9th Annual DIA Conference on

# Contemporary Pharmacovigilance and Risk Management Strategies

**January 11-13, 2010 Tutorial: January 10**

Renaissance Washington DC Hotel, Washington, DC, USA

## PROGRAM COMMITTEE

**Mariette Boerstoel-Streefland, MD, MBA, MS(epi)**
Chief Safety Officer, Executive Director
Pharmacovigilance / Risk Management
Forest Research Institute, Forest Laboratories Inc.

**William W. Gregory**
Senior Director, Safety and Risk Management
Pfizer Inc.

**Carol Krueger, RN, BSN**
Consumer Safety Officer
Surveillance Programs Team
CDER, FDA

**Wenda K. Brennan, RPh**
Director, Pharmacovigilance
United BioSource Corporation

**Toni Piazza-Hepp, PharmD**
Associate Director for Regulatory Affairs
Office of Surveillance and Epidemiology
CDER, FDA

## SPECIAL ADVISOR

**Annette Stemhagen, DrPH, FISPE**
Senior Vice President, Safety, Epidemiology, Registries & Risk Management
United BioSource Corporation

## Who Should Attend

Professionals with at least 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


**Worldwide Headquarters**
Drug Information Association, Inc.
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Horsham, PA 19044, USA

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**DRUG INFORMATION ASSOCIATION**
800 Enterprise Road, Suite 200
Horsham, PA 19044-3595 USA


## Find Solutions to the Challenges Facing Pharmacovigilance and Risk Management Programs

Robust drug safety systems and processes and thorough ongoing safety surveillance are more critical than ever in the development and evaluation of the safe use of marketed medicinal products. This comprehensive three-day program will discuss the current complexities and controversies in pharmacovigilance and risk management throughout all phases of development and marketed use, how to optimally utilize epidemiological, clinical pharmacological and other techniques, risk management strategies, and how to create an effective organizational "system." This program will focus primarily on drug products and biologics, but medical devices will have a limited role in the discussions.

## Featured Topics

- Latest international regulatory developments
- How to generate and assess critical safety data during development
- Compliance with clinical safety and post-marketing pharmacovigilance regulatory requirements in an evolving global environment
- Recent multinational initiatives under the International Conference on Harmonization (ICH) and Council for International Organizations of Medical Sciences (CIOMS) on Drug Safety Update Reports (DSURs) in premarketing clinical trial safety
- New approaches in risk management, risk communication, labeling and packaging to optimize medical product benefit while minimizing preventable harm

**This program has been developed by the Clinical Safety and Pharmacovigilance SIAC.**

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**Disclosure Policy:** It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

**LEARNING OBJECTIVES** At the conclusion of this meeting, participants should be able to:

- Discuss the latest regulatory frameworks for global pharmacovigilance
- Understand new views on periodic safety reporting during clinical development
- Identify best practices for quality assurance in post-marketing pharmacovigilance and clinical safety
- Review current FDA, EMEA, EU, and ICH risk management approaches
- Discuss the impact of public health actions and health professional education on medical product safety
- Recognize why shared responsibility among multiple stakeholders (including government, industry, health professionals and consumers) is essential for effective medical product risk management and minimization



# DAY 1 | SUNDAY, JANUARY 10

**7:30-8:30 AM** **MORNING TUTORIAL REGISTRATION**

**8:30 AM-12:00 PM** **MORNING TUTORIALS #1, #2, AND #3**

**TUTORIAL #1**

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

**Manfred Hauben, MD, MPH**
Senior Director, Risk Management Strategy
Pfizer Inc

This tutorial will provide a theoretical and methodological review of the application of data mining techniques to safety surveillance, its application in signal detection, and the critical role of clinical case assessment. An overview of strategies and specific situation applications will be presented.

**LEARNING OBJECTIVES:**

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

- Recognize the basic concepts of data mining and principles of signal detection
- Identify specific applications of data mining technology
- Explain the role of clinical case assessment in signal evaluation
- Describe the strengths and limitations of data mining in performance high-quality pharmacovigilance

**TARGET AUDIENCE:**

This tutorial is designed for clinical safety professionals involved in the areas of pharmacovigilance, pharmacoepidemiology, regulatory affairs, quality assurance, medical product safety assessment, and labeling.

**TUTORIAL #2**

## Periodic Safety Update Reports (PSUR): A Guide to the Construction and Analysis of PSURs, ASRs, and DSURs

**Steve Jolley**
Principal
SJ Pharma Consulting

This tutorial will explain how to create a PSUR based on the ICH E2C guideline and will describe a methodology for signaling analysis of PSUR data. The tutorial will also address Annual Safety Reports for clinical trials, together with an introduction to the forthcoming Development Safety Update Report (DSUR).

**LEARNING OBJECTIVES:**

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

- Develop a Period Safety Update report
- Describe the timing for preparation and submission of PSURs
- Analyze data in a PSUR in order to identify potential safety signals
- Discuss key aspects of the ASR and DSUR
- Prepare an Annual Safety Report (ASR) and a Development Safety Update Report (DSUR)

**TARGET AUDIENCE:**

This tutorial is designed for drug safety and pharmacovigilance professionals who are involved in the preparation of PSURs, ASRs, and the soon to be required DSURs. In addition, this tutorial will assist senior pharmacovigilance personnel deploy an intuitive approach to the analysis of periodic safety data in order to identify potential safety signals.

TUTORIAL #3

## Applied Epidemiology Techniques for Pharmacovigilance Risk Management

**Andrew T. McAfee, MD, MSc**
Global Head for Epidemiology
i3 Drug Safety

This tutorial will provide an overview of basic epidemiology methods and study designs. Topics will include design and conduct of case-control studies and cohort studies and an introduction to basic measures of frequency and risk.

### LEARNING OBJECTIVES:

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

- Define basic epidemiologic principles
- Distinguish case-control and cohort study designs
- Identify applications for epidemiology in pre- and postmarketing pharmaceutical product risk assessment

### TARGET AUDIENCE:

This is a basic-level course for individuals who would like a general understanding of the role of epidemiology in pharmacovigilance and risk management.

**12:00-1:30 PM** **AFTERNOON TUTORIAL REGISTRATION**

**1:30-5:00 PM** **AFTERNOON TUTORIALS #4 AND #5**

TUTORIAL #4

## Applying MedDRA® in Clinical Safety, Pharmacovigilance and Labeling

**Judy Harrison, MD**
Medical Officer
MedDRA MSSO

This tutorial will look at the applications of MedDRA in pharmacovigilance and clinical safety. It will provide an overview of data retrieval and presentation options for MedDRA-coded data as outlined in the ICH-endorsed "MedDRA Data Retrieval and Presentation: Points to Consider" document and will describe the use of Standardized MedDRA Queries (SMQs) as tools to investigate drug safety issues and to aid in case identification and signal detection. In addition, recent initiatives involving MedDRA versioning practices will be addressed.

### LEARNING OBJECTIVES:

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

- Review the various strategies for retrieval and subsequent analysis of MedDRA-coded data in clinical safety and pharmacovigilance
- Discuss the issues relating to MedDRA versioning

### TARGET AUDIENCE:

This tutorial is designed for pharmacovigilance and clinical research professionals, clinical data managers, medical writers, and regulatory affairs professionals who already have a basic knowledge of MedDRA and wish to explore the implications of its use in clinical safety and pharmacovigilance.

TUTORIAL #5

## Pharmacovigilance and Risk Management Planning

**G. K. Anand, MD**
Benefit-Risk Management, Biologics
Johnson & Johnson Pharmaceutical Research and Development

This tutorial will examine current national, regional and international perspectives and approaches to pharmacovigilance planning and risk management throughout the medical product life cycle. Current EMEA and FDA regulatory requirements and standards, in combination with the critical ICH E2E guideline, will be discussed along with case examples of risk assessment and minimization methods and the challenges that industry faces in performing high-quality risk management in a global environment.

### LEARNING OBJECTIVES:

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

- Discuss the ICH "Pharmacovigilance Planning" E2E Guideline
- Compare and contrast FDA's "Development and Use of Risk Minimization Action Plans" guidance, EMEA's "Guideline on Risk Management Systems for Medicinal Products for Human Use," and FDAAA-mandated Risk Evaluation and Mitigation Strategies (REMS)
- Describe the relationship between pharmacovigilance planning and post-marketing risk management
- Recognize the strengths and limitations of different methods of risk minimization

### TARGET AUDIENCE:

This tutorial is designed for professionals involved with premarketing and postmarketing pharmacovigilance, clinical trials, pharmacoepidemiology, regulatory affairs, risk management and labeling.

**5:00-7:00 PM** **WORKSHOP REGISTRATION**

## DAY 2 | MONDAY, JANUARY 11

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

8:30-8:45 AM WELCOME AND OPENING REMARKS

8:45-10:00 AM KEYNOTE PRESENTATION

### Global Regulatory Outlook: Current Landscape and Emerging Markets

**E. Stewart Geary, MD**
Vice President
Eisai Co., Ltd., Japan

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-5:00 PM SESSION 1

### Regulations for Pharmacovigilance and Medical Product Safety: National and International Perspectives

**CDER Pre- and Post-marketing Update**
**Gerald J. Dal Pan, MD, MPH**
Director, Office of Surveillance and Epidemiology
CDER, FDA

**CBER Pre- and Post-marketing Update (Blood and Vaccines)**
**Craig Zinderman, MD, MPH**
Acting Branch Chief
Therapeutics and Blood Safety Branch
Office of Biostatistics and Epidemiology
CBER, FDA

**Vaccines**
**Speaker invited**

12:00-1:00 PM LUNCHEON

**CDRH Pre-and Post-marketing Update**
**Jonathan Sackner-Bernstein, MD**
Associate Director, Post Marketing Operations
CDRH, FDA

**EMEA Pre-and Post-marketing Regulatory Update — via teleconference**
**Sabine Brosch, PhD, PharmD**
Scientific Administrator Pharmacovigilance and Risk Management
EMEA EU

2:45-3:15 PM REFRESHMENT BREAK

**MHRA Pre- and Post-marketing Regulatory Update**
**MHRA Speaker Invited**

4:00-5:00 PM ASK THE EXPERTS – QUESTION AND ANSWER PANEL

## DAY 3 | TUESDAY, JANUARY 12

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

8:30 AM-11:30 AM SESSION 2

### Early Understanding of Safety and Risk

**The Principles of Program Design**
**Joanna F. Haas, MD, MSc**
Vice President, Pharmacovigilance/Medical Information
Genzyme Corporation

**Preparing for Pre-Marketing Clinical Trials – Determining What Studies are Needed and How to Evaluate and Review the Study Protocols for Safety and Risk**
**Joseph J. DeGeorge, PhD**
Vice President, Safety Assessment
Merck & Company, Inc.

10:00-10:30 AM REFRESHMENT BREAK

**Preparing for Pre-Marketing Clinical Trials – Weighing the Benefit Risk and Informed Consent**
**Speaker Invited**

11:30 AM-12:00 PM ASK THE EXPERTS – QUESTION AND ANSWER PANEL

12:00-1:00 PM LUNCHEON

1:00-2:30 PM SESSION 3

### Safety Reporting for Drugs and Biologics

**Basic Requirements for Safety Reporting**
**Thomas Steinbach, MD, PhD, FFPM (Dis)**
Germany

**Establishing Safety Profiles, Individual Case Safety Reports (ICSR), Aggregate Reports (Annual Safety Reports (ASRs), DSURs, IND Annual Reports)**
**Ellis Unger, MD**
Deputy Director, Division of Cardiovascular and Renal Products
CDER, FDA

**Integrated Summary of Safety (ISS)**
**Sally Van Doren, PharmD**
President & CEO
BioSoteria, Inc.

2:30-3:00 PM REFRESHMENT BREAK

3:00-4:30 PM SESSION 4

## Pre-marketing Assessment of Drug Safety

**Pre-marketing Statistical Information and Analysis, NDA Safety**
**Chuck Cooper, MD**
Senior Safety Policy Advisor, Safety Policy and Communication Staff
CDER, FDA

4:30-5:00 PM ASK THE EXPERTS – QUESTION AND ANSWER PANEL

5:00-6:00 PM NETWORKING RECEPTION

# DAY 4 | WEDNESDAY, JANUARY 13

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

8:30-10:00 PM SESSION 5

## How to Prepare Risk Management Documentation

**Risk Management Plans in the EU**
**Thomas Steinbach, MD, PhD, FFPM (Dis)**
Germany

**Risk Evaluation and Mitigation Strategies in the US**
**Kelly D. Davis, MD**
Vice President, Epidemiology & Risk Management
United BioSource Corporation

**Risk Management Plans in the Asia/Pacific Rim Area**
**E. Stewart Geary, MD**
Vice President
Eisai Co., Ltd.
Japan

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-11:40 PM SESSION 6

## Spontaneous Reporting and Beyond

**Basic Requirements for Safety Reporting**
**Toni Piazza-Hepp, PharmD**
Associate Director for Regulatory Affairs
Office of Surveillance and Epidemiology
CDER, FDA

**Signaling / Expedited Aggregate Reporting (CIOMS 8)**
**William W. Gregory**
Senior Director, Safety and Risk Management
Pfizer Inc.

**Post-authorization Safety Studies, Registries, Clinical and Epidemiology Studies**
**Annette Stemhagen, DrPH, FISPE**
Senior Vice President, Safety, Epidemiology, Registries & Risk Management
United BioSource Corporation

11:40 AM-12:00 PM ASK THE EXPERTS – QUESTION AND ANSWER PANEL

12:00-1:00 PM LUNCHEON

1:00-2:30 PM SESSION 7

## Risk Communications

**FDA Transparency and the FDA Risk Communication Advisory Committee**
**Nancy Ostrove, PhD**
Senior Risk Communication Advisor
Office of the Commissioner
FDA

**Patient-focused Labeling and Communication**
**Jodi M. Duckhorn**
Patient Information & Research Team Leader,
Division of Risk Management
FDA

**Healthcare Provider-focused Communications**
**Helen Hochstetler, PharmD**
Medical Information Consultant
Lilly USA, LLC
**Nayan Acharya, MBBS, MRCP, MFPM**
Senior Director, Global Patient Safety
Eli Lilly and Company

**New Technologies**
**Speaker Invited**

2:30-3:00 PM REFRESHMENT BREAK

3:00-4:30 PM SESSION 8

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

**FDA Approach**
**Carol Krueger, RN, BSN**
Consumer Safety Officer
Surveillance Programs Team
CDER, FDA

**European Approach - via teleconference**
**Fergus Sweeney, PhD**
Head, Compliance and Inspections
EMEA, EU

**Japanese Approach**
**Mr. Shinya Yamauchi**
Operating Officer, Pharmacovigilance Department
Otsuka Pharmaceutical Co., Ltd.

4:30-5:00 PM ASK THE EXPERTS – QUESTION AND ANSWER PANEL

5:00 PM CONFERENCE ADJOURNS

## REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

# 9th Annual DIA Conference on Contemporary Pharmacovigilance and Risk Management Strategies

**Event #10002 • Tutorials: January 10 • Workshop: January 11-13, 2010**

Renaissance Washington DC Hotel, Washington, DC, USA

**Registration Fees** If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

| **Member Early-bird Opportunity**<br>Available on nondiscount member fee only | On or before DEC. 21, 2009 | After DEC. 21, 2009 |
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**TUTORIAL** US $405 ❑

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**GROUP DISCOUNTS*** Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

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❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

**TRAVEL AND HOTEL** The most convenient airport is Ronald Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Renaissance Washington DC Hotel is holding a block of rooms at the reduced rate below until December 18, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

**Single $234** **Double $234**

Please contact the Renaissance Washington DC Hotel by telephone at +1-800-HOTELS-1 or +1-202-898-9000 and mention the DIA event. The hotel is located at 999 9th St. NW, Washington, DC 20001, USA.

**CANCELLATION POLICY: On or before JANUARY 4, 2010**
**Administrative fee that will be withheld from refund amount:**
**Member or Nonmember = $200**
**Government or Academia or Nonprofit (Member or Nonmember) = $100**
**Tutorial (if applicable) = $50**

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

**DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.**

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## TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the event and receptions.
Contact **Jeff Korn, Exhibits Associate,** Phone **+1.215.442.6184**
Fax **+1.215.442.6199,** email **Jeff.Korn@diahome.org**

## EVENT INFORMATION

Contact **Ellen Diegel, Program Manager,** Phone **+1.215.442.6158**
Fax **+1.215.442.6199,** email **Ellen.Diegel@diahome.org**

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