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.

Course Directors

Beatriz Silva Lima
Professor, Lisbon University, Portugal
Per Spindler
Director, BioLogue, University of Copenhagen, Denmark

Course Faculty

Eric Abadie
Afssaps, France
Rolf Bass
Professor for Pharmacology and Toxicology, Retired from BfArM, Germany
Gerd Bode
Consultant, University of Göttingen, Germany
Peter Kasper
Director, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Klaus Olejniczak
Director, Federal Institute for Drugs and Medical Devices (BfArM), Germany
Jan Willem van der Laan
Senior Assessor, Preclinical Safety Group, RIVM, MEB, The Netherlands

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, pharamaco-toxicokinetics, metabolism, reproduction toxicology protocols and interpretation for pregnancy labeling 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

Marriott Lisbon, Portugal
November 23-27, 2009
ID# 09551
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
<th>Location</th>
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<tbody>
<tr>
<td>08:30</td>
<td>Course Introduction and Overview</td>
<td>Beatriz Silva Lima, Lisbon University, Portugal</td>
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<tr>
<td>08:45</td>
<td>The drug development process and regulatory aspects</td>
<td>Beatriz Silva Lima, Lisbon University, Portugal</td>
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<td>09:45</td>
<td>Clinical impact from a clinician</td>
<td>Eric Abadie, Afssaps, France</td>
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<td>10:45</td>
<td>Coffee Break</td>
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<tr>
<td>11:15</td>
<td>Procedures and guidelines</td>
<td>Rolf Bass, Retired from BfArM, Germany</td>
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<td></td>
<td>• The European regulatory systems/procedure including Centralised, DCP, MRP, national.</td>
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<td>• The role of the working parties (SWP, Scientific Advice etc.) Orphan, Pedco, CAT committees</td>
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<td>12:15</td>
<td>What is ICH? ICH Safety-Guidelines</td>
<td>Gerd Bode, Consultant, University of Göttingen, Germany</td>
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<td>13:00</td>
<td>Lunch Break</td>
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<td>14:00</td>
<td>Common Technical Document and labelling</td>
<td>Gerd Bode, Consultant, University of Göttingen, Germany</td>
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<td>15:00</td>
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<td>15:30</td>
<td>Pharmacokinetics and metabolism (toxicokinetics)</td>
<td>Gerd Bode, Consultant, University of Göttingen, Germany</td>
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<td>16:30</td>
<td>Species selection in drug development. Alternatives to animal studies - the 3Rs</td>
<td>Beatriz Silva Lima, Lisbon University, Portugal</td>
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<td>Integrating kinetics and metabolism case studies with round table discussion</td>
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<td>18:00</td>
<td>End of Day One</td>
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<td>18:00</td>
<td>Reception</td>
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<td>19:00</td>
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<td>08:30</td>
<td>Non-clinical testing of vaccines</td>
<td>Jan Willem van der Laan, Preclinical Safety Group, RIVM, MEB, The Netherlands</td>
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<td>16:00</td>
<td>Coffee Break</td>
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<tr>
<td>16:30</td>
<td>Group activity</td>
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<td>17:30</td>
<td>End of group activity</td>
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<td>19:00</td>
<td>Working Dinner</td>
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<td>22:30</td>
<td>Including oral presentation of case study outcome</td>
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<td>08:30</td>
<td>Strategies for carcinogenicity testing of human pharmaceuticals</td>
<td>Jan Willem van der Laan, Preclinical Safety Group, RIVM, MEB, The Netherlands</td>
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<td>09:30</td>
<td>Special organ toxicity – Part One: Immune system toxicity</td>
<td>Jan Willem van der Laan, Preclinical Safety Group, RIVM, MEB, The Netherlands</td>
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<td>10:30</td>
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<td>11:00</td>
<td>Special organ toxicity – Part Two: Liver toxicity</td>
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<td>13:00</td>
<td>M3 Guidelines - Preclinical studies to support first human clinical trials</td>
<td>Gerd Bode, Consultant, University of Göttingen, Germany</td>
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<td>14:00</td>
<td>Integrating the risk assessment. Concepts in risk assessment</td>
<td>Peter Kasper, Federal Institute for Drugs and Medical Devices (BfArM), Germany</td>
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<td>14:45</td>
<td>Introduction of Case Study</td>
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<td>• General introduction</td>
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<td>• Risk management plan</td>
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<td>• Risk benefit balance considerations</td>
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<td>• Labelling</td>
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<td>15:00</td>
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<td>15:30</td>
<td>Case study on integrated risk assessment</td>
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<td>17:00</td>
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**Disclosure Policy**

It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the programme audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unlabelled or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.
**Thursday November 26**

**Safety Testing of Biopharmaceuticals**

08:30  **Genotoxicity**  
Peter Kasper, Federal Institute for Drugs and Medical Devices (BfArM), Germany

09:30  **Repeated dose**  
Klaus Olejniczak, Director, Federal Institute for Drugs and Medical Devices (BfArM), Germany

10:30 **Coffee Break**

11:00 **Preclinical studies to support clinical trials in special patient populations (II) Preclinical studies with juvenile animals**  
Beatriz Silva Lima, Lisbon University, Portugal

12:00 **Lunch Break**

13:00 **Non-clinical development of anti-cancer drugs**  
Klaus Olejniczak, Director, Federal Institute for Drugs and Medical Devices (BfArM), Germany

13:30 **Toxicological qualification of impurities**  
Peter Kasper, Federal Institute for Drugs and Medical Devices (BfArM), Germany

14:30 **Coffee Break**

15:00 **Environmental risk assessment of medicinal products for human use**  
Per Spindler, Director, BioLogue, University of Copenhagen, Denmark

16:00 **End of Day Four**

**Friday November 27**

9:00 **Introduction to principles and first in human with case study**  
Beatriz Silva Lima, Lisbon University, Portugal

11:00 **Exam**  
Beatriz Silva Lima, Lisbon University, Portugal  
Per Spindler, Director, BioLogue, University of Copenhagen, Denmark

13:00 **Lunch**

14:00 **End of Training Course**

**Hotel Information**

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

Marriott Lisbon  
Avenida dos Combatentes  
Lisbon  
1600-042  
Portugal

Tel.: +351 217 235 400  
Fax: +351 217 264 347

at the special rate of EUR 80.00 including breakfast, service and VAT.

To reserve a room, please call the hotel referring to the DIA Training Course on *Non-Clinical Safety Sciences* or use the booking form on the DIA website.

**IMPORTANT:** To be assured of accommodation at the Marriott Lisbon, registrants are recommended to complete their reservation by October 25, 2009 at the latest.
**Non-Clinical Safety Sciences and Their Regulatory Aspects**

**MARRIOTT LISBON, PORTUGAL - NOVEMBER 23-27, 2009**

**ID# 09551**

### Cancellation and Transfer Policies

**Cancellation Policy**
- Cancellations received by the date above are subject to an administrative fee: Industry (Member/Non-Member) = EUR 200.00; Government and Academia (Member/Non-Member) = EUR 100.00.
- Registrants who do not cancel by the date above, and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel and travel reservations.

**Transfer Policy**
- You may transfer your registration to a colleague prior to the course start but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable.

### Transfer and Payment Methods

**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.
  - VISA
  - MC
  - AMEX

**Cheques** should be made payable to: Drug Information Association. Mail your cheque together with the registration form to facilitate identification of attendee to: DIA Europe, Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland.

**Bank Transfers** When DIA Europe completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payment should be in EURO and your name and company, as well as the course ID# 09551 and invoice number, must be included on the transfer document to ensure correct allocation of your payment. Payments must be net of all charges and bank charges must be borne by the payee.

Persons under 18 are not allowed to attend DIA meetings.

### DIA Europe Office Information

DIA, Elisabethenanlage 25, Postfach 4002 Basel, Switzerland / Phone: +41 61 225 51 51 / Fax: +41 61 225 51 52

Email: diaeurope@diaeurope.org / www.diahome.org

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### Conference Registration Form

Please indicate your areas of professional interest:

- AH - Academic Health Care
- 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
- JM - Information Management
- IMP - Impact
- IS - Investigator Site
- IT - Information Technology / e-Business
- MA - Marketing / Advertising
- MC - Medical Communications / Information
- MH - Managed Healthcare
- IVN - 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 - Pharmaceuticals
- PD - Professional Development
- FE - Pharmacoeconomics / 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 / GMP
- RD - Research & Development / Strategic Issues
- ST - Statistics / Biostatistics / Mathematical Modelling
- TR - Training
- VA - Validation

**REGISTRANT**

- Last Name
- First Name
- Company
- Job Title
- Street Address / P.O. Box
- City
- Country
- Telephone
- Fax (Required for confirmation)
- Email (Required for confirmation)

**PREFERRED METHOD OF PAYMENT**

- Check
- Credit Card
- Electronic Funds Transfer

**PLEASE CHARGE MY CREDIT CARD**

- VISA
- MC
- AMEX

- Card Number
- Exp. Date
- Cardholder’s Name
- Date of Birth
- Cardholder’s Signature

**FEE**

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<th>TOTAL FEE</th>
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<td>€ 2'961.00</td>
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<td>Government/Academia (Full-Time)</td>
<td>€ 1'481.00</td>
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**NON-MEMBER FEE**

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**NON-MEMBER FEE (without optional membership)**

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<td>Student (Full-Time)</td>
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**TOTAL AMOUNT DUE:** €

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

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IF DIA CANNOT VERIFY YOUR MEMBERSHIP UPON RECEIPT OF REGISTRATION FORM, YOU WILL BE CHARGED THE NON-MEMBER FEE. If all payments are not made in full, DIA Europe reserves the right to alter the venue and dates if necessary.