

# REGULATORY I: THE IND PHASE

Updated  
for 2007

## Course Description

This course will offer insight into the regulatory background of the IND and outline the content and data requirements for an IND submission to FDA. The course will focus on drug and well-characterized biological products and not the regulatory process for devices, generic products or traditional biologics.

## Who Should Attend

This course is designed for newly hired regulatory affairs professionals with backgrounds of less than six months experience or who are making a career change into regulatory affairs. The course will benefit those pharmaceutical industry professionals who are new to the Investigational New Drug Application (IND) process.

This course will also benefit professionals in clinical research, data processing, biostatistics, basic research, project management, and marketing, who would like to gain a better understanding of the regulation of investigational new drugs and well characterized biologics.

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

Prior to attending this course, attendees are encouraged to visit DIA's website at [www.diahome.org](http://www.diahome.org) and take the free eLearning module **History of US Drug Regulation**.

**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 18.25 AMA PRA Category 1 Credit(s)<sup>™</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity.



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 1.8 continuing education units (CEUs) to participants who successfully complete this program.

If you would like to receive a statement of credit, you must attend the program, sign-in at the registration desk each morning, and complete the on-line credit request process through My Transcript at [www.diahome.org](http://www.diahome.org).

Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on Thursday, March 29, 2007.

**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 8:30AM  
FINAL DAY CONCLUDES 2:45 PM**

For detailed program information including faculty and topics, please contact Susan Mazak at +1-215-442-6183 or [Susan.Mazak@diahome.org](mailto:Susan.Mazak@diahome.org)

## COURSE HIGHLIGHTS

- ◆ OVERVIEW OF THE DRUG DEVELOPMENT PROCESS
- ◆ IND PROCESS
- ◆ QUALITY ASSURANCE IN DRUG DEVELOPMENT (GXPs)
- ◆ FDA'S ACTIONS ON THE ORIGINAL IND AND AMENDMENTS
- ◆ ACTIVITIES AND SUBMISSIONS AFTER THE ORIGINAL IND
- ◆ INTERACTION WITH FDA
- ◆ PROCEDURES FOR REPORTING ADVERSE EVENTS (AEs)

## LEARNING OBJECTIVES

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

- Discuss the role of regulatory affairs within the pharmaceutical industry
- Discuss the role of FDA and composition of FDA's review teams
- Plan and organize an initial IND and subsequent amendments
- Report adverse events which occur in clinical trials appropriately to FDA and investigators
- Describe meetings to be held with the FDA and discuss appropriate etiquette for FDA interactions during the IND phase

## 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
- ◆ Hands-on activities enhance understanding



**Park Hyatt Philadelphia at the Bellevue  
PHILADELPHIA, PA, USA  
MARCH 26-28, 2007**

*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.

## REGULATORY I: THE IND PHASE

Meeting I.D. #07419: March 26-28, 2007  
Park Hyatt Philadelphia at the Bellevue  
Philadelphia, PA, 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 \$1595	<input type="checkbox"/>	Government/Academia Member	US \$800	<input type="checkbox"/>
Nonmember*	US \$1725	<input type="checkbox"/>	Government/Academia Nonmember*	US \$930	<input type="checkbox"/>

\*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 # 07419

First day begins 8:30 am; Final day concludes 2:45 pm

### TRAVEL AND HOTEL INFORMATION

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

#### TRAINING COURSE LOCATION

**Park Hyatt Philadelphia at the Bellevue**  
Broad and Walnut Streets  
Philadelphia, PA 19102 USA

#### Travel Information

The Park Hyatt Philadelphia is located at the Bellevue, in the heart of Philadelphia's downtown historic theater district. The Philadelphia International Airport is 8 miles from the hotel. The hotel is within walking distance of the Liberty Bell, Independence Hall and to restaurants, theaters and world-class shopping. Contact the hotel for airport shuttle information.

#### Hotel Information

A limited block of rooms has been reserved at the Park Hyatt Philadelphia at the Bellevue at a low rate per night until the **release date of March 5, 2007**. 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 \$235 Double \$260**

Attendees must make their own hotel reservations. To reserve your room, contact the Park Hyatt Philadelphia at the Bellevue by telephone at +1-800-233-1234 or by fax at +1-215-893-1234 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 MARCH 12, 2007**  
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 to a colleague at any time but membership is not transferable. Please notify the DIA North American office of such transfers in writing as soon as possible. Substitute registrants will be responsible for the nonmember fee, if applicable.*