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 under the umbrella of the Centre for Pharmacology and Drug Research & Development, in collaboration with the Department of Pharmaceutics at Faculty of Pharmaceutical Sciences

Name of subject:

Authorization and approval of medicinal products

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in English: Authorization and approval of medicinal products

in German: not applicable

Credit value: 5

Semester: 2025/2026 1st

in which the subject is taught according to the curriculum

Hours per semester	Lecture	Course work	Consultation
150	14	125+8 hours project work presentation	3

Hours per week	Lecture	Course work	Consultation
Course blocks tailored to the students' employment obligations on Fridays and Saturdays Course dates: 3rd October 14.00-18.00 15th November 9.00-12.00 22nd November 9.00-12.00 12th December 14.00-18.00 Project work presentations 24th January			

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: Prof. Istvan Antal

Course coordinator location of work, telephone availability:
Department of Pharmaceutics, +36206632740

Course coordinator position: professor, director

Course coordinator Date and number of habilitation: 2003, 8/2003 SZTE

Objective of instruction and its place in the curriculum:

The objective of the course is to review the authorization process of medicinal products as well as the aspects of the development and evaluation of the information and documentation required for approval. Students will learn the basics of marketing authorization, the regulatory environment and system of requirements that determine the content and formal requirements of technical documentation, including drug quality, as well as the tasks related to the application for marketing authorizations, official evaluation and the maintenance of authorizations. The subject provides an overview of industrial and official processes prior to placing on the market. It presents, in general, the activities and knowledge materials required for maintaining and amending the license after obtaining it.

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

lectures, project work.

Competencies acquired through completion of course:

Completing the course the students should be able to use knowledge about the regulatory requirements including documentation and approval of medicinal products.
Students acquire several competencies including:

- understanding the approval process and requirements for development, registration.
- understanding the significance of quality, safety, efficacy and their relationship and aspects related to authorization,
- knowledge of regulatory directives and guidelines (e.g. ICH, EMA, FDA)
- knowledge of requirements for the structure and submission of documentation (Common Technical Document, CTD).
- knowledge of structure and content of Product Information documents (Summary of Product Characteristics (SmPC) and Patient Information Leaflets (PIL), package inserts

Course outcome (names and codes of related subjects):

The course will serve as a basis for general aspects of phamaceutical innovations and product development. Related subjects are: Food supplements: development, market and regulation, Manufacturing- Pharmaceutical formulation, optimization, quality assurance, logistics, supply chain

Prerequisites for course registration and completion: (CODE):

none

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!)

- Introduction: aspects of quality, safety and efficacy
  How medicinal products are approved. Evolution of drug authorization and approval
- From laboratory to the patient: research and developments, scientific advices, evaluation, authorization, access, monitoring safety
- Roles and responsibilities Data integrity requirements
- Drug authorization procedures, types of the marketing authorisation.
  Modification processes of already authorized pharmaceutical products
- Legal framework, regulatory directives and guidelines (e.g. ICH, EMA, FDA)
- Marketing authorisation of a new medicinal product assessed by a professional authority
- Registration documentation.
  Structure and submission of documentation (Common Technical Document, CTD).
  Product Information documents (Summary of Product Characteristics (SmPC) and Patient Information Leaflets (PIL), package inserts
- The planning process for the development of original medicines
  The planning process for the development of generic drugs
- Planning process for the development of generic added value medicines
  Biological medicines and biosimilar preparations
  Planning of WEU and its traditional development
- Aspects of pharmacovigilance, clinical trials
- Aspects of quality assurance
- Audits and inspections in pharmaceutical production

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):

Food supplements: development, market and regulation, Manufacturing- Pharmaceutical formulation, optimization, quality assurance, logistics, supply chain

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

Full attendance is required. Consultations 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)**

Students can improve the marks according to the general regulations

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

Personal attendance of lectures and practical expected according to study regulations. The written test (last educational week) must be passed ("accepted").

Completed individual work can be selected from several topics of approval procedures, e.g. related to

- Common Technical Documentation

- Summary of product characteristics (SmPC), patient information,

- Quality aspects

Requirements for the successful completion of the course:

Attendance of lectures, preparation and interpretation of project works, written test

Type of assessment:

written test and oral (presentation of project work)

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)

Lecture slides will be published on Moodle with test questions related to reviewed topics.

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)

Formulation of the grade:
88 to 100 points: excellent (5)
76-87,5 points: good (4)

63-75 points: average (3)
50-62 points: satisfactory (2)
Less than 50 points: unsatisfactory (1)

Half of the points are coming from the test, half from the assessment of the project work.

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

Prof. Dr. István Antal

Dean

Signature of the director of the host institution:

Prof. Dr. Péter Ferdinandy	Prof. Dr. István Antal
Head of Department	Dean

Date of submission:

11th August 2025