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 I, 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
Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of DIA Europe.

Speakers and agenda are subject to change without notice. Recording of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.
FRIDAY | 25 NOVEMBER 2011

08:30  Clinical impact from a clinician
       Joao Oliveira, University of Lisbon

09:00  Environmental risk assessment of medicinal products for human use
       Per Spindler

10:00  COFFEE BREAK

10:30  Examination
       Beatriz Silva Lima, Per Spindler

13:30  END OF TRAINING COURSE

Hotel Information

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

SANA Metropolitan Hotel
Rua Soeiro Pereira Gomes, Parcela 2
1600-198 Lisboa
Portugal

Tel.: + 351 217 982 531
Fax : + 351 217 950 863
Email: reu.metropolitan@sanahotels.com

at the special rate of
EUR 69.00 per room and night for single occupancy
EUR 74.00 per room and night for double occupancy

The rates include buffet breakfast, service and VAT.
REGISTRATION FORM
Non-Clinical Safety Sciences and Their Regulatory Aspects
21 - 25 November 2011 | Faculty of Pharmacy, University of Lisbon, Portugal

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.

<table>
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<th>CATEGORY</th>
<th>Member Fee</th>
<th>Non-Member (with optional membership) Fee*</th>
<th>Non-Member (without optional membership) Fee*</th>
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</table>

TOTAL AMOUNT DUE: €___________________

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

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

Regrettfully, 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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