

Medicademy Regulatory Affairs Module 7

Non-clinical Development and Documentation

Date: February 29 – March 2, 2012

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Aim:

To provide the students with a comprehensive overview of the requirements and critical issues of non-clinical studies and at the same time support clinical development, and provide them with an overview of how to build up a Common Technical Document of the non-clinical part of a registration dossier (e.g. CTD Module 2 and 4).

The programme will focus on the development process:

- How do I select the right studies at the right time to meet the company's needs and the regulatory requirements?
- How do I evaluate the results? What is the predictive value of the results?
- What should I know about CMC and clinical development?

By the end of this module, the student should be able to:

- **understand** the purpose of each category of the non-clinical safety studies needed to support clinical development of pharmaceuticals, and understand how to build up the non-clinical part of a registration dossier

- **analyse** non-clinical requirements for specific types of medicine, clinical indications, and implications in relation to the composition and conduct of the non-clinical safety study programme

- **use best practices** when interacting with non-clinical specialists as well as with clinicians, CMC specialists, and the regulatory agencies in order to ensure that non-clinical safety information is

generated, interpreted and communicated correctly to the benefit of patient safety

Contents:

Non-clinical studies to support clinical development, including special populations and line extensions, predictive value of non-clinical studies, risk assessment of non-clinical studies, CTD Module 4 and the non-clinical part of Module 2

- Overview of Pharmacology, Pharmacokinetics and Toxicology
- Timing of Non-Clinical Studies
- Pharmacology
- Pharmacokinetics
- General Toxicity Studies
- Local Tolerance and Other Studies
- Application for First-in-Man
- Carcinogenicity
- Reproduction – including Juvenile Toxicity
- Immunotoxicity
- Interaction with Quality (CTD Module 3)
- Biotechnology Products
- Implications of Non-Clinical Findings for the EU and FDA Labelling Text
- Life Cycle Management
- Selection of Animal Species, and Predictive Value of Non-Clinical Studies
- Risk Assessment – Industry View
- Risk Assessment – Regulatory Body View

Lecturers:

- **Dr. Gerd Bode**, MD, PhD, Specializations in Pathology, Neuropathology, Legal Medicine, Pharmacology and Toxicology, Independent Lecturer and Consultant, Germany
- **David Jones**, BSc, MSc, Expert Pharmaco-Toxicologist, Licensing Division, the Medicines and Healthcare Products Regulatory Agency (MHRA), UK
- **Allan Dahl Rasmussen**, MSc, PhD, Head of Department, Regulatory Toxicology & Safety Assessment, H. Lundbeck A/S, Denmark
- **David Tweats**, BSc, PhD, Genetic Toxicology Consultant, UK
- **Ann Christine Korsgaard**, MSc Pharmacy, Vice President, Regulatory Affairs Genmab A/S, Denmark
- **Jørgen Schützack**, DVM, DABT, Senior Toxicologist, Preclinical Development, LEO Pharma A/S, Denmark
- **Andrew Makin**, MSc Applied Zoology, Managing Director, LAB Research A/S, Denmark
- **Graham Bailey**, Senior Research Fellow, Reproduction Toxicology, Department of Toxicology, Global Preclinical Development, Johnson & Johnson, Belgium
- **Vibeke Miller Breinholt**, Master's and PhD-degree in Toxicology, responsible for preclinical safety activities and the preclinical regulatory component, Genmab, Denmark
- **Paul Baldrick**, BSc and PhD, Head, Regulatory Affairs for Pharmaceuticals within the Consultancy and Regulatory Services Department, Covance-Harrogate, UK
- **Lena Alifrangis**, Senior Scientist, Development DMPK, Novo Nordisk A/S, Denmark
- **Lars Iversen**, Senior non-clinical project manager, Novo Nordisk A/S, Denmark

Course Leaders:

- **Jens Thing Mortensen**, DVM, DABT, European Registered Toxicologist, Principal Senior Scientist, LAB Research (Scantox), Denmark
- **Peter Ravn Brinck**, Director, Tox and Safety Pham at Novo Nordisk A/S, Denmark

Practical Information

Date:

February 29 – March 2, 2012

Venue:

Medicademy, Lersø Parkallé 101, DK-2100 Copenhagen, Denmark

Course Fee:

DKK 17,000 (approx. EUR 2,285) + VAT 25%, including: meals and refreshments, course materials, networking dinner and daily bus transport between Hotel Twentyseven and the Medicademy facilities.

Exam fee

DKK 2,500 (approx. EUR 337)

Registration Deadline:

January 25, 2012

Exam:

March 23, 2012

Please note that you can sit the exam in any country! Students are required to register separately for the exam!

For Further Information

Visit our website: www.medicademy.net or contact Program Director Mrs. Tina Jensen: tj@medicademy.net

Medicademy - is an international educational program established in 2002 by The Danish Association of the Pharmaceutical Industry (Lif) in collaboration with the University of Copenhagen and the Danish Medicines Agency.

Medicademy is a module based, flexible, part-time postgraduate educational program offering education within Pharmacovigilance and Regulatory Affairs. The aim of the highly qualifying Medicademy Education is to provide participants with an in-depth and up-to-date knowledge at university level of the most important theoretical and practical aspects of pharmacovigilance and regulatory affairs issues relating to pharmaceutical and biological products.