

2023/2024. ACADEMIC YEAR

PROGRAM OF STUDY

Full (Hun) name of the subject: Gyógyszerészi informatika (elmélet+gyakorlat)							
Program: Undivided program (pharmaceutical)							
Schedule: full-time							
Short name of the subject: Pharmaceutical Informatics							
English name of the subject: Pharmaceutical Informatics (theory+practice)							
German name of the subject: Pharmazeutische Informatik (Vorlesung+Praktikum)							
Type of registration: <u>obligatory</u> /obligatory elective/elective/criteria requirement							
Neptun code of the subject: GYKDEI099G1A							
Responsible Department: Institute of Digital Health Sciences							
Responsible tutor: Dr. Szócska Miklós Contact information: – phone: – email: titkarsag.dei@semmelweis-univ.hu				Title, academic degree: professor, PhD			
Name of the persons responsible for the teaching of the subject: Dr. Zajzon Gergely Dr. Tamus Zoltán Ádám Dr. Tóth Tamás Dr. Iváncsy Tamás				Title, academic degree: assistant lecturer senior lecturer, PhD associate professor, PhD guest lecturer, PhD			
Class per week: 2				Credit point(s): 1			
Professional content, intent of acquirement and it's function in order to implement the goals of the program: To acquaint students with the IT systems and applications used in pharmacy. The subject reviews the life cycle of medicines and related legislation, and then presents in detail the IT tools that can be used during each step, from drug development and official licensing to drug distribution.							
Short description of the subject: Successful completion of the subject will result in the acquisition of the following competencies: Knowledge of the processes of drug development, authorization and distribution. Getting to know the IT methods, tools, code systems and databases used in these.							
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
9 th semester	10	10	–	–	20	Autumn semester* Spring semester Both semesters (* Please underline)	–

Program of semester**

Topics of theoretical classes (pro week):

1. week: Lifecycle of pharmaceutical products, Introduction to the relevant legal hierarchy
2. week: Methods of computer molecular design
3. week: Drug development process, approval of clinical trials
4. week: Introduction to Drug authorization (Regulatory Affairs): CTD (Common Technical Document), eCTD standards
5. week: Pharmacovigilance, related IT systems, databases (EudraVigilance, E2B, PSUR)
6. week: Drug Reimbursement system and relevant databases
7. week: Pharmacy IT systems, Serialisation
8. week: Mobile devices, portable devices, sensors, smart devices in healthcare
9. week: IT tools for evidence-based medicine and personalized medicine
10. week: Prescription software, electronic prescription

Topics of practical classes (pro week):

1. week: Clinical trial related IT systems – EudraCT, clinicaltrials.gov, clinicaltrialsregister.eu
2. week: National and international pharmaceutical databases (OGYÉI database, basics of pharmaceutical electronic register system, EudraPharm, EudraGMP, EudraNET)
3. week: CTD, eCTD
4. week: IT background of pharmaceutical reimbursement: Pupha, OWL, fix reimbursement
5. week: Pharmaceutical code systems and standards (ATC, DDD)
6. week: Pharmaceutical code systems and standards (Active ingredients register, INN, BNO, MedDRA)
7. week: QRD, Readability, structure of product information files (SmPC, PIL)
8. week: Pharmaceutical promotion and marketing
9. week: IT systems for pharmaceutical sales information – OSAP1913 – P@NKA, IMS
10. week: ORKA prescription software

Schedule of consultations:

by agreement

Course requirements

Prerequisites:

Pharmacy Administration I. GYEGYGIMG1A

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

Attendance of at least 75% of the classes. Max. 3 absences are allowed

Number, topics and dates of tests during the semester, opportunities of makeup and improvement of results*:**

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Requirements of signature:

Attendance of at least 75% of the classes

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

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<p>Type of the semester-end examination: signature*/<u>practical grade</u>*/semi-final*/final* <i>(* Please underline)</i></p> <p>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>*/oral*/combined examination* <i>(* Please underline)</i></p>
<p>The possibility and conditions for offering grades: –</p>
<p>Scientific, course related researches, publications, essays:</p> <p>The educational materials are available at http://dei-cloud.semmelweis.hu. Username and password are announced at the first class.</p>
<p>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****:</p> <p>yes*/<u>no</u>*/on and individual assessment basis* <i>(* Please underline)</i></p>
<p>The course description was prepared by:</p> <p>Dr. Zajzon Gergely and Dr. Tóth Tamás</p>