# REGULATORY AFFAIRS: Part I: The IND Phase & Part II: The CTD/NDA Phase

***Two Courses in One***

## Course Description

This course combines the two three-day courses into one extended four-day offering. It describes the regulatory background of the IND and NDA and provides an overview of the requirements and recommendations for preparing and managing these applications.

## Who Should Attend

Professionals who want to gain a better understanding of the basics of submitting applications for product approval and post-marketing regulatory requirements, including:

- Professionals with less than six months' experience or who are making a career change into regulatory affairs
- Professionals who are new to the IND and NDA processes
- Clinical Research
- Data Processing
- Biostatistics
- Project Management
- Basic Research
- Marketing

***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 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 17.5 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 (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 3.2 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. 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 Friday, November 9, 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 8:00 AM**
**FINAL DAY CONCLUDES 5:15 PM**

**For detailed program information including faculty and topics, please contact Susan Mazak at +1-215-442-6183 or Susan.Mazak@diahome.org**

## COURSE HIGHLIGHTS

- OVERVIEW OF THE DRUG DEVELOPMENT PROCESS
- IND PROCESS
- QUALITY ASSURANCE IN DRUG DEVELOPMENT
- FDA ACTIONS ON THE ORIGINAL IND AND AMENDMENTS
- ACTIVITIES AND SUBMISSIONS AFTER THE ORIGINAL IND
- INTERACTIONS WITH FDA
- PROCEDURES FOR REPORTING ADVERSE DRUG EVENTS (AEs) THAT OCCUR DURING CLINICAL INVESTIGATIONS AND POST APPROVAL
- NDA IN CTD FORMAT
- REGULATORY COMPLIANCE AND FDA INSPECTIONS
- POST-APPROVAL REGULATORY REQUIREMENTS
- REGULATORY REQUIREMENTS FOR PRESCRIPTION PRODUCT LABELING, ADVERTISING, AND PROMOTION

## 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
- Participate in the preparation of the NDA/BLA using the Common Technical Document format
- Recognize FDA oversight and processes during the post-approval phase
- Explain the regulatory requirements for prescription drug labeling and advertising/promotion
- Describe meetings to be held with the FDA and discuss appropriate etiquette for FDA interactions during the IND/NDA phases

DRUG INFORMATION ASSOCIATION

**www.diahome.org**

## Park Hyatt Philadelphia at the Bellevue

# PHILADELPHIA, PA, USA
# NOVEMBER 5-8, 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***

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

## REGULATORY AFFAIRS TRAINING COURSE
## Part I: The IND Phase • Part II: THE CTD/NDA Phase

**Meeting ID# 07412: November 5-8, 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.***

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| **Member** | **US $2750** ☐ | **Gov't /Academia Member** | **US $1375** ☐ |
| **Nonmember*** | **US $2880** ☐ | **Gov't /Academia Nonmember*** | **US $1505** ☐ |

**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 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. You may pay in the currency of your choice. Your name and company, as well as the above Meeting I.D. Number, 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_____

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Last Name First Name Middle Initial

_____ ☐ Dr. ☐ Mr. ☐ Ms.
Degrees

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Job Title

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Affiliation (Company)

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Address

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

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email

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*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 # 07412

**First day begins 8:00 AM; Final day concludes 5:15 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 October 15, 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 $249 Double $274**

Attendees must make their own hotel reservations. To reserve your room, contact the Hotel by telephone at +**1-800-233-1234** or +**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*** **OCTOBER 22, 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.*