

2023/2024. ACADEMIC YEAR	
PROGRAM OF STUDY (FOR STUDENTS OF 5TH YEAR)	
Full (Hun) name of the subject: Gyógyszeripari és gyógyszerfelügyeleti, hatósági ismeretek- Gyógyszerinnováció és klinikai vizsgálatok (elmélet+gyakorlat)	
Program: Undivided program (pharmaceutical)	
Schedule: full-time	
Short name of the subject: Drug innovation and clinical examinations	
English name of the subject: Knowledge of the Pharmaceuticoindustrial and Pharmacovigilance Authorities – Drug innovation and clinical examinations (theory+practice)	
German name of the subject: Behördenkenntnisse der pharmazeutischen Industrie und Arzneimittelüberwachung - Arzneimittelinnovation und klinische Studien (Vorlesung+Praktikum)	
Type of registration: obligatory	
Neptun code of the subject: GYKGYI105G1A	
Responsible Department: Semmelweis University, Department of Pharmaceutics	
Responsible tutor Dr. István Antal Contact information: - phone: 06-1-217-0914 - email: antal.istvan@semmelweis.hu	Title, academic degree: University Professor, PhD, Dr. habil
Name of the persons responsible for the teaching of the subject: Dr. Miléna Lengyel Phone: +36-1-459-1500 Extension: 53069 E-mail: lengyel.milena@semmelweis.hu Dr. Romána Zelkó Dr. Nikolett Kállai-Szabó Dr. Ágnes Mészáros Dr. Bálint Basa Dr. Szabolcs Barótfi Dr. Éva Kollár Dr. István Laszlovszky	Title, academic degree: Assistant professor, PhD University Professor, Dr. habil Associate Professor, PhD Associate Professor, PhD PhD Student, PharmD invited lecturer, Ph.D. invited lecturer invited lecturer
Class per week: 8/sem lectures 8/sem practices	Credit point(s): 1 credit
Professional content, intent of acquirement and it's function in order to implement the goals of the program: The purpose of teaching the subject is for the student to master the most important theoretical and practical aspects necessary for the innovation activity of pharmaceutical products, with particular regard to the development of original and generic products, industrial property rights protection, and aspects of clinical trials.	
Short description of the subject: The topic of the subject includes the pharmaceutical aspects of pharmaceutical innovation and research and development, the basics of strategic planning of products, the basics of industrial rights protection and the patentability of inventions, as well as the most important issues of drug development and licensing of original, generic and super-generic (innovative drug technology) preparations. In addition, the subject aims to summarize the phases, significance, objectives and course of clinical trials based on the GCP directive, and also to provide insight into the related ethical aspects.	

Course data							
Recommend ed term	Contact hours (lecture)	Contact hours (practice)	Contact hours (seminar)	Individual lectures	Total number of contact hours/semester	Normal course offer	Consult ations
9th semester	8	8	-	-	16	<u>Autumn semester*</u> Spring semester Both semesters (* Please underline)	On demand
Program of semester**							
<p>Topics of theoretical classes (2-week course in the 1-2. weeks of the semester) Pharmaceutical innovation from the perspective of industry Pharmaceutical research and development today, opportunities, limitations, trends Pharmaceutical industry aspects of industrial law protection Regulatory environment for drug development and licensing Development of original, generic, generic+ preparations: preclinical and clinical studies Clinical trials in research and development Phases of a clinical trial, authorisation, ethical aspects</p>							
<p>Topics of practical classes (pro week): Strategic planning, life cycle, product life curve theory, BCG matrix Patent description structure and content aspects Clinical trial protocol Practical conduct of clinical tests, Statistical evaluation</p>							
<p>Other subjects (both compulsory and optional) relating to the transversal issues of the subject. Possible overlaps between subjects:</p>							
<p>Schedule of consultations: On request</p>							
Course requirements							
<p>Prerequisites: Pharmacology and Toxicology III. Pharmaceutical Technology IV.</p>							
<p>Conditions of attending the classes, amount of acceptable absents, way of presentation of leave, opportunity for makeup: Attendance as in STUDY AND EXAMINATION REGULATIONS, makeup on individual request in the 3. week of the semester</p>							
<p>The grading method; the conditions for getting the signature; the number, topic(s) and date(s) of the mid-term assessments-(reports, term tests), and the process in which they contribute to the final grade; and the possibility of their retake or their upgrading retake (as provided in §§ 25-28 of the STUDY AND EXAMINATION REGULATIONS):</p>							
<p>Requirements of signature (as provided for in STUDY AND EXAMINATION REGULATIONS § 29): Attendance (max. 25% absence) attendance at visit at pharmaceutical plants</p>							
<p>Number and type of projects students have to perform independently during the semester and their deadlines: -</p>							
<p>Type of the semester-end examination: signature*/<u>practical grade*</u>/ comprehensive examination*/final/end-term examination* Examination requirements: as published by the education-research department on the MOODLE interface by the start of the academic term.</p>							
<p>Form of the semester-end examination: <u>written*</u>/<u>oral*</u>/combined examination/practical examination/the assessment of completing project work (according to STUDY AND EXAMINATION REGULATIONS 30.§)* (* Please underline)</p>							

The possibility and conditions for offering grades:

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A list of the basic notes, textbooks, resources and literature that can be used to acquire the knowledge necessary to master the curriculum and to complete the assessments, with exact description about which of them is required to acquire which part of the syllabus (e.g. description based on topics)), as well as the main technical and other aids and study aids that can be used:

Lecture slides and practical documents can be found on Moodle.

In the case of a subject lasting more than one semester, the position of the teaching/research department on the possibility of parallel enrolment and the conditions for admission**:**

yes*/no*/on and individual assesment basis* (*Please underline*)

The course description was prepared by: Dr. István Antal