DIA Non-Clinical Safety Sciences and Their Regulatory Aspects Training Course

Course #12571
19-22 November 2012
Faculty of Pharmacy, University of Lisbon, Portugal

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Continuing Education

The "Non-Clinical Safety Sciences and Their Regulatory Aspects" training course has been accredited with 5 ECTS credits by the University of Lisbon, Portugal.

DIA meetings and trainings 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 and certificates are available.

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.

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.

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

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

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DAY ONE

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 TWO

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

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 THREE

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 FOUR

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 Examination

18:00 End of Training Course

ABOUT DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

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

REGISTRATION FORM

DIA Non-Clinical Safety Sciences and Their Regulatory Aspects Training Course

19-22 November 2012 | Faculty of Pharmacy, University of Lisbon, Portugal

ID # 12571

DIA www.diahome.org

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.

CATEGORY	Member Fee*	Non-Member Fee*
Industry	€ 2`888.00 ❑	€ 3`003.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 1`444.00 ❑	€ 1`559.00 ❑
Student (Full-Time)	€ 722.00 ❑	€ 750.50 ❑

*All fees are subject to 23% Portuguese VAT

Join DIA now to qualify for the member rate — **Fee** € 115.00 ❑

TOTAL AMOUNT DUE: €_____ NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT

GROUP DISCOUNT/SME RATES AVAILABLE - PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION 12571DIAWEB

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.

__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research & Development
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Medical Communications
__ Medical Writing
__ Non-clinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pricing/Reimbursement
__ Project Management
__ Professional Education & Training
__ Public Policy/Law
__ Quality Assurance/Quality Control
__ Regulatory Affairs
__ Statistics
__ IT/Validation

ATTENDEE DETAILS

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

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PAYMENT METHODS - Credit cards are the preferred payment method.

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Payments must be net of all charges and bank charges must be borne by the payer.

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
Regretfully, if you do not cancel five working days prior to the course 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 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.

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

HOW TO REGISTER

The DIA Europe 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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