

# DRUG SAFETY SURVEILLANCE AND EPIDEMIOLOGY

## Course Description

This course is designed to provide a comprehensive overview of domestic and international safety surveillance, including the role of epidemiology, from both industry and FDA perspectives. This overview of safety surveillance and epidemiology issues is not a "how to" course in completing adverse event forms for regulatory reporting.

## Target Audience

This course will particularly benefit managers and directors with experience in pharmacovigilance, clinical development, research, medical affairs and/or marketing.

*Faculty comprises professionals in the pharmaceutical and related industries who are experts actively practicing in their particular disciplines.*



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 15.5 contact hours or 1.55 continuing education units (CEUs). 286-000-06-017-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 1.6 continuing education units (CEUs) to participants who successfully complete this program.

**ACCME:** 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 15.5 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

To receive a statement of credit, participants must attend the program, sign in at the registration desk each morning, and complete the CE Request and Evaluation Forms and return them to DIA. Statements of credit will be mailed to participants within one month of program completion.

**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 disclosures will be included in the course materials.

**FIRST DAY BEGINS 9:00 AM**  
**FINAL DAY CONCLUDES 11:30 AM**

For detailed program information including faculty and topics, please contact Dori Eberhardt at +1-215-442-6192 or [Dori.Eberhardt@diahome.org](mailto:Dori.Eberhardt@diahome.org)

## KEY TOPICS

- ◆ THE ROLE OF EPIDEMIOLOGY IN SAFETY SURVEILLANCE
- ◆ DOMESTIC AND INTERNATIONAL SAFETY SURVEILLANCE
- ◆ REGULATORY AND INDUSTRY PERSPECTIVES ON SAFETY SURVEILLANCE AND EPIDEMIOLOGY

## LEARNING OBJECTIVES

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

- Discuss the historical and regulatory framework for safety surveillance during drug development and postapproval marketing
- Explain the strategic, legal and regulatory importance of safety within a drug's overall profile
- Recognize domestic and international safety surveillance regulatory requirements
- Describe FDA initiatives for safety surveillance of drugs, biologics and vaccines
- Identify methods for signal detection, investigation and interpretation
- Apply epidemiologic methods to drug safety surveillance

## SPECIAL FEATURES OF DIA TRAINING COURSES

- ◆ Experienced faculty in the pharmaceutical industry share the most up-to-date information
- ◆ Limited attendance allows active involvement and encourages meaningful interaction between faculty and students
- ◆ Informal dialogues continue each day at lunch
- ◆ Hands-on activities enhance understanding



**Sheraton National Hotel**  
**ARLINGTON, VA, USA**  
**SEPTEMBER 18-20, 2006**

*This course is limited to 50 participants. Register early!*

# TRAINING COURSE REGISTRATION FORM

Registration is limited to 50 and is reserved for the first 50 registrants.

Walk-in registration will NOT be accepted. Registration must be confirmed in writing by the DIA office. If you have not received confirmation within 5 business days, please contact **Tim Hershey** at Tel. +1-215-442-6157, Fax +1-215-442-6105, or email [Tim.Hershey@diahome.org](mailto:Tim.Hershey@diahome.org)

PLEASE CONSIDER THIS FORM AN INVOICE. Registration will be accepted by mail, fax or online.

## DRUG SAFETY SURVEILLANCE AND EPIDEMIOLOGY

Meeting I.D. #06449: September 18-20, 2006  
Sheraton National Hotel  
Arlington, VA, USA

**TUITION/REGISTRATION FEES:** Registration fee includes continental breakfasts, luncheons, reception and all course materials. *If DIA cannot verify your membership upon receipt of this registration form, you will be charged the nonmember fee.*

Member US \$1400  Government/Academia Member US \$700   
Nonmember\* US \$1530  Government/Academia Nonmember\* US \$830

\*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

Please check the applicable category below.

Academia  Government  Industry  CSO  Student (Full-time, verification required)

**PAYMENT METHODS – Register online at [www.diahome.org](http://www.diahome.org) or check payment method.**

**CHECK** drawn on a US bank payable to: Drug Information Association, mailed along with this form to: DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595. **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.

**CREDIT CARD** number may be faxed to: +1-215-442-6105. *You may prefer to pay by check or bank transfer since non-US credit card payment will be subject to the currency conversion rate at the time of the charge.*

Visa  MC  AMEX Exp Date \_\_\_\_\_ # \_\_\_\_\_

Name of Cardholder \_\_\_\_\_

Signature \_\_\_\_\_

Last Name \_\_\_\_\_ First Name \_\_\_\_\_ Middle Initial \_\_\_\_\_

Degrees \_\_\_\_\_  Dr.  Mr.  Ms.

Job Title \_\_\_\_\_

Affiliation (Company) \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_ Country \_\_\_\_\_  
(Please write your address in the format required for delivery to your country.)

email \_\_\_\_\_

\*Telephone Number \_\_\_\_\_ \*Fax Number \_\_\_\_\_ \*(A telephone and fax number are required for faxed confirmation.)

**I am unable to attend this course but would like information on future dates of this course.**

**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.

**Meeting ID # 06449**

Begins 9:00 AM; concludes 11:30 AM

## TRAVEL AND HOTEL INFORMATION

Hotel reservations should be made **ONLY** after receipt of written registration confirmation from DIA.

### TRAINING COURSE LOCATION

**Sheraton National Hotel**  
900 South Orme Street  
Arlington, VA 22204 USA

### Travel Information

The Sheraton National Hotel is located right outside Washington, DC, in Arlington, Virginia. Local attractions include the Arlington National Cemetery, the Kennedy Center, and the National Mall. World-class dining and exciting shopping are located just a few miles from the hotel. Contact the hotel for shuttle information from Reagan National Airport and Washington Dulles International Airport.

### Hotel Information

A limited block of rooms has been reserved at the Sheraton National Hotel at a low rate per night until the **release date of August 28, 2006**. We urge you to make your hotel reservations early and plan on staying at the hotel in order to facilitate interactive discussion with faculty and fellow participants.

**Single \$149 Double \$149**

Attendees must make their own hotel reservations. To reserve your room, contact the Sheraton National Hotel by telephone at +1-800-627-8210 or +1-800-325-3535 and mention the DIA Training Course.

### United Airlines & US Airways

#### Save through Area Pricing and Discount Fees

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).

## CANCELLATION POLICY

**On or before SEPTEMBER 4, 2006**  
Administrative fee that will be deducted = \$200

Cancellations must be made two weeks prior to the course with a \$200 administrative charge deducted from fee. Cancellations must be in writing and received in the DIA office by the date above. After this date, there will be no refunds. Registrants are responsible for cancelling their own hotel and travel reservations. Registrants who do not cancel prior to the course and do not attend will be responsible for the full registration fee. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.

## TRANSFER POLICY

You may transfer your registration and payment, only once, from one course to a future date of that same course. If you are unable to attend the new date selected, there will be no refund of the registration fee. Transfers must be in writing and received in the DIA office by the date of the course.