DIA Learning

A Comprehensive Review of Regulatory Procedures for New Drug Applications (NDAs) / Biologics License Applications (BLAs) in the US

30-31 October 2018
Holiday Inn London Kensington Forum, UK

OVERVIEW

As drug development has become a global process, have you had questions about US Regulatory requirements? Do you wonder why your US colleagues ask for certain documents or information for the marketing application?

This course will focus on marketing applications (NDA/BLA) for drug and biologic products; the regulatory process for medical devices or multisourced (generic) products will not be addressed.

LEARNING OBJECTIVES

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

- Define the key principles and processes used by the US Food and Drug Administration (FDA) in regulatory submission and approval
- Define official regulatory policies and other issues pertinent to a successful US regulatory strategy
- Describe the requirements for marketing applications for drugs and biologics, New Drug Application (NDA) and Biologics License Application (BLA) and document preparation
- Recognise FDA oversight and processes during the post-approval phase
- Interact appropriately with the FDA during all phases of drug development

Participants will complete a knowledge check at the end of the course to ensure learning objectives are attained.

KEY TOPICS

- Regulation of drugs and biologics in the US: The basics
- Overview of the FDA
- US Regulatory requirements for drug development and approval
- Interactions with FDA
- Submitting the NDA in CTD format – What's unique to FDA
- FDA review of and actions on applications
- Post-approval regulatory requirements for NDAs/BLAs
- US regulatory requirements for advertising and labelling
- Regulatory compliance and FDA Inspections: What to expect after submitting the NDA/BLA

WHO WILL ATTEND

This course is specifically designed for persons with a background in pre-clinical research (e.g., pharmacology, toxicology, and drug metabolism), clinical research, quality assurance or academia, with novice to intermediate experience in Regulatory Affairs, who need knowledge of the US regulatory processes.

This course will also enhance understanding and be beneficial to persons who work in clinical research, data management, biostatistics, basic research, project management and marketing, etc.

DIA also welcomes attendance by regulatory agency staff members.

FACULTY

Michael R. Hamrell
Course Director
President, MORIAH Consultants, USA

Carol H. Danielson
President, Regulatory Advantage, USA

SPECIAL OFFER

Register for both Comprehensive Review of Regulatory Procedures in the US training courses and save up to EUR 765!

See registration form on the back for details.

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

ONLINE BEFORE THE COURSE

SESSION 1

INTRODUCTION TO REGULATION OF DRUGS AND BIOLOGICS IN THE US

- Historical perspectives of drug and biologics regulation in the US
- Regulation of drugs and biologics in the US
  - o Federal Food, Drug and Cosmetic Act
  - o Public Health Service Act
- Roles and responsibilities of FDA
- Key definitions

SESSION 2

INTRODUCTION TO THE DEVELOPMENT PROCESS FOR DRUGS AND BIOLOGICS IN THE US: A REGULATORY PERSPECTIVE

- Phases of pharmaceutical product development
- Role of the regulatory professional in drug and biologic product development
- Use of the target product profile (TPP) to facilitate product development process and strategy

DAY 1

12:30 REGISTRATION

13:00 WELCOME AND OVERVIEW

Michael Hamrell

13:15 SESSION 1

THE NDA - A GENERAL INTRODUCTION

Michael Hamrell

- Getting from the IND to the NDA
- Considerations in planning for the NDA
- Study data from different populations
- Types of NDAs
- Exclusivity determinations

14:15 SESSION 2

THE NDA IN CTD FORMAT - MODULES 1 & 3

Michael Hamrell

- The CTD - Overview
- Module 1
- Module 3 - Quality

15:00 COFFEE BREAK

15:15 SESSION 3

THE NDA IN CTD FORMAT - MODULES 4, 5 & 2

Michael Hamrell

- Module 4 – Safety
  - o Nonclinical pharmacology and toxicology study reports
- Module 5 – Efficacy
  - o Clinical study reports & affiliated materials
- Module 2 – CTD summaries
- Safety update reports (CTD Module 5)

16:45 NETWORKING RECEPTION

17:45 END OF DAY ONE

DAY 2

08:00 SESSION 4

HOW TO SUBMIT AN NDA/BLA AND FDA ACTIONS ON APPLICATIONS

Carol Danielson

- How to submit a new drug application
- Electronic submissions
- Processing an NDA
- FDA review of applications
- Amendments to an unapproved application
- FDA actions on applications
- Reasons applications are not approved
- Benchmarks: Prescription Drug User Fee Act (PDUFA) metrics

09:00 SESSION 5

POST-NDA APPROVAL REGULATORY REQUIREMENTS

Michael Hamrell

- Post-NDA approval obligations
- Post-marketing (phase 4) requirements and commitments
- Supplements and other changes to an approved application
- Post-marketing reporting of adverse drug experiences
- 15-day alert reports
- NDA annual reports
  - PSUR/PBER/PADER
- NDA field alert reports
- Biologic product deviation reports
- FDA's Drug Registration and Listing System (DRLS)

10:00 COFFEE BREAK

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 11.75 credits.

Special rates available for SwAPP and SGPM members.

SwAPP Swiss Association of Pharmaceutical Professionals

Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

10:15 SESSION 6

NDA POSTAPPROVAL SUBMISSIONS WORKSHOP

Carol Danielson

11:15 SESSION 7

INTERACTIONS WITH THE FDA

Carol Danielson

- FDA's guidance on meetings and how to request them
- Time course of events in requesting and preparing for a meeting
- Objectives and conduct of specific meetings with FDA
- Principles for communicating with FDA
- Meeting etiquette
- How to resolve issues or disputes with FDA
- Summary on interacting with FDA advisory committee meetings

12:15 LUNCH

13:15 SESSION 8

MOCK FDA MEETING WORKSHOP

Michael Hamrell

15:00 COFFEE BREAK

15:15 SESSION 9

REGULATORY COMPLIANCE AND FDA INSPECTIONS: WHAT TO EXPECT BEFORE, DURING AND AFTER SUBMITTING THE NDA

Carol Danielson

- GLP inspections
- GCP inspections
- Inspection outcomes: Additional considerations in GCP inspections
- GMP inspections
- Inspection outcomes (GLPs, GCPs, GMPs)
- FDA enforcement actions
- Application Integrity Policy (AIP)

16:15 SESSION 10

REGULATORY REQUIREMENTS FOR PRESCRIPTION DRUG LABELLING & ADVERTISEMENT

Michael Hamrell

- Definitions
- Requirements for labels of immediate containers and cartons
- Prescribing information; package insert (PI)
- Sections of the labeling (prescribing information) under the physician labeling rule
- Labeling for systemic antibacterial drugs
- Labeling format requirements
- Patient labeling
- Structured product labeling
- Prescription drug/biologics advertising and promotional labeling

17:00 END OF TRAINING COURSE

Training Course Venue

HOLIDAY INN KENSINGTON FORUM

97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9100
Email: reservations@hikensington.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 28 to 31 October 2018 at the rate of GBP 165..00 per standard double room for single use per night including full English breakfast, taxes and service fee.

In order to book a hotel room, please contact the hotel directly and quote the booking reference "DIA".
The room rate is available until 28 September 2018 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Heathrow Airport take the London Underground Victoria line and get off at Gloucester Road. The hotel is located within 3 min walking distance from the station.

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted 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 only available for the industry rate.

To take advantage of this offer, please print the 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.

For groups of 5 or more individuals, please contact Basel@diaglobal.org for a custom group rate.

Follow **@DrugInfoAssn**

REGISTRATION FORM

Comprehensive Overview of Regulatory Procedures for NDAs in the US #18555
30-31 October 2018 | Holiday Inn London Kensington Forum | London, UK

DIA Learning

REGISTRATION FEES

Registration fee includes refreshment breaks, lunch on the 2nd day of the course and electronic access to training course material. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'240.00 ❑	€ 1'395.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 620.00 ❑	€ 775.00 ❑
I would like register for the ***Comprehensive Overview of Regulatory Procedures for INDs in the US*** #18554 (29-30October 2018) AND the ***Comprehensive Overview of Regulatory Procedures for NDAs/BLAs in the US*** #18555 (30-31 October 2018) courses to benefit from a combo discount.		
INDUSTRY	€ 1'870.00 ❑	€ 2'025.00 ❑
Join DIA now to qualify for the member rate	€ 155.00 ❑	

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.

DIA MEMBERSHIP

All non-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click here. If you want a membership, please indicate your preference below.

❑ **I would like to receive a one year complimentary DIA membership at no aditional cost**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
Tel. :+41 61 225 51 51 **Fax:** +41 61 225 51 52
Email: Basel@diaglobal.org **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland **Web:** www.DIAglobal.org

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click here.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click here. You agree that your personal data will be transferred to DIA in the US.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number Fax Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N° | | | | | | | | | | | | | | | | |

Exp. Date | | / | |

Cardholder's Name

❑ **Bank transfers:** 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. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #18555 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature