Non-Clinical Safety Sciences and Their Regulatory Aspects

Course #10562
22-26 November 2010
Faculty of Pharmacy, University of Lisbon, Portugal

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This course has limited capacity. Register early.

Featuring tailor-made case studies including in-depth discussion of specific contemporary scientific/regulatory preclinical issues, case-studies and/or instructor-led group work on specific cases.

Course Overview

This course provides a full introduction to preclinical safety testing relating to regulations and guidelines in Europe (national, CHMP, ICH level). The course faculty is European-based leading experts in preclinical safety testing and safety sciences. Topics will be presented through interactive lecture and hands-on workshop training methods, with an emphasis on practical application of the regulations and guidelines pertinent to preclinical and clinical medicines development and registration. The content for this course focuses on development of small molecule medicines and biologically-derived medicines.

Who Will Attend

Professionals in preclinical research and development, project management, regulatory affairs, medical writing, clinicians for Phase 1, and pharmacovigilance. The course is valuable for professionals in regulatory agencies outside Europe. Participants should preferably have a previous fair understanding of aspects of medicines development and registration.

Learning Objectives

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

- Discuss the scope and needs for preclinical safety programmes in relation to clinical trials in Europe
- Discuss calculations of First-In-Human doses
- Identify requirements for successful preclinical medicines development in Europe
- Describe European culture and complexity in the registration system
- Explain the fundamentals of preclinical medicines development in Europe, and in ICH environment
- Share recent real world experiences of preclinical medicines development agencies and companies in Europe

Key Topics

- Role of preclinical safety studies in medicines development and registration in Europe
- Outline of preclinical medicines discovery and development, regulatory and industry perspectives
- Translational aspects of preclinical safety sciences, including safety biomarkers
- Scope and type of preclinical safety studies and timing to clinical development and registration
- Contemporary scientific and regulatory topics of interest: environmental risk assessment, single and repeat dose toxicity, establishing first human dose, juvenile animals studies, safety pharmacology, toxicity to the immune system, genotoxicity carcinogenicity testing, pharmaco-toxicokinetics, metabolism, reproduction toxicology protocols and interpretation for pregnancy labelling of pharmaceuticals, when mechanistic studies are needed, impurities and others
- Specific aspects of, e.g., vaccines, anticancer medicines, biotechnology-derived medicines
- The Common Technical Document and Assessment Report structures in Europe may be included on case-by-case basis

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DAY 1

General Introduction

08:30	Course Introduction and Overview
08:45	The drug development process and regulatory aspects
09:45	Procedures and guidelines • The European regulatory systems/procedure including Centralised, DCP, MRP, national. • The role of the working parties (SWP, Scientific Advice etc.) Orphan, Pedco, CAT committees
10:45	Coffee Break
11:15	What is ICH? ICH Safety-Guidelines
12:00	Common Technical Document and labelling
13:00	Lunch Break
14:00	Pharmacokinetics and metabolism (toxicokinetics)
15:00	Coffee Break
15:30	Species selection in drug development. Alternatives to animal studies - the 3Rs
16:30	Integrating kinetics and metabolism case studies with round table discussion
17:30	End of Day One
17:30-18:30	Reception

DAY 2

First Entry into Humans

08:30	M3 Guidelines - Preclinical studies to support first human clinical trials
09:30	Safety pharmacology
10:30	Coffee Break
11:00	Repeated dose
12:00	Genotoxicity
13:00	Lunch Break
14:00	Introduction to principles and first in human with case study
16:00	Coffee Break
16:30	Group activity
17:30	End of group activity
19:00-22.30	Working Dinner Including oral presentation of case study outcome

DAY 3

Development up to Marketing Authorisation

08:30	Reprotoxicity
09:30	Strategies for carcinogenicity testing of human pharmaceuticals
10:30	Coffee Break
11:00	Special organ toxicity – Part One: Immune system toxicity
12:00	Lunch Break

13:00	Special organ toxicity – Part Two: Liver toxicity
14:00	Integrating the risk assessment. Concepts in risk assessment
14:45	Introduction of Case Study • General introduction • Risk management plan • Risk benefit balance considerations • Labelling
15:00	Coffee Break
15:30	Case study on integrated risk assessment
17:00	End of Day Three

DAY 4

Safety Testing of Biopharmaceuticals

08:30	Preclinical considerations for biotechnology products
10:30	Coffee Break
11:00	Non-clinical development of anti-cancer drugs
12:00	Lunch Break
13:00	Preclinical studies to support clinical trials in special patient populations (II) Preclinical studies with juvenile animals
14:00	Preclinical aspects of “biosimilars”
15:00	Coffee Break
15:30	Non-clinical testing of vaccines
16:15	Toxicological qualification of impurities
17:00	End of Day Four

DAY 5

Examination

09:00	Environmental risk assessment of medicinal products for human use
10:00	Clinical impact from a clinician
10:30	Coffee Break
11:00	Examination
14:00	End of Training Course

DIA Upcoming Training Courses in 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
5-7 May 2010 | Vienna, Austria | ID 10527
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs

An Introduction to Product Information Management (PIM)
26-27 April 2010 | Vienna, Austria | ID 10541
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview
4-6 October 2010 | Location to be confirmed

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
26-28 April 2010 | Vienna, Austria | ID 10529
5-7 December 2010 | United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
3-4 June 2010 | Prague, Czech Republic | ID 10538
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
26-28 April 2010 | Paris, France | ID 10543
27-29 October 2010 | Geneva, Switzerland | ID 10547

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Quality by Design
Training Course is currently under development by the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
26 April 2010 | Paris, France | ID 10550
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 | Paris, France | ID 10551
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
2-4 June 2010 | Prague, Czech Republic | ID 10525
1-3 December 2010 | Paris, France | ID 10526

EudraVigilance Information Day at the European Medicines Agency
22 June 2010 | London, United Kingdom | ID 10534
19 October 2010 | London , United Kingdom | ID 10535

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD) at the European Medicines Agency
Courses throughout the year | European Medicines Agency, London, UK
For course details on EV, please visit www.diahome.org > Educational Offerings > EudraVigilance > Click on Related Courses

Non-Clinical Research

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas

Crisis Management
3-4 June 2010 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

REGISTRATION FORM

Non-Clinical Safety Sciences and Their Regulatory Aspects

22-26 November 2010 | Faculty of Pharmacy, University of Lisbon, Portugal

ID# 10562

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**

REGISTRATION FEES	MEMBER Fee	VAT 20%	TOTAL	NON-MEMBER (with optional membership) Fee	VAT 20%	Membership	TOTAL	NON-MEMBER (without optional membership) Fee	VAT 20%	TOTAL
Industry	€ 2'961.00	592.20	**€ 3'553.20** ❑	€ 2'961.00	592.20	€ 115.00	**€ 3'668.20** ❑	€ 3'076.00	615.20	**€ 3'691.20** ❑
Government/Academia (Full-Time)	€ 1'481.00	296.20	**€ 1'777.20** ❑	€ 1'481.00	296.20	€ 115.00	**€ 1'892.20** ❑	€ 1'596.00	319.20	**€ 1'915.20** ❑
Student (Full-Time)	€ 741.00	148.20	**€ 889.20** ❑	€ 741.00	148.20	€ 28.50	**€ 917.70** ❑	€ 769.50	153.90	**€ 923.40** ❑

TOTAL AMOUNT DUE: € _____

NOTE: Payment of registration fees must be received before commencement of the training course.

Please indicate your areas of professional interest:

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❑ AH - Academic Health Centres
❑ AM - Alternative / Herbal Medicine
❑ BT - Biotechnology
❑ CD - Clinical Data Management
❑ CH - Chemistry / Drug Design
❑ CL - Clinical Laboratory Data
❑ CM - CMC
❑ CP - Clinical Safety/Pharmacovigilance
❑ CR - Clinical Research & Development
❑ CS - Clinical Supplies
❑ DC - Dictionaries / Data Standards
❑ DE - Devices
❑ DM - Document Management
❑ FI - Finance
❑ EC - e-Clinical
❑ GC - GCP
❑ GE - Generic Manufacturing
❑ GL - GLP
❑ GM - GMP
❑ IM - Information Management
❑ IMP - Impact
❑ IS - Investigator Site
❑ IT - Information Technology / e-Business
❑ LA - Legal Affairs
❑ MA - Marketing / Advertising
❑ MC - Medical Communications / Information
❑ MH - Managed Healthcare
❑ MN - Manufacturing: Drug Substance, Drug Product, Packaging
❑ MW - Medical / Scientific Writing
❑ NC - Non-clinical Safety & Efficacy / Toxicology
❑ NH - Natural Health Products
❑ OS - Outsourcing / Virtual Development
❑ OT - Over the Counter
❑ PC - Pharmaceutics
❑ PD - Professional Development
❑ PE - Pharmacoepidemiology / Quality of Life / Health Economics / Outcomes Research / Managed Healthcare
❑ PH - Pharmacology
❑ PK - Pharmacokinetics / Metabolism / Pharmacodynamics
❑ PM - Project Management
❑ PP - Public Policy / Law
❑ QC- Quality Control / Quality Assurance
❑ RA - Regulatory Affairs / Policy / Drug or Device Approval / GRP
❑ RD - Research & Development / Strategic Issues
❑ ST - Statistics / Biostatistics / Mathematical Modelling
❑ TR - Training
❑ VA - Validation

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS , OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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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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❑ **Cheques** should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:
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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# 10562 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.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA European Office, Postfach, 4002 Basel, Switzerland