Safety Is Global: Contemporary Pharmacovigilance and Medical Product Risk Management Strategies

December 10-12, 2008 | Pan Pacific Singapore Hotel, Singapore

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Registration available online only.

Comprehensive Three-day Program to Address the Current Complexities and Controversies in Pharmacovigilance and Risk Management.

OVERVIEW

The field of medical product safety continues to grow in complexity, with both clinical trial safety and postmarketing pharmacovigilance becoming ever more critical in the development and marketed use of medical products. The inherent limitations of premarketing testing and ongoing focus on the risks associated with medical product use have fostered new thinking and methods for monitoring the evolving safety profiles of marketed products throughout their lifecycles. Further, while the field of risk management has added a new dimension to product safety, as an evolving discipline it requires ongoing refinement in order to enhance its applicability and value to public health by helping one another through sharing our experiences.

Learn the latest safety-related regulatory initiatives, how to optimally utilize epidemiological, clinical pharmacological and other techniques, state-of-the-art risk management strategies, and how all of this can be pulled together to create a "System."

FEATURED TOPICS

- Latest international regulatory developments
  - US FDA and EMEA risk management initiatives
  - The global impact of EU pharmacovigilance inspections
  - Implementation of Volume 9A
  - Japanese regulatory agency organizational changes
  - Pharmacovigilance programs in Asia/Pacific Rim
- Generating and assessing critical safety data during development
  - Role of animal toxicology studies
  - Application of clinical pharmacology in establishing product safety profile
  - Importance of epidemiology and natural history of disease
  - Generating case narratives of high quality
  - Statistical considerations in analyzing premarketing data
  - Risk assessment and the Integrated Summary of Safety
- Compliance with clinical safety and postmarketing pharmacovigilance regulatory requirements in an evolving global environment
- Relationship between compliance and quality in safety-related processes and procedures
- Recent multinational initiatives under the International Conference on Harmonization (ICH) and Council for International Organizations of Medical Sciences (CIOMS) relating to pharmacovigilance and benefit/risk assessment processes
- New approaches in risk management, risk communication, labeling, and packaging to optimize medical product benefit while minimizing preventable harm
- Patient safety – a shared responsibility

PROGRAM COMMITTEE

STEPHEN A. GOLDMAN, MD, FAPM, DFAPA
Managing Member, Stephen A. Goldman Consulting Services, LLC; Former Medical Director, MedWatch, US FDA

L. PAUL STARKEY, MD, FAAFP
Executive Director, Medical Affairs - Americas, PRA International

MARIA GRAZIA ZURLO, MD
Vice President, Safety and Risk Management, EU Qualified Person for Pharmacovigilance Pfizer Inc, Italy

JOHN KNIGHT, MBBS, MA, FRACP
Vice President, Strategic & Business Planning, Benefit Risk Management, Johnson & Johnson

JOHN McEWEN PSM, MBBS, MSc, MPS
Visiting Lecturer, Department of Pharmacy, University of Canberra; Former Principal Medical Adviser, Therapeutic Goods Administration, Australia

WHO SHOULD ATTEND

This program will benefit professionals with at least a basic knowledge of, and experience in clinical safety, and who are involved in:

- Pharmacovigilance
- Clinical research
- Regulatory affairs
- Risk management
- Medical product safety assessment
- Data analysis
- Epidemiology
- Labeling
- Quality assurance/quality control
- Compliance
- Medical information

THIS PROGRAM WAS DEVELOPED BY THE CLINICAL SAFETY AND PHARMACOVIGILANCE SPECIAL INTEREST AREA COMMUNITY

CONTACT INFORMATION
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CONTINUING EDUCATION

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Learning Objectives

At the conclusion of this conference, participants should be able to:

- Explain key aspects of current global safety reporting requirements for pharmaceuticals and medical devices;
- Discuss the latest regulatory frameworks for pharmacovigilance in the US, Europe, Japan, Australia, New Zealand, Singapore, Thailand, India and China;
- Describe how data from preclinical animal and human clinical pharmacology testing are integrated into premarketing safety assessment and lifecycle management;
- Explain the application of epidemiological approaches in drug development;
- Outline new views on periodic safety reporting during clinical development as proposed by the CIOMS VII Working Group and the ICH E2F Expert Working Group;
- Describe regulatory agency clinical safety and pharmacovigilance inspection programs in the US, Europe, and Japan;
- Identify best practices for company processes and procedures to help ensure regulatory compliance and enhance quality in postmarketing pharmacovigilance and clinical safety;
- Discuss current FDA, EMEA, MHLW, and ICH risk management approaches;
- Outline new labeling initiatives and their implications to safety;
- Discuss the impact of public health actions and health professional education on medical product safety;
- Describe methods to enable safer prescribing behavior to better mitigate risk; and
- Explain why shared responsibility among multiple stakeholders (including government, industry, health professionals and consumers) is essential for effective medical product risk management and minimization.

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TUESDAY • DECEMBER 9

5:00-7:00 PM CONFERENCE REGISTRATION

WEDNESDAY • DECEMBER 10

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 AM-5:15 PM **DAY 1**

REGULATIONS FOR PHARMACOVIGILANCE AND MEDICAL PRODUCT SAFETY: NATIONAL AND INTERNATIONAL PERSPECTIVES

With international initiatives continuing to influence pharmacovigilance and risk management, it is imperative to stay current on the latest requirements related to medical product safety in all ICH regions (US, EU and Japan) and countries that are not official participants in ICH. Towards that end, updates will be presented on FDA drug safety regulations and guidances, along with the latest on the European Union's Volume 9A and pharmacovigilance requirements in Japan, Australia, New Zealand, Singapore, Thailand, India and China. In addition, there will be discussion of the medical device Global Harmonization Task Force. A day-ending panel discussion will explore whether international efforts are fostering true harmonization in pharmacovigilance.

8:30-8:45 AM

WELCOME AND OPENING REMARKS

Stephen A. Goldman, MD, FAPM, DFAPA
Managing Member, Stephen A. Goldman Consulting Services, LLC
Former Medical Director, MedWatch, US FDA

8:45-9:25 AM

ICH and CIOMS: The Relationship to Global Pharmacovigilance
Elliot G. Brown, MB, ChB, BMedSci, MRCGP, FFPM
Elliot Brown (Consulting) Ltd., UK
Former Member, Pharmacovigilance Working Party, EMEA

9:25-10:05 AM

Pre- and Postmarketing Pharmaceutical Safety Regulation in the US
Stephen A. Goldman, MD, FAPM, DFAPA

10:05-10:20 AM **REFRESHMENT BREAK**

10:20-10:55 AM

Pre- and Postmarketing Pharmaceutical Safety Regulation in Europe
Maria Grazia Zurlo, MD
Vice President, Safety and Risk Management, EU Qualified Person for Pharmacovigilance, Pfizer Inc, Italy

10:55-11:30 AM

Medical Devices and the Global Harmonization Task Force
Larry G. Kessler, ScD
Director, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health (CDRH), FDA, USA

11:30 AM-12:00 PM

Questions and Answers

12:00-1:15 PM **LUNCHEON**

AFTERNOON SESSION HOST

John McEwen PSM, MBBS, MSc, MPS
Visiting Lecturer, Department of Pharmacy, University of Canberra
Former Principal Medical Adviser, Therapeutic Goods Administration, Australia

1:15-1:45 PM

Regulatory Update: Pharmacovigilance in Japan
Kaoru Misawa
Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

1:45-2:15 PM

Pharmacovigilance in Australia and New Zealand
Arlene Amor, MD
Asia Pacific Regional Director, Benefit Risk Management, Johnson & Johnson

2:15-3:00 PM

Regulatory Update: Pharmacovigilance in Singapore and Thailand
Chan Cheng Leng, BSc (Pharm) Honors
Head, Pharmacovigilance Unit, Health Sciences Authority, Singapore
Wimon Suwankesawong, B.Sc (Pharm), MPA
Head of Pharmacovigilance Unit, Adverse Product Reaction Monitoring Centre, Food and Drug Administration, Thailand

3:00-3:15 PM **REFRESHMENT BREAK**

3:15-3:45 PM

Pharmacovigilance in India
Dr. Nilima A. Kshirsagar
Emeritus Professor, Department of Clinical Pharmacology
Seth G S Medical College and KEM Hospital, India

3:45-4:15 PM

Pharmacovigilance in China
Xiaojun Guo, MD, PhD
Safety Manager, Patient Safety
AstraZeneca China R&D, China

4:15-5:15 PM

PANEL DISCUSSION:
Have International Efforts at Harmonization in Pharmacovigilance Enhanced Patient Safety?

MODERATOR

John McEwen PSM, MBBS, MSc, MPS

PANELISTS

Kaoru Misawa
Arlene Amor, MD
Chan Cheng Leng, BSc (Pharm) Honors
Wimon Suwankesawong, B.Sc (Pharm), MPA
Dr. Nilima A. Kshirsagar
Xiaojun Guo, MD, PhD

THURSDAY • DECEMBER 11

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 AM-4:55 PM DAY 2

Drug Development and Clinical Trial Safety: Data Gathering and Assessment in Premarketing

This session will provide a sequential examination of the steps and challenges in gathering and reviewing data from preclinical animal testing through production of the final approved labeling of a new pharmaceutical. We will assess how each step adds information, resulting in improved safety and lower risk for the marketed product, and ultimately leading to the development of the benefit-risk assessment for a compound during clinical development. A panel discussion will explore the pitfalls in premarketing safety assessment, and what can be done to avoid them.

8:30-8:35 AM

Welcome and Opening Remarks
L. Paul Starkey, MD, FAAFP
Executive Director, Medical Affairs - Americas
PRA International

8:35-9:05 AM

Non-Clinical Studies and Adverse Effect Prediction in Humans
K.S. Rao, MVSc, PhD, DABT
Senior Director, Toxicology and Safety Pharmacology,
Advinus Therapeutics Pvt. Ltd.
President, The Society of Toxicology, India

9:05-9:40 AM

Clinical Pharmacology in Drug Development and Pharmacovigilance
John McEwen PSM, MBBS, MSc, MPS

9:40-10:00 AM REFRESHMENT BREAK

10:00-10:35 AM

Fostering Quality Adverse Event Data via Active Query and Applied Clinical Expertise
Stephen A. Goldman, MD, FAPM, DFAPA

10:35-11:05 AM

Investigating and Crafting the Medical Narrative
L. Paul Starkey, MD, FAAFP

11:05 AM-12:00 PM

Questions and Answers

12:00-1:15 PM LUNCHEON

AFTERNOON SESSION HOST
Maria Grazia Zurlo, MD

1:15-1:50 PM

The Integrated Summary of Safety
Maria Grazia Zurlo, MD

1:50-2:25 PM

Epidemiology during Drug Development: Applying Natural History of Disease to Understanding Safety
Vaishali Patadia, MPH, RD
Director & Head, Pharmacoepidemiology
Product Safety and Pharmacovigilance
Astellas Pharma US, Inc

2:25-2:45 PM REFRESHMENT BREAK

2:45-3:20 PM

Creating the Label: A Critical Risk Management Tool
John McEwen PSM, MBBS, MSc, MPS

3:20-3:55 PM

ICH E2F and CIOMS VII: The Development Safety Update Report
Kaoru Misawa

3:55-4:55 PM

PANEL DISCUSSION:
Studying Safety during Drug Development: Challenges in Benefit-Risk Assessment

Moderator
Maria Grazia Zurlo, MD

Panelists
Elliot G. Brown, MB, ChB, BMedSci, MRCGP, FFPM
John Knight, MBBS, MA, FRACP
Kaoru Misawa
John McEwen PSM, MBBS, MSc, MPS
Vaishali Patadia, MPH, RD

FRIDAY • DECEMBER 12

7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:30 AM-12:00 PM DAY 3

Inspections and Audits of Clinical Safety and Pharmacovigilance Operations

Compliance with safety requirements will be covered through examination of how FDA, EMEA, and MHLW conduct clinical trial and pharmacovigilance inspections of company safety departments, and via lessons learned from independent nonregulatory audits of safety departments. A panel discussion will explore whether, in the current evolving global safety environment, it is possible to achieve compliance harmonization.

8:30-8:35 AM

WELCOME AND OPENING REMARKS

Elliot G. Brown, MB, ChB, BMedSci, MRCGP, FFPM

8:35-10:35 AM

Clinical Safety and Pharmacovigilance Inspections: FDA, European Union, and Japanese Approaches

Carol L. Krueger, BSN, RN
Surveillance Programs Team, Division of Compliance Risk Management and Surveillance, Office of Compliance, CDER, FDA

Moin Don
Associate Director (Asia Pacific), Pharmacovigilance Quality Assurance, Johnson and Johnson PRD

10:35-10:50 AM REFRESHMENT BREAK

10:50-11:30 AM

Auditing Company Processes and Procedures for Global Clinical Safety and Pharmacovigilance: The Critical Relationship between Compliance and Quality

Stephen A. Goldman, MD, FAPM, DFAPA

11:30 AM-12:00 PM

PANEL DISCUSSION:
Why is Compliance So Complicated? Challenges in the Evolving Global Clinical Safety and Pharmacovigilance Environment

MODERATOR

Maria Grazia Zurlo, MD

PANELISTS

Carol L. Krueger, BSN, RN
Moin Don
Stephen A. Goldman, MD, FAPM, DFAPA

12:00-1:15 PM LUNCHEON

AFTERNOON SESSION HOST

Stephen A. Goldman, MD, FAPM, DFAPA

1:15-5:00 PM

COMMUNICATION, MANAGEMENT AND MINIMIZATION OF MEDICAL PRODUCT RISK

The safety of medical products, and the risks associated with their use, is a major public health concern. Given the multifaceted nature of this critical issue, how signals of concern are detected and evaluated will be discussed, along with methods by which effectiveness of public health actions and health professional risk education are measured. From both US and EU perspectives, there will be a presentation on risk management planning throughout a medical product's life cycle. An interactive panel session to address how these aspects might best be integrated into an effective risk management framework in which responsibility is shared among all involved parties, including regulated industry, regulatory agencies, health professionals and consumers, will conclude the conference.

1:15-1:50 PM

Signal Detection, Case Assessment and Data Mining in Pharmacovigilance: Current State of the Art

Andrew Bate, PhD, MA
Manager, Research and Development, Uppsala Monitoring Centre, WHO, Sweden

1:50-2:25 PM

Public Health Actions and Health Professional Risk Education

Larry G. Kessler, ScD

2:25-2:50 PM REFRESHMENT BREAK

2:50-4:00 PM

Risk Management Planning throughout Product Life Cycle: US and EU Perspectives

L. Paul Starkey, MD, FAAFP
Elliot G. Brown, MB, ChB, BMedSci, MRCGP, FFPM

4:00-5:00 PM

PANEL DISCUSSION:
Communication, Management and Minimization of Medical Product Risk – Is Responsibility Truly Being Shared?

MODERATOR

Stephen A. Goldman, MD, FAPM, DFAPA

PANELISTS

Andrew Bate, PhD, MA
Larry G. Kessler, ScD
L. Paul Starkey, MD, FAAFP
Elliot G. Brown, MB, ChB, BMedSci, MRCGP, FFPM

5:00 PM CONFERENCE ADJOURNED

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