

Regulatory Affairs for Biologics

The IND & BLA Phases



October 22-25, San Diego, CA

Basics of IND/BLA submissions and Postmarketing Regulatory Requirements

Learn the basic FDA regulations and expectations for the content, submission, and review of IND/BLAs and get the latest information on traditional Biologics, Biotechnology products and Biosimilars.

WHAT YOU WILL LEARN

- ▶ Fundamentals of the Investigational New Drug and Biologics License Application processes
 - Preparation
 - Content
 - Regulatory pathways
- ▶ Meetings and other interactions with FDA

CONTINUING EDUCATION



Drug Information Association has been approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102; (703) 506-3275.

Drug Information Association is authorized by IACET to offer 3.1 CEUs for this program. Participants **must attend the entire** course in order to be eligible to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you **must attend the entire course**, sign-in at the DIA registration desk each day of the course, 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 two weeks after the last day of the course.

Disclosure Policy: It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Faculty disclosures will be included in the course materials.

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

- Recognize content and format requirements for IND/BLA in the Common Technical Document Format
- Plan and prepare an IND/BLA, and know the reporting requirements for IND/BLA amendments
- Identify FDA review processes for evaluating IND/BLAs
- Define BLA post-approval responsibilities and requirements
- Identify regulatory mechanisms to facilitate development of new products
- Report adverse events in accordance with current FDA regulations
- Apply formal meeting principles and practices when interacting with the FDA during the IND/BLA phase
- Outline the regulatory requirements for product labeling and advertising/promotion

FACULTY

CAROL H. DANIELSON, PhD, MA, MS
President
Regulatory Advantage

CYNTHIA L. KIRK, PhD, RAC
Consultant
Catalyst Regulatory Services

WHO SHOULD ATTEND

Professionals involved in:

- ▶ Regulatory affairs professionals new to the IND/BLA processes
- ▶ Clinical development professionals
- ▶ Biostatisticians
- ▶ Basic researchers
- ▶ Quality and manufacturing professionals
- ▶ Medical writers
- ▶ Business and marketing professionals
- ▶ Clinical research academicians
- ▶ Project management professionals

For registration questions, please contact Elizabeth Espich at +1-215-293-5802 or Elizabeth.Espich@diahome.org

For agenda details, please contact Susan Berkelbach at +1.215.442.6183 or Susan.Berkelbach@diahome.org

Unless otherwise disclosed, the statements made by speakers represent their own opinions and not necessarily those of the organization they represent, or that of the Drug Information Association. Speakers, agenda, and CE information are subject to change without notice. Recording of any DIA educational material in any type of media, is prohibited without prior written consent from DIA.

To view DIA's Grievance Policy, please visit the CE page on DIA's website at www.diahome.org.

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REGISTRATION FORM • Meeting ID# 12432 • Registration is limited. Register early.

You may register online at www.diahome.org, or you may return this completed form by mail to DIA at the address below under check payment method, or by fax to **+1.215.442.6199**. Walk-in registration will **NOT** be accepted. **Registration must be confirmed in writing by the DIA office.** If you have not received confirmation within five business days, please telephone DIA at **+1.215.442.6100** or email confirmationservices@diahome.org.

► REGULATORY AFFAIRS FOR BIOLOGICS

October 22-25 • Meeting ID# 12432 • The Westgate Hotel, San Diego, CA, USA

For additional offerings, visit www.diahome.org.

TUITION/REGISTRATION FEES: Registration fee includes continental breakfast(s), luncheon(s), reception (if applicable), and all course materials. If DIA cannot verify your membership, you will be charged the nonmember fee.

MEMBER EARLY-BIRD OPPORTUNITY

Available on **nondiscount** member fee only.

MEMBER FEE

On or before Oct. 2

US \$3120

After Oct. 2

US \$2920

To qualify for the early-bird discount, registration and accompanying payment must be received by the date above. Early-bird does not apply to government/academia/nonprofit members.

Join DIA now to qualify for the early-bird member fee (if applicable) and to enjoy all the benefits of membership for a full year! www.diahome.org/Membership

MEMBERSHIP

*US \$175

NONMEMBER FEE

US \$3345

DISCOUNT FEES

Member Government/Academia/Charitable Nonprofit (Full-time) US \$1715

Nonmember Government/Academia/Charitable Nonprofit (Full-time) US \$1940

*NONMEMBERS:
JOIN DIA & SAVE.
Check MEMBERSHIP
above.

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.

Please indicate that this form is part of a group registration by checking this box and list below the names of the other three registrants from your company.

1. _____
2. _____
3. _____

PAYMENT METHODS: Register online at www.diahome.org or check the preferred 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: **+1.215.442.6199** 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 _____

Card # _____

Cardholder Name _____

Signature _____

Meeting ID # 12432

First day begins 8:00 AM

Final day concludes 4:30 PM

COURSE CANCELLATION AND TRANSFER POLICIES

On or before September 30

Cancellations: Cancellations must be received two weeks prior to the first day of the course. A \$200 administrative charge will be deducted from the original registration fee. Cancellations must be in writing and received in the DIA office according to the timeline above. There will be no refund if cancellation is received within two weeks from the first day of the course. 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.

Transfers: 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.

TRAINING COURSE LOCATION

The Westgate Hotel

1055 Second Avenue

San Diego, CA, 92101, USA

HOTEL INFORMATION

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

The Westgate Hotel

1055 Second Avenue

San Diego, CA, 92101, USA

The Westgate Hotel in San Diego, California offers the luxury and pleasures of the world's finest metropolitan hotels, and the best of Southern California! The Westgate Hotel is located minutes from the airport and the San Diego Convention Center, steps from the trolley/train station and is readily accessible by freeway. The Westgate is a one-of-a-kind hotel, completed in 1970 and filled with timeless elegance not found anywhere else in San Diego, California. It is filled with priceless antiques and appointments one would find in an elegant home.

Within walking distance is the Museum of Contemporary Art, the Opera and the Symphony, Horton Plaza shops and the Gaslamp Quarter.

A limited block of rooms has been reserved at the The Westgate Hotel at a low rate per night until the release date of until the release date of September 30, 2012. 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 \$159 / Double \$159

Attendees must make their own hotel reservations. To reserve your room, contact The Westgate Hotel by telephone at **+1.800.522.1564** and ask about the DIA Training Course

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

REGISTRANT'S CONTACT INFORMATION

Please check the applicable category: Academia Government Industry CSO Student (Full-time, verification required)

Registrant's Name _____
Last Name First Name M.I.

Degrees _____ Dr. Mr. Ms.

Job Title _____

Company _____

Address _____

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

*email _____

*(An email address is required for confirmation.)

Tel Number _____ Fax Number _____