



## Course 1.1 Drug Discovery and Development

*1– 5 November 2010, Faculty of Pharmaceutical Sciences, University of Copenhagen*

*22 - 26 November 2010, Home Assignment (Case Studies and Course questions)*

European Modular Education and Training Programme  
in Safety Sciences for Medicines

## Drug Discovery and Development Course: Key questions to be tackled by the course

- ✓ Target evaluation and validation
- ✓ Identification of lead structures
- ✓ Biologics
- ✓ Medicinal chemistry: Lead optimization and synthesis
- ✓ NonClinical Safety
- ✓ Pharmacology and animal biology
- ✓ Pharmaceutics
- ✓ Clinical Development
- ✓ Registration
- ✓ Health economics and Marketing



Website:  
[www.safescimet.eu](http://www.safescimet.eu)

E-mail:  
[info@safescimet.eu](mailto:info@safescimet.eu)

Blackboard:  
[bb.vu.nl](http://bb.vu.nl)

Student Office Telephone:  
**+46 18 471 4015**

## Introduction

Drug Discovery and Development is the introductory course to a new European Masters degree for Advanced Safety Sciences for Medicines designed by SafeSciMET as part of the European Innovative Medicines Initiative (IMI).

SafeSciMET is a new and unique pan European network of academics and pharmaceutical industry who have come together to establish a comprehensive Safety Sciences Modular Education & Training programme covering all aspects of safety in drug development to ensure European Drug Safety Scientists in the pharmaceutical industry, regulatory authorities and academia are at the forefront of their field.

## Why join the course in Drug Development?

Drug development is a long, complicated process requiring the interaction of numerous specialist fields. The many disciplines are rooted in different scientific cultures and languages, and the players involved in the various phases and fields of drug research do not always recognize and understand each other well enough. It is important for key employees of organizations involved in drug development to have a broad overview and the ability to understand the connections between all stages of the development process from discovery to marketing. This is especially important for young safety scientist who in their job has to liaise with other professionals within the company as well as with external partners in the multidisciplinary project teams.

## Course Objectives

This introductory course consists of 5 days in Copenhagen with lectures and casework followed by a week at home dedicated to an individual assignment. Thus the total course will provide the participants with a comprehensive overview of the steps in drug development from discovery to marketing approval with special emphasis on drug safety, providing an ideal background for the more detailed and specific courses that make up the rest of the programme

### *Key areas covered by this course*

- **Roadmap to drug discovery and development**
- **Target evaluation and validation**
- **Lead optimization and synthesis**
- **Pharmacology & animal biology**
- **Pharmacokinetics, safety pharmacology & toxicology**
- **Development of biologics**
- **Pharmaceutics**
- **Translational medicine**
- **Clinical development & safety**
- **Regulatory process**
- **Health economics, IP & marketing**

## Target Group

SafeSciMET students, academics and workers in the pharmaceutical industry and regulatory authorities who need a broad comprehensive understanding of the drug development process with particular emphasis on safety.

## Learning outcomes

The course provides participants with a comprehensive overview of drug development and a sound grasp of the fundamentals of major implicated disciplines, conveys an understanding of the dynamics of the drug development and allows participants to practice inter-communication across research fields.

More specifically, participants will be able to:

- Identify critical factors and bottlenecks that influence the drug development process
- Appraise the integration of the various basic disciplines into the process
- Analyse the sequence and flow of the various steps in the process
- Use the regulatory framework to plan a development process
- Identify translational aspects, important transition points and required involvement of authorities
- State milestones for leadership reviewing the progress of the development
- Demonstrate ability to communicate in professional terms about the drug development process
- Summarize all major steps and elements of the drug development process
- Outline definitions of key concepts and the fundamentals of the major implicated disciplines



## Course Programme

### The Syllabus

A syllabus containing an introductory chapter, lecture hand outs, list of abbreviations, definitions and reading materials will be provided by the course leader 14 days prior to the course. The material for the home assignment will be provided during the first week of the course

### Assessment

The assessment is based on a 2-hour written examination on the last day of the course and on the evaluation of the home assessment

**Type:** The purpose of the examination is to test that the examinee has a broad knowledge and comprehension of the drug development process as a whole. The percentage of items on the test devoted to a particular topic will roughly correspond to the emphasis given the topic in teaching of the course:  
Discovery : 15%  
Pre-clinical : 35%  
Translational : 15%  
Clinical : 15%  
Health economics and marketing 20%

**Assessors(s)** Course Directors

**Exam aids:** All written exam aids are allowed.

Course administrator Ole J. Bjerrum, Universitetsparken 2, DK - 2100 Copenhagen, Denmark, +45 35336320  
ojb@farma.ku.dk

## Practical Information

**Course Credits:** 3 ECTS credits

**Level:** Master's level (second cycle higher education)

**Course Dates:** November 1.-5.2010

**Location:** The Faculty of Pharmaceutical Sciences, University of Copenhagen, Universitetsparken 2, DK-2100 Copenhagen

**Teaching methods** Lectures, case workgroup discussions, presentations and discussions. In order to emphasise the flow of the process, the course is to a large extent based on the use of cases in both lectures and assignments.

**Student Workload:** Preparation: 15 hours  
Course: 38 hours  
Assignment: 45  
Examination: 2 hours  
Total: 90

**Course fee:** 2,500 Euro—750 Euro dependant on category of student (please visit [www.SafeSciMET.eu](http://www.SafeSciMET.eu). **How to apply for more information**)

**Application deadline:** **1. October 2010**

**Course capacity:** 36 participants

**Language:** The official language of the course is English. No simultaneous translations will be provided

**Course notes:** Complete course notes, except for the textbook, will be available for all the participants  
'Drug discovery and Development' H.P. Rang, Ed, Churchill Livingstone 2006

**Course accreditation:** The course meets the criteria for continuous professional Development (CPD) diplomas, and it will be part of a (forthcoming European) Masters of advanced Safety Sciences degree. More information can be obtained through our website: <http://www.SafeSciMET.eu>

## Course Leaders

Professor [Ole J. Bjerrum](#) Department of Pharmacology and Pharmacotherapy , Faculty of Pharmaceutical Sciences, University of Copenhagen , Denmark

Professor Daan Crommelin, TI-pharma , Leiden, The Netherlands

Vice President Helle Northeved, H. Lundbeck, Copenhagen , Denmark

Vice President Derek Newall, GlaxoSmithKline, Herts, UK

### Lecturers.

Asser Sloth-Andersen	Novo Nordisk, DK
Birgitte Søgaard	H. Lundbeck, DK
Colin Fish	GlaxoSmithKline, Herts, UK
Daan Crommelin	TI-Pharma, NL
Derek Newall	GlaxoSmithKline, Herts, UK
Fredrik Björkling	Faculty of Pharmaceutical Sciences, DK
Frank Larsen	H. Lundbeck, DK
Gitte Dyhr	H. Lundbeck, DK
Helle Northeved	H. Lundbeck, DK
Jacques Descotes	University of Lyon, F
Jens Peter Balling	Novo Nordisk, DK
Jens Hansen	Leo Pharmaceuticals, DK
Kim Dekermendjian	H. Lundbeck, DK
Rikke Hvid Lindecrona	Novo Nordisk
Klaus Gjervig Jensen	H. Lundbeck, DK
Lars Kellberg	Novo Nordisk, DK
Niels Dragsted	Novo Nordisk, DK
Ole J. Bjerrum	Faculty of Pharmaceutical Sciences, DK
Kjeld Moller Petersen	University of Southern Denmark, DK
Klaus Henning Jensen	Novo Nordisk, DK

### REGISTRATION

Please visit [www.safescimet.eu](http://www.safescimet.eu) to register. On the homepage, please go to **How to Apply** and sign up:

[For MSc of Advanced Safety Courses](#)

[For Continuing Professional Development \(CPD\)](#)

[For Single courses](#)

You will be notified that your registration has been received

**The closing date to register for this course is the October 1st 2010**

Please note that the number of participants is limited to 36. It is highly advisable to send in your registration form as soon as possible. Registration will be made on a **first come first served** basis

### TRANSPORT

The course takes place in central Copenhagen, 12 km from the airport.

### ACCOMMODATION

Hotels can be arranged individually via [www.visitcopenhagen.dk](http://www.visitcopenhagen.dk)

Otherwise a number of rooms are blocked for accommodation in a nearby regular Hotel Kong Arthur. Nørre Søgade 11, DK-1370 København K, 33 11 12 12, [hotel@kongarthur.dk](mailto:hotel@kongarthur.dk), **Booking code: 196315**

### CANCELLATION

Cancellation of a pre-registered student is possible, upon written notice by 15th October 2010. Before that date the Course fee will be refunded except for an administrative fee of EUR 75,- After that date, no refunds can be made for cancellations

