Semmelweis University, Faculty of Medicine

Pharmaceutical Innovation and Business Administration Master of Science

Name of the host institution (and any contributing institution):

Department of Pharmacology and Pharmacotherapy hosting the MSc course announcing this specific subject in collaboration with the Richter Department

Name of subject: Preclinical Discovery of Medicines

in English: Preclinical Discovery of Medicines

in German: not applicable

Credit value: 5

Semester: 2025/2026 1st Semester

in which the subject is taught according to the curriculum

Hours per semester	Lecture	Course work	Seminar
150	28	122	-

Hours per week	Lecture	Practical lesson	Seminar
Course blocks tailored to the students' employment obligations on Fridays and Saturdays Course dates: 12th September 14.00-18.00 13rd September 9.00-13.00 19th September 14.00-18.00 20th September 9.00-13.00 18th October 9.00-13.00 25th October 9.00-13.00 8th November 9.00-13.00			

Type of course:

compulsory

Academic year:

2025/2026

Language of instruction (for optional and elective subjects):

English

Course code:

(in the case of a new course, to be completed by the Dean's Office, following approval

Course coordinator name: Balazs Lendvai MD PhD DSc

Course coordinator location of work, telephone availability: Semmelweis University Richter Department Budapest, 1085 Budapest, Üllői út 26. +36-20-240-9058

Course coordinator position: Head of Richter Department (Semmelweis University), Manager of division, Pharmacological and Drug Safety Research (Gedeon Richter Plc.),

Course coordinator Date and number of habilitation: -

Objective of instruction and its place in the curriculum:

The main objective is to provide an overall perspective of the R&D processes taken place in pharma industry including the major elements and specific knowledge of the area. In particular, there is a special focus on preclinical research where the discovery of next drug molecules happens and also involves the various aspects of drug developments and related modalities. It shows the details of various options of chemical starting points, the methods of finding new molecular targets, the screening of compound libraries, and the basis of pharmacokinetics and metabolism. The lectures allow deep insight to the fields of in vivo disease models, the current methodologies of translational research in pharma context, and actual challenges are also introduced for safety pharmacology the preclinical prediction is in focus. Moreover, the aspects of drug development are also discussed in relation to the discovery process. The lecturers are employees of Richter Gedeon and Richter Department of Semmelweis University, best experts in their specific fields, so that the specific knowledge is delivered from first hands. The success of these experts is highlighted by the approved medicines and ongoing clinical trials originated from this professional working group.

Method of instruction (lecture, group work, practical lesson, etc.):

lectures, group work

Competencies acquired through completion of course:

knowledge of basic information, timelines and practices of drug research

Course outcome (names and codes of related subjects):

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Prerequisites for course registration and completion: (CODE):

no special prerequisite for the students admitted to the MSc Course

In the case of multi-semester courses, position on the possibility of and conditions for concurrent registration:

none

The number of students required to start the course (minimum, maximum), student selection method:

all students admitted to the MSc course

Detailed course syllabus (if the course can be divided into modules, please indicate):

(Theoretical and practical instruction must be broken down into hours (weeks), numbered separately; names of instructors and lecturers must be listed, indicating guest lecturers/instructors. It cannot be attached separately! For guest lecturers, attachment of CV is required in all cases!)

1. Trends in pharma industry: Role of the small molecule research and development - Balázs Lendvai MD PhD DSc - 2x45'
2. The flow of original drug research in pharma - Balázs Lendvai MD PhD DSc - 2x45'
3. Molecular drug targets: sources and determinants, Balázs Lendvai MD PhD DSc 2x45'
4. Success rate and attrition in pharma drug research- Balázs Lendvai MD PhD DSc -2x45'
5. Examples from the history of Drug Research: lessons to learn - András Boros MSc Phd - 2x45'
6. Mechanism of action of drugs in Central Nervous System -András Boros MSc Phd - 2x45'
7. New drug targets-András Boros MSc Phd - 2x45'
8. Cell and gene therapies: new waves in pharma drug research -András Boros MSc Phd - 2x45'
9. Discovery pharmacokinetics in the preclinical stage - Ottilia Balázs MSc PhD - 2x45
10. Medicinal chemistry approaches for drug screening - János Éles MSc PhD - 2x45'
11. Current efficacy screening practices in vitro - Tamás Kovács MSc PhD - 2x45'
12. Induced pluripotent stem cells and in vitro disease modelling in the pharma - Zsolt Némethy MSc PhD - 2x45'
13. Toxicokinetic and human clinical pharmacokinetic studies in the development - Attila Kónya MSc PhD - 2x45'
14. Bioanalytical development practice - Attila Kónya MSc PhD - 2x45'

Other courses with overlapping topics (obligatory, optional, or elective courses) in interdisciplinary areas. To minimalize overlaps, topics should be coordinated. Code(s) of courses (to be provided):

none

Requirements for attendance, options for making up missed sessions, and method of absence justification:

Full attendance is required. Completing additional e-learning materials are required to make up missed courses.

Assessment methods during semester (number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks):

(**number, topics, and dates of midterms and reports, method of inclusion in the course grade, opportunities for make-up and improvement of marks)**

online test at the end of the semester

Number and type of individual assignments to be completed, submission deadlines:

project work focused on a given topic, after the end of lectures

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Requirements for the successful completion of the course:

project work approved + appropriate test results

Type of assessment:

score-based

Examination requirements (list of examination topics, subject areas of tests, lists of mandatory parameters, figures, concepts and calculations, practical skills, optional topics for the project assignment recognized as an exam and the criteria for its completion and evaluation)

project work submitted – test completed. Test includes questions regarding all topics of the subject.

Method and type of grading (Share of theoretical and practical examinations in the overall evaluation. Inclusion of the results in the end-of-term assessment. Possibilities of and conditions for offered grades.): (Share of theoretical and practical examinations in the overall evaluation, Inclusion of the results in the end-of-term assessment, Possibilities of and conditions for offered grades)

score-based evaluation of the test results. Assessment of the project work: whether it reached the required level.

Signature of habilitated instructor (course coordinator) announcing the course:

Signature of the director of the host institution:

Richter Department

Semmelweis University

Date of submission:

8th August 2025

2025.08.06.