DIA Learning

US Regulatory Affairs
A Comprehensive Review of Regulatory Procedures for NDAs in the US

17-18 October 2017
Holiday Inn London Kensington Forum, UK

OVERVIEW

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

This course will focus on drug and biologic products; the regulatory process for 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 key differences between US and EU regulatory requirements
- 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 and will be provided with feedback to ensure learning objectives are attained.

KEY TOPICS

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

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 Europe, Middle East & Africa 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

- Why do governments regulate drugs and biologics?
- Food and Drug Administration Amendments Act of 2007 (FDAAA)
- Role of FDA and other health regulatory agencies
- What is a regulatory strategy?
- Key definitions

SESSION 2

THE DRUG DEVELOPMENT PROCESS: AN OVERVIEW

DAY 1

12:30 REGISTRATION

13:00 INTRODUCTION TO NDA PART

Michael Hamrell

13:15 SESSION 1

THE NDA IN CTD FORMAT

Michael Hamrell

- Getting from the IND to the NDA
- Types of NDAs

14:15 SESSION 2

THE NDA IN CTD FORMAT: WHAT IS A CTD?

Michael Hamrell

- The CTD details
- Module 1
- Module 3
- Module 4

15:00 COFFEE BREAK

15:15 SESSION 3

THE NDA IN CTD FORMAT (CONTINUED)

Michael Hamrell

- Module 5
  - Structure and contents of clinical study reports - E3
- Module 2
- 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 A NDA AND ACTION ON APPLICATIONS

Carol Danielson

- How to submit a new drug application
- Electronic submissions
- Processing an NDA
- Amendments to an unapproved application
- FDA actions on applications
- 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) 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

10:15 SESSION 6

NDA POST-APPROVAL WORKSHOP

Carol Danielson

11:15 SESSION 7

INTERACTIONS WITH FDA

Carol Danielson

- FDA's guidance on meetings and how to request them
- Time course of events in requesting 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

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

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

13:15 SESSION 8

MOCK FDA MEETING
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 & PRESCRIPTION DRUG/BIOLOGICS ADVERTISING AND PROMOTIONAL LABELLING
Michael Hamrell

- Definitions
- Requirements for labels of immediate containers and cartons
- Prescription drug labelling: The package insert
- New prescription drug labelling regulations
- Structured product labelling
- Patient labelling
- Statutory basis for promotional regulations
- Required elements for advertisements and promotional labelling
- Reminder advertisements/labelling
- Pre-approval promotional activities
- Other types of advertising
- FDA enforcement actions
- Launch of promotional pieces
- Post-marketing submission of advertising

17:00 END OF TRAINING COURSE

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 EMEA@DIAglobal.org for a custom group rate.

Training Course Venue

Holiday Inn London Kensington Forum
97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9100
www.hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 15 to 18 October 2017 at the rate of GBP 160.00 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/PW3".
The room rate is available until 15 September 2017 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.

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

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REGISTRATION FORM

Comprehensive Overview of Regulatory Procedures for NDAs in the US #17555
17-18 October 2017 | 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*** #17554 (16-17 October 2017) AND the ***Comprehensive Overview of Regulatory Procedures for NDAs in the US*** #17555 (17-18 October 2017) 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.

The DIA Europe, Middle East & Africa 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: EMEA@DIAglobal.org **Mail:** DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland **Web:** www.DIAglobal.org

CANCELLATION POLICY

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa 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.

PHOTOGRAPHY POLICY

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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 # 17555 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 Europe, Middle East and Africa.**

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

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