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Curriculum for the

Master's Programme Pharmaceutical Sciences – Drug Development and Regulatory Affairs

At the Faculty for Chemistry and Pharmacy at the University of Innsbruck
and the Medical University of Innsbruck

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§ 1 Description of the joint study programme

(1) According to §54e of the Universities Act 2002 – UA (referred to as UA hereafter), the Master's Programme is a joint study programme at the Leopold-Franzens-University of Innsbruck (referred to as LFUI hereafter) and the Medical University of Innsbruck (referred to as MUI hereafter).

(2) The Master's Programme is based on a cooperation agreement between the LFUI and the MUI.

§ 2 Allocation of the study programme

Acc. to §54 par. 1 Universities Act, the master's programme is allocated to the group of natural science study programmes.

§ 3 Study objectives and qualification profile

(1) The objectives of this joint master's programme in English are to train experts who understand the processes required for the development of new medicinal products in their entirety and can apply and successfully implement them in their future professional environment.

(2) Graduates receive a professional and scientifically sound education in the field of drug development and the regulations required for this. This includes relevant knowledge of molecular disease processes that can be influenced by medicinal products and the molecular structures that can be used as therapeutics. Graduates have detailed knowledge of the strategies, methods and the theoretical and practical regulatory knowledge required for the preclinical and clinical development and testing of medicinal products for successful market authorisation in Europe. As a result, they are able to independently and successfully plan complex projects within the framework of modern drug development, organise them accordingly, carry them out and accompany them until final market approval. They have the opportunity to further specialise in the field of medicinal products within the framework of application-oriented projects.

(3) Graduates possess professional competences in the following fields in particular:
- pre-clinical drug development
- quality aspects of medicinal products
- clinical testing and development of medicinal products
- good manufacturing practice, good clinical practice, good laboratory practice
- biostatistics and data management
- drug regulation and market authorisation
- pharmacoeconomics, drug monitoring
- gender and diversity in the development and use of medicines

(4) Among other things, the master's programme qualifies students for later successful employment with pharmaceutical companies, drug authorities, clinical testing organisations and for further studies in national and international doctoral programmes.

§ 4 Scope and duration

The master's programme covers 120 ECTS-Credits. This corresponds to a duration of four semesters. One ECTS-Credit corresponds to a workload of 25 hours.

§ 5 Language

The language of instruction in the study programme is English.

§ 6 Admission:

(1) Admission at the LFUI is based on the admission procedure specified in the admission regulations of the LFUI and the MUI. According to §54e par. 4 Universities Act, the students also become members of the MUI upon admission.

(2) The admission to the master's programme requires the completion of a subject-specific bachelor's or diploma programme or a subject-relevant bachelor's programme at a university of applied sciences or another equivalent degree programme at a recognised post-secondary educational institution home or abroad.

(3) The completion of the Bachelor's or Diploma Programmes in Pharmacy, Chemistry or Biology at the LFUI and the completion of the Bachelor's Programme in Molecular Medicine or the Diploma Programme in Human Medicine at the MUI are in any case subject-relevant study programmes.

(4) If equivalence is given in principle with only a few supplements missing for full equivalence, additional courses and examinations corresponding to a maximum of 30 ECTS-Credits may be prescribed for full equivalence, which must be taken by the end of the second semester of the master's programme.

§ 7 Types of courses and maximum number of students per course

(1) Courses without continuous performance assessment:

Lectures (VO) are courses held in lecture format. They introduce the research areas, methods and schools of thought for a given subject. No maximum number of participants.

(2) Courses with continuous performance assessment: maximum number of participants is 10.

1. Practical courses (UE) focus on the practical treatment of concrete scientific tasks within an area.
2. Seminars (SE) provide in-depth treatment of scientific topics through students' presentations and discussion thereof.
3. Lectures with practical elements (VU) focus on the practical treatment of concrete scientific tasks that are discussed during the lecture parts of the course.
4. Practical training courses (PR) provide practical experience with concrete scientific tasks, complementing occupational and academic training.

§ 8 Limited number of places

The number of places for the study programme is limited and is redefined for each academic year by decree of the Rectorates.

The place for courses with a limited number of participants are allocated as follows:

1. Students for whom the study duration would be extended due to the postponement are to be given priority.
2. If criterium no. 1 does not suffice to regulate the admission to the course, then first students who take the course as part of a compulsory module and secondly students for whom this course is part of an elective module are given a place.
3. If the criteria in no. 1 and no. 2 do not suffice to regulate the admission, then the available places are drawn at random.

§ 9 Compulsory and elective modules

(1) The following compulsory modules covering altogether 80 ECTS-Credits are to be passed:

1.	Compulsory Module: Introduction	h	ECTS-Credits	Univ.
a.	**VO From Medical Need to Authorised Drug** Process of agent discovery and drug development; life cycle of a drug (from drug candidate to market access and regulatory aspects); presentation of case studies.	0.5	0.5	LFUI/ MUI
b.	**VO Selected Topics in Fundamentals in Natural Sciences** Two different courses covering 2 semester hours and 3 ECTS-Credits each, as announced in the course catalogue, are to be passed.	4	6	LFUI/ MUI

c.	**SE Aspects of Gender and Diversity in Drug Development and Application** Gender-specific aspects of drug development and application.	0.5	1	LFUI/ MUI
	Total	**5**	**7.5**	
	Learning Outcomes: The students understand what knowledge and skills are required for the process of drug discovery and drug development, including gender-specific aspects and requirements for drug approval. The lectures on scientific topics offer the individual opportunity to expand the required knowledge in selected sub-areas.			
	Prerequisites: none			

2.	**Compulsory Module: Preclinical Research and Development**	**h**	**ECTS-Credits**	**Univ.**
a.	**VO Cellular Signalling Pathways and Physiology of Drug Targets** Biochemistry, physiology and pathophysiology of important cellular signalling pathways	2	4	LFUI/ MUI
b.	**VO Mechanisms of Drug Action** Basic principles of pharmacodynamics and pharmacokinetics, including gender-specific aspects	1	2	LFUI/ MUI
c.	**VO Preclinical Pharmacology** Primary, secondary pharmacodynamics, preclinical animal studies, in vivo and in vitro safety pharmacology, including GLP and gender aspects; model organisms and animal models; animal models; alternatives to animal testing and ethical aspects.	2.5	5	LFUI/ MUI
d.	**UE Preclinical Pharmacology** Analysis and interpretation of preclinical pharmacological data on the basis of concrete examples	3.5	4	LFUI/ MUI
	Total	**9**	**15**	
	Learning Outcomes: The students have knowledge of exemplary signalling pathways with relevant drug targets, understand quantitative and qualitative pharmacodynamic and pharmacokinetic aspects of the effect of therapeutic molecules and their application to preclinical drug development. They have the competence to apply theoretical knowledge for the design of preclinical studies and for the interpretation of preclinical drug data and the skill to work under conditions of Good Laboratory Practice (GLP).			
	Prerequisites: none			

3.	**Compulsory Module: Quality Aspects of Investigational Medicinal Products (IMP)**	**h**	**ECTS-Credits**	**Univ.**
a.	**VO Drug Design, Production and Quality Control of Medicinal Products** Fundamental aspects of pharmaceutical chemistry and pharmaceutical technology, including aspects of drug action, drug optimisation stability and quality control; drug analysis including validation and validation and GLP aspects; structural diversity of drug molecules, Advanced Therapy Medicinal Products, ATMP, vaccines.	4	6	LFUI/ MUI

b.	**UE Drug Analysis and Validation Parameters** Practical exercises on drug analysis and validation parameters using selected analytical methods	1	1.5	LFUI/ MUI
	Total	**5**	**7.5**	
	Learning Outcomes: The students have knowledge of the types of drug molecules and forms, including ATMPs and vaccines and understand the principles of design, formulation, production and quality control of medicinal products.			
	Prerequisites: none			

4.	**Compulsory Module: Clinical Development of Medicinal Products**	**h**	**ECTS-Credits**	**Univ.**
a.	**VO Clinical Development Strategy** Translation of preclinical results into clinical development strategies up to the first application in humans; assessment of medical need; gender-specific aspects	1	1.5	LFUI/ MUI
b.	**VO Regulatory Environment in Europe** Regulations of European (including EMA) and national authorities	1	2	LFUI/ MUI
c.	**VU Good Manufacturing Practice (GMP)** General overview of GMP, students work on practical examples	2	4	LFUI/ MUI
	Total	**4**	**7.5**	
	Learning Outcomes: The students have knowledge of the process of clinical drug development and of the criteria required. They have an in-depth understanding of the regulatory environment for medicinal products in Europe and understand the principles of GMP with a focus on drug development. They are able to understand the framework for the clinical introduction of medicinal products.			
	Prerequisites: successful completion of compulsory modules 1 and 2			

5.	**Compulsory Module: Biostatistics and Data Management**	**h**	**ECTS-Credits**	**Univ.**
a.	**VO Biostatistics** Fundamentals of biostatistics for clinical trials	2	4	LFUI/ MUI
b.	**UE Applied Biostatistics** Practical statistical calculations for clinical trials; statistical analysis plan, data management	2	3.5	LFUI/ MUI
	Total	**4**	**7.5**	
	Learning Outcomes: Students acquire knowledge of the principles of biostatistics as well as the competence to apply them in the context of the drug development process, in particular for statistical planning of clinical trials.			
	Prerequisites: none			

6.	**Compulsory Module: Conducting Clinical Trials**	**h**	**ECTS-Credits**	**Univ.**
a.	**VO Design of Clinical Trials** Principles of clinical trial design, including goals of a development program, strategy for successful drug approval, gender issues	1.5	2.5	LFUI/ MUI

b.	**VO Clinical Aspects of Adverse Drug Reactions** Cell toxicology; drug safety monitoring; safety update reports, safety measures, clinical development freeze, gender issues	1	2	LFUI/ MUI
c.	**SE Investigational Medicinal Product (IMP) - Dossier** Structure and content of documentation on quality, safety, pharmacological and pharmaceutical properties of a new medicinal product	1	1	LFUI/ MUI
d.	**VO Regulation of Clinical Trials, Good Clinical Practice (GCP)** EU regulations and GCP requirements for conducting clinical trials	0.5	1	LFUI/ MUI
e.	**SE Organisational Aspects in Clinical Trials, Protocol for Clinical Trials** Registration of clinical studies, application and implementation of a clinical investigation (CTA), ethics committees, surveillance and standards in implementation	1	1	LFUI/ MUI
	Total	**5**	**7.5**	
	Learning Outcomes: Students will gain knowledge of the main principles of clinical trial design and how trial design can influence the approval process, including drug safety assessment and documentation. They will gain in-depth knowledge of the necessary documents and processes required to initiate and conduct clinical trials, including regulatory filing and the principles of Good Clinical Practice (GCP), and will be able to apply this knowledge independently.			
	Prerequisites: successful completion of compulsory modules 1 and 2			

7.	**Compulsory Module: Matters of Medicines Regulation and Market Approval**	**h**	**ECTS-Credits**	**Univ.**
a.	**VO Market Approval** General requirements, regulations and procedures for marketing authorisation, including regulatory scientific advice	1.5	3	LFUI/ MUI
b.	**VO Pharmaceutical Drug Safety/Pharmacovigilance** Pharmacovigilance obligations after the market authorisation, databases, risk management plan, benefit-risk assessment, pharmacoepidemiology, including gender aspects	0.5	1	LFUI/ MUI
c.	**VO Intellectual Property Rights and Legal Data Protection** Legal fundamentals for the protection of intellectual property, including patent law, trademark law; legal basis of lawful data processing; protection of personal data.	0.5	1	LFUI/ MUI
d.	**VO Market Access, Analysis of Medical Demand, Production and Distribution of Authorised Medicinal Products** Process of market access (including Compassionate Use, Named Patient Programme, Temporary Use Authorisation/Recommendation), principles of medical demand analysis and production and distribution of the medicinal products	1	1.5	LFUI/ MUI
e.	**VU Generics, Biosimilars, Bioequivalence, Legal Aspects** Regulatory, legal and pharmacological aspects of quality assessment of generics and biosimilars	0.5	1	LFUI/ MUI
	Total	**4**	**7.5**	

	Learning Outcomes: The students acquire knowledge about the procedure for applying for market authorization and understand post-market drug safety surveillance, including pharmacovigilance and risk-benefit assessment. They know how to find official scientific advice and how to create a "briefing book". The students understand the principle of market analysis for the medical demand for drugs. They have the necessary skills to independently implement knowledge about the protection of intellectual property, the bioequivalence of medicinal products and data protection in the process of market access.
	Prerequisites: successful completion of compulsory modules 1 and 2

8.	**Compulsory Module: Application for Clinical Trial and Approval**	**h**	**ECTS-Credits**	**Univ.**
a.	**SE Application for Clinical Trials and the Approval of a New Medicinal Product** Interdisciplinary seminar on the preparation of a complete clinical trial application for a new medicinal product and subsequent preparation of an application for medicinal product approval	5	12	LFUI/ MUI
b.	**UE Scientific Advice** Official scientific advice on a drug application or a clinical trial	1	1.5	LFUI/ MUI
c.	**VU Health Technology Assessment (HTA), Pharmaco-economics, Reimbursement Guidelines** Fundamentals of health-technology and pharmaco-economic evaluation of medicinal products, reimbursement by social security funds	1	1.5	LFUI/ MUI
	Total	**7**	**15**	
	Learning Outcomes: Students have the practical skill to file an application for a clinical trial of a medicinal product including the study design. They have the competence to provide regulatory scientific advice for a hypothetical medicinal product application and to create the required documentation for a medicinal product (investigational or for approval) in CTD format. The students acquire the knowledge how to manage data within the application process and have an in-depth understanding of the calculation of quantitative parameters (e.g. cost-benefit parameters).			
	Prerequisites: successful completion of compulsory modules 1 to 7			

9.	**Compulsory Module: Preparation of the Master's Thesis**	**h**	**ECTS-Credits**	**Univ.**
	SE Introduction to Scientific Working Planning and conception of the Master's Thesis project, instructions for writing a formally correct Master's Thesis, preparation of an synopsis of the Master's Thesis and development of a Master's Thesis agreement.	0.5	2.5	LFUI/ MUI
	Total	**0.5**	**2.5**	
	Learning Outcomes: After successfully completing the module, the students are able to write a brief description of the content of the planned Master's Thesis (synopsis), to outline the timeline of their project and to draw up a written Master's Thesis agreement.			
	Prerequisites: successful completion of elective module 1 or 2			

10.	Compulsory Module: Master's Thesis Defence	h	ECTS-Credits	Univ.
	Final oral defence of the Master's Thesis		2.5	LFUI/ MUI
	Total		**2.5**	
	Learning Outcomes: The students are able to reflect on the overall context of the Master's Thesis as part of the master's programme. In doing so, they demonstrate theoretical understanding, methodical foundations and have the ability to impart the results of the Master's Thesis and to present them accordingly.			
	Prerequisites: successful completion of all other compulsory and the required elective modules as well as the Master's Thesis			

(2) One elective module covering altogether 15 ECTS-Credits must be passed:

1.	Elective Module: Practice in Industry	h	ECTS-Credits	Univ.
a.	**Practice** Practice covering 350 working hours to test and apply the acquired knowledge and competences or to orientate oneself about the professional and/or scientific practice and to acquire job-relevant and/or scientific qualification. The practice may also be passed during the lecture-free period, namely in institutions of the pharmaceutical industry or similar institutions. Before starting the practice, it must be approved by the responsible study law authority. The duration, scope and contents of the work performed must be confirmed in writing by the resp. institution. Furthermore, a report must be written as part of the practice.	-	14	LFUI/ MUI
b.	**SE Practice in Industry or Similar Institutions** Summarising and discussing the knowledge and skills acquired during the practice	1	1	LFUI/ MUI
	Total		**15**	
	Learning Outcomes: The students apply knowledge and skills in practice in a professional and/or scientific environment. They have the competence to reflect on and implement the professional knowledge, thinking and action for their professional and/or scientific practice against the background of the professional and/or scientific practice. They know about the conditions of professional and/or scientific practice.			
	Prerequisites: successful completion of compulsory modules 1 - 7			

2.	Elective Module: Specialisation in Medicinal Product Development and Regulating Environment	h	ECTS-Credits	Univ.
	These courses provide students with individual training to deepen the required knowledge in selected fields of knowledge. Courses as announced in the course catalogue from one or more of the following areas: computer-aided approaches for drug discovery, pharmacology, bioanalytics, drug screening, project management, health technology assessment (HTA) and pharmacoeconomics, public health, investigator course or similar training, phytopharmaceuticals drug approval or registration procedures, diagnostics.		15	LFUI/ MUI
	Total		**15**	
	Learning Outcomes: Students have in-depth knowledge of related areas of medicinal product design, medicinal product development and regulatory affairs from authorities, industry or in science.			
	Prerequisites: successful completion of compulsory modules 1-7			

§ 10 Master's Thesis

(1) A Master's Thesis covering 25 ECTS-Credits is to be written. The Master's Thesis is a scientific piece of work which serves to prove the students' ability to autonomously work on a scientific topic using adequate scientific methods in relation to methodology and content.

(2) Before starting the Master's Thesis an synopsis and a Master's Thesis agreement (compulsory module 9) must be handed in at the responsible study law authority of the LFUI for approval. Bases on the synopsis, the study law authority should be able to assess whether the project in the planned form meets the formal, scientific and methodological expectations of a Master's Thesis.

(3) The topic for the Master's Thesis must be related to one of the modules 1 – 8.

(4) Several students may work on one topic if the performance of the individual students can be assessed separately.

§ 11 Examination regulations

(1) Modules are evaluated by module examinations. Module examinations are examinations to proof the knowledge and skills acquired in one module. The respective modules are completed by successful completion of all parts of a module examination.

(2) Courses of modules are evaluated by course examinations. Course examinations are

1. examinations that assess the knowledge and skills covered in an individual course in which course assessment is based on a single examination at the end of the course. The course instructor has to define the method of examination (written and/or oral) as well as the evaluation criteria before the start of the course.
2. examinations for courses with continuous performance assessment, for which course assessment is based on regular written and/or oral contributions by participants. The course instructor has to define and announce the exam method (written and/or oral) and the evaluation criteria before the start of the course.
3. The evaluation of the Elective Module "Practice in Industry" is based on the written report on the practical experience. Positive evaluation reads "participated with success", negative evaluation "participated without success".

(3) The performance of the Module Preparation of the Master's Thesis is assessed by the supervisor based on a synopsis. Positive evaluation reads "successfully completed", negative evaluation "unsuccessfully completed".

(4) The performance of the Module Master's Thesis Defence is evaluated by an oral exam. According to the cooperation agreement of the joint study programme, the Master's Thesis Defence takes place at the LFUI as the admitting university. The examination board has to consist of members of both universities who are appointed in accordance with the study law regulations of the LFUI.

§ 12 Evaluation measures

Regular course evaluations are carried by a person appointed by the steering group in the cooperation agreement in accordance with the guidelines to be applied at the respective university.

§ 13 Academic degree

Graduates of the Master's Programme in **Pharmaceutical Sciences – Drug Development and Regulatory Affairs** will be awarded the academic degree "Master of Science", abbreviated as "MSc".

§ 14 Coming into force

This curriculum comes into force on 1 October 2022.