BULLETIN

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MSc in Pharmaceutical Research and Development Management

FACULTY OF PHARMACY

Coordinating Center for International Education

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CHAPTER 1
INTRODUCTION

The aim of the University of Debrecen is to become a university of medical sciences committed to the prevention and restoration of health of the people, not only in its region but in the entire country. In the past two decades both medical science and health care have entered a new era: the medical science of the 21st century. Molecular medicine is opening up and new possibilities are available for the diagnosis, prevention, prediction and treatment of the diseases. One can witness such a progress in medical sciences that has never been seen before. Modern attitudes in health care should be enforced in practice, including therapeutical approaches that consider the explanation and possible prevention of diseases, and attempt to comprehend and take the human personality into consideration. These approaches demand the application of the most modern techniques in all fields of the medical education.

All curricula wish to meet the challenges of modern times and they embody some very basic values. They are comprehensive; they take into consideration the whole human personality (body and soul) in its natural and social surroundings; and they are based upon the best European humanistic traditions. Moreover, all curricula prepare students for co-operation and teamwork.

With respect to education, both students and teachers are inspired to acquire higher levels of professionalism, precision, and problem solving skills, upon which the foundations of specialist training and independent medical practice can be built. This approach enables the assimilation of new scientific developments, facilitating further education and the continuous expansion of knowledge. The interplay of these factors ensures the ability to understand and handle the changing demands of health care.

With respect to research, the faculty members continuously acquire, internalize and subsume new knowledge, especially concerning the genesis, possible prevention and treatment of diseases. Moreover, new information aimed at improving, preserving and restoring the health of the society is also absorbed. The University of Debrecen is already internationally recognized in the fields of both basic and clinical research, and the clinicians and scientists of the University are determined to preserve this achievement. Special attention is given to facilitate and support the close co-operation of researchers representing basic science and clinical research, and/or interdisciplinary studies.

With respect to therapeutic practice, the main objective is to provide high quality, effective, up to date and much devoted health care to all members of the society, showing an example for other medical institutions in Hungary. One of the primary tasks is to continuously improve the actual standards of the diagnostic and therapeutic procedures and techniques, and to establish regional or even nationwide protocols.

With respect to serving the community, all faculty members wish to play a central role in shaping the policies of the health service; both within the region and in Hungary. They also want to ensure that sufficient number of medical doctors, dentists and other health care experts with university education is provided for the society.

With respect to the development, all employees strive for reinforcing those features and skills of the lecturers, scientists, medical doctors, health care professionals, collaborators and students which are of vital importance in meeting the challenges of medical education, research and therapy of the 21st century. These include humanity, empathy, social sensitivity, team-spirit, creativity, professionalism, independence, critical and innovative thinking, co-operation and management.

The organizational structure, including the multi-faculty construction of the institution, is a constantly improving, colorful educational environment, in which co-operation is manifest between the individual faculties and colleges, the various postgraduate programs as well as the molecular- and medical biology educations.

HIGHER EDUCATION IN DEBRECEN

A Brief History

1235: First reference to the town of Debrecen in ancient charters.
1538: Establishment of the “College of Reformed Church” in Debrecen.
1567: Higher education begins in the College.
1693: Declaration of Debrecen as a “free royal town”.
1849: Debrecen serves as the capital of Hungary for 4 months.
1912: Establishment of the State University of Debrecen comprising the Faculties of Arts, Law, Medicine and Theology.
1918: Inauguration of the Main Building of the Medical Faculty by King Charles IV of Hungary.
1921: The Medical Faculty becomes operational.
1932: Completion of buildings of the campus.
1944: Although during the Second World War, Debrecen became the capital of Hungary again (for 100 days), the University itself is abandoned for a while.
1949: The only year when the University has five faculties.
1950: The Faculty of Law idles; the Faculty of Science is established.
1951: The University is split up into three independent organizations: Academy of Theology, Medical School, Lajos Kossuth University of Arts and Sciences.
1991: The “Debrecen Universitas Association” is established.
1998: The “Federation of Debrecen Universities” is founded.
2000. The federation is transformed into the unified “University of Debrecen” with all the relevant faculties and with some 20,000 students.

Debrecen is the traditional economic and cultural center of Eastern Hungary. In the 16th century Debrecen became the center of the Reformed Church in Hungary and later it was referred to as the "Calvinist Rome". The 17th century was regarded as the golden age of the city because Debrecen became the mediator between the three parts of Hungary: the part under Turkish occupation, the Kingdom of Hungary and the Principality of Transylvania. For short periods of time, Debrecen served twice as the capital of Hungary. Nowadays, with its population of approximately a quarter of a million, it is the second largest city in Hungary.

Debrecen is a unique city: although it has no mountains and rivers, its natural environment is rather interesting. One of the main attractions and places of natural uniqueness in Hungary is Hortobágy National Park, known as “puszta" (“plain”), which begins just in the outskirts of Debrecen. This is the authentic Hungarian Plain without any notable elevations, with unique flora and fauna, natural phenomena (e.g. the Fata Morgana), and ancient animal husbandry traditions. The region is unmatched in Europe, no matter whether one considers its natural endowments or its historic and ethnographic traditions. A very lovely part of Debrecen is the “Nagyerdő” (“The Great Forest”), which is a popular holiday resort. Besides a number of cultural and tourist establishments, luxurious thermal baths and spas, Nagyerdő accommodates the University campus too.

The history of higher education in Debrecen goes back to the 16th century when the College of the Reformed Church was established. The University Medical School of Debrecen has its roots in this spiritual heritage. It was in the year of the millennium of the establishment of Hungary (1896) when the foundation of the present University was decided. The University of Debrecen was established in 1912, initially having four faculties (Faculties of Arts, Law, Medicine and Theology). The University was officially inaugurated by King Charles IV of Hungary on October 23rd, 1918.

The educational activity at the University started in 1924, although the construction of the whole University was completed only in 1932. In 1951 the Faculty of Medicine became a self-contained, independent Medical University for training medical doctors.

The special training of dentists began in 1976. As a further development the University Medical School established the Health College of Nyíregyháza in 1991. In 1993, as part of a nationwide

program, the University was given the rights to issue scientific qualifications and new Ph.D. programs were also launched. Several new programs (e.g. the training of molecular biologists, pharmacists, general practitioners) were commenced in the ’90s. The Faculty of Public Health was established in 1999, while the Faculty of Dentistry was founded in 2000.
The Faculty of Medicine celebrated the 90th anniversary of its foundation in October 2008 with a highly successful international scientific conference.

Education at the University of Debrecen
Debrecen, the second largest city of Hungary, is situated in Eastern Hungary. Students enrolled in the various programs (e.g. Medicine, Dentistry, Pharmacy, Public Health, Molecular Biology, etc.) study on a beautiful campus situated in the area called “Great Forest”.
The Hungarian Government gives major priorities to the higher education of health sciences in its higher education policy. One of these priorities is to increase the ratio of college level training forms within the Hungarian higher education system. The governmental policy wishes to implement conditions in which the whole health science education system is built vertically from the lowest (post-secondary or certificate) to the highest (PhD-training) levels. In fact, this governmental policy was the reason behind the establishment of the new Health Science Education Center within the Federation of Debrecen Universities (DESZ), based partially on the intellectual resources of the University of Debrecen. The new programs – with specialized training for paramedics – will help to correct the balance of the Hungarian labor-market that became rather unsettled in the past few decades.
The Act of Higher Education (1993) has restored the rights of the medical universities to award postgraduate degrees and residency, and permission was also given to license Physicians’ procedures. This kind of training required a new structure, a new administrative apparatus, and a suitable training center. The new residency programs were commenced in 1999.
The introduction of the credit system, starting in September 2003, has been mandatory in every Hungarian university, helping the quantitative and qualitative evaluation of the students’ achievements. Admission requirements for Hungarian students are defined at national level, and they are applicable for every student wishing to be enrolled into the Medicine or Dentistry programs.
International students must pass an entrance exam in biology and (depending on their preference) in physics or chemistry. In some special cases it may be possible for the candidates to apply for transfer to higher years on the basis of their previous studies and achievements. International students study in English language. Entrance for certain courses of the Health College is also possible on the basis of a special evaluation (scoring) and an entrance interview.
The syllabuses and classes of all courses correspond to European standards. The total number of contact hours in medical education is over 5,500, which can be divided into three main parts: basic theoretical training (1st and 2nd year), pre-clinical subjects (3rd year) and clinical subjects (4th and 5th year) followed by the internship (6th year). The proportion of the theoretical and practical classes is 30% to 70%; whereas the students/instructors ratio is about 8/1. The first two years of dentistry education are similar to the medicine program, but the former contains a basic dental training that is followed by a three-year-long pre-clinical and clinical training. Besides the medicine and dentistry programs, there are several other courses also available, including molecular biology. The various Health College courses include more and more new curricula.
The Medicine program delivered in English and intended for international students was commenced in 1987; whereas the Dentistry and Pharmacy programs for international students started in 2000 and 2004, respectively. The curriculum of the English language Medicine program meets all the requirements prescribed by the European medical curriculum, which was outlined in 1993 by the Association of Medical Schools in Europe. Compared to the Hungarian program, the most important differences are:
-Hungarian language is taught,

-More emphasis is laid upon the tropical infectious diseases (as parts of the “Internal Medicine” and “Hygiene and Epidemiology” courses).
Otherwise, the English language curriculum is identical with the Hungarian one. The 6th year of the curriculum is the internship that includes Internal Medicine, Pediatrics, Surgery, Obstetrics and Gynecology, Neurology, and Psychiatry. The completion of these subjects takes at least 47 weeks, although students are allowed to finish them within a 24-month-long period. The successfully completed internship is followed by the Hungarian National Board Examination. Just like the rest of the courses, the internship is also identical in the Hungarian and English programs.
A one-year-long premedical (Basic Medicine) course, which serves as a foundation year, is recommended for those applicants who do not possess sufficient knowledge in Biology, Physics and Chemistry after finishing high school.
After graduation, several interesting topics are offered for PhD training, which lasts for three years. If interested, outstanding graduates of the English General Medicine and Dentistry programs may join these PhD courses (“English PhD-program”). Special education for general practitioners has been recently started and a new system is in preparation now for the training of licensed physicians in Debrecen.

The accredited PhD programs include the following topics:
-Molecular and Cell Biology; Mechanisms of Signal Transduction
-Microbiology and Pharmacology
-Biophysics
-Physiology-Neurobiology
-Experimental and Clinical Investigations in Hematology and Hemostasis
-Epidemiological and Clinical Epidemiological Studies
-Cellular- and Molecular Biology: Study of the Activity of Cells and Tissues under Healthy and Pathological Conditions
-Immunology
-Experimental and Clinical Oncology
-Public Health
-Preventive Medicine
-Dental Research

The PhD-programs are led by more than 100 accredited, highly qualified coordinators and tutors.

Medical Activity at the Faculty of Medicine
The Faculty of Medicine is not only the second largest medical school in Hungary, but it is also one of the largest Hungarian hospitals, consisting of 38 departments; including 21 different clinical departments with more than 1,800 beds. It is not only the best-equipped institution in the area but it also represents the most important health care facility for the day-to-day medical care in its region.
The Kenézy Gyula County Hospital (with some 1,400 beds) is strongly affiliated with the University of Debrecen and plays an important role in teaching the practical aspects of medicine. There are also close contacts between the University and other health care institutions, mainly (but not exclusively) in its closer region. The University of Debrecen has a Teaching Hospital Network consisting of 26 hospitals in Israel, Japan and South Korea.
It is also of importance that the University of Debrecen has a particularly fruitful collaboration with the Nuclear Research Institute of the Hungarian Academy of Sciences in Debrecen, allowing the coordination of all activities that involve the use of their cyclotron in conjunction with various diagnostic and therapeutic procedures (e.g. Positron Emission Tomography 'PET').

Scientific Research at the Faculty of Medicine
Scientific research is performed both at the departments for basic sciences and at the laboratories of

clinical departments. The faculty members publish about 600 scientific papers every year in international scientific journals. According to the scientometric data, the Faculty is among the 4 best of the more than 80 Hungarian research institutions and universities. Lots of scientists reach international recognition, exploiting the possibilities provided by local, national and international collaborations. Internationally acknowledged research areas are Biophysics, Biochemistry, Cell Biology, Immunology, Experimental and Clinical Oncology, Hematology, Neurobiology, Molecular Biology, Neurology, and Physiology. The scientific exchange program involves numerous foreign universities and a large proportion of the faculty members are actively involved in programs that absorb foreign connections (the most important international collaborators are from Belgium, France, Germany, Italy, Japan, the UK and the USA).

CHAPTER 2
ORGANISATION STRUCTURE

RECTOR OF THE UNIVERSITY OF DEBRECEN	
Rector	Zoltán Bács Ph.D.
Address	4032 Debrecen, Egyetem tér 1.
Phone	+36-52-416-060
Phone/fax	+36-52-416-490
E-mail	rector@unideb.hu
COORDINATING CENTER FOR INTERNATIONAL EDUCATION	
Director	Attila Jenei M.Sc., Ph.D.
Address	4032 Debrecen, Nagyerdei krt. 94.
Phone	+36-52-258-058
E-mail	info@edu.unideb.hu
FACULTY OF MEDICINE	
Dean	Norbert Németh M.D., MBA, Ph.D., D.Sc.
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone	+36-52-258-086
E-mail	dekan@med.unideb.hu
Vice Dean of Specialization and Further Education	Andrea Szegedi M.D., Ph.D., D.Sc.
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone	+36-52-258-086
E-mail	dekan@med.unideb.hu
Vice-Dean for Scientific Affairs	György Panyi M.D., Ph.D., D.Sc.
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone	+36-52-258-086
E-mail	dekan@med.unideb.hu

Vice-Dean for Educational Affairs	Zsuzsanna Bereczky M.D., Ph.D., D.Sc.
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone	+36-52-258-08
E-mail	dekan@med.unideb.hu
Vice-Dean for International Affairs	Péter Fülöp, M.D., Ph.D.
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone	+36-52-258-08
E-mail	dekan@med.unideb.hu
DEAN'S OFFICE OF THE FACULTY OF MEDICINE	
Head of Dean's Office	Katalin Juhász M.A.
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone	+36-52-258-085
E-mail	kjuhasz@edu.unideb.hu
REGISTRAR'S OFFICE	
Head of Registrar's Office	Pál Pap M.Sc., Ph.D.
Address	4032 Debrecen, Nagyerdei krt. 94.
Phone/Fax	+36-52-258-001
E-mail	pap.pal@med.unideb.hu
FACULTY OF DENTISTRY	
Dean	Kinga Bágyi D.M.D., Ph.D. habil
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone/Fax	+36-52-255-208
E-mail	bagyi.kinga@dental.unideb.hu
Vice-Dean for Educational Affairs	Norbert Szentandrássy M.D., Ph.D.
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone/Fax	+36-52-255-208
E-mail	szentandrassy.norbert@med.unideb.hu
Vice-Dean for General Affairs	Gabriella Kovalecz D.M.D., Ph.D.
Address	4032 Debrecen, Nagyerdei krt. 98.

Phone/Fax	+36-52-255-208
E-mail	kovalecz.gabriella@dental.unideb.hu
FACULTY OF PHARMACY	
Dean	Ildikó Bácskay Pharm.D.,Ph.D.
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone/Fax	+36-52-411-717/54034
E-mail	bacskay.ildiko@pharm.unideb.hu
Vice-Dean for Educational Affairs	István Lekli Pharm.D., Ph.D.
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone/Fax	+36-52-411-717/55719
E-mail	Lekli.istvan@pharm.unideb.hu
Vice-Dean For General and Scientific Affairs	Gábor Halmos Pharm.D,.Ph.D
Address	4032 Debrecen, Nagyerdei krt. 98.
Phone/Fax	+36-52-411-600/55292
E-mail	halmos.gabor@pharm.unideb.hu
Vice-Dean for Public Relations	Anikó Borbás Ph.D., D.Sc.
Address	4032, Debrecen, Egyetem tér 1.
Phone/Fax	+36-52-512-900/22475
E-mail	borbas.aniko@pharm.unideb.hu
FACULTY OF HEALTH SCIENCES	
Dean	Marianna Móré Ph.D. habil
Address	4400, Nyíregyháza, Sóstói út 2-4.
Phone	+36-42-598-235
Fax	+36-42-408-656
E-mail	more.marianna@foh.unideb.hu
Vice-Dean for General and Scientific Affairs	Anita Rusinné Fedor Ph.D. habil
Address	4400, Nyíregyháza, Sóstói út 2-4.
Phone	+36-42-598-235
Fax	+36-42-408-656
E-mail	fedor.anita@foh.unideb.hu

Vice-Dean for Educational Affairs	Renáta Erdei Jávorné Ph.D.
Address	4400, Nyíregyháza, Sóstói út 2-4.
Phone	+36-42-404-411
Fax	+36-42-408-656
E-mail	erdei.renata@etk.unideb.hu
Clinical Vice-Dean	Mariann Harangi Ph.D.
Address	4032, Debrecen, Nagyerdei krt. 98.
Phone	+36-52-255-600/55468
E-mail	Harangi.mariann@med.unideb.hu
INTERNATIONAL STUDENT UNION DEBRECEN	
Internet	https://hu-hu.facebook.com/ISUDebrecen/
E-mail	isudebrecen@gmail.com
DEENK LIFE AND NATURAL SCIENCES LIBRARY	
Address	4032 Debrecen, Egyetem tér 1.
Phone/Fax	+36-52-518-610
E-mail	info@lib.unideb.hu
Internet	http://lib.unideb.hu/en

CHAPTER 3
ADMINISTRATIVE UNITS

DEAN'S OFFICE OF FACULTY OF PHARMACY

rex Ferenc u. 1., Debrecen, 4002, Tel: +36-52-411-717/58400, 58402
E-mail: vaszily.maria@pharm.unideb.hu

Full Professor, Dean	Ms.	Ildikó Bácskay D.Pharm., Ph.D.
Associate Professor, Vice-Dean for Educational Affairs		István Lekli D.Pharm., Ph.D.
Full Professor, Vice-Dean for General and Scientific Affairs		Gábor Halmos D.Pharm., Ph.D.
Full Professor, Vice-Dean for Public Relations	Ms.	Anikó Borbás Ph.D., D.Sc.
Invited Lecturer		Tibor Bárd D.Pharm.
		Dávid Bárd D.Pharm.
		Ádám Deák D.V.M., Ph.D.
		László Elek J.D.
		Gábor Ladányi D.Pharm.
	Ms.	Csilla Pozsgay M.D.
		Attila Sohajda D.Pharm.
		Attila Szabó M.Sc., Ph.D.
		András Ujvárosy M.Sc.
Head of Dean's Office	Ms.	Mária Vaszily
Administration Officer	Ms.	Lívia Ianas

REGISTRAR'S OFFICE

Nagyerdei krt. 94., Debrecen, 4032, Tel: +36-52-258-008
E-mail: eduoffice@med.unideb.hu; deaokto@med.unideb.hu

Head of Registrar's Office		Pál Pap M.Sc., Ph.D.
Secretary	Ms.	Viktória Rubos-Varga B.A.
Neptun Coordinator		Ádám Richárd Jasák B.A.
	Ms.	Réka Mosolygó M.A.
English Program Officer		Gábor Hatvani
	Ms.	Regina Marcis B.A.
	Ms.	Éva Ludánszki
	Ms.	Réka Rónai M.Sc.
	Ms,	Annamária Bagoly-Kiss M.A.
Hungarian Program Officer	Ms.	Zsuzsa Barta B.A.

		Tamás Buka M.A.
	Ms.	Nóra Faragó M.Sc.
	Ms.	Anikó Karcza B.Sc.
	Ms.	Andrea Beáta Kondás-Molnár M.Sc.
	Ms.	Katinka Major B.Sc.
	Ms.	Ágnes Ojtozi M.A.
	Ms.	Anna Mária Pásztori B.Sc.
		Imre Karap B.A.

COORDINATING CENTER FOR INTERNATIONAL EDUCATION

Nagyerdei krt. 94., Debrecen, 4032, Tel: +36-52-258-058
E-mail: info@edu.unideb.hu, Web: www.edu.unideb.hu

Director		Prof. Attila Jenei M.Sc., Ph.D.
Program Coordinator		Prof. Ferenc Erdődi M.Sc., Ph.D., D.Sc.
BMC Coordinator	Ms.	Beáta Lontay M.Sc., Ph.D.
Manager Assistant	Ms.	Márta Hajdu M.A.
	Ms.	Eszter Balázsy M.Sc.
	Ms.	Dóra Mónus M.A.
	Ms.	Rita Kovács LL.M.
	Ms.	Angelika Kiss M.Sc.
	Ms.	Arifa Katalin Davarci M.Sc.
	Ms.	Zsófia Münnich M.Sc.
Admission Coordinators	Ms.	Dóra Benkő M.A. (Admission, Visa Issues, BMC,)
	Ms.	Eszter Fercsák M.Sc. (Tuition fee, Financial certificates, Refunds)
	Ms.	Regina Tóth-Berei B.A. (Health Insurance, Tuition fee)
	Ms.	Adrienn Gagna-Szakó M.Sc. (Admission, Visa issues, USMLE)
	Ms.	Ildikó Lakatos M.A. (Admission, Visa Issues)
	Ms.	Annamária Bagoly-Kiss M.A. (Admission, Visa Issues)
	Ms.	Mária Tóth M.Sc. (Stipendium Hungaricum Scholarship)
IT Project Coordinator		Imre Szűcs B.Sc.

CHAPTER 4
DEPARTMENTS OF THE FACULTY OF PHARMACY

DEPARTMENT OF PHARMACEUTICAL SURVEILLANCE AND ECONOMICS

Nagyerdei krt. 98., Debrecen, 4032, Tel: +36-52-411-717/54474

Full Professor, Acting Head of Department		Miklós Vecsernyés D.Pharm., Ph.D.
Associate Professor, Head of Department		Béla Tóth E. M.D., MBA, Ph.D.
Assistant Professor		László Horváth D.Pharm., Ph.D.
Administration officer	Ms.	Henrietta Zágonyi-Szabó

DEPARTMENT OF PHARMACEUTICAL TECHNOLOGY

Rex Ferenc u.1., Debrecen, 4002, Tel: +36-52-411-717/58426

Full Professor, Dean	Ms.	Ildikó Bácskay D.Pharm., Ph.D.
Associate Professor	Ms.	Pálma Fehér D.Pharm., Ph.D.
	Ms.	Judit Váradi D.Pharm., Ph.D.
Assistant Professor		Daniel Alves Barcelos M.Sc., Ph.D.
	Ms.	Petra Arany D.Pharm., Ph.D.
		Ádám Haimhoffer D.Pharm., Ph.D.
	Ms.	Liza Józsa D.Pharm., Ph.D.
	Ms.	Dóra Boros-Kósa D.Pharm., Ph.D.
		Dániel Nemes D.Pharm., Ph.D.
	Ms.	Ágota Pető D.Pharm., Ph.D.
	Ms.	Ágnes Tóth-Klusóczki M.Sc., Ph.D.
Assistant Lecturer		József Baka D.Pharm.
	Ms.	Boglárka Kiss-Papp D.Pharm.
PhD Student	Ms.	Raghad Alsheikh M.Sc.
	Ms.	Barbara Nóra Balogh D.Pharm.
	Ms.	Krisztina Bodnár M.Sc.
	Ms.	Orsolya Csendes D. Pharm.
		Mengenli Akay Dogan D. Pharm.
		Bence Vámosi D. Pharm.
Academic Advisor	Ms.	Pálma Fehér D.Pharm., Ph.D.
Administration Officer	Ms.	Szilvia Sipos

DEPARTMENT OF PHARMACOLOGY

Nagyerdei krt. 98., Debrecen, 4032, Tel: +36-52-427-899

Associate Professor, Head of Department		István Lekli D.Pharm., Ph.D.
Full Professor		Árpád Tósaki D.Pharm., Ph.D., D.Sc.
Associate Professor		István Bak M.Sc., Ph.D. habil.
Assistant Professor	Ms.	Adina Fésűs D. Pharm, Ph.D.
	Ms.	Alexandra Gyöngyösi Ph.D.
	Ms.	Éva Sipos D. Pharm, Ph.D.
	Ms.	Erzsébet Szabó M.Sc., Ph.D.
	Ms.	Kitti Szőke D. Pharm, Ph.D.
Assistant lecturer	Ms.	Lídia Ambrus D. Pharm, Ph.D.
PhD Student		Simon Eskeif, M.Sc.
		Richard Kajtar, D.Pharm
	Ms.	Eszter Varga D.Pharm
Laboratory Assistant	Ms.	Edit Komóczi
Academic Advisor		István Lekli D.Pharm., Ph.D.
Administration Officer	Ms.	Eniko Berczi-Kun

DEPARTMENT OF BIOPHARMACY

Rex Ferenc u. 1., Debrecen, 4002, Tel: +36-52-411-717/ 58431
E-mail: halmos.gabor@pharm.unideb.hu

Professor, Head of Department	Gábor Halmos D.Pharm., Ph.D
Assistant Professor	Ms. Zsuzsanna Szabó M.Sc., Ph.D.
PhD Student	Ms. Petra Fodor M.Sc.
	Gábor Kónya M.Sc.
	Ms. Anna Vass D.Pharm.
Academic Advisor	Ms. Zsuzsanna Szabó M.Sc., Ph.D.

DEPARTMENT OF INDUSTRIAL PHARMACEUTICAL TECHNOLOGY

Rex Ferenc u. 1., Debrecen, 4002, Tel: +36-52-411-717/58424
E-mail: ujhelyi.zoltan@pharm.unideb.hu

Head of Department, Associate Professor		Zoltán Ujhelyi D.Pharm., Ph.D.
Assistant Research Felow	Ms.	Réka Révész D. Pharm.
Department Engineer		Zoltán Kerekes M.Sc.

PHARMACEUTICAL ECOSYSTEM CENTRE

Rex Ferenc u.1., Debrecen, 4002, Tel: +36-52-411-717/58426
E-mail: vaszily.maria@pharm.unideb.hu

Full Professor, Dean	Ms. Ildikó Bácskay D.Pharm., Ph.D.
Lecturer	Zsolt Ráduly D.Pharm., Ph.D.

CHAPTER 5
OTHER DEPARTMENTS

COORDINATION CENTER FOR DRUG AND FOOD DEVELOPMENT

Nagyerdei körút 98., Debrecen, 4032, Tel: +36-52-411-717/56456

Full Professor, Director		Dénes Páll M.D., Ph.D., DSc
Acting Deputy Director		László Maroda D.Pharm., Ph.D.
Managing Expert	Ms.	Melinda Nyisztor
	Ms.	Katalin Kulcsár
	Ms.	Enikő Kitti Lovász
	Ms.	Ibolya Zsirosné Paulusz
Lawyer	Ms.	Orsolya Benkő
Financial Expert	Ms.	Anett Kocsis

INSTITUTE OF ACCOUNTING AND FINANCE

138 Böszörményi út, Debrecen 4032, Phone: 52/508-444

Professor, Head of Institute		Prof. Dr. habil. Zoltán Bács Ph.D.
Administrator	Ms.	Beáta Józsa

Department of Controlling

Professor, Head of Department	Ms.	Prof. Dr. habil Veronika Fenyves Ph.D.
Associate Professor	Ms.	Dr. Dóra Gazdag-Kerezsi
		Dr. Tibor Kárpáti
	Ms.	Dr. Anita Kiss
		Dr. Gergő Tömöri
Senior Lecturer		Dr. Péter Bajnai
Assistant Lecturer	Ms.	Nemessályi-Bistey Judit

DEPARTMENT OF METAGENOMICS

Nagyerdei körút 98., Debrecen, 4032

Associate Professor, Head of Department		Gábor Kardos M.D., Ph.D.
Full Professor	Ms.	Krisztina Szarka M.Sc., Ph.D.

Coordinator	Levente Laczkó
	Zoltán Rádai

DEPARTMENT OF MEDICAL IMAGING
Nagyerdei krt. 98, Debrecen, 4032, Tel: +36-52-255-510

Full Professor, Head of Department	Ervin Berényi M.D., Ph.D.
College Associate Professor	Ms. Réka Révészné Tóth M.Sc., Ph.D.
Assistant Professor	Tamás Papp M.D., Ph.D.
	Ms. Judit Tóth M.D.
Assistant Lecturer	Ms. Teréz Nyesténé Nagy M.D., B.Sc.
	Ms. Nikoletta Vasas M.D., Ph.D.

Division of Nuclear Medicine and Translational Imaging
Nagyerdei krt. 98., Debrecen, 4032, Tel: +36-52-255-510

Associate Professor, Head of Division,	György Trencsényi M.Sc., Ph.D.
Full Professor	Ervin Berényi M.D., Ph.D.
Professor Emeritus	László Galuska M.D., D.Sc.
	Lajos Trón M.Sc., Ph.D., D.Sc.
Associate Professor	Miklós Emri M.Sc., Ph.D.
	Ms. Ildikó Garai M.D., Ph.D.
	István Hajdu M.Sc., Ph.D.
Senior Research Fellow	István Kertész M.Sc., Ph.D.
Assistant Professor	István Jószai M.Sc., Ph.D.
	Ms. Zita Képes M.D., Ph.D.
	Sándor Kristóf Barna M.D., Ph.D.
	Dezső Szikra M.Sc., Ph.D.
Scientific Advisor	László Balkay M.Sc., Ph.D.
Assistant Lecturer	Ms. Noémi Dénes M.Sc., Ph.D.
Research Fellow	Gábor Opposits M.Sc., Ph.D.
Junior Research Fellow	Csaba Aranyi M.Sc., Ph.D.
	Ms. Judit Péliné Szabó M.Sc., Ph. D.
PhD Student	Ms. Viktória Arató D.Pharm.
Resident	Csaba Csikos M.D.
Chemist	Ms. Anikó Fekete M.Sc., Ph.D.
	Ms. Viktória Botárné Forgács M.Sc., Ph.D.
	Ms. Tünde Miklovicz M.Sc.

	Ms.	Enikő Németh Várhalminé M.Sc.
		Norbert Pótári M.Sc.
Pharmacist	Ms.	Zsuzsanna Ésik D.Pharm.
		Gergely Farkasinszky D.Pharm.
		Dániel Szücs D.Pharm., M.Sc.
Specialist		Zoltán Barta M.D.
		Bence Farkas M.D.
	Ms.	Anna Rebeka Kovács M.D., Ph.D.
		Iván Mihovk M.D.
		Iván Gábor Nagy M.D.
Invited Lecturer, Associate Professor (ret.)		József Varga M.Sc., Ph.D.
Academic Advisor		István Hajdu M.Sc., Ph.D.

DEENK LIFE AND NATURAL SCIENCES LIBRARY
Egyetem tér 1., Debrecen, 4032, Tel: +36-52-518-610
E-mail: info@lib.unideb.hu, Web: https://lib.unideb.hu/en

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Associate Director of User Insight and Communications		Leonárd Petró M.A.
Customer Services	Ms.	Ayrinka Ildikó Vajas B.A.
Education and Research Support Department	Ms.	Judit Éva Fazekas-Paragh M.Sc.

CHAPTER 6
UNIVERSITY CALENDAR

UNIVERSITY CALENDAR FOR PHARMACEUTICAL RESEARCH AND DEVELOPMENT MANAGEMENT PROGRAM 2026/2027 ACADEMIC YEAR

JOINT OPENING CEREMONY FOR THE ACADEMIC YEAR: September 6, 2026

1st SEMESTER

REGISTRATION WEEK: August 31, 2026 – September 6, 2026

Year	Course	Examination Period
M.Sc. in Pharmaceutical Research and Development Management	September 7, 2026 – December 11, 2026 (14 weeks)	December 14, 2026 – January 29, 2027 (7 weeks)

2nd SEMESTER

REGISTRATION WEEK: February 1, 2027 – February 7, 2027

SPRING BREAK: April 19,2027-April 23, 2027 (1 week)

Year	Course	Examination Period
M.Sc. in Pharmaceutical Research and Development Management	February 8, 2027 – May 21, 2027 (10+4 weeks)	May 24, 2027 – July 9, 2027 (7 weeks)
Final year students of Pharmaceutical Research and Development Management	February 1, 2027 – April 30, 2027 (11+1 weeks)	May 3, 2027 – June 11, 2027 (6 weeks)

SUMMER PRACTICE

Year	Dates in 2027
Non-final-year students (4 weeks)	July 12, 2027 – August 6, 2027 or July 19, 2027 – August 13, 2027

CHAPTER 7
CREDIT SYSTEM

The introduction of the credit system became compulsory in every Hungarian university, including the University of Debrecen by September, 2003. The aim of the credit system is to ensure that the students' achievements can be properly and objectively evaluated both quantitatively and qualitatively.

A credit is a relative index of cumulative work invested in a compulsory, a required elective or a freely chosen subject listed in the curriculum. The credit value of a course is based upon the number of lectures, seminars and practical classes of the given subject that should be attended or participated in (so called "contact hours"), and upon the amount of work required for studying and preparing for the examination(s). Together with the credit(s) assigned to a particular subject (quantitative index), students are given grades (qualitative index) on passing an exam/course/class. The credit system that has been introduced in Hungary meets the standards of the European Credit Transfer System (ECTS). The introduction of the ECTS promotes student mobility, facilitates more effective organization of students' exchange programs aimed at further education in foreign institutions, and allows recognition of the students' work, studies and achievements completed in various foreign departments by the mother institution. Credit-based training is flexible. It provides a wider range of choice, enables the students to make progress at an individual pace, and it also offers students a chance to study the compulsory or required subjects at a different university, even abroad. Owing to the flexible credit accumulation system, the term "repetition of a year" does not make sense any longer. It should be noted, however, that students do not enjoy perfect freedom in the credit system either, as the system does not allow students to randomly include subjects in their curriculum or mix modules. Since knowledge is based on previous studies, it is imperative that the departments clearly and thoroughly lay down the requirements to be met before students start studying a subject.

The general principles of the credit system are the following:

1. Students can be given their degree if, having met other criteria as well, they have collected 120 credits during their studies. Considering the recommended curriculum, this can be achieved in two years.

2. According to the credit regulations, students should obtain an average of 30 credits in each semester.

3. The criterion of obtaining 1 credit is to spend 30 hours (including both contact and non-contact hours) studying the given subject.

4. Credit(s) can only be obtained if students pass the exam of the given subject.

5. Students accumulate the required amount of credits by passing exams on compulsory and freely chosen subjects. Completion of every single compulsory credit course is one of the essential prerequisites of getting a degree. A certain amount of credits should be obtained by selecting from the freely chosen courses, which are usually not related to the basic (and thus mandatory) subjects, but they offer a different type of knowledge.

6. 98, 10 and 12 credits of the total of 120 credits should be accumulated by completing the compulsory, freely chosen courses and thesis writing and defense, respectively.
The curriculum in English program corresponds with the curriculum in Hungarian program.

7. The aim of the course is to educate drug research and development managers who are familiar with the whole process of drug development, the national and international regulatory environment of this process, are able to manage the work of research groups on a professional level in pre-clinical, clinical, registration and marketing, and are aware of the increasingly important international regulations. They are familiar with the European Union legislation and procedures relating to the research and development and registration of medical devices, the criteria for the production and notification of food supplements, the registration of medicinal products and the research and development (R&D) activities associated with this, including the circumstances of pharmaceutical production, the professional and legal rules of the relevant medical and pharmaceutical research. The course will also provide the opportunity to start scientific research, and the knowledge acquired will provide the basis for entry into doctoral studies and the subsequent award of an academic degree.

8. The pilot curricula show the recommended pacing of compulsory courses. If these courses are carefully supplemented with credits obtained from the necessary number of freely chosen courses, students can successfully accumulate the credits required for their degree within 4 semesters.

9. Physical Education: Fulfilling the physical education requirements is a prerequisite for receiving the final certificate (absolutorium) in the full-time program.
Occupational Safety: Completion of the Occupational Safety course is a prerequisite for beginning studies. The Occupational Safety and Physical Education courses are each worth 1 credit, which must be earned in addition to the number of credits required for the degree as specified in the program’s training and learning outcomes.
10. There are 2 compulsory final examinations in the curriculum.

11. The diploma work is worth 14 credits.

12. Regulations concerning the training of students in the credit system prescribe a minimum amount of credits for certain periods as outlined in the Rules and Regulations for English Program Students.

13. Evaluation of the students' achievements needed for grants or applications is described in Rules and Regulations for English Program Students.

14. Further information is available in the Rules and Regulations for English Program Students.

We very much hope that the system of training will contribute to the successful completion of your studies.
We wish you good luck with your university studies.

CHAPTER 8
ACADEMIC PROGRAM FOR CREDIT SYSTEM

Compulsory courses for the 1st year								
Sem	**Subjects**	**Neptun code**	**L**	**S**	**P**	**Exam**	**Crd**	**Prerequisites of taking the subject**
1	Basic principles of industrial pharmaceutical manufacturing	GYGYF-IGYA0.ND25EN	42		14	ESE	4	None
1	Drug development theory	GYGYF-GYFE0.ND25EN	28	14		ESE	3	None
1	Quality assurance and quality management skills (GXP)	GYGYF-MBIZ0.ND25EN	42			ESE	3	None
1	Principles of pharmacology, toxicology, biopharmacy	GYGYF-FTXB0.ND25EN	28	14		ESE	3	None
1	Theory and principles of pharmacovigilance	GYGYF-FVEL0.ND25EN	28			ESE	2	None
1	Pharmaceutical management, sales and marketing, basic health economics	GYGYF-GYMN0.ND25EN	28	28		ESE	4	None
1	Database management, biostatistics, pharmacometrics	GYGYF-ABBS0.ND25EN	28		14	ESE	3	None
1	General legal education, health law	GYGYF-JOGI0.ND25EN	28			ESE	2	None
1	Bioethics, research ethics	GYGYF-BIOE0.ND25EN	14			ESE	1	None
1	Professional English language I.	GYGYF-ANNY1.ND25EN			28	AW5	2	None

Compulsory courses for the 1st year								
Sem	**Subjects**	**Neptun code**	**L**	**S**	**P**	**Exam**	**Crd**	**Prerequisites of taking the subject**
2	Preclinical studies I.	GYGYF-PKLV1.ND25EN	14	14		ESE	2	Drug development theory, Basic principles of industrial pharmaceutical manufacturing
2	Clinical studies I.	GYGYF-KLVI1.ND25EN	28	14		ESE	3	Principles of pharmacology, toxicology, biopharmacy
2	Clinical trial authorisation, legal and ethical aspects	GYGYF-KVEN0.ND25EN	14	14		ESE	2	Database management, biostatistics, pharmacometrics
2	Drug registration I.	GYGYF-TZSK1.ND25EN	28		14	ESE	3	Quality assurance and quality management skills (GXP)
2	Pharmacovigilance I.	GYGYF-FVGL1.ND25EN	14	14		ESE	2	Theory and principles of pharmacovigilance
2	Project management I.	GYGYF-PRMN1.ND25EN	28		28	ESE	4	Pharmaceutical management, sales and marketing, basic health economics
2	Professional English language II.	GYGYF-ANNY2.ND25EN			28	AW5	2	Professional English language I.
2	Summer practice	GYGYF-SZGY0.ND25EN			80	AW3	12	

Compulsory courses for the 2nd year								
Sem	**Subjects**	**Neptun code**	**L**	**S**	**P**	**Exam**	**Crd**	**Prerequisites of taking the subject**
1	Preclinical studies II.	GYGYF-PKLV2.ND25EN	14		14	ESE*	2	Preclinical studies I.
1	Clinical studies II.	GYGYF-KLVI2.ND25EN	28		28	ESE	4	Clinical studies I., Clinical trial authorisation, legal and ethical aspects
1	Drug registration II.	GYGYF-TZSK2.ND25EN	28		14	ESE*	3	Drug registration I.
1	Clinical studies and registration of medical devices	GYGYF-OEKV0.ND25EN	14		14	ESE*	2	Drug registration I.
1	Presentation and publication skills	GYGYF-PREZ0.ND25EN	14		28	ESE	3	Project management I.
1	Pharmacovigilance II.	GYGYF-FVGL2.ND25EN	28	14		ESE*	3	Pharmacovigilance I.
1	Project management II.	GYGYF-PRMN3.ND25EN	28		14	ESE	3	Project management I.
1	Thesis consultation	GYGYF-DIPK0.ND25EN			28	AW5	4	

Compulsory courses for the 2nd year

Sem	Subjects	Neptun code	L	S	P	Exam	Crd	Prerequisites of taking the subject	
2	Clinical studies III.	GYGYF-KLVI3.ND25EN	42		14	FE	4	Clinical studies II.	
2	Data management, closure and archiving of clinical trials	GYGYF-KVAK0.ND25EN	28		28	ESE*	4	Drug registration II.	
2	Project management III.	GYGYF-PRMN3.ND25EN	28		28	FE	4	Project management II.	
2	Communication in healthcare	GYGYF-EUKO0.ND25EN	14		14	ESE	2	Clinical trial authori-sation, legal and ethical aspects	Bioethics, research ethics
2	Leadership styles and skills	GYGYF-VZST0.ND25EN	14		14	ESE	2	Project management II.	
2	Food, cosmetics regulatory knowledge	GYGYF-EKSZ0.ND25EN	28		14	ESE	3	General legal education, health law	Drug registration II.
2	Business communication	GYGYF-UKOM0.ND25EN	14		14	ESE	2	Bioethics, research ethics, Project management II.	
2	Thesis	GYGYF-DIPI0.ND25EN			28	AW5	8	Thesis consultation	

Freely chosen courses								
Sem	**Subjects**	**Neptun code**	**L**	**S**	**P**	**Exam**	**Crd**	**Prerequisites of taking the subject**
	Authorisation and testing of veterinary medicinal products	GYGYF-AKEV0.ND25EN	28			ESE	2	None
	Antibiotic stewardship in clinical practice	GYGYF-ABKL0.ND25EN	14			ESE	1	None
	Promotion and information on products available in pharmacies	GYGYF-REKL0.ND25EN	14			ESE	1	None
	Drugs surveillance	GYGYF-KABF0.ND25EN	14			ESE	1	None
	Clinical psychology	GYGYF-KPSZ0.ND25EN	14			ESE	1	None
	Public health and epidemiology	GYGYF-KEGT0.ND25EN	14			ESE	1	None
	Instrumental analytical principles for preclinical studies	GYGYF-PKLA0.ND25EN	14		14	ESE	2	None
	Radiopharmacy	GYGYF-RADI0.ND25EN			14	ESE	1	None
	Theory of cell culturing	GYGYF-STNY0.ND25EN	14		14	ESE	2	None
	Animal models for scientific research	GYGYF-TKUT0.ND25EN			28	ESE	2	None
	Change management	GYGYF-VMEN0.ND25EN	14			ESE	1	None
	Leadership styles and skills, human resource management	GYGYF-HRMN0.ND25EN	14			ESE	1	None

CHAPTER 9
ACADEMIC PROGRAM FOR THE 1ST YEAR

Department of Pharmaceutical Technology

Subject: **BASIC PRINCIPLES OF INDUSTRIAL PHARMACEUTICAL MANUFACTURING**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Lecture: **42**
Practical: **14**

1st week:
Lecture: Introduction to pharmaceutical industry. Basic concepts, historical overview and actual trends.
Practical: Conventional Solid Dosage Forms I – Tablets

2nd week:
Lecture: Pharmaceutical legislation in the EU
Practical: Conventional Solid Dosage Forms II – Capsules

3rd week:
Lecture: Innovative Drug Development: Discovery and development of medicinal products and life-cycle management
Practical: Modified-Release Oral Solids (Retard & Enteric-Coated

4th week:
Lecture: How to design a Target Product Profile
Practical: Liquid Dosage Forms I – Oral Solutions & Suspensions

5th week:
Lecture: Anatomy of a Pharmaceutical Company: Corporate Structure and Cross-Functional Alignment
Practice: Liquid Dosage Forms II – Sterile Parenterals (Injections & Infusions)

6th week:
Lecture: Active Pharmaceutical Ingredient (API) Development and Manufacturing; APIs of Innovative and Generic Drugs
Practical: Specialized Sterile Forms – Lyophilized Powders

7th week:
Lecture: Formulation development and drug delivery
Practical: Semi-Solid Dosage Forms (Ointments, Creams, Gels)

8th week:
Lecture: Quality by Design in Pharmaceutical Development
Practical: Transdermal Therapeutic Systems (Patches)

9th week:
Lecture: Quality control of different pharmaceutical forms
Practical: Inhalation Dosage Forms (MDI & DPI)

10th week:
Lecture: Clinical Development Requirements for Innovative Drugs from an Industry Perspective
Practical: Primary Packaging as Part of the Dosage Form

11th week:
Lecture: Development of biotechnological products
Practical: Capstone Simulation – Strategic Dosage Form Selection

12th week:
Lecture: Quality assessment – Drug substance and drug product
Practical: Project work presentation of dosage forms I.

13th week: **Lecture:** Bioequivalence studies **Practical:** Project work presentation of dosage forms I.	14th week: **Lecture:** Consultation **Practical:** Consultation

Requirements

Conditions for Signature (Course Completion):

- Attendance is required at a minimum of 30% of the lectures.
- Attendance at practice sessions is mandatory. A maximum of 4 absences is allowed; if more than 4 are missed, the course signature will not be granted**.**
- Practical Assessment: Continuous evaluation based on a semester project work

Assessment Method:

- Written exam during the exam period.
- Three exam opportunities are provided: A, B, and C exams.
- The exam material covers the full content of both lectures and practices.

Literature:

Syed Asif, E., & Usmani, S. B. (2024). Basics of Pharmaceutical Manufacturing and Quality Operations: A Comprehensive Guide. CRC Press. ISBN: 9781032432052.

Guidelines

International Council for Harmonisation (ICH). (2000). ICH Q7: Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.
Available at: International Council for Harmonisation website.

International Council for Harmonisation (ICH). (2009). ICH Q8(R2): Pharmaceutical Development.
Available at: International Council for Harmonisation website.

International Council for Harmonisation (ICH). (2023). ICH Q9(R1): Quality Risk Management.
Available at: International Council for Harmonisation website.

International Council for Harmonisation (ICH). (2008). ICH Q10: Pharmaceutical Quality System.
Available at: International Council for Harmonisation website.

U.S. Food and Drug Administration (FDA). Current Good Manufacturing Practice (cGMP) Regulations.
Title 21 CFR Parts 210 and 211. Available at: FDA official website.

European Medicines Agency (EMA). EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use.
EudraLex - Volume 4. Available at: EMA website.

World Health Organization (WHO). (2022). WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles (Annex 2, WHO Technical Report Series, No. 1025).
Available at: WHO website.

Department of Industrial Pharmaceutical Technology

Subject: **DRUG DEVELOPMENT THEORY**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Lecture: **28**
Seminar: **14**

1st week:
Lecture: Historical overview and significance of drug development
Seminar: Classic examples from pharmaceutical research milestones (e.g. penicillin, insulin, aspirin)

2nd week:
Lecture: The process of drug research and development: an overview
Seminar: Practical examples of the stages of drug development

3rd week:
Lecture: Target identification and target validation
Seminar: Modern target research: gene expression and proteomics methods

4th week:
Lecture: Searching for active ingredients: hit identification and hit to lead
Seminar: In silico screening and virtual molecular design methods

5th week:
Lecture: Lead Optimization and Pharmaceutical Chemistry Aspects
Seminar: ADMET (Absorption, Distribution, Metabolism, Excretion, Toxicity) Screening Practice

6th week:
Lecture: Fundamentals of formulation development
Seminar: Innovative drug delivery systems (e.g. nanoparticles, liposomes)

7th week:
Lecture: Preclinical studies – pharmacological and toxicological evaluation the role of animal models and alternative approaches (e.g. in vitro, in silico models)
Seminar: Test 1

8th week:
Lecture: Preclinical drug safety and risk assessment
Seminar: NOAEL, LOAEL and calculation of safety limits

9th week:
Lecture: Clinical trials: Phases I-IV and their structure
Seminar: Analysis of study protocol through an example

10th week:
Lecture: Registration dossier and authorization process (EMA, FDA)
Seminar: Structure of CTD (Common Technical Document) and analysis of examples

11th week:
Lecture: Development of generics and biosimilars
Seminar: Evaluation of bioequivalence studies

12th week:
Lecture: Post-marketing studies and pharmacovigilance
Seminar: Analysis of an adverse event report and a case study

13th week:
Lecture: Future directions: personalised medicine, artificial intelligence, digital medicines
Seminar: Test 2

14th week:
Lecture: The impact of new technologies on drug development – roundtable discussion or student presentations
Seminar: Consultation

Requirements

Attendance
Attending 30% of the lectures is compulsory. If a student is late it is considered as an absence. Attending the seminars is compulsory. Students can miss maximum 2 seminars. In case of more than 2 absences, the signature may be refused.

Testing, evaluation
During the exam period the students have an oral exam.
Three exam opportunities are provided: A, B, and C exams.
The exam material covers the full content of both lectures and practices.

Department of Industrial Pharmaceutical Technology

Subject: **QUALITY ASSURANCE AND QUALITY MANAGEMENT SKILLS (GXP)**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Lecture: **42**

1st week:
Lecture: Introduction to quality assurance and quality management – basic concepts, the role and significance of quality assurance in industry.

2nd week:
Lecture: Overview of GxP systems: concepts and legal background – Definition of GxP, laws and standards, international regulations.

3rd week:
Lecture: Basics of GMP (Good Manufacturing Practice) – GMP purpose, principles, specific requirements of pharmaceutical manufacturing and the healthcare industry.

4th week:
Lecture: The GCP (Good Clinical Practice) and GLP (Good Laboratory Practice) systems – Clinical research and laboratory practices, the importance of proper regulation.

5th week:
Lecture: GxP-based documentation and records management – Document and record management, archiving, and ensuring traceability.

6th week:
Lecture: Quality Control (QC) and Quality Assurance (QA) Systems– The difference and cooperation between quality control and quality assurance.

7th week:
Lecture: Validation and verification in GxP systems – Principles, tools and significance of validation during production and development.

8th week:
Lecture: Risk Management in GxP Systems – Risk Assessment Methods, Risk Management Strategies and Their Application in Quality Assurance.

9th week:
Lecture: The importance of on-site audits and inspections – The role of internal and external audits, preparation for FDA and EMA investigations.

10th week:
Lecture: Quality management systems (ISO 9001) and their application in the pharmaceutical industry – ISO 9001 standard, application in pharmaceutical manufacturing and other industries.

11th week:
Lecture: Monitoring and supervising compliance with GMP regulations – The process of official inspection, GMP inspections, quality control.

12th week:
Lecture: Change Management and Change

Management Procedures – Change management in production and development processes, documentation and enablement.

13th week:
Lecture: Quality Problem Management and Nonconformance (CAPA) System – Identifying, investigating, and correcting non-conformities.

14th week:
Lecture: The Future of GxP Systems: Digital Solutions and Innovations – Application of Digital Technologies in Quality Management, Future Trends.

Requirements

The examination of the subject Quality Assurance and Quality Management Knowledge at the end of the semester takes place in the form of an oral colloquium. During the colloquium, students draw two movements. They report on their knowledge in an oral exam.

Department of Pharmacology

Subject: **PRINCIPLES OF PHARMACOLOGY, TOXICOLOGY, BIOPHARMACY**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Lecture: **28**
Seminar: **14**

1st week:
Lecture: Basic concepts of pharmacology I.: Receptors and signaltrasduction.
Seminar: In vitro pharmacokinetic models: LADME (drug absorption, permeability testing on biological membranes, models of metabolism - Fenton reaction, etc. - elimination, measurement of drug concentration by UV-VIS spectrophotometry)

2nd week:
Lecture: Basic concepts of pharmacology I.: agonist, antagonist, competition, abuse, addiction, dependence, drug effect etc.
Seminar: In vitro pharmacokinetic models: LADME (drug absorption, permeability testing on biological membranes, models of metabolism - Fenton reaction, etc. - elimination, measurement of drug concentration by UV-VIS spectrophotometry)

3rd week:
Lecture: Drug Categories: Gastrointestinal tract and metabolism, Blood and Blood-Forming Organs, Cardiovascular system
Seminar: In vitro pharmacokinetic models: LADME (drug absorption, permeability testing on biological membranes, models of metabolism - Fenton reaction, etc. - elimination, measurement of drug concentration by UV-VIS spectrophotometry)

4th week:
Lecture: Drug Categories: Hormontherapy, Anticancer and immunomodulating therapy, Sensory organs therapy
Seminar: In vitro pharmacokinetic models: LADME (drug absorption, permeability testing on biological membranes, models of metabolism - Fenton reaction, etc. - elimination, measurement of drug concentration by UV-VIS spectrophotometry)

5th week:
Lecture: Drug Categories: Musculoskeletal system, Central nervous system
Seminar: In vitro pharmacokinetic models: LADME (drug absorption, permeability testing on biological membranes, models of metabolism - Fenton reaction, etc. - elimination, measurement of drug concentration by UV-VIS spectrophotometry)

6th week:
Lecture: Drug Categories: Systemic anti-infectives, antiparasitics, anthelmintics, and

repellents, Respiratory system
Seminar: In vitro pharmacokinetic models: LADME (drug absorption, permeability testing on biological membranes, models of metabolism - Fenton reaction, etc. - elimination, measurement of drug concentration by UV-VIS spectrophotometry)

7th week:
Lecture: Basic concepts of Pharmacokinetics, LADME, parameters
Seminar: Official websites (WHO, CDC, ECDC, MEDSCAPE, MICROMEDEX, etc.) ATC, ICD code systems: identification of drug and disease groups. Toxicology: official treatment protocols, practical examples.

8th week:
Lecture: Basic concepts of Pharmacokinetics, LADME, parameters
Seminar: Official websites (WHO, CDC, ECDC, MEDSCAPE, MICROMEDEX, etc.) ATC, ICD code systems: identification of drug and disease groups. Toxicology: official treatment protocols, practical examples.

9th week:
Lecture: Basic concepts of Pharmacokinetics, LADME, parameters
Seminar: Official websites (WHO, CDC, ECDC, MEDSCAPE, MICROMEDEX, etc.) ATC, ICD code systems: identification of drug and disease groups. Toxicology: official treatment protocols, practical examples.

10th week:
Lecture: Basic concepts of Pharmacokinetics, LADME, parameters
Seminar: Official websites (WHO, CDC, ECDC, MEDSCAPE, MICROMEDEX, etc.) ATC, ICD code systems: identification of drug and disease groups. Toxicology: official treatment protocols, practical examples.

11th week:
Lecture: General toxicology
Seminar: Official websites (WHO, CDC, ECDC, MEDSCAPE, MICROMEDEX, etc.) ATC, ICD code systems: identification of drug and disease groups. Toxicology: official treatment protocols, practical examples.

12th week:
Lecture: Intoxication: alcohol, heavy metals, pesticides, herbicides, fungi, street drugs
Seminar: Official websites (WHO, CDC, ECDC, MEDSCAPE, MICROMEDEX, etc.) ATC, ICD code systems: identification of drug and disease groups. Toxicology: official treatment protocols, practical examples.

13th week:
Lecture: Clinical pharmacology: phases of clinical trials. Drug allergy: symptoms, actions, therapy.
Seminar: Official websites (WHO, CDC, ECDC, MEDSCAPE, MICROMEDEX, etc.) ATC, ICD code systems: identification of drug and disease groups. Toxicology: official treatment protocols, practical examples.

14th week:
Lecture: Consultation
Seminar: Consultation

Requirements

During the semester students have to take written exam. There is no opportunity for improvement below 50%. In such cases, we will deny the semester credit, and the student's semester will be considered unsuccessful.
At the end of the semester, the exam in Basic pharmacology theory takes the form of an oral colloquium (2 topics from the list, a short elaboration, then an oral exam). During the semester, it is possible to get exemption of 1 topic for the oral colloquium. In the case of grades calculated as four (minimum 80%) and five (minimum 90%) from the written exam, 1 topic will be asked on the final exam.
At least 70% of the seminars must be visited. In addition to the theoretical write exam, students also write a paper based on the seminar topic. The practical grade is assigned based on the results of the seminar written exam. The practice grades: (2) from 60%, (3) from 70%, (4) from 80%, (5) from 90%.

Department of Pharmaceutical Surveillance and Economics

Subject: **THEORY AND PRINCIPLES OF PHARMACOVIGILANCE**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Lecture: **28**

1st week:
Lecture: Theoretical and practical foundations of pharmacovigilance, its development history

2nd week:
Lecture: The concept and approach of pharmacovigilance – perspectives, scientific and public health aspects

3rd week:
Lecture: Definitions: drug effect, side effect, adverse drug reaction (adr), definition of seriousness. types of side effects: severity, intensity, and causality

4th week:
Lecture: characteristics, regulations, participants, and practices of pharmacovigilance activities

5th week:
Lecture: Description and evaluation of side effects (naranjo, ctc, etc.) classifications

6th week:
Lecture: Drug side effects and interactions: clinical practice and possibilities. the role and assessment of exogenous and endogenous factors modifying drug effects

7th week:
Lecture: Classification of side effects (types a-e). endogenous factors (liver, kidney, endocrine, metabolic systems, receptor variants), special populations

8th week:
Lecture: Principles and methodology of signal detection. signals indicating new or changed risks

9th week:
Lecture: Risks and benefits of drug use; risk management, basic principles, and methodology of benefit-risk analysis

10th week:
Lecture: Routine and additional pharmacovigilance activities. drugs under enhanced surveillance

11th week:
Lecture: Routine pharmacovigilance tasks: informing patients and professionals

12th week:
Lecture: Drug package leaflets: smpc, pl, labeling content and formal requirements

13th week:
Lecture: The role of age, special populations, and genetic factors in side effect development

14th week:
Lecture: Characteristics of "drug-drug," "drug-food," and "drug-herbal" interactions, through practical examples

Requirements

The course's end-of-term assessment is conducted as an oral examination.
During the semester, students take two quizzes (ZH) based on the lecture material. The average of these two quizzes (40%) counts towards the final grade.

During the oral exam, students draw two topics (maximum 60 points). The final grade is determined by the combined score of the oral performance and the written assessments (maximum 100 points). The grade thresholds are as follows:
- Above 50%: Pass (2)
- Above 65%: Satisfactory (3)

- Above 75%: Good (4)
- Above 89%: Excellent (5)

Participation in practical sessions is mandatory. More than four unexcused absences will result in the semester not being accepted.

Department of Pharmaceutical Surveillance and Economics

Subject: **PHARMACEUTICAL MANAGEMENT, SALES AND MARKETING, BASIC HEALTH ECONOMICS**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Lecture: **28**
Seminar: **28**

1st week:
Lecture: Pharmaceutical organization and management in the hungarian healthcare system, pharmaceutical supply and specific issues
Seminar: Tasks of national authorities related to healthcare and pharmaceuticals

2nd week:
Lecture: Principles and variants of health insurance. the hungarian healthcare system: health care insurance and pharmaceutical product pricing
Seminar: Basic economic concepts and indicators

3rd week:
Lecture: Basics of the microeconomic models of markets, market mechanisms, supply and demand, price-value, and the marginal utility functions. market equilibrium
Seminar: Pharmaceuticals as a special remedies

4th week:
Lecture: Basics of macroeconomics. money and goods markets, labor market, and their interrelations and evaluation
Seminar: Policy and macroeconomic effects

5th week:
Lecture: Characteristics and changes in household drug consumption. the role of generics and otc medicines. registries and electronic systems
Seminar: Pharmacoepidemiologic research, the role of big data and the AI

6th week:
Lecture: The role of community pharmacies within the healthcare system. pharmaceutical supply – retail and wholesale aspects
Seminar: Product groups, markups, sustainability

7th week:
Lecture: Adherence, compliance – concepts. patient education, health maintenance, and prevention in primary care
Seminar: Effective patient communication: goals, opportunities, and outcomes

8th week:
Lecture: The "lifecycle" of medicines, investment-return, lifecycle management. financial aspects. basics of return on investment calculations
Seminar: Examples of drug development programs

9th week:
Lecture: Basics of pharmaceutical marketing. portfolio analysis, swot analysis, marketing strategies, ansoff matrix, bcg matrix. corporate and multinational strategies
Seminar: Advertising and Marketing Tools

10th week:
Lecture: Non-pharmacy and pharmacy-based marketing opportunities and regulations. pharmaceutical advertising regulations. ethics and market strategies
Seminar: Regulatory strategy

11th week:
Lecture: The concept of health. direct and indirect determination of quality of life (qol), measurement methods (qol questionnaires, vas, and specific scales)
Seminar: Quality of life questionnaires

12th week:
Lecture: The purpose and economic significance of health technology assessment (hta)
Seminar: HTA calculations with examples

13th week:
Lecture: Basics of financial calculations in business: costs, revenues, profits, expected returns, NPV
Seminar: Return on investment, cash flow, business planning

14th week:
Lecture: Principles of pharmaceutical supply and management, wholesale and retail processes. new systems and methods
Seminar: Quality assurance in pharmaceutical supply

Requirements

The subject's end-of-term assessment is conducted in the form of an oral exam.
During the semester, students submit two project assignments based on the topics of lectures and project practice sessions. The sum of these two project assignments (40%) counts towards the final exam grade.

During the oral exam, students pick one topic and one practical task (for maximum 60 points). The final exam grade is determined by the combined performance on the oral exam and the assignments (maximum 100 points). The grade thresholds are as follows:
- Above 55%: Pass (2)
- Above 65%: Satisfactory (3)
- Above 75%: Good (4)
- Above 89%: Excellent (5)

Participation in practical sessions is mandatory. More than four unexcused absences will result in the semester not being accepted.

Coordination Center for Drug and Food Development

Subject: **DATABASE MANAGEMENT, BIOSTATISTICS, PHARMACOMETRICS**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Lecture: **28**
Practical: **14**

1st week:
Lecture: The role of biostatistics in pharmaceutical and clinical research.
Practical: Introduction to databases; identification of variables.

2nd week:
Lecture: Structure of databases: rows, columns and identifiers.
Practical: Checking database structure; identifying incorrect data structures.

3rd week:
Lecture: Variable types: categorical, ordinal and continuous variables.
Practical: Recoding variables, assigning labels and preparing a simple variable list.

4th week:
Lecture: Data cleaning: missing data, incorrect values, extreme values and logical inconsistencies.
Practical: Identifying missing and incorrect data; basic data-checking procedures.

5th week:
Lecture: Descriptive statistics: frequency, proportion, percentage, mean, median and standard deviation.
Practical: Preparing a descriptive statistical table based on a pharmaceutical example.

6th week:
Lecture: Graphical presentation of data: bar chart, pie chart, histogram and boxplot.
Practical: Creating and interpreting basic graphs.

7th week:
Lecture: Basics of probability, distributions and confidence intervals.
Practical: Interpretation of mean, median, standard deviation and 95% confidence intervals using practical examples.

8th week:
Lecture: Basics of hypothesis testing: null hypothesis, p-value, statistical significance.
Practical: Choosing the appropriate statistical method for different research questions.

9th week:
Lecture: Comparison of two groups: t-tests.
Practical: Application of independent-samples and paired comparisons in practice.

10th week:
Lecture: Comparison of multiple groups: ANOVA.
Practical: Comparison of three treatment or dose groups.

11th week:
Lecture: Analysis of categorical variables: cross-tabulations, chi-square test.
Practical: Analysis of adverse events, adherence and medication dispensing using cross-tabulations.

12th week:
Lecture: Basic risk measures: relative risk and odds ratio.
Practical: Calculation and interpretation of odds ratios and relative risks.

13th week:
Lecture: Basics of correlation and regression: Pearson and Spearman correlation. Regression.
Practical: Examination of associations and relationships using pharmaceutical examples.

14th week:
Lecture: Basics of pharmacometrics: dose, concentration, effect and simple pharmacokinetic parameters.
Practical: Interpretation of pharmacokinetic parameters and concentration–time data.

Requirements

Attendance at a minimum of 30% of the lectures is compulsory. If a student is late, it is considered an absence. Attendance at the practices is compulsory. Students may miss a maximum of 2 practices. In case of more than 2 absences from practices, the signature may be refused.

Department of Pharmaceutical Technology

Subject: **GENERAL LEGAL EDUCATION, HEALTH LAW**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Lecture: **28**

1st week:
Lecture: Legal hierarchy, legal basics

2nd week:
Lecture: The role of the state in the regulation and operation of health care system

3rd week:
Lecture: Human Rights, Patients' Rights, International and Community Regulations

4th week:
Lecture: Right to access health care

5th week:
Lecture: Right to be treated with respect

6th week:
Lecture: Right to have visitors

7th week:
Lecture: Right to leave the medical service provider facility

8th week:
Lecture: Right to make informed consent

9th week:
Lecture: Right to make decisions about medical treatment

10th week:
Lecture: Right to refuse medical treatment

11th week:
Lecture: Right to privacy and confidentiality

12th week:
Lecture: Right to access medical records

13th week:
Lecture: Medical liability

14th week:
Lecture: The institution of patient rights representatives, consumer protection in health care

Requirements

During the semester, students must complete two project assignments on legal topics assigned by the instructor (e.g., analysis of court decisions). Completion of one project assignment is required to receive signature. Students receive a pre-exam mark if they complete both project assignments. Subject completion takes place as a colloquium, with a written exam, which takes place during the exam period. The score limits of the grades are as follows: above 60%: satisfactory (2), above 70% : medium (3), above 80% : good (4), above 90%: excellent (5).

Department of Pharmaceutical Technology

Subject: **BIOETHICS, RESEARCH ETHICS**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Lecture: **14**

1st week:
Lecture: Introduction and basic concepts

2nd week:
Lecture: General basics of ethics

3rd week:
Lecture: Medical ethics

4th week:
Lecture: Ethical issues of medical interventions

5th week:
Lecture: Patient rights

6th week:
Lecture: Justice in healthcare I.

7th week:
Lecture: Justice in healthcare II.

8th week:
Lecture: Ethical issues of incurable illnesses

9th week:
Lecture: Ethical issues of euthanasia and suicide

10th week:
Lecture: Ethical issues of reproduction: social policy, abortion

11th week:
Lecture: Ethical issues of organ and tissue transplantation

12th week:
Lecture: Research Ethics I. Animal Experiments

13th week:
Lecture: Research Ethics II. Human Studies

14th week:
Lecture: Summary

Requirements

Signature is conditional on 30% attendance at the lectures.
Subject completion takes place as a colloquium, with a written exam, which takes place during the exam period. The score limits of the grades are as follows: above 60%: satisfactory (2), above 70% : medium (3), above 80% : good (4), above 90%: excellent (5).

Department of Pharmaceutical Technology

Subject: **PROFESSIONAL ENGLISH LANGUAGE I.**
Year, Semester: 1st year/1st semester
Number of teaching hours:
Practical: **28**

1st week:
Practical: Introduction based on professional criteria. Familiarisation with the necessary terminology.

2nd week:
Practical: Revision of basic grammar I.

3rd week:
Practical: Revision of basic grammar II.

4th week:
Practical: Basic concepts of body regions, body parts and related symptoms.

5th week:
Practical: Indications, disease names and surgical procedures

6th week:
Practical: Health areas, medical terms.

7th week:
Practical: Parts of the prescription, patient information in professional language.

8th week:
Practical: Test I.

9th week:
Practical: Pharmaceutical forms and modern therapeutic systems

10th week:
Practical: Use of medications, contraindication**.**

11th week:
Practical: Professional language terminologies related to medical devices and dietary supplements**.**

12th week:
Practical: Learning the parts of formal correspondence and how to use them**.**

13th week:
Practical: Basics of making a professional presentation.

14th week:
Practical: Oral test, assessment of language competences.

Requirements

A maximum of 2 absences is allowed; more than 2 absences, the student may make up the absence with an assignment agreed with the instructor (maximum of 2 times); a student who misses more than 25% of the practical classes will not be allowed to get a signature.
In the case of more than the permitted number of absences, a medical certificate of permanent illness or hospitalisation is required.
Active attendance in class; at least satisfactory completion of both written and oral test.

Order of mid-term control
Written test, studied until week 8.
Oral test from the topics studied during the semester
Improvement test, at pre-arranged appointment

Evaluation
The final grade is evaluated according to the grades of written test (improvement test is included), oral test and classwork. The fail mark of the written test or oral test must be repeated – the fail mark also counts towards the final grade.
Evaluation of written and oral tests:
0–50% = fail (1)
51–60% = pass (2)
61–75% = satisfactory (3)
76–89% = good (4)
90–100% = excellent (5)
Final grade is a 5 grades practical mark.

Requirements for obtaining credits
End of semester signature. Fail (1) mark is not accepted for practical mark.

Required literature
Teaching materials given during the class.

Department of Pharmacology

Subject: **PRECLINICAL STUDIES I.**
Year, Semester: 1st year/2nd semester
Number of teaching hours:
Lecture: **14**
Seminar: **14**

1st week:
Lecture: Introduction to drug development. The drug discovery process.
Seminar: Project work

2nd week:
Lecture: Basic concepts of preclinical studies. The stages of development process.
Seminar: Project work

3rd week:
Lecture: Ethical and legal regulations. EU and domestic legislation. (40/2013. VM)
Seminar: Project work

4th week:
Lecture: Ethical and legal regulations. 3R: Replacement, Reduction and Refinement
Seminar: Project work

5th week:
Lecture: Ethical and legal regulations. (Animal testing regulations, role of ethics committee, animal husbandry rules, laboratory permits)
Seminar: Project work

6th week:
Lecture: Design of preclinical studies. (Sample number, model selection, pharmacokinetic and pharmacodynamic parameters)
Seminar: Project work

7th week:
Lecture: Design of preclinical studies. (Toxicological and statistical analysis, documentation)
Seminar: Project work

8th week:
Lecture: Basic concepts of toxicological testing.
Seminar: Project work

9th week:
Lecture: Types of toxicological tests. (Acute and subchronic toxicity: LD50, NOAEL, LOAEL, Specific target organ toxicity)
Seminar: Project work

10th week:
Lecture: Types of toxicological tests. (Chronic, carcinogenic, teratogenic, mutagenic. Genotoxicological in vitro tests)
Seminar: Project work

11th week:
Lecture: Types of model systems (in vitro, in vivo, ex vivo)
Seminar: Project work

12th week:
Lecture: In vitro models. (Cell lines and their applications, 3D cultures)
Seminar: Project work

13th week:
Lecture: In vitro studies. (Cytotoxicity, proliferation, apoptosis, cell permeability, etc.).
Seminar: Project work

14th week:
Lecture: Consultation
Seminar: Consultation

Requirements

During the semester students have to take written exam. There is no opportunity for improvement below 50%. In such cases, we will deny the semester credit, and the student's semester will be considered unsuccessful.
At the end of the semester, the exam in Precinical studies I. theory takes the form of an oral colloquium (2 topics from the list, a short elaboration, then an oral exam). During the semester, it is possible to get exemption of 1 topic for the oral colloquium. In the case of grades calculated as four (minimum 80%) and five (minimum 90%) from the written exam, 1 topic will be asked on the final exam.
At least 70% of the seminars must be visited.

Pharmaceutical Ecosystem Centre

Subject: **CLINICAL STUDIES I.**
Year, Semester: 1st year/2nd semester
Number of teaching hours:
Lecture: **28**
Seminar: **14**

1st week:
Lecture: Development of Human Clinical Research.
Seminar: Development of Human Clinical Research.

2nd week:
Lecture: Background and basic elements, key principles of new medicine research and development.
Seminar: Background and basic elements, key principles of new medicine research and development.

3rd week:
Lecture: The legal background and principles in clinical research
Seminar: The legal background and principles in clinical research

4th week:
Lecture: The types and phases of clinical trials, study design, objectives, endpoints.
Seminar: The types and phases of clinical trials, study design, objectives, endpoints.

5th week:
Lecture: Interventional and non-interventional clinical trials.
Seminar: Interventional and non-interventional clinical trials.

6th week:
Lecture: Basic documents of human clinical trials.
Seminar: Basic documents of human clinical trials.

7th week:
Lecture: Planning and development of human clinical trials (objectives and purpose, study designs).
Seminar: Planning and development of human clinical trials (objectives and purpose, study designs).

8th week:
Lecture: Legal background of Human Clinical Trials**.**
Seminar: Legal background of Human Clinical Trials**.**

9th week:
Lecture: The Role of the Ethics Committee in Human Clinical Trials.
Seminar: The Role of the Ethics Committee in Human Clinical Trials.

10th week:
Lecture: The principles and objectives of ICH-GCP.
Seminar: The principles and objectives of ICH-GCP.

11th week:
Lecture: Site selection and site qualification of clinical trials and the feasibility process
Seminar: Site selection and site qualification of clinical trials and the feasibility process

12th week:
Lecture: Approval of Human Clinical Trials. The role of Regulatory Authority and Ethics Committee in the approvals, composition, functions and operations.
Seminar: Approval of Human Clinical Trials. The role of Regulatory Authority and Ethics Committee in the approvals, composition, functions and operations.

13th week:
Lecture: The role of Regulatory authority in Clinical Trials.
Seminar: The role of Regulatory authority in Clinical Trials.

14th week:
Lecture: International Approval Processes for Clinical Trials
Seminar:
International Approval Processes for Clinical Trials

Requirements

Conditions for Signature (Course Completion):

- Attendance is required at a minimum of 30% of the lectures.

- Attendance at Seminar sessions is mandatory. A maximum of 4 absences is allowed; if more than 4 are missed, the course signature will not be granted**.**
- Practical Assessment: Continuous evaluation based on a semester project work

Assessment Method:

- Written exam during the exam period.
- Three exam opportunities are provided: A, B, and C exams.
- The exam material covers the full content of both lectures and seminars.

Literature:

- Clinical trials in human medicines -EMA Guidelines
- ICH E6 Good clinical practice - Scientific guideline
- The Practical Guide to Clinical Research and Publication1st Edition - August 6, 2021 Imprint: Academic Press, Author: Uzung Yoon, ISBN: 9780128245170
- Cook, J. A. (2023). *An Introduction to Clinical Trials*. Oxford University Press. ISBN: 9780198885238.

Pharmaceutical Ecosystem Centre

Subject: **CLINICAL TRIAL AUTHORISATION, LEGAL AND ETHICAL ASPECTS**
Year, Semester: 1st year/2nd semester
Number of teaching hours:
Lecture: **14**
Seminar: **14**

1st week:
Lecture: The Clinical Trial Authorization Process: Role of Regulatory Authorities in International and National Approval Procedures I
Seminar: The Clinical Trial Authorization Process: Role of Regulatory Authorities in International and National Approval Procedures I

2nd week:
Lecture: The Clinical Trial Authorization Process: Role of Regulatory Authorities in International and National Approval Procedures II.
Seminar: The Clinical Trial Authorization Process: Role of Regulatory Authorities in International and National Approval Procedures II.

3rd week:
Lecture: The Clinical Trial Authorization Process: Role of Regulatory Authorities in International and National Approval Procedures III.
Seminar: The Clinical Trial Authorization Process: Role of Regulatory Authorities in International and National Approval Procedures III.

4th week:
Lecture: The Clinical Trial Authorization Process: Role of Regulatory Authorities in International and National Approval Procedures IV.
Seminar: The Clinical Trial Authorization Process: Role of Regulatory Authorities in International and National Approval Procedures IV.

5th week:
Lecture: Introduction and Use of the CTIS System I.
Seminar: Introduction and Use of the CTIS System I.

6th week:
Lecture: Introduction and Use of the CTIS System II.
Seminar: Introduction and Use of the CTIS System II.

7th week:
Lecture: Introduction and Use of the CTIS System III.
Seminar: Introduction and Use of the CTIS System III.

8th week:
Lecture: Pharmacovigilance in Clinical Trials – Legal and Ethical Aspects I.
Seminar: Pharmacovigilance in Clinical Trials – Legal and Ethical Aspects I.

9th week:
Lecture: Pharmacovigilance in Clinical Trials – Legal and Ethical Aspects II.
Seminar: Pharmacovigilance in Clinical Trials – Legal and Ethical Aspects II.

10th week:
Lecture: Pharmacovigilance in Clinical Trials – Legal and Ethical Aspects III.
Seminar: Pharmacovigilance in Clinical Trials – Legal and Ethical Aspects III.

11th week:
Lecture: Development and Role of ICH GCP – Structure and Components I.
Seminar: Development and Role of ICH GCP – Structure and Components I.

12th week:
Lecture: Development and Role of ICH GCP – Structure and Components II.
Seminar: Development and Role of ICH GCP – Structure and Components II .

13th week:
Lecture: Ethics Committees and Their Role
Seminar: Ethics Committees and Their Role

14th week:
Lecture: Consultation
Seminar: Consultation

Requirements

Conditions for Signature (Course Completion):

- Attendance is required at a minimum of 30% of the lectures.
- Attendance at Seminar sessions is mandatory. A maximum of 4 absences is allowed; if more than 4 are missed, the course signature will not be granted**.**

Assessment Method:

- Written exam during the exam period.
- Three exam opportunities are provided: A, B, and C exams.
- The exam material covers the full content of both lectures and practices.
- Practical Assessment: Continuous evaluation based on a semester project work

Literature:

1. REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC
2. **ICH E6(R2) – Good Clinical Practice (GCP) Guideline**
   International Council for Harmonisation (ICH).
   Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)
3. **Ethics in Clinical Research – Declaration of Helsinki**
   World Medical Association (WMA).
   Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects
4. **CTIS – Clinical Trials Information System (EU CTR)**
   European Medicines Agency (EMA).

Clinical Trials Information System – Supporting the implementation of the EU Clinical Trials Regulation (EU CTR 536/2014)

Pharmaceutical Ecosystem Centre

Subject: **DRUG REGISTRATION I.**
Year, Semester: 1st year/2nd semester
Number of teaching hours:
Lecture: **28**
Practical: **14**

1st week:
Lecture: Types of Marketing Approval Applications
Practice: ICH Safety guidelines I.

2nd week:
Lecture: Marketing authorisation procedures: decentralised,mutual recognition,centralised procedures
Practice: ICH Safety guidelines II.

3rd week:
Lecture: Content and Format Requirements of the Marketing Authorization Dossier; CTD
Practice: The CTD Module Mapping Challenge (Cross-Functional Data Assembly) I.

4th week:
Lecture: Regulatory data protection
Practice: The CTD Module Mapping Challenge (Cross-Functional Data Assembly) II.

5th week:
Lecture: Benefit / Risk assessment
Practice: ICH Quality Guidelines I.

6th week:
Lecture: Marketing authorisation and Product Information
Practice: ICH Quality Guidelines II.

7th week:
Lecture: Off-label use
Practice: Off-label use in practice
Practical: Off-label use

8th week:
Lecture: Special authorisation types
Practice: Special authorisation types in practice

9th week:
Lecture: Marketing authorisation outside the EU
Practice: Worldwide analysis of marketing authorisation

10th week:
Lecture: Variation procedures
Practice: Variation procedures in practice

11th week:
Lecture: Marketing authorization of combination medicinal products
Practice: Project work demonstration I.

12th week:
Lecture: Scientific Advice procedure
Practice: Project work demonstration II.

13th week:
Lecture: Falsified medicines legislation in the EU
Practice: Falsified medicines in practice

14th week:
Lecture: Consultation
Practice: Project work demonstration

Requirements

Conditions for Signature (Course Completion):

- Attendance is required at a minimum of 30% of the lectures.

- Attendance at practice sessions is mandatory. A maximum of 4 absences is allowed; if more than 4 are missed, the course signature will not be granted**.**
- Practical Assessment: Continuous evaluation based on a semester project work

Assessment Method:

- Written exam during the exam period.
- Three exam opportunities are provided: A, B, and C exams.
- The exam material covers the full content of both lectures and practices.

Literature:

1. **European Medicines Agency (EMA): Centralised Procedure**
European Medicines Agency. (2025). *Applying for Centralised Marketing Authorisation*.
EMA official guidance on the centralised procedure, including application requirements, timelines, and evaluation process.

2. **European Commission: Notice to Applicants, Volume 2A, Chapter 1**
European Commission, Directorate-General for Health and Food Safety. (2019). *Notice to Applicants, Volume 2A, Chapter 1: Procedures for Marketing Authorisation*.
Official EU guideline describing the centralised, decentralised, mutual recognition, and national procedures for granting marketing authorisation in the EU.

3. **European Commission: Pharmaceutical Legislation Reform**
European Commission. (2025). *Pharmaceutical Legislation Revision – Main Documents and Guidelines*.
Includes the latest legislative proposals, guidelines, and concept papers on pharmaceutical policy, supply, and regulatory science in the EU.

Department of Pharmaceutical Surveillance and Economics

Subject: **PHARMACOVIGILANCE I.**
Year, Semester: 1st year/2nd semester
Number of teaching hours:
Lecture: **14**
Seminar: **14**

1st week:
Lecture: Practical foundations of pharmacovigilance in research and clinical practice
Seminar: Examples of practical decision-making during research and market authorization phases

2nd week:
Lecture: Defined roles and tasks in pharmacovigilance activities
Seminar: The EMA / PRAC committee and drug authorities

3rd week:
Lecture: Unwanted drug reactions (adr), adverse events (ae), serious ae (sae): definitions, types, severity, intensity, and causality
Seminar: AE/SAE reporting

4th week:
Lecture: Clinical classification of side effects and interactions, pk and pd mechanisms
Seminar: Discussion of side effects and interactions in ctd modules (co/nco)

5th week:
Lecture: Content and procedures for reporting side effects
Seminar: Side Effect Reporting (ADR)

6th week:
Lecture: Principles and practical steps of signal

detection
Seminar: Signal detection calculations: frequency, subpopulation and epidemiological data, decisions, and consequences

7th week:
Lecture: Risk assessment and management: principles and practical options. content of rmp documentation
Seminar: Practical issues in rmp documentation

8th week:
Lecture: Content and requirements of formatting for smpc and pl, planning by qrd template
Seminar: Modifications of SmPC and PL

9th week:
Lecture: Routine and additional pharmacovigilance methods
Seminar: Practice of readability tests (readability test evaluation report)

10th week:
Lecture: Content and formatting of PSUR and PBRER reports
Seminar: PSUR reporting

11th week:
Lecture: Central reports (PAR, EPAR)
Seminar: Content elements of the public assessment report

12th week:
Lecture: Signals indicating changed risks, evaluation, and decision-making
Seminar: Managing changed risks

13th week:
Lecture: EudraVigilance system: EV modules, reporting system, permissions
Seminar: Search in EV database

14th week:
Lecture: Post-marketing additional pharmacovigilance, patient registries, data collection systems. The role of AI and big data.
Seminar: Project consultation

Requirements

The end-of-term assessment for this course is an oral examination.
During the semester, students submit two individual project assignments based on the lecture and seminar material. The average of these two assignments (40%) counts towards the final grade.

During the exam, students draw one topic and one practical task (maximum 60 points). The final grade is determined by the combined score of the oral performance and the written assessments (maximum 100 points). The grade thresholds are as follows:
- Above 50%: Pass (2)
- Above 65%: Satisfactory (3)
- Above 75%: Good (4)
- Above 89%: Excellent (5)

Participation in practical sessions is mandatory. More than four unexcused absences will result in the semester not being accepted.

Department of Pharmaceutical Surveillance and Economics

Subject: **PROJECT MANAGEMENT I.**
Year, Semester: 1st year/2nd semester
Number of teaching hours:
Lecture: **28**
Practical: **28**

1st week:
Lecture: Management fundamentals: goal-oriented planning, organization, control, and leadership tasks

Practical: Project management tools and planning exercises: SWOT analysis – internal/external

2nd week:
Lecture: Basic concepts of organization and management theory – organizational structure and description
Practical: Project management tools and planning exercises: SWOT analysis – internal/external

3rd week:
Lecture: The role of the leader, management theories, leadership styles (e.g., Goleman, Lewin models)
Motivational theories (Herzberg, Maslow)
Practical: PESTEL analysis – political, economic, social environment analysis – identification and management of risks

4th week:
Lecture: Fundamentals of change management – models for organizational resistance and implementation
Practical: DICE method

5th week:
Lecture: The Project Team: structure, roles, and responsibilities – Team development models, stakeholder identification and analysis
Practical: Project KPI performance measurement and evaluation

6th week:
Lecture: Basics and concepts of HR Management (Human Resources Management), Compensation and remuneration, Career planning, RACI matrix – roles and responsibilities
Practical: HR techniques practice I

7th week:
Lecture: Planning the phases of clinical projects, resource, time, and financial planning constraints in Phases I-III and PASS studies
Practical: HR techniques practice II.

8th week:
Lecture: Cost calculation, cost accounting systems, cost optimization, and allocation methods
Practical: Gantt chart – visual tool for scheduling, creating timelines on real projects

9th week:
Lecture: Project resources and allocation planning – Critical Path Method (CPM) – used for time management
Practical: Critical Path Method (CPM) exercises

10th week:
Lecture: PERT (Program Evaluation and Review Technique) – project time estimation based on probability
Practical: Periodic project evaluation and PEJ reports exercises

11th week:
Lecture: Questions and principles related to work organization in clinical research practice
Practical: Milestone-based planning task

12th week:
Lecture: Steps and tools of management and controlling – Project KPIs, performance measurement, and evaluation – criteria
Practical: Project closing reports exercises

13th week:
Lecture: Cost calculation: Cost optimization strategies
Practical: Balanced Scorecard (BSC) – performance measurement across multiple dimensions

14th week:
Lecture: : The Waterfall model – linear project planning – milestone-based planning
Practical: Cost analysis and optimization strategies – communication in projects

Requirements

The subject's end-of-term assessment is conducted in the form of an oral exam.
During the semester, students submit two project assignments based on the topics of lectures and project practice sessions. The sum of these two assignments (40%) counts towards the final exam

grade.

During the oral exam, students pick one topic and one practical task (for maximum 60 points). The final exam grade is determined by the combined performance on the oral exam and the assignments (maximum 100 points). The grade thresholds are as follows:
- Above 55%: Pass (2)
- Above 65%: Satisfactory (3)
- Above 75%: Good (4)
- Above 89%: Excellent (5)

Participation in practical sessions is mandatory. More than four unexcused absences will result in the semester not being accepted.

Department of Pharmaceutical Technology

Subject: **PROFESSIONAL ENGLISH LANGUAGE II.**
Year, Semester: 1st year/2nd semester
Number of teaching hours:
Practical: **28**

1st week:
Practical: Revision of what you learned in the previous semester.

2nd week:
Practical: Technical terms used in quality control, quality assurance and quality auditing.

3rd week:
Practical: Technical terms used in pharmaceutic pedigree

4th week:
Practical: Terminology used in human clinical trials I.

5th week:
Practical: Terminology used in human clinical trials II.

6th week:
Practical: Test

7th week:
Practical: Discussing and evaluating human clinical case studies in professional language I.

8th week:
Practical: Discussing and evaluating human clinical case studies in professional language II.

9th week:
Practical: Discussing and evaluating human clinical case studies in professional language III.

10th week:
Practical: Technical terms related to pharmaceutical management I.

11th week:
Practical: Technical terms related to pharmaceutical management II.

12th week:
Practical: Preparing a professional presentation

13th week:
Practical: Writing formal correspondence.

14th week:
Practical: Oral test, assessment of language competences.

Requirements

A maximum of 2 absences is allowed; more than 2 absences, the student may make up the absence with an assignment agreed with the instructor (maximum of 2 times); a student who misses more

than 25% of the practical classes will not be allowed to get a signature.
In the case of more than the permitted number of absences, a medical certificate of permanent illness or hospitalisation is required.
Active attendance in class; at least satisfactory completion of both written and oral test.

Order of mid-term control
Written test, studied until week 8.
Oral test from the topics studied during the semester
Improvement test, at pre-arranged appointment

Evaluation
The final grade is evaluated according to the grades of written test (improvement test is included), oral test and classwork. The fail mark of the written test or oral test must be repeated – the fail mark also counts towards the final grade.
Evaluation of written and oral tests:
0–50% = fail (1)
51–60% = pass (2)
61–75% = satisfactory (3)
76–89% = good (4)
90–100% = excellent (5)
Final grade is a 5 grades practical mark.

Requirements for obtaining credits
End of semester signature. Fail (1) mark is not accepted for practical mark.

Required literature: Teaching materials given during the class.

CHAPTER 10
ACADEMIC PROGRAM FOR THE 2ND YEAR

Department of Pharmacology

Subject: **PRECLINICAL STUDIES II.**
Year, Semester: 2nd year/2nd semester
Number of teaching hours:
Lecture: **14**
Practical: **14**

1st week:
Lecture: Basic concepts of in vivo studies. The role of animal experiments in the preclinical phase.
Practice: In vitro toxicological studies (MTT assay, Neutral Red test).

2nd week:
Lecture: Model selection. Animal models: Rodents. (Mouse models: transgenic, knock-out, xenograft; rat: cardiovascular models).
Practice: In vitro toxicological studies (MTT assay, Neutral Red test).

3rd week:
Lecture: Animal models: Other mammals (Rabbit, dog, pig models and their applications).
Practice: In vitro toxicological studies (MTT assay, Neutral Red test).

4th week:
Lecture: Animal models: Non-human primates (monkey: benefits, ethical dilemmas).
Practice: In vitro toxicological studies (MTT assay, Neutral Red test).

5th week:
Lecture: Alternative models and ethical research (Zebra zebrafish, Drosophila melanogaster, C. elegans).
Practice: Blood, kidney and liver function parameters in rodent, dog and pig models.

6th week:
Lecture: Basic concepts of pharmacokinetics. (Absorption mechanisms (passive diffusion, active transport). Measurement of bioavailability in preclinical models. In vitro and in vivo absorption studies (e.g. Caco-2 model).
Practice: Blood, kidney and liver function parameters in rodent, dog and pig models.

7th week:
Lecture: Basic concepts of pharmacokinetics. (Distribution: plasma protein binding, tissue penetration, definition of Vd (volume of distribution).
Practice: Blood, kidney and liver function parameters in rodent, dog and pig models.

8th week:
Lecture: Basic concepts of pharmacokinetics. (Metabolism: primary sites, enzyme systems (CYP450) metabolites, investigation of toxic metabolites).
Practice: Blood, kidney and liver function parameters in rodent, dog and pig models.

9th week:
Lecture: Basic concepts of pharmacokinetics. (Excretion, clearance calculation in preclinical models. Examination of kidney function in animal models).
Practice: Introduction to rapid tests based on immunoanalytical methods.

10th week:
Lecture: Basic concepts of pharmacodynamics and measurement methods. (Mechanisms of action: receptor-linked, enzymatic, ion channels).
Practice: Introduction to rapid tests based on immunoanalytical methods.

11th week:
Lecture: Basic concepts of pharmacodynamics and measurement methods. (Dose-response

curves).
Practice: Introduction to rapid tests based on immunoanalytical methods.

12th week:
Lecture: PK/PD models. (Compartment and non-compartment modeling).
Practice: Presentation of genotoxicity, DNA damaging effect.

13th week:
Lecture: Application of PK/PD data in clinical development. Determination of human dose, therapeutic window and therapeutic index and toxicological considerations.
Practice: Presentation of genotoxicity, DNA damaging effect.

14th week:
Lecture: Consultation
Practical: Consultation

Requirements

During the semester students have to take written exam. There is no opportunity for improvement below 50%. In such cases, we will deny the semester credit, and the student's semester will be considered unsuccessful.

At the end of the semester, the exam in Precinical studies II. theory takes the form of an oral colloquium (2 topics from the list, a short elaboration, then an oral exam). During the semester, it is possible to get exemption of 1 topic for the oral colloquium. In the case of grades calculated as four (minimum 80%) and five (minimum 90%) from the written exam, 1 topic will be asked on the final exam.

At least 70% of the practice must be visited.

Coordination Center for Drug and Food Development

Subject: **CLINICAL STUDIES II.**
Year, Semester: 2nd year/1st semester
Number of teaching hours:
Lecture: **28**
Practical: **28**

1st week:
Lecture: Site initiation of human clinical trials, preparation, requirements and assumption I.
Practice: Site initiation of human clinical trials, preparation, requirements and assumption I.

2nd week:
Lecture: Site initiation of human clinical trials, preparation, requirements and assumption II.
Practice: Site initiation of human clinical trials, preparation, requirements and assumption II.

3rd week:
Lecture: Responsibilities of Institutions and Clinical Trial Units I.
Practice: Responsibilities of Institutions and Clinical Trial Units I.

4th week:
Lecture: Responsibilities of Institutions and Clinical Trial Units II.
Practice: Responsibilities of Institutions and Clinical Trial Units I.

5th week:
Lecture: The professional clinical trial units
Practice: Responsibilities of Institutions and Clinical Trial Units I.

6th week:
Lecture: Responsibilities of the sponsor during the clinical trial.
Practice: Responsibilities of Institutions and Clinical Trial Units I.

7th week:
Lecture: Clinical research in the pharma company point of view, main considerations
Practice: Clinical research in the pharma company point of view, main considerations

8th week:
Lecture: Monitoring process of clinical trials I.
Practice: Monitoring process of clinical trials I.

9th week:
Lecture: Monitoring process of clinical trials II.
Practice: Monitoring process of clinical trials II.

10th week:
Lecture: Monitoring process of clinical trials III.
Practice: Monitoring process of clinical trials III.

11th week:
Lecture: Source documents and verification, and practical aspects
Practice: Source documents and verification, and practical aspects

12th week:
Lecture: Data managements and randomisation I.
Practice: Data management and randomisation I.

13th week:
Lecture: Data managements and randomisation II.
Practice: Data management and randomisation II.

14th week:
Lecture: Consultation
Practice: Project work demonstration

Requirements

Conditions for Signature (Course Completion):

- Attendance is required at a minimum of 30% of the lectures.
- Attendance at Practical sessions is mandatory. A maximum of 4 absences is allowed; if more than 4 are missed, the course signature will not be granted**.**

Assessment Method:

- Written exam during the exam period.
- Three exam opportunities are provided: A, B, and C exams.
- The exam material covers the full content of both lectures and practices.
- Practical Assessment: Continuous evaluation based on a semester project work

Literature:

- Clinical trials in human medicines -EMA Guidelines
- ICH E6 Good clinical practice - Scientific guideline
- The Practical Guide to Clinical Research and Publication1st Edition - August 6, 2021. Imprint: Academic Press, Author: Uzung Yoon, ISBN: 9780128245170
- Cook, J. A. (2023). *An Introduction to Clinical Trials*. Oxford University Press. ISBN: 9780198885238.
- Good clinical practice (GCP) inspection procedures EMA guidelines

Pharmaceutical Ecosystem Centre

Subject: **DRUG REGISTRATION II.**
Year, Semester: 2nd year/1st semester
Number of teaching hours:
Lecture: **28**
Practical: **14**

1st week:
Lecture: Pre-clinical development of medicinal products
Practice: ICH Efficacy guidelines I.

2nd week:
Lecture: The Role of GMP Inspections and Audits
Practice: ICH Efficacy guidelines II.

3rd week:
Lecture: Industry View on Audits and Inspections
Practice: ICH multidisciplinary guidelines I.

4th week:
Lecture: The Role of Regulatory Inspections in the Pharmaceutical Industry
Practice: ICH multidisciplinary guidelines II.

5th week:
Lecture: Chemistry, manufacturing and control in CTD
Practice: Chemistry, manufacturing and control in CTD, practical workshop-

6th week:
Lecture: Use of European and National Regulatory Databases in the Pharmaceutical Industry
Practice: Data handling practice

7th week:
Lecture: Regulatory information management (RIM)
Practice: Database searching practice

8th week:
Lecture: Advanced therapy and gene therapy medicinal products
Practice: Navigating the European Pharmacopoeia (Ph. Eur.) for Supplier Qualification and Regulatory Compliance I.

9th week:
Lecture: Leadership and strategic management in regulatory affairs
Practice: Navigating the European Pharmacopoeia (Ph. Eur.) for Supplier Qualification and Regulatory Compliance II.

10th week:
Lecture: Regulatory Intelligence – influencing, lobbying
Practice: Regulatory organizations in the world

11th week:
Lecture: European Medicines Agency
Practice: Navigating CHMP Scientific Assessments, "Clock Stops," and Oral Explanations.

12th week:
Lecture: Regulatory activities and responsibilities of the pharmaceutical division of the NNGYK
Practice: Regulatory activities and responsibilities of the pharmaceutical division of the NNGYK – Practical workshop

13th week:
Lecture: Digital transformation in the regulatory environment
Practice: Presentation of project works

14th week:
Lecture: Consultation
Practice: Project work demonstration

Requirements

Conditions for Signature (Course Completion):

- Attendance is required at a minimum of 30% of the lectures.
- Attendance at practice sessions is mandatory. A maximum of 4 absences is allowed; if more than 4 are missed, the course signature will not be granted**.**

Assessment Method:

- Written exam during the exam period.
- Three exam opportunities are provided: A, B, and C exams.
- The exam material covers the full content of both lectures and practices.
- Practical Assessment: Continuous evaluation based on a semester project work

Literature:

1. **European Medicines Agency (EMA): Centralised Procedure**
European Medicines Agency. (2025). *Applying for Centralised Marketing Authorisation*.
EMA official guidance on the centralised procedure, including application requirements, timelines, and evaluation process.

2. **European Commission: Notice to Applicants, Volume 2A, Chapter 1**
European Commission, Directorate-General for Health and Food Safety. (2019). *Notice to Applicants, Volume 2A, Chapter 1: Procedures for Marketing Authorisation*.
Official EU guideline describing the centralised, decentralised, mutual recognition, and national procedures for granting marketing authorisation in the EU.

3. **European Commission: Pharmaceutical Legislation Reform**
European Commission. (2025). *Pharmaceutical Legislation Revision – Main Documents and Guidelines*.
Includes the latest legislative proposals, guidelines, and concept papers on pharmaceutical policy, supply, and regulatory science in the EU.

Pharmaceutical Ecosystem Centre

Subject: **CLINICAL STUDIES AND REGISTRATION OF MEDICAL DEVICES**
Year, Semester: 2nd year/1st semester
Number of teaching hours:
Lecture: **14**
Practical: **14**

1st week:
Lecture: Medical Device: definition, types and main categories Med Dev, IVD, Active Implantable Device. Borderline devices, Classification
Practical: Examples from practice, Classification

2nd week:
Lecture: The History and the regulatory approach– until today, Directives and regulations, Delegated act, Implementing Act. Roles and Responsibilities of actors
Practical: Product's lifecycle

3rd week:
Lecture: Main concept of an EU MDD and MDR registration. Safety and efficiency of a medical

device or combination product**.**
Practical: CE for medical device, statement of compliance

4th week:
Lecture: Medical Device lifecycle: design validation stage, project plan, prototipe usability and evaluations, preclinical and cliinical evaluations, production and distribution
Practical: Usability, Biocompatibility Testing, Biological Evaluation Plan (BEP)

5th week:
Lecture: Tec. Docs and the QMS, QA/RA management, PRRC (Person Responsible for Regulatory Compliance)
Practical: Tech Doc and QMS maintenance

6th week:
Lecture: Clinical Evaluation Report (CER), Clinical Evaluation Plan (CEP), Post-Marketing Clinical Follow-up (PMCF)
Practical: Clinical development plan, exploratory and confirmatory investigations

7th week:
Lecture: : Clinical Evaluation (CE) study setup and requirements, Regulatory application and approval Ethical opinion
Practical: Protocol and study management

8th week
Lecture: The risk management, evaluating the risks, manage by risk analysis in theory and practice.
Practical: Risk management of a product, Toxicological Risk Assessment.

9th week
Lecture: National Regulatory agencies, in the EU EUDAMED, Medical Device Coordination Group (MDCG)
Practical: MDR practice, Actors Module, UDI Devices Module, MDCG endorsed documents

10th week:
Lecture: The role of a Notified Body, Local Actor Administrator
Practical: Procedures and responsibilities

11th week:
Lecture: Economic Operators, definition, roles and compliance
Practical: Manufacturer, Importeur, Distributor, Authorised Representataive

12th week:
Lecture: In-Vitro Diagnostics (IVD) definition, use, IVDR guidelines
Practical: Practice and the clinical use

13th week:
Lecture: Software as Medical Device (SaMD) definitions, and specific documentation
Practical: General purpose software, or in combination or interface with, other medical devices

14th week:
Lecture: Vigilance, Post-Marketing Clinical Follow-up (PMCF) Post-marketing surveillance PMS, incident report, Post-Marketing Surveillance Plan
Practical: Reactive and proactive activities Periodic Safety Update Report (PSUR)

Requirements

The course's end-of-term assessment is conducted as an oral examination.
During the semester, students take two quizzes (ZH) based on the lecture material. The average of these two quizzes (40%) counts towards the final grade.

During the oral exam, students draw two topics (maximum 60 points). The final grade is determined by the combined score of the oral performance and the written assessments (maximum 100 points). The grade thresholds are as follows:
- Above 50%: Pass (2)
- Above 65%: Satisfactory (3)
- Above 75%: Good (4)
- Above 89%: Excellent (5)

Participation in practical sessions is mandatory. More than four unexcused absences will result in the semester not being accepted.

DEENK Life and Natural Sciences Library

Subject: **PRESENTATION AND PUBLICATION SKILLS**
Year, Semester: 2nd year/1st semester
Number of teaching hours:
Lecture: **14**
Practical: **28**

1st week:
Lecture: Scientific communication
Practical: Scientific communication

2nd week:
Lecture: Types of Scientific Publications
Practical: Paper Analysis

3rd week:
Lecture: Manuscript Preparation, Authorship and Ethics
Practical: Manuscript Preparation, Authorship and Ethics

4th week:
Lecture: Peer Review and the Publication Process
Practical: Peer Review Roleplay

5th week:
Lecture: Scientific Posters and Visual Communication
Practical: Poster Planning

6th week:
Lecture: Presentation Design
Practical: Presentation Practice

7th week:
Lecture: Communication with Non-scientific Audiences
Practical: Communication with Non-scientific Audiences

8th week
Lecture: Research Data Lifecycle
Practical: Research Data Lifecycle

9th week
Lecture: Data Management in Pharmaceutical Research
Practical: Data Management in Pharmaceutical Research

10th week:
Lecture: Using Scientific Databases
Practical: Search Practice

11th week:
Lecture: AI tools for research
Practical: AI tools for research

12th week:
Lecture: Systematic Literature review
Practical: Systematic Review with PRISMA

13th week:
Lecture: Introduction to Meta-analysis
Practical: Data Extraction for Meta-analysis

14th week:
Lecture: Basic Statistics for Meta-analysis
Practical: Meta-analysis Case Study

Requirements

Participation and Engagement

-
Students are expected to engage actively in classroom activities, including peer review, group discussions, and presentations.
-
Practical sessions are based on collaborative and experiential learning, so in-class participation is essential.
To successfully complete the course, students must:
-
Prepare and deliver a short scientific presentation (5–8 minutes) on a selected topic.
-
Design a scientific poster, either individually or in pairs.
-
Complete in-class activities, including: abstract and figure critique, a mini peer-review exercise, structured literature searches and data extraction (for the data management module). (All tasks are designed to be completed during class sessions. No additional homework is required unless the student misses a session or chooses to further refine their work.)
The final grade is based on:
-
Presentation (25%)
-
Poster design (25%)
-
In-class exercises (50%)

Department of Pharmaceutical Surveillance and Economics

Subject: **PHARMACOVIGILANCE II.**
Year, Semester: 2nd year/1st semester
Number of teaching hours:
Lecture: **28**
Seminar: **14**

1st week:
Lecture:
Lecture: Pharmacovigilance in drug development: responsibilities of manufacturers/ /sponsors, reporting responsibilities: sponsor, CRO, communication with NCA, EMA, EC
Seminar: Preclinical and clinical data and drug safety

2nd week:
Lecture: Documentation and reporting for AE/SAE in clinical phase trials. rules for detection and management of unexpected and AE of special interest (AESI) Adverse Reactions
Seminar: SAE Report Templates, Listing of AE Data

3rd week:
Lecture: Pharmacovigilance during clinical development phases: DSUR / PSUR obligations and practice, safety database
Seminar: DSUR Report

4th week:
Lecture: Patient safety during the clinical trial. content elements of Informed Consent Forms (ICF) / Patient Information Sheet
Seminar: Content of ICF in clinical phase trials

5th week:
Lecture: Safety Services, DSO / Safety Service Provider
Seminar: Roles and responsibilities of DSO / QPPV

6th week:
Lecture: Pharmacovigilance in Phase I Trials
Seminar: FIM, Dose Escalation Study

7th week:
Lecture: Pharmacovigilance in Phase II/III Trials
Seminar: AE Registration and Monitoring During Trials, AE/SAE Reporting and Follow-up in Double-Blind Studies

8th week
Lecture: Post-marketing and additional pharmacovigilance: PASS / PAES trials
Seminar: safety aspects and reporting obligations in phase IV trials

9th week
Lecture: Safety Issues and Reporting in Non-Interventional (NI) Studies
Seminar: Practical Examples and Case Studies

10th week:
Lecture: Pharmacovigilance of research studies without medicinal products (Food and Functional Food)
Seminar: Case study

11th week:
Lecture: Procedures and safety obligations for medical device trials
Seminar: Drug-device combinations

12th week:
Lecture: Pharmacovigilance of OTC Products
Seminar: The OTC Switch

13th week:
Lecture: ATC and MedDRA Coding Systems
Seminar: Practice in MedDRA Coding

14th week:
Lecture: EU-GVP "Good Vigilance Practice" related to drug use
Seminar: Chapters of GCP, GVP, and EudraLex

Requirements

The end-of-term assessment for this course is an oral examination.
During the semester, students submit two individual project assignments based on the lecture and seminar material. The average of these two assignments (40%) counts towards the final grade.

During the exam, students draw one topic and one practical task (maximum 60 points). The final grade is determined by the combined score of the oral performance and the written assessments (maximum 100 points). The grade thresholds are as follows:
- Above 50%: Pass (2)
- Above 65%: Satisfactory (3)
- Above 75%: Good (4)
- Above 89%: Excellent (5)

Participation in practical sessions is mandatory. More than four unexcused absences will result in the semester not being accepted.

Department of Pharmaceutical Surveillance and Economics

Subject: **PROJECT MANAGEMENT II.**
Year, Semester: 2nd year/1st semester
Number of teaching hours:
Lecture: **28**
Practical: **14**

1st week:
Lecture: Clinical Development Management I – Preclinical and Clinical Phases, Life Cycle
Practical: Clinical project time and financial planning exercise I

2nd week:
Lecture: Clinical Development Management II –

Endpoints, goals, methods, and protocol design
Practical: Clinical project time and financial planning exercise II

3rd week:
Lecture: Clinical Research Protocols I – Protocol Design and Writing
Practical: Clinical project time and financial planning exercise III

4th week:
Lecture: Clinical Research Protocols II – Protocol Design and Writing
Practical: Project Budgeting I

5th week:
Lecture: Statistical and Data Management Methods, Data Privacy Regulations
Practical: Real project budget correction

6th week:
Lecture: Project Time Allocation, HR Planning Steps, and Control
Practical: Results evaluation, statistics, Feasibility analysis

7th week:
Lecture: Budgeting and R&D planning in Clinical Development, Steps and Control
Practical: Multinational teamwork with international research

8th week:
Lecture: Budgeting – Financing Strategies
Practical: Kick-Off Meeting, Investigators Meeting, Communication

9th week:
Lecture: Supplier and Subcontractor / Vendor Management, Supply Chain Planning Perspective
Practical: Steps for initiation, activation, enrollment

10th week:
Lecture: Enrollment Management and Strategy in Clinical Trials
Practical: Enrollment management exercises

11th week:
Lecture: Feasibility Data and Reliability Issues
Practical: Database closure, CSR final report

12th week:
Lecture: Feasibility Plan
Practical: Risk identification and management, sharing experiences and evaluation

13th week:
Lecture: Telemedicine and Clinical Applications
Practical: Study Closure Meeting

14th week:
Lecture: Risks and Alternative Solutions
Practical: Simulation of Ethical Issues

Requirements

The subject's end-of-term assessment is conducted in the form of an oral exam.

During the semester, students submit two project assignments based on the topics of lectures and project practice sessions. The sum of these two assignments (40%) counts towards the final exam grade.

During the oral exam, students pick one topic and one practical task (for maximum 60 points). The final exam grade is determined by the combined performance on the oral exam and the assignments (maximum 100 points). The grade thresholds are as follows:

- Above 55%: Pass (2)

- Above 65%: Satisfactory (3)

- Above 75%: Good (4)

- Above 89%: Excellent (5)

Participation in practical sessions is mandatory. More than four absences will result in the semester not being accepted.

Pharmaceutical Ecosystem Centre

Subject: **CLINICAL STUDIES III.**
Year, Semester: 2nd year/2nd semester
Number of teaching hours:
Lecture: **42**
Practical: **14**

1st week:
Lecture: Management of the Investigational product
Practice: Management of the Investigational product

2nd week:
Lecture: Pharmacovigilance of clinical trials
Practice: Pharmacovigilance of clinical trials

3rd week:
Lecture: Adverse events and safety monitoring
Practice: Adverse events and safety monitoring

4th week:
Lecture: Data management of clinical trials I.
Practice: Data management of clinical trials I.

5th week:
Lecture: Documentation process and requirements
Practice: Documentation process and requirements

6th week:
Lecture: Data management of clinical trials II: data analysis (eCRF, EDC, interim assessment)
Practice: Data management of clinical trials II: (eCRF, EDC, interim assessment)

7th week:
Lecture: Statistical planning of clinical trials
Practice: Statistical planning of clinical trials

8th week:
Lecture: Patient information and consent
Practice: Patient information and consent

9th week: **Lecture:** Quality assurance and quality control in clinical trials **Practice:** Quality assurance and quality control in clinical trials 10th week: **Lecture:** Audit and Inspection (GCP, GMP, GLP, GVP, guidelines and manuals, regulations I. **Practice:** Audit and Inspection (GCP, GMP, GLP, GVP, guidelines and manuals, regulations I. 11th week: **Lecture:** Audit and Inspection (GCP, GMP, GLP, GVP, guidelines and manuals, regulations II.	**Practice:** Audit and Inspection (GCP, GMP, GLP, GVP, guidelines and manuals, regulations II. 12th week: **Lecture:** Study Close-Out and Archiving Procedures **Practice:** Study Close-Out and Archiving Procedures 13th week: **Lecture:** The main actors and their roles in clinical trials **Practice:** The main actors and their roles in clinical trials 14th week: **Lecture:** Consultation **Practice:** Project work demonstration

Requirements

Conditions for Signature (Course Completion):

- Attendance is required at a minimum of 30% of the lectures.
- Attendance at Practical sessions is mandatory. A maximum of 4 absences is allowed; if more than 4 are missed, the course signature will not be granted**.**
- Practical Assessment: Continuous evaluation based on a semester project work

Assessment Method:

- Final exam during the exam period.
- Three exam opportunities are provided: A, B, and C exams.
- The exam material covers the full content of both lectures and practices.

Literature:

- Clinical trials in human medicines -EMA Guidelines
- ICH E6 Good clinical practice - Scientific guideline
- The Practical Guide to Clinical Research and Publication1st Edition - August 6, 2021. Imprint: Academic Press, Author: Uzung Yoon, ISBN: 9780128245170
- Cook, J. A. (2023). *An Introduction to Clinical Trials*. Oxford University Press. ISBN: 9780198885238.
- Good clinical practice (GCP) inspection procedures EMA guidelines

Pharmaceutical Ecosystem Centre

Subject: **DATA MANAGEMENT CLOSURE AND ARCHIVING OF CLINICAL TRIALS**
Year, Semester: 2nd year/2nd semester
Number of teaching hours:
Lecture: **28**
Practical: **28**

1st week:
Lecture: Data management of Clinical Trials I.
Practice: Data management of Clinical Trials I.

2nd week:
Lecture: Data management of Clinical Trials II.
Practice: Data management of Clinical Trials II.

3rd week:
Lecture: Data management, data clarification, interim analysis (eCRF, EDC, interim assesement).
Practice: Data management, data clarification, interim analysis (eCRF, EDC, interim assesement).

4th week:
Lecture: Statistical planning I.
Practice: Statistical planning I.

5th week:
Lecture: Statistical planning II.
Practice: Statistical planning II.

6th week:
Lecture: Quality assurance and quality control in clinical data.
Practice: Quality assurance and quality control in clinical data.

7th week:
Lecture: Quality Data Before, During, and After the Clinical Trial (Audit, Inspection, GCP, GMP, GLP, GPV, Guidelines, Manuals, Regulations) I.
Practice: Quality Data Before, During, and After the Clinical Trial (Audit, Inspection, GCP, GMP, GLP, GPV, Guidelines, Manuals, Regulations) I.

8th week:
Lecture: Quality Data Before, During, and After the Clinical Trial (Audit, Inspection, GCP, GMP, GLP, GPV, Guidelines, Manuals, Regulations) II.

Practice: Quality Data Before, During, and After the Clinical Trial (Audit, Inspection, GCP, GMP, GLP, GPV, Guidelines, Manuals, Regulations) II.

9th week:
Lecture: The main stakeholders of clinical trials and their roles in data management
Practice: The main stakeholders of clinical trials and their roles in data management

10th week:
Lecture: Roles and responsibilities of clinical trial stakeholders in trial closure and archiving
Practice: Roles and responsibilities of clinical trial stakeholders in trial closure and archiving

11th week:
Lecture: Management of Clinical Trial Documentation and Study Files
Practice: Management of Clinical Trial Documentation and Study Files

12th week:
Lecture: Close-out processes and archives of clinical studies
Practice: Close-out processes and archives of clinical studies

13th week:
Lecture: Patient information and consent in clinical data management
Practice: Patient information and consent in clinical data management

14th week:
Lecture: Consultation
Practice: Consultation

Requirements

Conditions for Signature (Course Completion):

- Attendance is required at a minimum of 30% of the lectures.
- Attendance at Practical sessions is mandatory. A maximum of 4 absences is allowed; if more than 4 are missed, the course signature will not be granted**.**
- Practical Assessment: Continuous evaluation based on a semester project work

Assessment Method:

- Written exam during the exam period.
- Three exam opportunities are provided: A, B, and C exams.
- The exam material covers the full content of both lectures and practices.

Literature:

- Prokscha, S. (2024). Practical Guide to Clinical Data Management (4th ed.). CRC Press. ISBN: 9781032495583.
- Clinical trials in human medicines -EMA Guidelines
- ICH E6 Good clinical practice - Scientific guidelines

Department of Pharmaceutical Surveillance and Economics

Subject: **PROJECT MANAGEMENT III.**
Year, Semester: 2nd year/2nd semester
Number of teaching hours:
Lecture: **28**
Practical: **28**

1st week:
Lecture: Effective Project Management I – Proactive Management
Practice: Project Management Planning Exercise (project plan, monitoring plan)

2nd week:
Lecture: Effective Project Management II – Agile Management Approach
Practice: Project Management Planning Exercise (project plan, monitoring plan)

3rd week:
Lecture: The Advantages of Flexible, Iterative Methods in Project Management
Practice: Project team and case study simulation exercises

4th week:
Lecture: Risk-Based Quality Management
Practice: Project team and case study simulation exercises

5th week:
Lecture: Risk-Based Quality Management – Risk Management and Handling
Practice: Real-world examples and solutions demonstrating the connection between theory and practice

6th week:
Lecture: CAPA (Corrective and Preventive Action)
Practice: CAPA exercises (handling errors and managing corrections)

7th week:
Lecture: The “5 Whys” Technique – Root Cause Analysis of Problems
Practice: Risk management exercises – analysis of real situations

8th week:
Lecture: PDCA Cycle (Plan-Do-Check-Act) – Continuous Quality Improvement
Practice: Risk management exercises – analysis of real situations

9th week:
Lecture: “Milestone-Based” and “Efforts-Based” Management
Practice: Structured, case study-based exercises

10th week:
Lecture: “Milestone-Based” and “Efforts-Based” Management
Practice: Steps for identifying errors, investigation, corrective plans, preventive measures, and feedback – Part I

11th week:
Lecture: Digital Project Management Tools
Practice: Steps for identifying errors, investigation, corrective plans, preventive measures, and feedback – Part II

12th week:
Lecture: Modern Digital Tools for Project Management (e.g., Asana, MS Project, JIRA, Redmine)
Practice: Steps for identifying errors, investigation, corrective plans, preventive measures, and feedback – Part III

13th week:
Lecture: Modern Digital Tools for Project Management in Healthcare (e.g., Asana, MS Project, JIRA, Redmine)
Practice: What tools are recommended for use in healthcare

14th week:
Lecture: Project Communication
Practical: Project team communication exercises, alternative solutions, and evaluation

Requirements

The end-of-term assessment for this course is conducted in the form of an oral exam.
During the semester, students submit two project assignments based on the lectures and practical sessions. The total points from these two assignments (40 points) count towards the final grade and are added to the results of the two practical assignments from previous semesters (20 + 20 points).

During the oral exam, students draw one topic (maximum 60 points) and two practical tasks (maximum 60 points). The final exam grade is determined by the combined performance on the oral exam and the assignments (maximum of 200 points / 2 = 100% points). The grade thresholds are as follows:
- Above 55%: Pass (2)
- Above 65%: Satisfactory (3)
- Above 75%: Good (4)
- Above 89%: Excellent (5)

Participation in practical sessions is mandatory. More than four absences (without retake) will result in the semester not being accepted.

Department of Pharmaceutical Technology

Subject: **COMMUNICATION IN HEALTHCARE**
Year, Semester: 2nd year/2nd semester
Number of teaching hours:
Lecture: **14**
Practical: **14**

1st week:
Lecture: Introduction to healthcare communication, communication basics
Practice: Introduction to healthcare communication, communication basics

2nd week:
Lecture: Verbal and non-verbal communication
Practice: Situation-based exercises

3rd week:
Lecture: Metacommunication, congruent and incongruent communication, vegetative communication
Practice: Situation-based exercises

4th week:
Lecture: Characteristics of the doctor-patient relationship and its impact on communication
Practice: Paternalistic vs. partnership model analysis, modern doctor-patient relationship

5th week:
Lecture: Communication models in the health sector
Practice: Models in health psychology

6th week:
Lecture: Communication with different patient groups
Practice: Situation-based exercises

7th week:
Lecture: Reporting health crises and bad news
Practice: Empathic reactions, self-reflection

8th week:
Lecture: Patient education and preventive communication
Practice: Review and analysis of prevention materials

9th week:
Lecture: Ethical issues in communication
Practice: Case studies

10th week:
Lecture: Conflict resolution
Practice: Situation-based exercises

11th week:
Lecture: Interdisciplinary communication
Practice: Communication between doctors, nurses, physiotherapists and pharmacists

12th week:
Lecture: Digital health communication
Practice: Telemedicine, artificial intelligence in healthcare

13th week:
Lecture: Differences and challenges - cultural competence
Practice: Multicultural environment and health communication, language barriers

14th week:
Lecture: Consultation
Practical: Consultation

Requirements

Attendance at 30% of the presentations is compulsory, if this is not completed, the signature will be refused. The submission of the project work set during the semester constitutes 50% of the mininimum grade for the colloquium.

Department of Controlling

Subject: **LEADERSHIP STYLES AND SKILLS**
Year, Semester: 2nd year/2nd semester
Number of teaching hours:
Lecture: **14**
Practical: **14**

1st week:
Lecture: Introduction and leadership skills
Practical: Leadership competencies, the skill tree of leadership

2nd week:
Lecture: Development of management and leadership theories
Practical: Management versus leadership

3rd week:
Lecture: Managerial functions and roles
Practical: Training exercises

4th week:
Lecture: New leadership models (eg. ethical leadership, authentic leadership, spiritual leadership, charismatic leadership)
Practical: Case studies on new leadership models

5th week:
Lecture: Personality models
Practical: Self-awareness tests

6th week:

Lecture: Self-awareness and Emotional intelligence
Practical: EI test, improving of EI

7th week:
Lecture: Basic motivational models
Practical: Motivational factors tests, improving of motivation

8th week:
Lecture: Group-management, Team-building I.
Practice: Team-building exercises

9th week:
Lecture: Group-management, Team-building II.
Practice: Team-building exercises

10th week:
Lecture: Time management
Practice: Developing of effective time management

11th week:
Lecture: Power and politics in organizations
Practice: Case studies and exercises on power and politics

12th week:
Lecture: Influencing others, Impression Management, competitive behavior
Practice: Impression management tactics

13th week:
Lecture: Conflicts in organizations
Practice: Conflict-handling styles, situational exercises

14th week:
Lecture: Resilience, stress management
Practice: Stress management techniques

Requirements

Assignment: 50%
Final test: 50%

Assignment:
A 5-page written paper related to the student's leadership skills, based on self-awareness tests, case studies, and situational tasks.

Final Test:
A written test consisting of multiple-choice and true/false questions.

Department of Pharmaceutical Technology

Subject: **FOOD, COSMETICS REGULATORY KNOWLEDGE**
Year, Semester: 2nd year/2nd semester
Number of teaching hours:
Lecture: **28**
Practical: **14**

1st week:
Lecture: The system of food regulation. General knowledge about food regulation. Food categories.
Practical: The system of food regulation. General knowledge about food regulation. Food categories.

2nd week:
Lecture: EU regulations covering food categories in general – hygiene requirements, contaminants.
Practical: EU regulations covering food categories in general – hygiene requirements, contaminants.

3rd week:
Lecture: EU regulations covering food categories in general – additives, GMOs, organic, and bio regulations.
Practical: EU regulations covering food categories in general – additives, GMOs, organic, and bio regulations.

4th week:
Lecture: EU regulations covering food categories in general – labeling, claims, use of claims.
Practical: EU regulations covering food categories in general – labeling, claims, use of claims.

5th week:
Lecture: EU regulations covering food categories in general – fortification, novel food.
Practical: EU regulations covering food categories in general – fortification, novel food.

6th week:
Lecture: Foods for specific groups – general information.
Practical: Foods for specific groups – general information.

7th week:
Lecture: Foods for specific groups – infant formulae, follow-on formulae.
Practical: Foods for specific groups – infant formulae, follow-on formulae.

8th week:
Lecture: Foods for specific groups – foods for special medical purposes, total diet replacement products.
Practical: Foods for specific groups – foods for special medical purposes, total diet replacement products.

9th week:
Lecture: Food supplements – general information about food supplements.
Practical: Food supplements – general information about food supplements.

10th week:
Lecture: Food supplements – novel food, additives.
Practical: Food supplements – novel food, additives.

11th week:
Lecture: Food supplements – labeling, claims. Risk assessment.
Practical: Food supplements – labeling, claims. Risk assessment.

12th week:
Lecture: Cosmetics – general regulation, legal framework.
Practical: Cosmetics – general regulation, legal framework.

13th week:
Lecture: Cosmetics – cosmetic active ingredients and their approval.
Practical: Cosmetics – cosmetic active ingredients and their approval.

14th week:
Lecture: Cosmetics – the product information dossier.
Practical:
Cosmetics – the product information dossier.

Requirements

Conditions for Signature (Course Completion):

- Attendance is required at a minimum of 30% of the lectures.
- Attendance at practice sessions is mandatory. A maximum of 4 absences is allowed; if more than 4 are missed, the course signature will not be granted**.**

Assessment Method:

- Written exam during the exam period.
- Three exam opportunities are provided: A, B, and C exams.
- The exam material covers the full content of both lectures and practices.

Department of Controlling

Subject: **BUSINESS COMMUNICATION**
Year, Semester: 2nd year/2nd semester
Number of teaching hours:
Lecture: **14**
Practical: **14**

1st week:
Lecture: Basic communication skills
Practical: Basic communication skills

2nd week:
Lecture: Nonverbal communication
Practical: Nonverbal communication

3rd week:
Lecture: Nonverbal communication II.
Practical: Nonverbal communication II..

4th week:
Lecture: Effective Communication
Practical: Effective Communication

5th week:
Lecture: The report
Practical: The report

6th week:
Lecture: Communication issues in business
Practical: Communication issues in business

7th week:
Lecture: Practising verbal communication
Practical: Practising verbal communication

8th week:
Lecture: Business presentation in theory
Practical: Business presentation in theory

9th week:
Lecture: Presentation exercises
Practical: Presentation exercises

10th week:
Lecture: Presentation exercises II.
Practical: Presentation exercises II.

11th week:
Lecture: Presentation exercises III.
Practical: Presentation exercises III.

12th week:
Lecture: Negotiation techniques
Practical: Negotiation techniques

13th week:
Lecture: Negotiation techniques II.
Practical: Negotiation techniques II.

14th week:
Lecture: Assertive communication
Practical: Assertive communication

Requirements

The course material is mastered by the students through training sessions, small lectures, group role-plays and presentations. It requires active participation from all those present.
The semester ends with a practical grade.

CHAPTER 11
TITLES OF THESES

Department of Pharmaceutical Surveillance and Economics
1. Title: Drug utilization research
2. Title: Pharmacoepidemiology
Tutor: László Horváth D.Pharm., Ph.D.
3. Title: Aspects of Pharmacoecomony in Therapy management
4. Title: Interactions in the practice of Pharmacovigilance by the aspects of a patient
5. Title: Management of compliance by patient profile and risk evaluation
6. Title: Pharmacovigilance in practice by the aspects of pharmacists and the patients
Tutor: Béla Tóth E. M.D., MBA, Ph.D.

Department of Pharmaceutical Technology
1. Title: Pharmaceutical technology. Modified-Release Therapeutic systems.
2. Title: Innovation and sustainablity in the pharmaceutical technology
Tutor: Ildikó Bácskay, Pharm.D., Ph.D.
3. Title: Advanced Process Analytical Technologies (PAT) in Continuous Manufacturing of Pharmaceuticals
Tutor: Ágota Pető, Pharm.D., Ph.D.
4. Title: Implementation of ICH Guidelines in Pharmaceutical Technology Projects: Challenges and Best Practices
Tutor: Ágota Pető, Pharm.D., Ph.D.
5. Title: Development and Documentation of Modern Cosmetic Products
Tutor: Pálma Fehér, Pharm.D., Ph.D.
6. Title: Analysis of a selected legal regulation on the field of pharmaceutical industry.
Tutor: Dániel Nemes, Pharm.D., Ph.D.

Department of Pharmacology
1. Title: Sample preparation techniques used in the analysis of drugs and drug related compounds
2. Title: Application of mass spectrometry in the drug R&D
Tutor: István Bak M.Sc., Ph.D.
3. Title: Modern therapeutic opportunities for cancer treatment
4. Title: New therapeutic approaches in gynecological pathology
5. Title: The role of the microbiome in gastrointestinal diseases
Tutor: Pharm.D., Ph.D.

Department of Industrial Pharmaceutical Technology
1. Title: Vaccine adjuvants - pharmaceutical technology aspects
2. Title: Pharmaceutical development of vaccines
3. Title: Artificial Intelligence Applications in Formulation Design
4. Title: Sustainable Practices in Pharmaceutical Manufacturing
Tutor: Zoltán Ujhelyi Pharm.D., Ph.D.

Pharmaceutical Ecosystem Centre
1. Title: Validation and comparative analysis of critical process parameters in Continuous Manufacturing for solid dosage forms.
2. Title: Development of a cleaning validation protocol and sampling plan in a multi-product facility using health-based exposure limits (PDE).
3. Title: Statistical and data-driven analysis of biomarker-guided patient selection efficiency in oncology clinical trials.
4. Title: Environmental Risk Assessment (ERA) studies and monitoring of active pharmaceutical ingredient residues in regulatory submissions.
5. Title: Quality assurance, analytical testing, and experimental stability monitoring of a botanical-containing food supplement.
6. Title: Practical compilation of a toxicological and safety dossier for Novel Foods based on EFSA guidelines.
7. Title: Validation and GMP compliance verification of automated optical inspection systems in pharmaceutical packaging lines.
Tutor: Zsolt Ráduly, Pharm.D., Ph.D.

Department of Controlling

1. Title: Group-management, Team-building
2. Title: Basic motivational models

Tutor: Veronika Fenyves Ph.D.

Coordination Center For Drug and Food Development

1. Title: Design and Methodology of Clinical Trials
2. Title: Population Modeling

Tutor: Dénes Páll M.D., Ph.D., DSc

CHAPTER 12
LIST OF TEXTBOOKS

1st year

Basic principles of industrial pharmaceutical manufacturing:

Syed Asif, E., & Usmani, S. B. (2024). Basics of Pharmaceutical Manufacturing and Quality Operations: A Comprehensive Guide. CRC Press. ISBN: 9781032432052.

Guidelines

International Council for Harmonisation (ICH). (2000). ICH Q7: Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. Available at: International Council for Harmonisation website.

U.S. Food and Drug Administration (FDA). Current Good Manufacturing Practice (cGMP) Regulations.

Title 21 CFR Parts 210 and 211. Available at: FDA official website.

European Medicines Agency (EMA). EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use.

EudraLex - Volume 4. Available at: EMA website.

World Health Organization (WHO). (2022). WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles (Annex 2, WHO Technical Report Series, No. 1025).

Available at: WHO website.

M.E. Aulton: Pharmaceutics: The science of dosage form design. 2002.

Drug development theory:

M.E. Aulton: Pharmaceutics: The science of dosage form design. 2002.

Quality assurance and quality management skills (GXP):

McCormick, K.: Quality (Pharmaceutical Engineering Series). Butterworth, Oxford, 2002. ISBN: 0-7506-5113X.

Principles of pharmacology, toxicology, biopharmacy:

Laurence L. Brunton (editor): Goodman & Gilman's The pharmacological Basis of Therapeutics. 13th edition. McGraw Hill Medical, 2017. ISBN: 978-1259584732. Árpád Tósaki Ph.D., D.Sc., D.Pharm: Pharmacology and therapy. URL: http://gyogyszertankonyv.med.unideb.hu/files/Pharmacology_and_therapy.pdf

Theory and principles of pharmacovigilance:

Thao Doan, Updesh Dosanjh, Nicholas Moore: Pharmacovigilance: A Practical Approach. 1st Edition (2018, Academic Press)

Elizabeth B. Andrews, Nicholas Moore: Pharmacovigilance: An Introduction. 1st Edition (2014, Springer)

Michael J. Klepper: Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk. 2nd Edition (2012, CRC Press)

EMA GVP Modules (Good Pharmacovigilance Practices)

Pharmaceutical management, sales and marketing, basic health economics:

John Talbot, Jeffrey K. Aronson: Stephens' Detection and Evaluation of Adverse Drug Reactions: Principles and Practice. 7th Edition (2020, Wiley-Blackwell)

Thao Doan, Updesh Dosanjh, Nicholas Moore: Pharmacovigilance: A Practical Approach. 1st Edition (2018, Academic Press)

Elizabeth B. Andrews, Nicholas Moore: Pharmacovigilance: An Introduction. 1st Edition (2014, Springer)

Michael J. Klepper: Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk. 2nd Edition (2012, CRC Press)

EMA GVP Modules (Good Pharmacovigilance Practices)

Database management, biostatistics, pharmacometrics:

Abraham Silberschatz, Henry F. Korth, S. Sudarshan: Database System Concepts. 7th Edition (2020, McGraw-Hill)
Wayne W. Daniel, Chad L. Cross: Biostatistics: A Foundation for Analysis in the Health Sciences. 11th Edition (2019, Wiley)

General legal education, health law:

Carla Caldwell Stanford: Law for Healthcare Professionals. 3rd Edition (2020, Jones & Bartlett Learning)

Bioethics, research ethics:

Glannon, W.: Biomedical Ethics. 1st. Oxford University Press, 2004. ISBN: 0- 1951-4431-7. Leonard J. Weber: Profits Before People?: Ethical Standards And the Marketing of Prescription Drugs. Indiana University Press, 2006. Tony Hope: Medical Ethics: A Very Short Introduction. Oxford University Press, 2004. Walter Glannon: Bioethics and the Brain. Oxford University Press, 2006. Francis Fukuyama: Our Posthuman Future: Consequences of the Biotechnology Revolution. Picador, 2003. David B. Resnik: The Ethics of Science: An Introduction. Routledge, 2005. Gregory E. Pence - Medical Ethics Accounts of Ground-Breaking Cases McGraw-Hill Education, 2016 Guidry-Grimes, Laura, Veatch, Robert - The Basics of Bioethics – Routledge, 2019

Professional English language I.:

Joanna Gamble: Communicating in the Pharmaceutical Industry. Routledge (2021)

Preclinical studies I.:

Laurence L. Brunton (editor): Goodman & Gilman's The pharmacological Basis of Therapeutics. 13th edition. McGraw Hill Medical, 2017. ISBN: 978-1259584732. Árpád Tósaki Ph.D., D.Sc., D.Pharm: Pharmacology and therapy. URL: http://gyogyszertankonyv.med.unideb.hu/files/Pharmacology_and_therapy.pdf

Clinical studies I.:

Clinical trials in human medicines -EMA Guidelines
ICH E6 Good clinical practice - Scientific guideline
The Practical Guide to Clinical Research and Publication1st Edition - August 6, 2021 Im-print: Academic Press, Author: Uzung Yoon, ISBN: 9780128245170
Cook, J. A. (2023). An Introduction to Clinical Trials. Oxford University Press. ISBN: 9780198885238.

Clinical trial authorisation, legal and ethical aspects:

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC
ICH E6(R2) – Good Clinical Practice (GCP) Guideline
International Council for Harmonisation (ICH). *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*
Ethics in Clinical Research – Declaration of Helsinki
World Medical Association (WMA). *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*
CTIS – Clinical Trials Information System (EU CTR)
European Medicines Agency (EMA). *Clinical Trials Information System – Supporting the implementation of the EU Clinical Trials Regulation (EU CTR 536/2014)*

Drug registration I.:

European Medicines Agency (EMA): Centralised Procedure
European Medicines Agency. (2025). *Applying for Centralised Marketing Authorisation*.
EMA official guidance on the centralised procedure, including application requirements, timelines, and evaluation process.
European Commission: Notice to Applicants, Volume 2A, Chapter 1
European Commission, Directorate-General for Health and Food Safety. (2019). *Notice to Applicants, Volume 2A, Chapter 1: Procedures for Marketing Authorisation*.
Official EU guideline describing the centralised, decentralised, mutual recognition, and national procedures for granting marketing authorisation in the EU.
European Commission: Pharmaceutical Legislation Reform

European Commission. (2025). *Pharmaceutical Legislation Revision – Main Documents and Guidelines*.
Includes the latest legislative proposals, guidelines, and concept papers on pharmaceutical policy, supply, and regulatory science in the EU.

Pharmacovigilance I.:

Thao Doan, Updesh Dosanjh, Nicholas Moore: Pharmacovigilance: A Practical Approach. 1st Edition (2018, Academic Press)
Elizabeth B. Andrews, Nicholas Moore: Pharmacovigilance: An Introduction. 1st Edition (2014, Springer)
Michael J. Klepper: Drug Safety Data: How to Analyze, Summarize and Interpret to Determine Risk. 2nd Edition (2012, CRC Press)
EMA GVP Modules (Good Pharmacovigilance Practices)

Project management I.:

Tony Kennedy: Pharmaceutical Project Management. 2nd Edition (2008, CRC Press)
Harold Kerzner: Project Management: A Systems Approach to Planning, Scheduling, and Controlling. 12th Edition (2022, Wiley)
Simon Cook: Clinical Trials Project Management. 2021, CRC Press

Professional English language II.:

Joanna Gamble: Communicating in the Pharmaceutical Industry. Routledge (2021)

2nd year

Preclinical studies II.:

Laurence L. Brunton (editor): Goodman & Gilman's The pharmacological Basis of Therapeutics. 13th edition. McGraw Hill Medical, 2017. ISBN: 978-1259584732. Árpád Tósaki Ph.D., D.Sc., D.Pharm: Pharmacology and therapy. URL: http://gyogyszertankonyv.med.unideb.hu/files/Pharmacology_and_therapy.pdf

Clinical studies II.:

Clinical trials in human medicines -EMA Guidelines
ICH E6 Good clinical practice - Scientific guideline
The Practical Guide to Clinical Research and Publication1st Edition - August 6, 2021. Imprint: Academic Press, Author: Uzung Yoon, ISBN: 9780128245170
Cook, J. A. (2023). An Introduction to Clinical Trials. Oxford University Press. ISBN: 9780198885238.
Good clinical practice (GCP) inspection procedures EMA guidelines

Drug registration II.:

European Medicines Agency (EMA): Centralised Procedure
European Medicines Agency. (2025). *Applying for Centralised Marketing Authorisation*.
EMA official guidance on the centralised procedure, including application requirements, timelines, and evaluation process.
European Commission: Notice to Applicants, Volume 2A, Chapter 1
European Commission, Directorate-General for Health and Food Safety. (2019). *Notice to Applicants, Volume 2A, Chapter 1: Procedures for Marketing Authorisation*.
Official EU guideline describing the centralised, decentralised, mutual recognition, and national procedures for granting marketing authorisation in the EU.
European Commission: Pharmaceutical Legislation Reform
European Commission. (2025). *Pharmaceutical Legislation Revision – Main Documents and Guidelines*.
Includes the latest legislative proposals, guidelines, and concept papers on pharmaceutical policy, supply, and regulatory science in the EU.

Clinical studies and registration of medical devices:

World Health Organization (WHO):Medical Device Regulations: Global Overview and Guiding Principles
Jonathan S. Kahan: Medical Device Development: Regulation and Law

Food, cosmetics regulatory knowledge:

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down

procedures in matters of food safety
Regulation (EC) No 852/2004 of the european parliament and of the council of 29 April 2004 on the hygiene of foodstuffs
Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006
Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed
REGULATION (EU) 2018/848 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007
REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004
REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 December 2006 on nutrition and health claims made on foods
REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001
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