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DRUG INFORMATION ASSOCIATION

Bridging the Gaps between GCP, Clinical Trial Safety and Postmarketing Vigilance:

Regulatory Compliance Challenges for International Pharmaceutical and Medical Device Companies

September 25-26, 2006 | Washington Marriott Hotel, Washington, DC, USA

PROGRAM COMMITTEE

STEPHEN A. GOLDMAN, MD, FAPM, FAPA
Managing Member
Stephen A. Goldman Consulting Services, L.L.C.

LOUISE N. LISANSKY, MS
President
LNL Clinical Research Consulting

CAROL KRUEGER, RN
Consumer Safety Officer
Division of Compliance Risk Management and Surveillance, Office of Compliance
CDER, FDA

TARGET AUDIENCE This program will benefit pharmaceutical, biotechnology, and medical device professionals involved in:

- **Postmarketing surveillance/ pharmacovigilance**
- **Premarketing clinical safety**
- **Clinical research**
- **Medical device clinical trials and postmarket safety**
- **Regulatory affairs**
- **Quality assurance**
- **Safety data management/analysis**
- **Risk management**
- **Project management**
- **Biostatistics**

INTERESTED SIACs

Academic Health Centers (AHC)
Biotechnology (BT)
Clinical Data Management (CDM)
Clinical Safety/Pharmacovigilance (CSP)
Clinical Research (CR)
Devices (DE)
Good Clinical Practices & Quality Assurance in Clinical Trials (I-IV) (GCP & QA)
Investigative Sites (IS)
Project Management (PM)
Quality Control/Quality Assurance (QC)
Regulatory Affairs (RA)

OVERVIEW

With increasing globalization of pharmaceutical, biotechnology and medical device companies, concerns about risks to patients participating in clinical trials and the use of marketed medical products have heightened. From public health and business standpoints, it has never been more critical for companies to ensure compliance with both national and international clinical safety and postmarketing vigilance regulatory requirements.

Effective international compliance is dependent on familiarity with the latest regulatory actions within and across ICH regions (US, EU, and Japan) and understanding of the established Good Clinical Practice (GCP), premarketing clinical safety and postmarketing medical product vigilance inspectional programs in these regions.

Towards that end, this program will address current challenges in global safety-related compliance, with each day culminating in interactive panel sessions exploring whether harmonization efforts have indeed fostered compliance.

During these two days, attendees will:

- Learn from regulators, industry personnel and consultants encompassing ICH sectors
- Explore premarketing (GCP; clinical safety) and postmarketing (pharmaceutical; medical device) regulatory requirements
- Discuss safety-related US, EU, and Japan inspectional programs
- Learn about the EU EudraVigilance and EUDRACT systems
- Understand legal implications of premarketing trials and postmarketing safety operations
- Review "lessons learned" regarding quality local and global company standard operating procedures (SOPs)
- Understand Global Harmonization Task Force (GHTF) medical device initiatives
- Review special issues in clinical trials:
  - Integrated Safety Summary and statistical/data analysis considerations
  - Institutional Review Boards (IRBs), Data Safety Monitoring Boards (DSMBs), and human subject protection
  - MedDRA® usage in clinical trials and premarketing safety

CONTACT INFORMATION

Meeting: **Ellen Diegel, Phone +1-215-442-6158/email Ellen.Diegel@diahome.org**

Tabletop Exhibits: **Erin Gilliland, Phone +1-215-442-6149/email Erin.Gilliland@diahome.org**

THIS PROGRAM WAS DEVELOPED BY THE PHARMACOVIGILANCE SPECIAL INTEREST AREA COMMUNITY

SIAC

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

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The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 13.75 *AMA PRA Category 1 Credit(s)*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a Provider of continuing pharmacy education. This program is designated for 13.75 contact hours or 1.375 continuing education units (CEU's). 286-000-06-33-L04.

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1620 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 1.4 continuing education units (CEUs) to participants who successfully complete this program.

Nursing
The Drug Information Association will offer nursing credits for this program in collaboration with Corexcel. Corexcel is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. This program is designated a maximum of 16.5 nursing contact hours.

To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your credit request and download your certificate will be provided onsite.

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:

- Describe GCP-related inspectional approaches in the US, EU, and Japan
- Discuss the global implications of the European Clinical Trials Directive
- Summarize strategies for optimizing quality and compliance when outsourcing clinical trials
- Outline clinical safety/pharmacovigilance-related inspectional approaches in the US, EU, and Japan
- Explain the importance of quality written processes to product safety and risk management regulatory compliance
- Discuss FDA's pre- and postmarketing medical device inspectional programs
- Describe MedDRA® usage in premarketing safety evaluation

SUNDAY • SEPTEMBER 24

6:00-8:00 PM REGISTRATION

MONDAY • SEPTEMBER 25

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

DAY ONE

Good Clinical Practice (GCP) and Special Issues in Clinical Trials

Global GCP issues related to clinical research and strategies to optimize compliance will be explored, particularly similarities and differences in regulatory agency GCP inspectional approaches and resultant implications for patient safety. Clinical trial-related topics of special interest will also be addressed: IRBs, DSMBs and ensuring protection of human subjects; quality considerations in outsourcing clinical trials; the European Clinical Trial Directive; the Integrated Safety Summary and statistical/data analysis considerations; and adverse event coding in premarketing safety. A panel discussion will explore whether global harmonization in GCP and premarketing clinical trials is achievable.

8:30-8:45 AM WELCOME AND OPENING REMARKS
Stephen A. Goldman, MD, FAPM, FAPA *(Day Two Host)*
Managing Member
Stephen A. Goldman Consulting Services, L.L.C.
Louise N. Lisansky, MS *(Day One Host)*
President
LNL Clinical Research Consulting

8:45-9:30 AM
Good Clinical Practice (GCP) – A Primer and Implications for Patient Safety
Joseph P. Salewski
Acting Director
Division of Scientific Investigations
Office of Compliance, CDER, FDA

9:30-10:15 AM
Strategies for Optimizing Quality when Outsourcing Clinical Trials
Louise N. Lisansky, MS
President
LNL Clinical Research Consulting

10:15-10:30 AM REFRESHMENT BREAK

10:30-11:15 AM

IRBs, Data Safety Monitoring Boards and Human Subject Protection

Melody H. Lin, PhD
Deputy Director
Office for Human Research Protections (OHRP)
National Institutes of Health

11:15-11:45 AM

Questions & Answers

11:45 AM-1:00 PM LUNCHEON

1:00-2:30 PM

GCP Inspections: FDA, European Union and Japanese Approaches

Mathew T. Thomas, MD
Pharmacologist and Project Officer
Division of Scientific Investigation
CDER, FDA

Shinya Yamauchi
Director, Global Pharmacovigilance
Otsuka Pharmaceuticals Co., Ltd., Japan

Gerhard Fortwengel
Director
Head of Quality Systems
Actelion Pharmaceuticals, Ltd., Switzerland

2:30-2:45 PM REFRESHMENT BREAK

2:45-3:30 PM

European Clinical Trial Directive: Implementation and Global Implications

Mariette Boerstoel-Streefland, MD, MSc
Global Head, Drug Safety
Mayne Pharma

3:30-4:15 PM

MedDRA® Usage in Clinical Trials and Premarketing Safety

Mark Vieder, RPh
Medical Coding Sector
PSI International, Inc.

4:15-5:00 PM

The Integrated Safety Summary and Statistical Considerations in Analyzing Premarketing Data

Greg Burkhart, MD, MS
Burkhart & Freiman, LLC

5:00-5:45 PM

Panel Discussion: Is Global Harmonization in GCP and Premarketing Clinical Trials Achievable?

Moderator
Louise N. Lisansky, MS

Panelists
Joseph P. Salewski
Mathew Thomas, MD
Shinya Yamauchi
Gerhard Fortwengel
Mariette Boerstoel-Streefland, MD, MSc
Greg Burkhart, MD, MS
Mark Vieder, RPh

6:00-7:00 PM NETWORKING RECEPTION

Sponsored by the Pharmacovigilance Special Interest Area Community

TUESDAY • SEPTEMBER 26

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

DAY TWO

Pharmaceutical and Medical Device Premarketing Clinical Trial Safety and Postmarketing Vigilance

Important clinical, legal and regulatory issues in clinical trial safety and postmarketing vigilance throughout the lifespan of regulated medical products will be explored, including the EU's EudraVigilance and EUDRACT systems; civil and criminal liabilities for individuals and companies; FDA and international approaches to medical device clinical trial and postmarket safety; the FDA, EU and Japanese regulatory approaches to premarketing clinical safety and pharmacovigilance inspections; and recommended practices based on inspectional and auditing findings across companies and countries. A panel discussion will explore whether global harmonization efforts in premarketing clinical trial safety and postmarketing pharmacovigilance are fostering compliance.

8:30-8:35 AM WELCOME AND OPENING REMARKS

Stephen A. Goldman, MD, FAPM, FAPA
Managing Member
Stephen A. Goldman Consulting Services, L.L.C.

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.
Speakers and agenda are subject to change without notice.

8:35-9:20 AM

EUDRAVIGILANCE: CLINICAL TRIAL MODULE AND EUDRACT

Thomas Steinbach, MD
Qualified Person for Pharmacovigilance
Advisor and EU Qualified Person for Pharmacovigilance,
Global Safety Products
Wyeth, UK

9:20-10:05 AM

LEGAL ASPECTS OF PREMARKETING CLINICAL TRIALS AND POSTMARKETING SAFETY

Grail Walsh Sipes, JD
Legal Associate
Covington & Burling

10:05-10:20 AM REFRESHMENT BREAK

10:20-11:20 AM

THE PREMARKETING MEDICAL DEVICE INSPECTIONAL PROGRAMS

Matthew Tarosky, PharmD, USPHS
Division of Bioresearch Monitoring
Office of Compliance
CDRH, FDA

UPDATE ON FDA AND INTERNATIONAL MEDICAL DEVICE SAFETY INITIATIVES

Larry Kessler, ScD
Director
Office of Science and Engineering Laboratories
CDRH, FDA

11:20-11:50 AM

QUESTIONS & ANSWERS

11:50 AM-1:00 PM LUNCHEON

1:00-3:00 PM

CLINICAL SAFETY AND PHARMACOVIGILANCE INSPECTIONS: FDA, EUROPEAN UNION AND JAPANESE APPROACHES

Carol Krueger, RN
Consumer Safety Officer
Division of Compliance Risk Management and Surveillance
Office of Compliance
CDER, FDA

Stephen Klincewicz, MD
Vice President, Safety Sciences
Benefit Risk Management
Johnson & Johnson Pharmaceuticals Group

Kaori Nomura
Visiting Expert, Unit of Postauthorization Evaluation of Medicines for Human Use, EMEA, EU
Principal Official for Electronic Data Submissions, Pharmaceuticals and Medical Devices Agency (PMDA), MHLW, Japan

3:00-3:15 PM REFRESHMENT BREAK

3:15-4:00 PM

AUDITING SAFETY-RELATED PROCESSES AND PROCEDURES: LESSONS LEARNED FOR GLOBAL COMPLIANCE AND QUALITY

Stephen A. Goldman, MD, FAPM, FAPA
Managing Member
Stephen A. Goldman Consulting Services, L.L.C.

4:00-4:45 PM

PANEL DISCUSSION: IS HARMONIZATION IN GLOBAL CLINICAL SAFETY AND PHARMACOVIGILANCE FOSTERING COMPLIANCE?

MODERATOR
Stephen A. Goldman, MD, FAPM, FAPA

PANELISTS
Carol Krueger, RN
Stephen Klincewicz, MD
Kaori Nomura
Thomas Steinbach, MD
Larry Kessler, ScD

4:45 PM CONFERENCE ADJOURNED

Upcoming DIA Events

WORKSHOPS

SEPTEMBER 18-19, 2006 Princeton, NJ
Clinical Research and Drug Registration in China and India

Four meetings co-located In Philadelphia, PA

SEPTEMBER 25-27, 2006
The Changing Pharma and Biotech Industry: Re-negotiating the Role of Project Management

SEPTEMBER 26-27, 2006
DIA Outsourcing Summit

SEPTEMBER 26-27, 2006
"Data on Demand": The Optimization of Clinical Data Management

SEPTEMBER 26-27, 2006
Global Electronic Labeling

OCTOBER 12-13, 2006 Washington, DC
Medical Imaging Conference – Critical Path Opportunities List: From Opportunities to Action

OCTOBER 16-17, 2006 Adelphi, MD
Developing Probiotics as Foods and Drugs: Scientific and Regulatory Challenges

OCTOBER 29-31, 2006 Ontario, CANADA
DIA's 4th Canadian Annual Meeting

NOVEMBER 2-3, 2006 San Diego, CA
eCTDs—Entering the Mainstream

NOVEMBER 6-7, 2006 Washington, DC
DIA/FDA/C-Path Rapid Diagnostics

DECEMBER 4-5, 2006 Baltimore, MD
Are your Intellectual Assets at Risk? Leveraging Knowledge Management, Process, and Technology for Secure Capture, Storage, and Distribution

DECEMBER 4-5, 2006 Baltimore, MD
ePRO Technology

DECEMBER 5-7, 2006 Baltimore, MD
The Quest to Enable the Electronic Clinical Trial: Finding Clarity in a Confusing World

WEBINARS

OCTOBER 5, 2006 | 11:00 AM-12:30 PM EDT
Overview for Regulatory Affairs on Requirements for Submission of Clinical Data in NDAs

TRAINING COURSES

AUGUST 7, 2006 Princeton, NJ
Overview of Drug Development

AUGUST 7-9, 2006 Boston, MA
Fundamentals of Clinical Research Monitoring

AUGUST 7-10, 2006 Boston, MA
Regulatory Affairs Part I: The IND Phase | Part II: The CTD/NDA Phase

AUGUST 14-16, 2006 Philadelphia, PA
Project Management

AUGUST 21-23, 2006 Philadelphia, PA
Advanced Topics in Clinical Research/Drug Development

AUGUST 28-29, 2006 Chicago, IL
European Regulatory Affairs: An In-depth Review of Registration Procedures in the European Union

AUGUST 28-30, 2006 Philadelphia, PA
Regulatory II: The CTD/NDA Phase

SEPTEMBER 15, 2006 Horsham, PA
Developing Standard Operating Procedures (SOPs)

SEPTEMBER 18-19, 2006 Baltimore, MD
Clinical Statistics for Nonstatisticians

SEPTEMBER 18-20, 2006 Philadelphia, PA
Regulatory I: The IND Phase

SEPTEMBER 18-20, 2006 Arlington, VA
Drug Safety Surveillance and Epidemiology

SEPTEMBER 22, 2006 Philadelphia, PA
Fundamentals of Project Management: What Everyone Involved in a Project Needs to Know

SEPTEMBER 25-28, 2006 Boston, MA
The Leadership Experience

SEPTEMBER 25-27, 2006 Philadelphia, PA
Introduction to Good Clinical Practices and Auditing

OCTOBER 16-17, 2006 Horsham, PA
Project Management: Planning, Executing and Controlling Projects in Pharmaceuticals and Biotechnology

OCTOBER 16-18, 2006 Washington, DC
Fundamentals of Clinical Research Monitoring

OCTOBER 16-18, 2006 Philadelphia, PA
Clinical Data Management

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 Washington Marriott Hotel is holding a block of rooms at the reduced rate below until September 4, 2006, for the DIA meeting attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $279 **Double $279**

Please contact the Washington Marriott Hotel by telephone at +1-800-228-9290 or +1-202-872-1500 and mention the DIA meeting. The hotel is located at 1221 22nd Street NW, Washington, DC 20037, USA.

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To obtain schedule information and the best fares, call United Airlines's Specialized Meeting Reservations Center at **1-800-521-4041**. ***Make sure you refer to Meeting ID Number 571AK***. Dedicated reservationists are on duty 7 days a week from 8:00 AM to 10:00 PM EST.

This special offer applies to travel on domestic segments of all United Airlines, United Express, PED, and United code share flights (UA*, operated by US Airways, US Airways Express and Air Canada).

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.**

Participants with Disabilities: *DIA meeting facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the meeting if requested at least 15 days prior to meeting. Contact the DIA office to indicate your needs.*

Drug Information Association | www.diahome.org

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BRIDGING THE GAPS BETWEEN GCP, CLINICAL TRIAL SAFETY AND POSTMARKETING VIGILANCE

Regulatory Compliance Challenges for International Pharmaceutical and Medical Device Companies

SEPTEMBER 25-26, 2006 | Washington Marriott Hotel, Washington, DC, USA | Meeting ID #06026

DAY ONE

Good Clinical Practice (GCP) and Special Issues in Clinical Trials

DAY TWO

Pharmaceutical and Medical Device Premarketing Clinical Trial Safety and Postmarketing Vigilance

Register online or fax this page to +1-215-442-6199

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

CONTACT & TABLETOP EXHIBIT INFORMATION

Attendees may visit the tabletop exhibits during the meeting and during receptions (if applicable).

Meeting information: Contact Ellen Diegel at the DIA office by telephone +1-215-442-6158, fax +1-215-442-6199 or email Ellen.Diegel@diahome.org.

Tabletop exhibit information: Contact Erin Gilliland, Exhibits Associate, at the DIA office by telephone +1-215-442-6149, fax +1-215-442-6199 or email Erin.Gilliland@diahome.org. For tabletop exhibit space, please check the box below.

❑ **To receive a tabletop exhibit application, please check.**

GROUP DISCOUNTS (not available online or on already discounted fees)

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. *See page 5 for complete details.*

Registration Fees *If DIA cannot verify your membership upon receipt of registration form, 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 *Available on nondiscount member fee only*	On or before SEPT. 5, 2006	After SEPT. 5, 2006
Member Fee	US $1125 ❑	US $1300 ❑

Join DIA now to qualify for the early-bird member fee! **www.diahome.org/docs/Membership** — MEMBERSHIP **US $ 130** ❑

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Nonmember Fee US $1430 ❑

A one-year membership to DIA is available to those paying a NONMEMBER meeting registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ❑ I do NOT want to be a DIA member ❑

Discount Fees	MEMBER	NONMEMBER*
Government (Full-time)	US $ 300 ❑	US $ 430 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 650 ❑	US $ 780 ❑

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CANCELLATION POLICY: On or before SEPTEMBER 19, 2006

Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial = $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.

❑ **I cannot attend but please keep me informed of DIA's future events.**
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Company

Address As required for postal delivery to your location Mail Stop

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Phone Number Fax Number Required for confirmation

Group Registrant #2 Last Name First Name Completed form required for each group registrant

Group Registrant #3 Last Name First Name Completed form required for each group registrant

Group Registrant #4 Last Name First Name Completed form required for each group registrant

PAYMENT OPTIONS

Register online at www.diahome.org or check payment method

❑ **CREDIT CARD** number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

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Card # _____

Name (printed) _____

Signature _____

❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

❑ **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 Meeting I.D. # must be included on the transfer document to ensure payment to your account.