Drug Discovery and Development
An introduction from A to Z
5-9 November 2012, Amsterdam
Optional: A second week with a home assignment (case studies)
Introduction
This Drug Discovery & Development course (1.1) is part of a European Masters Degree for Advanced Safety Sciences, designed by SafeSciMET, as part of the European Innovative Medicines Initiative (IMI).

SafeSciMET is a unique pan European network of scientists from academia and 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 that 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 Discovery and Development?
Drug discovery and development is a long, complicated process requiring the interaction of numerous specialists. The many disciplines are rooted in different scientific cultures 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 professionals 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 scientists who have to learn to liaise with other professionals.

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

A testimonial of a student from AstraZeneca who followed the last course:
“I wish I had attended this course during my first year in the pharmaceutical industry. This would have saved me a lot of time, which I spent searching, asking and chasing information by myself. All speakers gave high quality presentations and some of them were really outstanding. The parts I enjoyed most were the case studies and the timing just after lunch was ideal. I appreciated that the case studies had so much emphasis on the safety aspect.”
Learning outcomes

The course provides participants with a comprehensive overview of drug development and a sound grasp of the major disciplines involved. It provides an understanding of the dynamics of drug development and allows participants to practise communication across research fields.

More specifically, participants will be able to
- Summarise all major steps and elements of the drug development process
- Analyse the sequence and flow of the various steps in the process
- Identify critical factors and bottlenecks that influence the drug development process
- Appraise the integration of the various basic disciplines into the process
- Use the regulatory framework to plan a development process
- Define milestones for leadership reviewing the progress of the development
- Demonstrate ability to communicate in professional terms about the drug development process
- Outline definitions of key concepts and the fundamentals of the major implicated disciplines

The course also offers time for a break
Programme

Week one

Day 1 - Developing & selling medicines
Target product profiles, healthcare economics, patent strategy & marketing

Day 2 - Discovery of medicines
Target identification & validation, assay development, High Throughput Screening (HTS), pharmacology & biologicals

Day 3 - Interfacing discovery & development
Pharmacokinetics & -dynamics, pharmaceutics, safety, toxicology & risk management

Day 4 - Clinical development strategy
Phases, scenario analysis, ethics, clinical safety & monitoring and reporting

Day 5 - Regulatory affairs, drug surveillance and life cycle management
The regulatory process, drug surveillance and pharmaco epidemiology & life cycle management

Week two

The ‘second week’ is optional: a home assignment (case studies) in the period November 12, 2012 until January 1st, 2013

A testimonial from an academic perspective:
“The Drug Discovery and Development course allowed me to cross the border line from social science to life science and acquire a comprehensive overview of a drug’s life cycle. I really enjoyed the hands-on approach and the various stakeholders’ perspectives covered. As a direct follow up of attending this course, the European Journal of Pharmaceutical Sciences published a commentary on trends in the pharmaceutical industry based on the course assignments of two other colleagues and myself and allowed me to move from the “Romanian Academic Society” think tank to Pfizer’s Public Policy Team.”
Target Group
Scientists in the pharmaceutical industry, regulatory authorities and academia who need a broad comprehensive understanding of the drug discovery and development process.

(Pre)Reading Material
The following information will be provided before and during the course:

- Syllabus including list of abbreviations
- Paper handouts provided by the course leader during the course

Teaching methods
During the first course week there will be lectures, case work, group discussions and presentations. In order to emphasise the flow of the process, the course is to a large extent based on the use of cases studies in both the lectures and assignments. Optional: The ‘second week’ (40 hours over the period November 12, 2012 until January 1st, 2013) at home will be dedicated to an individual assignment.

Accreditation/Assessment
The course (including the ‘second week’ home assignment) is accredited by 3 ECTS credits (Master’s level). Assessment for accreditation will be done by the course directors based on a 2-hour written examination on the last day of the course, and an evaluation of the home assignment. It also meets the criteria for continuous professional development (CPD) diplomas as it will be part of a (forthcoming European) Masters of Advanced Safety Sciences degree.
Practical Information

Course Dates
• November 5 until November 9, 2012. A full week program, from 9 am until 17 pm, including a social program on Wednesday evening
• Optional: a second week (40 hours work) with a home assignment (case studies) in the period November 12, 2012 until January 1st, 2013

Location
The Royal Netherlands Academy of Arts and Sciences (KNAW) in Amsterdam (www.knaw.nl), The Netherlands

Contact
TI Pharma will be the course organizer. If you have any questions, please contact Karin Huiberts (karin.huiberts@tipharma.com or +31 71 332 2037). If you would like to contact the course leader, please send an email to Prof. Dr. Daan Crommelin (D.J.A.Crommelin@uu.nl).
Course fee
750 Euro – 2,500 Euro (dependent on category of student)
(please visit www.SafeSciMET.eu how to apply for more information)

Application deadline
October 1st, 2012

Course capacity
25 participants

Language
The official language of the course is English.

Course Directors
Professor Daan J.A. Crommelin, Top Institute Pharma, Leiden, The Netherlands
Professor Ole J. Bjerrum, Dept. Drug Design and Pharmacology, Faculty of Health and Medicines, University of Copenhagen, Denmark
Dr. Helle Northeved, H. Lundbeck, Copenhagen, Denmark
Dr. Derek Newall, GlaxoSmithKline, Ware, UK

Registration
Please visit www.safescimet.eu to register. On the homepage, please go to ‘How to Apply’, ‘registration form’ to create a new account to sign up. Registration will be made on a first come first served basis.

Accommodation
Hotel accommodation with reduced rates can be arranged individually via info@tipharma.com

Cancellation
Cancellation of a pre-registered student is possible through a written notice by October 15, 2012. 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.
European Modular Education and Training Programme in Safety Sciences for Medicines

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