DIA Training Course on

US Regulatory Affairs

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

Course #13552 6-8 November 2013 Hotel Mercure Paris la Villette, France



Faculty

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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 and post-marketing regulatory requirements in the US.

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
- Navigating the FDA on the internet

Learning Objectives

At the conclusion of this course, participants should 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 major 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 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.

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 credits for pharmaceutical medicine. All participants are eligible for these credits.

This course has limited capacity. Register early.

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MASTERING MEDICINES DEVELOPMENT



DAY 1

07:30 REGISTRATION

08:00 WELCOME AND INTRODUCTION

08:15 Session 1

IN TRODUCTION TO REG ULATION 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

09:15 Session 2

THE DRUG DEVELOPMENT PROCESS: AN OVERVIEW

09:45 Session 3

THE IND - A GENERAL INTRODUCTION

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

10:15 COFFEE BREAK

10:30 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
- Fincancial disclosure by clinical investigators

12:30 LUNCH

13:30 Session 6

IN D IN DETAIL - ITEM 7

• Chemistry, manufacturing and controls (CMC)

14:15 Session 7

IN D IN DETAIL - ITEMS 8, 9 AND 10

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

15:00 COFFEE BREAK

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15:15 Session 8

IN D 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: Post Prescription Drug User Fee Act (PDUFA)

09:30 COFFEE BREAK

09:45 Session 18

POST-NDA APPROVAL REG ULATORY 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

IN TERACTIONS 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

ABOUT DIA

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

13:30 Session 20

MOCK FDA MEETING

15:00 COFFEE BREAK

15:15 Session 21

REG ULATORY 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)

16:15 Session 22

REG ULATORY REQUIREMENTS FOR PRESCRIPTION DRUG LABELLING & REVIEW OF PRESCRIPTION DRUG/BIOLOGICS ADVERTISING AND PROMOTIONAL LABELLING

- Definition
- Requirements for labels of immediate containers and cartons
- Prescription drug labelling: The package insert
- New prescription drug labelling regulations
- Implementation of the physician labelling rule
- Structured product labelling
- Comparison of US package insert to European summary of product
- characteristics
- Patient labelling
- Statutory basis for promotional regulations
- Required elements for advertisements and promotional labelling
- Reminder advertisements/labelling
- Pre-approval promotional activities
- Other topics
- FDA enforcement actions
- · Launch of promotional pieces
- Post-marketing submission of advertising

17:15 WRAP-UP DISCUSSION AND QUESTIONS

17:30 END OF TRAINING COURSE

HOTEL INFORMATION

DIA has blocked a limited number of rooms at the following hotel:

Mercure Paris la Villette

216 Avenue Jean Jaurès

75019 Paris

France

Tel:+33 (0) 1 44 84 18 18

Fax:+33 (0) 1 44 84 18 20

Email: mercureparisv@alliance-hospitality.com

Website: http://www.mercure.com/fr/hotel-8816-mercure-paris-la-villette/index.shtml

at the rates of EUR 180.00 per room inclusive of breakfast and VAT.

To make your reservation, please use the hotel booking from available on the DIA website.

Important: The room rate is available until 22 September or until the group block is sold-out, whichever comes first.

Cancellation policy

No change or cancellation can be made after booking.

The client acknowledges that first night of the stay will be charged when the booking is made. This amount is non-refundable.

REGISTRATION FORM

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Please advise your European VAT number:	Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.	
	Registration fee includes: refresh	ments, lunches and training course material.
TOTAL AMOUNT DUE:	Payment is due 30 days after regist	ration and must be paid in full by commencement of the course.
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DIA reserves the right to include your name and affiliation on the attendee list.		

Cancellation Policy

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

- Industry (Member/Non-member) € 200.00
- $\bullet \ \ \text{Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member)} \in 100.00$
- Tutorial cancellation € 50.00

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 Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe 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 Europe 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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.