US Regulatory Affairs

Course #10552
October 18-21, 2010
Radisson SAS Alcron Hotel, Prague, Czech Republic

Course Faculty

Michael R. Hamrell, PhD, RAC (Course Director)
MORIAH Consultants, USA

Carol H. Danielson, PhD, MA, MS
Regulatory Advantage, USA

Drusilla L. Scott, PhD, RAC
Cempra Pharmaceuticals, USA

This course has limited capacity. Register early.

Course Description

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 and who have novice to intermediate experience in Regulatory Affairs, who need an enhanced knowledge of the US regulatory procedures. This course will also be beneficial to and enhance understanding of persons who are in Clinical Research, Data Processing, Biostatistics, Basic Research, Project Management, and Marketing, etc. DIA Europe also welcomes attendance by regulatory agency staff members. Attendees will need to have some knowledge of the ICH and in particular the Common Technical Document (CTD). Participants will gain a better understanding of the regulation of investigational new drugs and biologics, of the basics of submission of applications seeking marketing approval for a product, and post-marketing regulatory requirements.

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.
- Describe the requirements for New Drug Application (NDA) and Biologics License Application and document preparation.
- Demonstrate an understanding of the NDA and the Biologic License Application (BLA) processes and CTD document preparation.
- Recognize FDA oversight and processes during the post-approval phase.
- Interact appropriately with the FDA during all phases of drug development including the application of good review management practices.
- Explain the regulatory requirements for prescription drug labelling and advertising/promotion.

Workshops are utilised in the course to augment the lectures. During such workshops, participants will work in teams on case studies and will present the results to other participants.

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

Key Topics

- Role of the regulatory professional
- 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 Amendment
- Procedures for reporting Adverse Events (AEs) that occur during clinical investigations
- The NDA in CTD format
- 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

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MONDAY | 18 OCTOBER 2010

07:30 Registration

08:00 Welcome and Introduction

08:15 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
- Roles of Regulatory Affairs Professionals
- 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 Guidances 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, & Controls

14:15 Session 7

THE IND IN DETAIL - ITEMS 8, 9 AND 10

- IND Item 8: Nonclinical Pharmacology and Toxicology
- IND Item 9: Previous Human Experience
- IND Item 10: Additional Information

15:00 Coffee Break

15:15 Session 8

THE 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 Practices
- Institutional Review Boards
- Informed Consent
- Good Laboratory Practices
- Good Manufacturing Practices

TUESDAY | 19 OCTOBER 2010

08:00 Session 10

FDA'S ACTIONS ON THE ORIGINAL IND & FUTURE AMENDMENTS

- FDA's Review of 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

WORKSHOP - IND AMENDMENT

This session provides "hands-on" experience in the review of different types of IND amendments

11:00 Session 13

REPORTING ADVERSE EVENTS (AEs) DURING CLINICAL TRIALS

- Definitions Of Terms
- IND Safety Reports
- IND Annual Reports - Safety Information
- Termination of Studies for Safety Reasons

12:00 Lunch

13:00 Session 14

WORKSHOP: AE REPORTING

Examples of AEs will be given and participants will determine appropriate regulatory actions.

14:30 Session 1a

THE NDA IN CTD FORMAT

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

15:15 Coffee Break

15:30 Session 1b

THE NDA IN CTD FORMAT: WHAT IS A CTD?

- The CTD details
  - Module 1
  - Module 3

WEDNESDAY | 20 OCTOBER 2010

08:00 Session 1b

THE NDA IN CTD FORMAT: WHAT IS A CTD? (CONTINUED)

- Module 4
- Module 5
- ICH Guideline for Structure and Contents of Clinical Study Reports – E3
- Module 2
- Safety Update Reports (CTD Module 5)

09:30 Coffee Break

09:45 **Session 1c**

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-PDUFA

11:30 **Session 2**

THE FDA AND RISK MANAGEMENT

- Premarketing Risk Assessment
- Postmarketing Risk Assessment
- Risk Evaluation and Mitigation Strategies

12:30 **Lunch**

13:30 **Session 3**

POST-NDA APPROVAL REGULATORY REQUIREMENTS

- Post-NDA Approval Obligations
- Postmarketing (Phase 4) Commitments
- Supplements and other Changes to an Approved Application
- Postmarketing 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)

15:00 **Coffee Break**

15:15 **Session 4**

INTERACTIONS WITH FDA - PART 1

- 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

16:15 **Session 5**

INTERACTIONS WITH FDA - PART 2

- Principles for Communicating with FDA
- Meeting Etiquette
- How to Resolve Issues or Disputes with FDA
- Summary on Interacting with FDA
- Advisory Committee Meetings
- Advisory Committee Meeting Video

THURSDAY | 21 OCTOBER 2010

08:00 **Session 6**

MOCK FDA MEETING

09:30 **Session 7**

REGULATORY REQUIREMENTS FOR PRESCRIPTION DRUG LABELLING

(Coffee Break at approximately 10:30)

- Definitions
- 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
- Labelling for Systemic Antibacterial Drugs
- Structured Product Labelling
- Comparison of US Package Insert to European Summary of Product Characteristics
- Patient Labelling

11:15 **Session 8**

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)

12:30 **Lunch**

13:15 **Session 9**

FDA INSPECTION VIDEO

14:00 **Session 10**

REVIEW OF PRESCRIPTION DRUG/BIOLOGICS ADVERTISING AND PROMOTIONAL LABELLING

- Definitions
- Statutory Basis for Promotional Regulations
- Required Elements for Advertisements and Promotional Labelling
- Reminder Advertisements/Labelling
- Preapproval Promotional Activities
- Other Topics
- FDA Enforcement Actions
- Launch of Promotional Pieces
- Postmarketing Submission of Advertising
- Similarities and Differences in Regulatory Requirements for Drugs and Biologics
- Summary of Principles for Advertising and Promotion

15:30 **Wrap-Up Discussion and Questions**

15:45 **End of Training Course**

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the:

Radisson SAS Alcron Hotel
Štepánská 40
110 00 Prague 1
Czech Republic

Tel.: +420 2 22 820 000
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http://www.radissonblu.com/hotel-prague

at the special rate of:
Single Room EUR 140.00
Double Room EUR 140.00

This rate is per room, per night, service, taxes and buffet breakfast included. 9% VAT is excluded.

To reserve a room, please use the booking form available on the DIA website or call the hotel.

IMPORTANT: To be assured of accommodation at the SAS Radisson Alcron Hotel, registrants are recommended to complete their reservation by 17 September 2010 at the latest. Reservations received after that date are subject to availability.

REGISTRATION FORM

US Regulatory Affairs

October 18-21, 2010 - Radisson SAS Alcron Hotel, Prague, Czech Republic

ID# 10552

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day. Registration will be accepted by mail, fax, email or online at www.diahome.org

CATEGORY	MEMBER FEE			NON-MEMBER (with optional membership)				NON-MEMBER (without optional membership)		
	FEE	VAT 20%	TOTAL	FEE	VAT 20%	Membership	TOTAL	FEE	VAT 20%	TOTAL
Industry	€ 2'888.00	€ 577.60	**€ 3'465.60** ❑	€ 2'888.00	€ 577.60	€ 115.00	**€ 3'580.60** ❑	€ 3'003.00	€ 600.60	**€ 3'603.60** ❑
Government/Academia (Full-Time)	€ 1'444.00	€ 288.80	**€ 1'732.80** ❑	€ 1'444.00	€ 288.80	€ 115.00	**€ 1'847.80** ❑	€ 1'559.00	€ 311.80	**€ 1'870.80** ❑

TOTAL AMOUNT DUE: € _____

NOTE: Payment due 30 days after registration and must be paid in full by commencement of the event

All fees are shown excluding VAT which may be charged if applicable.

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RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

__ Advertising & Promotion
__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Manufacturing
__ Medical Communications
__ Medical Writing
__ Nonclinical
__ Outsourcing
__ Comparative Eff ectiveness/Health Technology Assessment/Evidence-based Medicine
__ Pharmacology
__ Pricing/Reimbursement
__ Project Management
__ Professional Education, Training & Development
__ Public Policy/Law/Corp. Compliance
__ Quality Assurance/Quality Control
__ Regulatory Aff airs
__ Research & Development
__ Statistics
__ Strategic Planning
__ IT/Validation

REGISTRANT

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PAYMENT METHODS

❑ **Please charge my credit card** - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

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❑ **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." including your name, company, Meeting ID# 10552 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.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee: Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00

Registrants who do not cancel five working days prior to the course start date and do not attend, 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 DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants. Registrants 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 registrants will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.**

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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