

2023/2024. ACADEMIC YEAR							
PROGRAM OF STUDY (FOR STUDENTS OF 5TH YEAR)							
<b>Full (Hun) name of the subject: Gyógyszeripari és gyógyszerfelügyeleti, hatósági ismeretek- Minőségbiztosítás (elmélet+gyakorlat)</b>							
<b>Program: Undivided program (pharmaceutical)</b>							
<b>Schedule: full-time</b>							
<b>Short name of the subject:</b> Quality Assurance							
<b>English name of the subject:</b> Knowledge of the Pharmaceuticoindustrial and Pharmacovigilance Authorities - Quality Assurance (theory+practice)							
<b>German name of the subject:</b> Behördenkenntnisse der pharmazeutischen Industrie und Arzneimittelüberwachung - Qualitätssicherung (Vorlesung+Praktikum)							
<b>Type of registration: obligatory</b>							
<b>Neptun code of the subject:</b> GYKGYI104G1A							
<b>Responsible Department:</b> Semmelweis University, Department of Pharmaceutics							
<b>Responsible tutor</b> Dr. István Antal				<b>Title, academic degree:</b> professor, Ph.D., Dr. habil.			
<b>Contact information:</b> - phone: 06-1-217-0914 - email: <a href="mailto:antal.istvan@semmelweis.hu">antal.istvan@semmelweis.hu</a>							
<b>Name of the persons responsible for the teaching of the subject:</b>  Dr. Miléna Lengyel Phone: +36-1-459-1500 Extension: 53069 E-mail: <a href="mailto:lengyel.milena@semmelweis.hu">lengyel.milena@semmelweis.hu</a>  Dr. Romána Zelkó Dr. Nikolett Kállai-Szabó Dr. Bálint Basa Dr. Lívia Gál Dr. Bulcsú Rác Dr. Dávid Szegvári				<b>Title, academic degree:</b>  Assistant professor, Ph.D.  University Professor, Dr. habil Associate Professor, Ph.D. PhD Student, PharmD invited lecturer, PharmD invited lecturer Ph.D. invited lecturer Ph.D.			
<b>Class per week:</b> 4/sem lectures 4/sem practices				<b>Credit point(s):</b> 1 credit			
<b>Professional content, intent of acquirement and it's function in order to implement the goals of the program:</b> The aim of the course is to familiarise students with the specific aspects of quality assurance in the pharmaceutical industry and the responsibilities arising from the legal framework.							
<b>Short description of the subject:</b> Students will be introduced to the most important activities, such as change management, risk management, variance investigation, OOS results management, qualification, validation, cross-contamination prevention, stability testing, microbiological issues, contaminants, etc. In the classroom exercises, students will be able to follow a risk management and investigation process.							
Course data							
Recommend ed term	Contact hours (lecture)	Contact hours (practice)	Contact hours (seminar)	Individu al lectures	Total number of contact hours/sem ester	Normal course offer	Consult ations
9th semester	4	4	-	-	8	<u>Autumn semester*</u> Spring semester Both semesters (* Please underline)	on demand

<b>Program of semester**</b>
<p><b>Topics of theoretical classes (pro week):</b></p> <p>Basics of pharmaceutical quality assurance  Responsibilities of the authorised person (QP), release of batches  Risk management, risk-based GMP  Investigation of manufacturing deviations, OOS  Qualification and process validation  Audits, inspections  Release (parametric, "real-time")  Process analysis, PAT</p>
<p><b>Topics of practical classes (pro week):</b></p> <p>Liberation  Risk analysis  Change management  Elements of PAT, typical methods, examples of PAT application</p>
<p><b>Other subjects (both compulsory and optional) relating to the transversal issues of the subject. Possible overlaps between subjects:-</b></p>
<p><b>Schedule of consultations:</b> on request</p>
<b>Course requirements</b>
<p><b>Prerequisites:</b>  Pharmaceutical Technology  IV. Pharmacy Administration I.</p>
<p><b>Conditions of attending the classes, amount of acceptable absents, way of presentation of leave, opportunity for makeup:</b>  max. 25% absence, according to the Study and Examination Rules, makeup on individual request</p>
<p><b>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):</b>  Attendance of lectures and practicals expected according to study regulations. The written exam (Moodle test on Sept. 29.) or makeup exam (3. educational week) must be passed ("accepted"). The overview lecture slides will be published on Moodle.</p>
<p><b>Requirements of signature(as provided for in STUDY AND EXAMINATION REGULATIONS § 29):</b>  Attendance according to Study and Examination Rules, max. 25% absence, attendance at visits at pharmaceutical plants</p>
<p><b>Number and type of projects students have to perform independently during the semester and their deadlines:</b>  -</p>
<p><b>Type of the semester-end examination:</b> signature*/<u>practical grade*</u>/ comprehensive examination*/final/end-term examination*  <b>Examination requirements:</b> as published by the education-research department on the MOODLE interface by the start of the academic term.</p>
<p><b>Form of the semester-end examination: <u>written*</u>/oral*/combined examination/practical examination/the assessment of completing project work (according to STUDY AND EXAMINATION REGULATIONS 30.§)*</b> (* Please underline)</p>
<p><b>The possibility and conditions for offering grades:</b>  -</p>

**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 will be published on Moodle. All necessary information for the successful exam can be found on the slides, however, the presenters provide deeper understanding of the schematic information slides.

**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**