

2023/2024. ACADEMIC YEAR							
PROGRAM OF STUDY (FOR STUDENTS OF 5TH YEAR)							
Full (Hun) name of the subject: Gyógyszeripari és gyógyszerfelügyeleti, hatósági ismeretek-Farmakovigilancia és farmakoepidemiológia (elmélet+gyakorlat)							
Program: Undivided program (pharmaceutical)							
Schedule: full-time							
Short name of the subject:							
English name of the subject: Knowledge of the Pharmaceuticoindustrial and Pharmacovigilance Authorities - Pharmacovigilance and pharmacoepidemiology (theory+practice)							
German name of the subject: Behördenkenntnisse der pharmazeutischen Industrie und Arzneimittelüberwachung - Pharmakovigilanz und Pharmakoepidemiologie (Vorlesung+Praktikum)							
Type of registration: obligatory							
Neptun code of the subject: GYKGYI103G1A							
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, Ph.D., 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. Tamás Tábi Dr. Panka Kónya Dr. Attila Oláh Dr. Orsolya Szokolóczy Dr. Zoltán Barna Dr. Bálint Basa Dr. Kohod Zsófia				Title, academic degree: Assistant professor, Ph.D. Associate Professor, Ph.D. invited lecturer, Ph.D. invited lecturer, Ph.D. invited lecturer, Ph.D. invited lecturer, PharmD PhD Student, PharmD PharmD			
Class per week: 4/sem lectures 4/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 aim of the course is to provide information on the national and European pharmacovigilance system established to promote the safe use of medicines and its importance to the pharmaceutical industry.							
Short description of the subject: The lectures will cover the most common mechanisms of adverse drug reactions, the industry and regulatory system of adverse drug reaction reporting and evaluation, with special emphasis on the national and EU practice. The course will cover the detection and investigation of new risks from drug safety data, the continuous monitoring and evaluation of the benefit/risk ratio of medicines, the proactive management of drug-related risks and their effective communication.							
Course data							
Recommended term	Contact hours (lecture)	Contact hours (practice)	Contact hours (seminar)	Individual lectures	Total number of contact hours/semester	Normal course offer	Consultations
9th semester	4	4	-	-	8	Autumn semester* Spring semester Both semesters (* Please underline)	on demand

Program of semester**

Topics of theoretical classes (pro week):

Importance of pharmacovigilance, regulations (GVP) and regulatory hierarchy, definitions (AE, ADR), special situations
QPPV person's tasks, responsibilities, obligations
Duties of a pharmacovigilance specialist, "how a day goes by", in which areas they work (industry, authority, etc.)
The relationship of pharmacovigilance with other areas, e.g. registration, quality assurance, drug development (clinical and post-marketing studies), marketing, etc.

Topics of practical classes (pro week):

Sources of side effect reporting, literature review,
Side effect reporting sheet and its parts,
Actions related to notifications, e.g. follow-up, targeted follow-up
Process and manner of reporting to authorities.

Other subjects (both compulsory and optional) relating to the transversal issues of the subject. Possible overlaps between subjects:

Schedule of consultations: On request

Course requirements

Prerequisites:

Pharmacology and Toxicology III.

Conditions of attending the classes, amount of acceptable absents, way of presentation of leave, opportunity for makeup:

On individual consultation.

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):

Moodle test at the last day of course (Sept 29.) Successful written exam (min. 2.00, min 50%) is accepted.

Requirements of signature (as provided for in STUDY AND EXAMINATION REGULATIONS § 29): Attendance according to Study and Examination Regulations (max. 25% absence)

Number and type of projects students have to perform independently during the semester and their deadlines:

-

Type of the semester-end examination: signature*/practical grade*/ 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.

Form of the semester-end examination: written*/oral*/combined examination/practical examination/the assessment of completing project work (according to STUDY AND EXAMINATION REGULATIONS 30.§)* (*Please underline*)

The possibility and conditions for offering grades:

-

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:**

Slides of lectures and practicals will be shared during the course.

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 assessment basis* (*Please underline*)

**The course description was prepared by::
Dr. Antal István**