worldwide Drug Safety best practices and issues
- 3 intensive and interactive workshops
- Over 10 hours of networking with key industry players and your peers from the region and worldwide

Key Benefits of Attending

Attend this timely conference to **beat safety woes** and **devise a holistic drug safety programme** by:

- Gaining valuable **regulatory** and **industrial viewpoints** from **across the region** and **the USA** on critical Drug Safety and Pharmacovigilance issues
- Optimising your **data collection, management and analysis** strategies
- Streamlining your **pre- and post-approval drug safety activities**
- Ensuring **drug safety in partnerships**
- Achieving **effective communication** with **consumers and the public**
- Improving the efficiency of your **signal detection** and **product recall and market withdrawal** process
- Staying ahead of competition by identifying **new and future trends** in ADR prevention and packaging

PLUS!
SEPARATELY
BOOKABLE

PRE-CONFERENCE WORKSHOPS (Monday | 16 February 2009)

A) STRUCTURING AND MAINTAINING AN EFFECTIVE PHARMACOVIGILANCE SYSTEM

B) ESTABLISHING AN EFFICIENT PRODUCT RECALL AND MARKET WITHDRAWAL STRATEGY

POST-CONFERENCE WORKSHOP (Thursday | 19 February 2009)

SIGNALS AND SIGNALING IN DRUG SAFETY

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DAY ONE TUESDAY 17 FEBRUARY 2009

08:00 Registration & Coffee

09:00 Chairperson's Welcome and Opening Speech

09:10 **KEYNOTE ADDRESS: Updates of the Surveillance Programme in Europe & USA**

- Drug safety surveillance regulations and practices in Europe and USA
- Drug safety risk management requirements in Europe and USA
- New drug safety initiatives in Europe and USA
- Comparison of systems between Europe/USA and Asia – what can be adopted



Dr. Songlin Xue, Vice President and Head Global Clinical Epidemiology, Integrated Medical Safety, Novartis Pharmaceuticals Corporation, USA

09:50 **KEYNOTE ADDRESS: Harmonisation of Requirements for Adverse Events (AEs) Reporting**

- Defining the criteria for "Serious"
- Reporting and prioritisation of AEs in package inserts
- Resolving the varying requirements for different countries
- Updating of information post-market



Dr. Arlene Amor, Director – Regional Head, BRM Asia Pacific, Johnson & Johnson, Australia

10:30 Networking & Morning Refreshments Break

11:10 **PANEL DISCUSSION: Identifying and Overcoming Key Challenges in Drug Safety Practices in Different Locales**

In this panel, representatives will share their experiences of challenges faced from innovation to production and post-market while maximising the safety of products, exemplified with real-life scenarios and solutions to overcome them. Be informed of these difficulties and potential pitfalls to avoid delays and minimise cost in your product lifecycle.

**Panellists:**

Dr. Songlin Xue, Vice President and Head Global Clinical Epidemiology, Integrated Medical Safety, Novartis Pharmaceuticals Corporation



Dr. Arlene Amor, Director – Regional Head, BRM Asia Pacific, Johnson & Johnson



Dr. Deepa Arora, Medical Advisor – International Clinical Research, Wockhardt Limited



Isobel Reid, Director, Asia Pacific Pharmacovigilance & Medical Information, Bristol-Myers Squibb

STREAMLINING THE COLLECTION AND MANAGEMENT OF QUALITY DATA

11:50 **INTERNATIONAL PRESENTATION: Establishing a Pharmacovigilance Database for High Quality Data**

- Importance and practical considerations of a global database
- Reviewing the current practices for managing multi-centered data collection
- Making use of effective systems to export data
- Tackling the common regulatory and compliance issues

Dr. William Gregory, Director, Safety and Risk Management, Pfizer Inc, USA

12:30 Networking Luncheon

13:30 **Preparing Meaningful Individual Case Safety Reports (ICSRs)**

- Understanding the key data elements and limitations of ICSR
- Case assessment during initial contacts and subsequent follow-up- getting adequate information
- Evaluating serious AE reports vs non serious AE reports; expected vs. unexpected AEs
- Establishing data quality criteria and the path forward



Dr. Deepa Arora, Medical Advisor – International Clinical Research, Wockhardt Limited, India

14:10 **Managing Pharmacovigilance Inspections & Audits**

- The purpose of pharmacovigilance inspections
- The notification process and scope of an inspection
- What should I do before and during the inspection?
- Common findings and key learnings from inspections



Isobel Reid, Director, Asia Pacific Pharmacovigilance & Medical Information, Bristol-Myers Squibb, Australia

14:50 Networking & Afternoon Refreshments Break

15:30 **TECHNOLOGY SHOWCASE: Application of Pharmacogenetics in Adverse Drug Reaction (ADR) Prevention**

- Valid pharmacogenomics markers used in "Personalised Medicine"
- Pre-screening as an effective strategy to lower the morbidity and mortality of drug-induced ADR
- CASE STUDY: Exploring the feasibility of preventive screening for high-risk individuals of carbamazepine-induced SJS/TEN



Dr. Jerome Shen, CEO, Pharmigene, Inc, Taiwan

16:10 **Ensuring Integrity & Authenticity of Data**

- Locking of data capturing and mining – E-methods and manual set-ups
- Developing independent statistical support mechanisms for safe data
- Validation mechanisms to ensure authenticity of data
- In this era of "cyber age", how do I rely and validate the data?



Dr. Akhilesh Sharma, Vice President – Medical Services, Glenmark Pharmaceuticals Ltd, India

16:50 Chairperson's Closing Remarks

17:00 End of Conference Day One



2nd Drug Safety Asia

DAY 2 WEDNESDAY 18 FEBRUARY 2009

08:00 Registration & Coffee

09:00 Chairperson's Welcome and Opening Speech

09:10 SPECIAL ADDRESS: Pharmacovigilance (PV) and Risk Management

- PV and risk management regulations and practices
- Reviewing the risk landscape
- Assessing risk-benefit profiles- methods and tools
- Establishing a Risk Management Plan (RMP)
- Real-world strategies to mitigate risks



Dr. Krishna Bahadursingh, Senior Global Pharmacovigilance & Medical Advisor Safety Management Department, Corporate Regulatory Affairs & Quality Assurance HQ, Eisai Co Ltd, Japan

09:50 ASIAN PERSPECTIVE: Pharmacovigilance at a Country & Regional Level

- Review of international drug safety procedures
- The use of electronic reporting for Clinical and post-market AEs
- Safety responsibilities for local products and audits and inspections
- Challenges for the Asian industry



Dr. Sushrut Bhatt, Pharmacovigilance & Quality Standards, GlaxoSmithKline Pharmaceuticals Ltd, India

10:30 Networking & Morning Refreshments Break

11:10 PANEL DISCUSSION: Evaluating The Value of Current and Future Trends of Pharmacovigilance

In this panel, we will be reviewing the current efforts in pharmacovigilance in Europe, USA and Asia, and the direction in which it is heading towards. Representatives will share their views on the advantages and limitations of current practices and future trends.

Panellists:



Dr. Krishna Bahadursingh, Senior Global Pharmacovigilance & Medical Advisor Safety Management Department, Corporate Regulatory Affairs & Quality Assurance HQ, Eisai Co Ltd



Dr. William Gregory, Director, Safety and Risk Management, Pfizer Inc



Dr. Sushrut Bhatt, Pharmacovigilance & Quality Standards, GlaxoSmithKline Pharmaceuticals Ltd

Dr. Peter Schüler, Vice President, Medical Affairs & Drug Safety Europe/Asia, ICON Clinical Research

11:50 Managing Safety Information in the Product Life Cycle

- Reviewing current requirements for drug safety during development phase and thereafter
- Discussing future proposals for streamlining both developmental and marketed product safety
- Summarizing learning points from existing & proposed safety processes



Dr. Rashmi Hegde, Director Pharmacovigilance, Asia-Middle East-Australia-Canada, Solvay Pharmaceuticals, India

12:30 Networking Luncheon

COMMUNICATING DRUG SAFETY TO CONSUMERS AND THE PUBLIC

13:30 CASE STUDY: Public/Consumer Reporting as a Strategy to Counter Under-Reporting of Adverse Drug Reactions (ADRs)

- Evaluating the current mechanism
- Lack of reporting by physicians; Making reporting mandatory
- Preparation and acceptance of patient reports
- Understanding the risk involved

Dr. William Gregory, Director, Safety and Risk Management, Pfizer Inc, USA

14:10 Revolutionary Pharmaceutical Packaging to Ensure Drug Safety

- Understand the regulatory requirements for pharmaceutical packaging
- Addressing counterfeit via strong differentiation with unique packaging materials and creative designs
- Using a scientific approach to identify optimum pharmaceutical packaging material for each specific formulation to avoid unnecessary high cost of over-packing or product recall
- Managing risk in off-label use



Samuell Ang, CEO, Asia Pacific, Bicare Singapore Pte Ltd, Singapore

14:50 Networking & Afternoon Refreshments Break

BUILDING COOPERATIVE EFFORT IN MAINTAINING PHARMACOVIGILANCE

15:30 Synergy Approach by Academia, Industry, Regulators and Media for Impactful Pharmacovigilance and Drug Safety

Please refer to www.ibc-asia.com/drugsafety for programme updates

Dr. Y.K. Gupta, Head, Dept. of Pharmacology; Coordinator, Zonal Pharmacovigilance Centre, All India Institute of Medical Sciences, India

16:10 Producing Safe Drugs When Outsourcing

- Shifting trend of drug safety responsibilities from sponsors to vendors
- Evaluating outsourced safety services and selecting the most practical packages
- How should the systems be mutually checked prior to any contractual agreement
- Adding value to pharmacovigilance activities via outsourcing



Dr. Peter Schüler, Vice President, Medical Affairs & Drug Safety Europe/Asia, ICON Clinical Research, Germany

16:50 Chairperson's Closing Remarks

17:00 End of Conference

BOOK YOUR SEAT TODAY!

Call (65) 6514 3180 or Fax back to
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CONFERENCE WORKSHOPS

PRE-CONFERENCE WORKSHOP A

STRUCTURING & MAINTAINING AN EFFECTIVE PHARMACOVIGILANCE SYSTEM

MONDAY 16 FEBRUARY 2009 | 9AM – 5PM

OVERVIEW:

Despite successful approval and licensing from regulatory authorities, the responsibility remains with the manufacturer to ensure follow-through from the point of drug development to post-marketing activities. Pre-approval testing alone is insufficient to warrant the complete safety of drugs for all potential consumers under all circumstances due to its limitations to the sample size and inability to detect less common side effects and Adverse Drug Reactions (ADRs). Pharmacovigilance is an essential tool to compliment this.

This workshop is designed to help participants understand this pharmacological science relating to the identification, assessment, understanding and prevention of Adverse Events (AEs), and learn how to build and manage a compliant and effective pharmacovigilance system.

KEY TOPICS TO BE COVERED IN THIS WORKSHOP INCLUDE:

1. Understanding the regulatory requirements
2. Building the fundamentals
3. What needs to be included
4. Be prepared for inspections
5. Case study presentations

Workshop Leader:

Dr. Y.K. Gupta, Head, Dept. of Pharmacology; Coordinator, Zonal Pharmacovigilance Centre, All India Institute of Medical Sciences, India

PRE-CONFERENCE WORKSHOP B

ESTABLISHING AN EFFICIENT PRODUCT RECALL AND MARKET WITHDRAWAL STRATEGY

MONDAY 16 FEBRUARY 2009 | 9AM – 5PM

OVERVIEW:

In the wake of the infamous Vioxx case where Merck losses surmounted to \$4.85bn (€3.33bn), the increase in regulatory scrutiny and public awareness of drug safety has forced drug manufacturers to rethink how they ensure the post-market safety of their products.

An efficient and proper product recall and market withdrawal is vital not only to protect the safety of end-users, but also to safeguard the manufacturer's reputation and product brand, as well as minimise substantial losses. A quick and complete removal of defective products from the shelves and distribution is also crucial for mitigating the risk involved.

Are you ready for a recall and know when is it necessary, how should you handle complaints, and whether is your strategy up to regulatory standards? Attend this workshop to have these clarified.

KEY TOPICS TO BE COVERED IN THIS WORKSHOP INCLUDE:

1. Product – commodity or a service, clear basics to mark recall strategy and deciding when to do so
2. Analysing customer complaints and convincing replies – create nodal points for direct communication
3. Designing and disseminating information to prescribers and non-prescribers
4. Sensitising distributors for chanelising reverse chain
5. Supervise and effectively manage withdrawal – creating working teams
6. Monitoring impact of withdrawal and replenish with back-up strategy



Workshop Leader:

Dr. Akhilesh Sharma, Vice President – Medical Services, Glenmark Pharmaceuticals Ltd, India

POST-CONFERENCE WORKSHOP

SIGNALS AND SIGNALING IN DRUG SAFETY

THURSDAY 19 FEBRUARY 2009 | 9AM – 5PM

OVERVIEW:

Safety remains the focus of the data generated during the period of drug development and after its marketing, leading to enormous data collection. Thus, it is very important that all alerts and alarms are thoroughly evaluated for correct and early confirmation (or rejection) of a potential signal.

Proper investigations of Individual Case Safety Reports (ICSRs) and causality assessment remain the cornerstone of signal detection. Pharmacoepidemiology and statistics play a significant role in the process of signal detection. Although, there are several quantitative methods for signal detection and automated tools have also been developed, an alert physician remains central to signal detection.

Once a signal has been confirmed, evaluation of its impact on the safety of the users and commercial implications is imperative. Clear communication to internal and external stakeholders is crucial. Safety personnel should work with regulators for ensuring appropriate changes in the label, redefining the status of the drug in the therapy, adequate risk communication and suitable steps for risk minimization

KEY TOPICS TO BE COVERED IN THIS WORKSHOP INCLUDE:

1. What is Safety Signal?
2. Investigating a Safety Signal
3. From Case reports to Case series
4. Maximizing Signal Detection Strategies
5. Signal Detection during Clinical Development
6. Confirmation of Signal – onward journey



Workshop Leader:

Dr. Deepa Arora, Medical Advisor – International Clinical Research, Wockhardt Limited, India

SPONSORSHIP & EXHIBITION OPPORTUNITIES

Enhance your corporate profile and promote your products and services to your potential market and key decision-makers. This focused event presents an excellent opportunity to showcase your expertise, products and solutions for drug safety to an exclusive audience of key decision-makers.

VARIOUS SPONSORSHIP AND EXHIBITION PACKAGES ARE AVAILABLE:

For further discussion, please contact Ms. Janice Tan,
Tel: +65 6835 5101, Email: janice.tan@ibcasia.com.sg

2nd Drug Safety Asia



17-18 February 2009 | Traders Hotel, Singapore

Fortifying Safety with Quality Data

FOREWORD FROM OUR CHAIRPERSON

Dear Colleague,

IBC Asia's **2nd Drug Safety Asia** conference comes at a time when rapid developments in drug safety related regulations and practice have been taking place in many Asian countries while increased availability and usage of many drugs in this region continue demand for more sophisticated and effective drug safety surveillance and management. Also it comes at the time when developed countries in North America and Europe are launching several new projects such as Critical Path, Sentinel Safety Surveillance, and Innovative Medicine Initiative for the purpose of developing safer drugs and ensuring safer use of drugs.

It is an undebatable fact that thousands of drugs developed in the past decades have been efficacious in extending lives and improving quality of lives for millions of patients. However, each drug has its own risk of causing adverse events and some of the adverse events can be severe and life-threatening. Although these severe adverse events occur infrequently, they represent important public health concerns. The best strategy to deal with this drug safety challenge is to prevent or minimize the safety risks while preserve the drugs' benefits based on good understanding of the safety profile of each drug. This requires not only extensive preclinical and clinical studies of the new drugs before marketing also needs continued efforts in postmarketing safety surveillance to identify, characterize, and quantify new safety issues. High quality safety data collection, timely reporting, good medical assessment, sound data analysis, and responsive communication of safety information are essential elements of an effective pharmacovigilance system. With mindful designing those critical topics will be the focus for this promising 2 day conference.

I look forward to meeting you in Singapore in February.

Songlin Xue, MD, PhD
Conference Chairperson

EVENT OVERVIEW

NO Drug is 100% Safe!

But it is the responsibility of the regulatory authority and most importantly, all drug manufacturers to ensure a favourable risk-benefit profile of all drugs marketed. With the recent product recall and withdrawal of several blockbuster drugs, improving the safety of drugs is a top priority. To do so, they need to continuously assess and mitigate the risk based on information obtained from the point of drug development to post-marketing activities. Information is processed data, it is therefore crucial for the data to be properly gathered, managed and evaluated.

At IBC Asia's **2nd Drug Safety Asia**, get both regulatory and industrial perspectives on national, regional and global drug safety and pharmacovigilance issues, with key focus on clinical and post-market surveillance data collection, monitoring and analysis. We will also look at how drug safety can be reinforced amidst evolving trends such as outsourcing, and how the safety and confidence of the public can be reassured via innovative packaging and product recalls/market withdrawals. Pharmacoepidemiology and signal detection will also be discussed.

REGISTER NOW at www.abc-asia.com/drugsafety
or call our **Registration Hotline: +65 6514 3180**

WHO SHOULD ATTEND

VICE PRESIDENTS, DIRECTORS, MANAGERS, PROFESSIONALS

With Responsibilities In		Industry
<ul style="list-style-type: none">• Drug Safety• Pharmacovigilance/ Post-marketing Surveillance• Medical Affairs/Writing• Data Management/Analysis• Quality Assurance/Quality Control• Risk Management	<ul style="list-style-type: none">• Regulatory Affairs• Pharmaco/Epidemiology• Packaging & Labelling• Pricing & Reimbursement• Partnership & Outsourcing• Strategy and Business Development	<ul style="list-style-type: none">• Pharmaceutical• Biotechnology• Healthcare• CROs• Consultancy• Government & Regulatory Authority

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2ND DRUG SAFETY ASIA

HOTEL INFORMATION

Traders Hotel, Singapore
1A Cuscaden Road,
Singapore 24971
Tel: (65) 67382222
Fax: (65) 6831 4330
Contact Person: Rachel Ng
Email:
rachel.ng@shangri-la.com

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<input type="checkbox"/> 4 Day Package – 2 Day Conference + 2 Day Workshops	SGD \$3,695	SGD \$1,495	SGD \$3,895	SGD \$1,295	SGD \$3,995	SGD \$1,195
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