DIA Training Course on

US Regulatory Affairs

A Comprehensive Review of Regulatory Procedures for INDs and NDAs in the US

14-16 November 2016
Pullman Brussels Centre Midi, Brussels, Belgium

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 is specifically designed for persons with a background in pre-clinical research (e.g., pharmacology, toxicology, 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 also welcomes attendance by regulatory agency staff members. Participants need to have some knowledge of the ICH and in particular the Common Technical Document (CTD). Participants will gain a better understanding of the US regulation of investigational new drugs (INDs) and biologics, of the basics of submission of applications seeking marketing approval for a product (NDA & BLA) and post-marketing regulatory requirements in the US.

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
- Understand the regulatory requirements for prescription drug labelling and advertising/promotion and differences with EU requirements.

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

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
- The IND - A general introduction
- The IND - In detail
- IND Amendments and maintenance
- Procedures for reporting Adverse Events (AEs) that occur during clinical investigations
- Submitting the NDA in CTD format – What's unique to FDA
- Post-approval regulatory requirements for NDAs
- Interactions with FDA
- US regulatory requirements for advertising and labelling
- Regulatory compliance and FDA Inspections: What to expect after submitting the NDA

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PharmaTrain MASTERING MEDICINES DEVELOPMENT

FACULTY

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DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

DIAglobal.org

DAY 1

07:30 REGISTRATION

08:00 WELCOME AND INTRODUCTION

08:15 SESSION 1 *(Material available as pre-recorded webinar)*

INTRODUCTION TO REGULATION OF DRUGS AND BIOLOGICS

- How does US government regulate drugs and biologics?
- Role of FDA
- What is a regulatory strategy?
- Key definitions

08:45 SESSION 2 *(Material available as pre-recorded webinar)*

THE DRUG DEVELOPMENT PROCESS: AN OVERVIEW

- Role of Regulatory professionals
- Regulatory strategies and TPP

09:15 SESSION 3

THE IND - A GENERAL INTRODUCTION

- What is an IND?
- When is an IND required/not required?
- Types of INDs

10:00 COFFEE BREAK

10:15 SESSION 4

THE IND IN DETAIL - ITEMS 1-6

- IND ITEM 1: Form FDA 1571
- IND ITEM 2: Table of contents
- IND ITEM 3: Introductory statement
- IND ITEM 4: General investigation plan
- IND ITEM 5: Investigator's brochure
- IND ITEM 6: Protocols

11:15 SESSION 5

SPECIAL TOPICS FOR CLINICAL RESEARCH UNDER AN IND

- Adequate and well-controlled trials
- Foreign clinical trials
- Surrogate endpoints
- Disease-specific guidance as resources
- Changes in the investigational drug in phases 2-3
- The Animal rule
- Financial disclosure by clinical investigators

12:30 LUNCH

13:30 SESSION 6

IND IN DETAIL - ITEM 7

- Chemistry, manufacturing and controls (CMC)

14:15 SESSION 7

IND IN DETAIL - ITEMS 8, 9 AND 10

- IND item 8: Non-clinical pharmacology and toxicology
- IND item 9: Previous human experience
- IND item 10: Additional information

15:00 COFFEE BREAK

15:15 SESSION 8

IND IN DETAIL - ADDITIONAL TOPICS

- Additional requirements for biologics and biotechnology-derived products
- Assembly and submission of an original IND

16:00 SESSION 9

QUALITY ASSURANCE IN DRUG DEVELOPMENT (GXPS)

- Good Clinical Practice (GCP)
  - Institutional Review Boards
  - Informed consent
- Good Laboratory Practice (GLP)
- Good Manufacturing Practice (GMP)

17:00 DRINKS RECEPTION

18:00 END OF THE DAY

DAY 2

08:00 SESSION 10

FDA'S ACTIONS ON THE ORIGINAL IND & FUTURE AMENDMENTS

- FDA's review on an IND
- Clinical Holds: Basis for imposition and process for removal
- Administrative actions

08:30 SESSION 11

ACTIVITIES AND SUBMISSIONS AFTER THE ORIGINAL IND

- Amendments to the IND
- Special protocol assessment
- Special development opportunities
- Annual reports

09:45 COFFEE BREAK

10:00 SESSION 12

REPORTING ADVERSE EVENTS (AES) DURING CLINICAL TRIALS

- Definitions of terms
- IND safety reports
- IND annual reports - Safety information
- Termination of studies for safety reasons

11:00 SESSION 13

THE NDA IN CTD FORMAT

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

12:00 LUNCH

13:00 SESSION 14

THE NDA IN CTD FORMAT: WHAT IS A CTD?

- The CTD details
- Module 1
- Module 3

14:30 SESSION 15

THE NDA IN CTD FORMAT

- Module 4
- Module 5
- ICH guideline for structure and contents of clinical study reports - E3
- Module 2
- Safety update reports (CTD module 5)

16:00 COFFEE BREAK

16:15 SESSION 16

THE FDA AND RISK MANAGEMENT

- Pre-marketing risk assessment
- Post-marketing risk assessment
- Risk evaluation and mitigation strategies

17:00 END OF DAY TWO

DAY 3

08:00 SESSION 17

THE NDA IN CTD FORMAT: HOW TO SUBMIT AND ACTION ON APPLICATIONS

- 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

09:30 COFFEE BREAK

09:45 SESSION 18

POST-NDA APPROVAL REGULATORY REQUIREMENTS

- 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
- NDA field alert reports
- Biologic product deviation reports
- FDA's Drug Registration and Listing System (DRLS)

11:15 SESSION 19

INTERACTIONS WITH FDA

- 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

12:30 LUNCH

13:30 SESSION 20

MOCK FDA MEETING

15:00 COFFEE BREAK

15:15 SESSION 21

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

- 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)

16:00 SESSION 22

REGULATORY REQUIREMENTS FOR PRESCRIPTION DRUG LABELLING & PRESCRIPTION DRUG/BIOLOGICS ADVERTISING AND PROMOTIONAL LABELLING

- 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

17:15 WRAP UP AND END OF TRAINING COURSE

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with 21.5 credits for pharmaceutical medicine. All participants are eligible for these credits.

SwAPP Swiss Association of Pharmaceutical Professionals

DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

Training Course Venue

The training course will take place at:

Pullman Brussels Centre Midi
Place Victor Horta 1
1060 Brussels
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H7431@accor.com
http://www.accorhotels.com/gb/hotel-7431-pullman-brussels-centre-midi/index.shtml

DIA has blocked a limited number of hotel rooms for the course participants from 13 to 15 November 2016 at the rate of EUR 140.00 per single room per night including breakfast, taxes and service fee.

REGISTRATION FORM

US Regulatory Affairs # 16554

14-16 November 2016 | Pullman Brussels Centre Midi, Brussels, Belgium

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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and training course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'870.00 ❑	€ 2'025.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 935.00 ❑	€ 1'090.00 ❑

*All registration fees are subject to the applicable Belgian VAT

Please enter your company's VAT number: _____

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

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

❑ I do not want complimentary membership

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.
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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 five working days 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 five working days 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

email (Required for confirmation) 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

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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.diahome.org/EUTerms

Date	Signature