Website: Website: http://semmelweis.hu/cemdc

MODULE 1

Place: Semmelweis University, Department of Pharmacology and Pharmacotherapy
Floor 4, Issekutz room
1089 Budapest, Nagyvárad tér 4.

Date: October 26-29, 2017

MODULE 1: AN OVERVIEW - PRINCIPLES OF THE DISCOVERY & DEVELOPMENT PLANNING OF MEDICINES

Module Leaders: Matthias Gottwald and Sándor Kerpel-Fronius

PHARMATRAIN BASE COURSE **MODULE M1: AN OVERVIEW PRINCIPLES OF THE DISCOVERY & DEVELOPMENT PLANNING OF MEDICINES**
LEARNING OUTCOMES
At the end of this Module the student should be able to demonstrate an understanding of the:
1. Process of drug development and identity of critical factors and decision points.
2. Importance of the patient in drug development.
3. Background to the development of the regulation of medicines and the role of the competent authorities.
4. Monitoring of drug safety.
5. Principles and practice of medical marketing.
6. Role of pathophysiology and molecular biology-based pharmacology in drug development.
7. Principal steps in discovering, modifying, assessing and patenting new chemical and biological compounds (including advanced therapies) according to their therapeutic indication.
8. Resource planning (in terms of project management, budgeting and cost-control) involved in the management of a drug development programme.
9. Principles of translational research and its role in drug development.
10. Functions and elements (including business aspects) involved in the integrated development of new drugs. The role and management of SMEs in drug development

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Day 1 - October 26, 2017 – Thursday

Time	Name of Lecturers	Titles and topics of the lectures and cases Topics to be covered by the lectures	Syllabus reference numbers	Learning outcomes reference number
9:00-9:20 9:20-9:30 9:30-9:40 9:40-10:00	S. Kerpel-Fronius P. Ferdinandy M. Gottwald S. Kerpel-Fronius	Introduction of the students Welcome The IMI project. IMI-PharmaTrain (PhT) harmonized educational program. The organization of the CEMDC. Educational concept. Chemical, biological, complex medicinal products and advanced therapies	1.5	6
10:00-10:45	M. Gottwald	Medicine development from the viewpoint of the pharmaceutical industry. Collaborative approaches in drug development between the pharmaceutical industry and the academia. IMI supported cooperative program, the Importance and handling of intellectual property rights in the IMI cooperation projects	1.1 -1.3	5, 7,10
11:00-11:45	P. Ferdinandy	The role of basic research. Medicine development from the viewpoint of the academic research sites. Initiation and maintenance of long term academic-industrial cooperation.	1.1-1.3	1, 6, 7, 8
12:00-12:45	P. Ferdinandy	Importance of small and medium enterprises (SMEs) in drug discovery and development. Management of innovative SMEs	1.1-1.3	1, 6, 7, 8, 10
13:00-14:30		**Lunch**		
14:30 15:15	J. Whitty	Financing of SME: resource planning (in terms of project management, budgeting and cost-control) involved in the management of a drug discovery and development program.	2.7	8, 10

15:30 16:15	P. Stonier	From drug discovery to market place. Overview of the development and life cycle management of medicines. The changing role of medical affairs in life cycle management and marketing	1.1, 1.2	1, 2, 3, 5
16:30- 17:15	M. Gottwald	Overview of medicine development project management techniques: development plan, project teams, target product profile (TPP), target product claims (TPC), registration dossier submission. Resource planning, budgeting and cost control, in- and out-sourcing.	2.3, 2.6, 2.7	8, 10
17:30- 18:30	J. Whitty	Budgeting of medicines development projects. Case presentation	2.7	8

Day 2 - October 27, 2017 - Friday

Time	**Name of Lecturers**	**Titles and topics of the lectures and cases** Topics to be covered by the lectures	**Syllabus reference numbers**	**Learning outcomes reference number**
9:00- 9:45 10:00- 10:45	P. Arányi,	Molecular mechanism of drug action; target identification, validation and selection. Principle steps in discovering, modifying, assessing and patenting new chemical and biological compounds.	1.2, 1.4, 1.5	6, 7
11:00- 11:45	S. Bátori	Lead optimisation and development candidate selection; testing for biological activity.	1.6, 1.7	7
12:00- 12:45	P. Stonier	Medicines development as a professional speciality. The global role of IFAPP. Competencies of the pharmaceutical professionals. Specialist in pharmaceutical medicines (SPM).	2.1, 2.4, 2.5, 2.6	1, 2, 4
13:00- 14:30		**Lunch**		

14:30-15:15	P. Stonier	The elements and functions necessary for the integrated development and management of medicines. R&D portfolio planning; in- and out-licensing of medicines. Medium & Big pharma strategies The role of the safety officer in drug development and management	1.6, 1.7, 2.1, 2.4, 2.5, 2.6	2, 4, 7, 10
15:30-16.15	E. Mikus	Principles of translational medicine: relationship between animal and human pharmacology; genomics, proteomics, epigenetics	1.3, 1.8, 1.9	6, 9
16:30-17:15	E. Mikus	Principles of translational medicine: biomarkers imaging, modeling, simulation Special populations. Predictive animal models, biomarker use in the laboratory and in the clinic	1.8, 1.9	6, 9
17.30-18:00	E. Mikus	Case study	1.8, 1.9	6, 9

Day 3 - October 28, 2017 - Saturday

Time	**Name of Lecturers**	**Titles and topics of the lectures and cases** Topics to be covered by the lectures	**Syllabus reference numbers**	**Learning outcomes reference number**
9:00-9:45	L. Hársing	Pathophysiology and molecular biology-based pharmacology. Molecular-based approaches: receptor agonists, antagonists, enzyme inhibitors	1.3, 3.1	6
10:00-10:45	L. Hársing	Pathophysiology and molecular biology-based pharmacology. Molecular-based approaches: receptor agonists, antagonists, enzyme inhibitors	1.3, 3.1	6
11:00-11:45	M. Vajdai	Overview of quality management in the global integrated development of new medicines	2.1, 2.2, 2.5	10

12:00-12:45	T. Paál	Overview of regulatory and safety evaluation of medicines during the life cycle of drugs. European Regulatory Network, EMA, scientific advice, control of the information provided by the pharmaceutical industry Pharmacovigilance system	Overview of topics in sections: 10, 11, 12	3
13:00-14:30		**Lunch**		
14:30-15:15	L. Tóthfalusi	Basic principles of pharmacokinetics. The importance of plasma level measurements in the non-clinical and clinical development of medicines	5.5, 5.6, 5.10, 5.12	2.9
15:30-16:15	L. Tóthfalusi	Basic principles of pharmacokinetics. The importance of plasma level measurements in the non-clinical and clinical development of medicines	5.5, 5.6, 5.10, 5.12	2.9
16:30-17:15	S. Kerpel-Fronius	Medicines development from the viewpoint of the clinical investigator. Chemical, biological medicinal agents, complex non-biological agents, AE reporting, Patient's view. Ethical issues.	1.2, 1.5, 1.7, 1.8, 1.9	1, 2, 4, 6

Day 4 - October 28, 2017 - Sunday

Time	**Name of Lecturers**	**Titles and topics of the lectures and cases** Topics to be covered by the lectures	**Syllabus reference numbers**	**Learning outcomes reference number**
9:00-11:00	**Examination: Modul I**			
11:00 11:45	**Joint discussion of the MCQs**			
12:00-12:45	J. Lendvay S. Kerpel-Fronius &	Administrative and financial matters		2

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Module: 1

List of mandatory preparatory readings and E-learning module

Defining Translational Research: Implications for Training
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2829707/pdf/nihms172799.pdf

Core competencies for pharmaceutical physicians and drug development scientists. Frontiers in Pharmacology, Pharmaceutical Medicine and Outcomes Research. 4 (Article105) 1-8, 2013. Doi: 10.3389/fphar.2013.00105. Honorio Silva*, Peter Stonier , Fritz Buhler , Jean-Paul Deslypere , Domenico Criscuolo, Gerfried Nell , Joao Massud, Stewart Geary , Johanna Schenk , Sandor Kerpel-Fronius, Greg Koski , Norbert Clemens , Ingrid Klingmann, Gustavo Kesselring , Rudolf van Olden and Dominique Dubois.
http://journal.frontiersin.org/article/10.3389/fphar.2013.00105/full

E-learning modules:
Select: Introductory module

- (created by Hibernia, with the support of AZ, Pfizer and Pharmed)

The website for finding and login for the PharmaTrain e-learning modules:
http://www.pharmatrain.eu/e-library/login.html.

You have to register for getting access:
New Registry:
A password has to be required here.

In the roll down menu indicate in the Main Area of Interest*: CEMDC course participants.
The Email module you should learn before the BM1 is the Introductory Module