M. Sc. Industrial Pharmacy

Module Handbook

Version 03

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Heinrich-Heine-University Düsseldorf

Table of Contents

Overview

The Master of Industrial Pharmacy at HHU Duesseldorf is a world-leading program of study in all aspects of pharmaceutical sciences in an industrial environment.

The course utilizes a transdisciplinary approach encompassing a range of perspectives from diverse fields. It integrates them with industry experiences, case studies, real-world projects, and self-directed study, equipping graduates with an understanding of state-of-the-art concepts and basic and advanced scientific technologies to transform research into industrial practice. Work experience/industry practice is an essential component of the course.

This course has been established to merge pharmaceutical and engineering sciences, bringing high-level science into best practices. Graduates will be educated in a way that they will be able to develop and produce innovative and better medicinal products and medical devices for future generations, taking into account the demanding aspects of gender differences, patient-specific needs, poverty-related diseases, and global pharmacoeconomics in aging societies.

Career options

The course prepares students for various emerging careers in the pharmaceutical industry and related areas. Graduates may be employed in drug discovery, pharmaceutical development, production, quality control, quality assurance and management, regulatory affairs, plant and equipment managers in pharmaceutical and chemical industries, and equipment manufacturers. This course provides additional expertise, targeting professionals who ultimately want to lead teams and or organizations at the chief scientific or executive level.

Entry and admission requirements

Applicants must have completed a second state examination in pharmacy or a bachelor's degree in either pharmacy, pharmaceutics, biology, chemistry, or engineering science with a focus on processing technologies or an equivalent or higher qualification.

Details are provided in the “Zugangs- und Zulassungsordnung” (Entry and Admittance Regulation) for the Master of Science course "Industrial Pharmacy”. If academic qualifications are not within these fields, the applicant must provide evidence of prior learning and demonstrated capabilities equal to the requested qualifications.

As admission to the master's program is limited to 40 students per year, an additional selection process and ranking by the grades of the previous study course may be needed.

International students

Visa requirements: International students outside the European Union must enroll full-time and on campus to obtain a student visa to study in Germany. Further information is available from the International Office at Heinrich Heine University.

Course duration and attendance

This course is offered on a two-year, full-time basis.

Course structure

Students must complete 120 credit points (cp) in total, comprising 44 credit points of mandatory core subjects (“C-modules”), at least 24 credit points of optional-compulsory (“O-modules”), additional 22 credit points of optional-compulsory (“O-modules”) or elective modules (“E-modules”) and 30 credit points for the master thesis.

Course program

The master’s program includes five mandatory modules for all students, nine optional compulsory modules, eight elective modules, and the master’s thesis. The program's setup enables pharmacists, natural scientists, and engineers to acquire basic knowledge from different areas and focus on specific areas in the electives. Examples of module schedules based on previously obtained skills are listed in Appendix 1.

Course completion compulsory modules (“C-modules”)

Code	Title		CP
MIP-C01	Pharmaceutical Development		10
MIP-C02	Pharmaceutical Manufacturing		10
MIP-C03	Quality Control		10
MIP-C04	Quality Management		4
MIP-C05	Drug Regulatory Affairs		10
		Total:	**44**
MIP-CT	Master’s Thesis		30

Course completion optional compulsory modules (“O-modules”)

Code	Title	CP
MIP-O01	Drug Discovery	8
MIP-O02	Drug Synthesis	8
MIP-O03	Medicinal Chemistry	8
MIP-O04	Natural Products	8
MIP-O05	Pharmaceutical Biotechnology	8
MIP-O06	Pharmaceutical Engineering	8
MIP-O07	Biopharmaceutics and Pharmacokinetics	6
MIP-O08	Statistics and DoE	8
MIP-O09	Stability Testing	8

a minimum of 24 CP

Course completion elective modules (“E-modules”)

Code	Title	CP
MIP-E01	Regulatory Framework	4
MIP-E02	Process and Plant Design	4
MIP-E03	Medical Devices	2
MIP-E04	Is now MIP-O09	
MIP-E05	Design and Supply of Clinical Studies	2
MIP-E06	Project Management	4
MIP-E07	Intellectual Properties	2
MIP-E08	International Pharma Business	2
MIP-E09	Continuous Manufacturing	2

Module overview

MIP-C01 Pharmaceutical Development (10 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz, JProf. Dr. M. Hacker, Dr. S. Braun Various external lecturers from the pharmaceutical industry e.g. Roche, Nextpharma, Bayer, Ashland, etc.
Assignment	M.Sc. Industrial Pharmacy Compulsory module
Term	Winter semester
Components	Lecture: 2 SWS Seminar: 2 SWS Exercise: 4 SpS
Work load	300 h, thereof 105 h presence and 195 h individual study
Language	English
Entry Requirements	---
Learning targets	• Fundamental understanding of material properties • General knowledge of APIs and the function of excipients • Knowledge of industrial development strategies • Establishment of a Target product profile (TPP) • Practical development of solids, liquids, semi-solids, and parenteral • Knowledge of practical solutions for special populations: pediatric, geriatric and veterinary patients • Good Scientific Practice
Contents	• Physicochemical characterization of APIs: particle size, solubility, intrinsic dissolution, analytical characterization • Particle engineering, milling, amorphisation • Function of pharmaceutical excipients: Preservatives, antioxidants, co-solvents, detergents etc. • Drug dosage forms: Powders, granules, tablets, capsules, liquids, injections, infusions, ointments, eye and nose drops etc. • Characterisation of drug dosage forms • Packaging requirements, materials, methods • Quality by design (QbD) concept, critical quality attributes (CQAs), critical process parameters (CPPs)
Examination	60% of the grade derives from a written exam at the end of the semester 40% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	A. Fahr “Voigt’s Pharmaceutical Technology” (2018), Wiley, Aulton, Taylor “Aulton’s Pharmaceutics”, 5th ed. (2018), Elsevier (both available via university library) Florence, Siepmann “Modern Pharmaceutics Vol. 1 & 2”, 5th ed. (2009), Informa Healthcare Mahler, Borchard, Luessen “Protein Pharmaceuticals: Formulation, Analytics and Delivery”, 1st ed. (2010), Editio Cantor Verlag Qiu, Chen, Zhang, Yu, Mantri “Developing solid oral dosage forms”, 2nd ed. (2017), Academic Press

MIP-C02 Pharmaceutical Manufacturing (10 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. Jörg Breitkreutz, Dr. S. Braun, Dr. S. Klinken Various external lecturers from the pharmaceutical industry e.g. Novartis, Bayer, Merck and others.
Assignment	M.Sc. Industrial Pharmacy Compulsory module
Term	Summer Semester
Components	Lecture: 2 SWS Seminar: 2 SWS Exercise: 4 SpS
Work load	300 h, thereof 120 h presence and 180 h individual study
Language	English
Entry Requirements	Successfully completed MIP-C01 Pharmaceutical Development module.
Learning targets	• Basic understanding of unit operations • Overview about common pharmaceutical manufacturing techniques • Hands on experience in the production of different dosage forms • Understanding of differences between batch and continuous manufacturing • Knowledge about documentation during manufacturing and packaging
Contents	• Principles of batch and continuous manufacturing • Focus on solid dosage forms: granules, pellets, different types of tablets, capsules • Preparation of water with pharmaceutical quality • Liquid and semisolid forms: solutions, emulsions, suspensions, ointments, creams, gels • Sterile product manufacturing, zone concepts • Packaging and labeling • Cleaning validation, data integrity, deviations, change control • Safety • Lean manufacturing, operational excellence • Manufacturing of APIs, crystallization, filtration
Examination	70% of the grade derives from a written exam at the end of the semester 30% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	Fahr, Voigt “Voigt’s Pharmaceutical Technology (2018) Wiley Florence, Siepmann “Modern Pharmaceutics Vol. 1 & 2”, 5th ed. (2009), Informa Healthcare Kleinebudde, Khinast, Rantanen “Continuous Manufacturing of Pharmaceuticals” 1st ed. (2017), Wiley

MIP-C03 Quality Control (10 CP)	
Responsible person	Prof. Dr. Holger Stark
Lecturers	Prof. Dr. H. Stark Various external lecturers from the pharmaceutical industry e.g. Dr. T. Lauterbach (formerly UCB), Dr. R. Bollig (DieCon)
Assignment	M.Sc. Industrial Pharmacy Compulsory module
Term	Summer semester
Components	Lecture: 3 SWS Seminar: 2 SWS Exercise: 3 SpS
Work load	300 h, thereof 101.25 h presence and 198.75 h individual study
Language	English
Entry Requirements	---
Learning targets	• Possibilities and limitations of modern analytical methods with focus on instrumental analytics • Evaluation and optimization of results • Regulation in quality control
Contents	• ISO 9001, ISO/IEC 17025, ISO 15189 • Methods and techniques in instrumental analytics • Probe sampling • Analysis preparation • Measurements • Trouble shouting • EU-GMP Vol 4 Part 1 Chapter 4 and Chapter 6, Annex 15 EU-GMP Vol 4 Part 2
Examination	70% of the grade derives from a written exam at the end of the semester 30% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	EMA - Human medicines: regulatory information (www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/landing/human_medicines_regulatory.jsp&mid=) European Pharmacopoeia (www.edqm.eu/en/european-pharmacopoeia-9th-edition) USP (www.usp.org/global-health/quality-assurance-medical-products) WHO (apps.who.int/medicinedocs/en/d/Jh1813e/) Prichard, Barwick “Quality Assurance in Analytical Chemistry” (2007), Wiley

MIP-C04 Quality Management (4 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz, Dr. S. Braun, Dr. R. Bollig (DieCon)
Assignment	M.Sc. Industrial Pharmacy Compulsory module
Term	Winter semester
Components	Lecture: --- Seminar: 4 SWS Exercise: ---
Work load	120 h, thereof 45 h presence and 75 h individual study
Language	English
Entry Requirements	Successfully completed MIP-C01 Pharmaceutical Development module.
Learning targets	• Use of regulatory sources on which the quality management system (QMS) is based • Understanding of the principles of a pharmaceutical QMS • Use of a pharmaceutical QMS in the industry • Establishment and maintenance of a pharmaceutical QMS • Knowledge of the importance of a pharmaceutical QMS

Contents	• EudraLex Vol 4
	  ○ Chapter 1 - Pharmaceutical Quality System
	  ○ Chapter 7 - Outsourced activities
	  ○ Chapter 9 - Self Inspection
	  ○ Annex 16: Certification by a Qualified Person and Batch Release
	• ICH Q9 Quality Risk Management
	• ICH Q10 Pharmaceutical Quality System
	• The basic structure of a pharmaceutical QMS
	• Structure and use of a GMP matrix
	• Key QMS documents like
	  ○ Site Master File (SMF)
	  ○ Validation Master Plan (VMP)
	  ○ Standard Operating Procedures (SOPs)
	  ○ Corrective Actions and Preventive Actions (CAPA)
	  ○ Change Control
	  ○ Deviations
	• Batch release by a qualified person or quality unit
	• Audits and inspections

Examination	70% of the grade derives from a written exam at the end of the semester 30% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	EudraLex Vol 4 ICH Q9 Quality Risk Management ICH Q10 Pharmaceutical Quality System

MIP-C05 Drug Regulatory Affairs (10 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz Various external lecturers from the pharmaceutical industry e.g.
Assignment	M.Sc. Industrial Pharmacy Compulsory module
Term	Winter semester
Components	Lecture: 2 SWS Seminar: 2 SWS Exercise: 4 SpS
Workload	300 h, thereof 105 h presence and 195 h individual study
Language	English
Entry Requirements	Successfully completed MIP-C01 Pharmaceutical Development module. Knowledge of regulatory framework preferred
Learning targets	• Tasks of drug regulatory affairs manager • Forming a registration strategy • Knowledge about and writing of required documents • Dossier for Marketing Authorization (MA)
Contents	• Definition and responsibilities of drug regulatory affairs • Global authorization of medicines • Common Technical Documents (CTD) • INDs and NDAs • Modules for marketing authorizations • Writing Paediatric Investigation Plans (PIPs) • Writing Investigational Medicinal Product Dossier (IMPD) • Writing Investigator Brochure (IB) • Marketing Authorization (MA) strategies • MA structure, writing and submission • Pharmacovigilance
Examination	70% of the grade derives from a written exam at the end of the semester 30% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	ICH, EMA and FDA guidelines (available by internet)

MIP-CT Master‘s Thesis (30 CP)	
Responsible person	Head of the Examination Committee
Examiners	Various supervisors (see appendix)
Assignment	M.Sc. Industrial Pharmacy Compulsory module
Term	All time
Components	Lecture: --- Seminar: --- Exercise: 35 SpS
Workload	900 h, thereof 600 h presence max. 780 h at the host institution for experimental work of the master thesis
Language	English
Entry Requirements	At least 75 CP from previous MIP modules to start the work. At least 90 CP before the master’s thesis can be submitted.
Learning targets	• Independent scientific work under the guidance of an experienced mentor. Scientific presentation of accomplishments in a written (thesis) and in an oral form (defense).
Contents	• Good scientific practice • Literature research, design of experiments, rational scientific investigations, data evaluation and treatment • Preparation of scientific reports in written and oral form
Examination	75% of the grade is derived from a written thesis 25% of the grade is derived from an oral defense of the thesis
Literature	No specific literature, may vary depending on the chosen topic.

MIP-O01 Drug Discovery: Target and Hit Identification (8 CP)	
Responsible person	Prof. Dr. Matthias Kassack
Lecturers	Prof. Dr. M. Kassack, Dr. Sonja Hinz, Prof. Dr. H. Gohlke (all HHU), Dr. T. Lauterbach (formerly UCB Pharma), Prof. Dr. B. Riedl (Bayer), Dr. H.-G. Lerchen (Vincerx)
Assignment	M.Sc. Industrial Pharmacy Optional compulsory module
Term	Winter semester
Components	Lecture: 1 SWS Seminar: 1 SWS Exercise: 4 SpS
Workload	240 h, thereof 82,5 h presence and 157,5 h individual study
Language	English
Entry Requirements	---
Learning targets	• Understanding the drug discovery process • Knowledge of drug targets, their structure and function • Understanding the process of identification of novel drug targets • Knowledge of the definition and identification of “hits” for drug targets
Contents	• Drug discovery: definitions and objectives. • Classes of drug targets. • Structure, function and biochemistry of drug targets. • Identification and validation of novel drug targets. • Ligands of drug targets: properties and characterization. • Strategies for hit identification. • Methods of biological screening: evaluation of the pharmaco-logical activity of compounds.
Examination	70% of the grade derives from a written exam at the end of the semester 30% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	Wermuth, Aldous, Raboisson, Rognan, “The Practice of Medicinal Chemistry”, 4th ed. (2015), Academic Press

MIP-O02 Drug Synthesis (8 CP)	
Person-in-charge	Prof. Dr. Thomas Kurz
Lecturers	Prof. Dr. T. Kurz, Dr. T. Lauterbach (formerly UCB), Dr. B. Riedl (Bayer)
Assignment	M.Sc. Industrial Pharmacy Optional compulsory module
Term	Winter semester
Components	Lecture: 1 SWS Seminar: 1 SWS Exercise: 4 SpS
Workload	240 h, thereof 82,5 h presence and 157,5 h individual study
Language	English
Entry Requirements	---
Learning targets	• Principles of Drug and API Synthesis • Understanding of reaction mechanism • Knowledge of synthetic strategies, implementation, and analysis
Contents	• Synthesis and applications of heterocycles, prodrugs, bio-isosteres, antibody-drug conjugates, fluorine-containing groups • Protecting groups and functional group activation • Selected reaction mechanism and name reactions • Retrosynthetic analysis • Stereochemistry and its role in drug synthesis • API Synthesis (upscaling, identification of critical steps of the synthetic process, development of synthetic and analytical methods for intermediates and the final API, preparation of API salts) • Preclinical drug development • Analytical methods for structure elucidation and purity determination (HPLC, ^{1}H-, ^{13}C-NMR)
Examination	75% of the grade derives from a written exam at the end of the semester. 25% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	Johnson, Li “The Art of drug synthesis”, Wiley, ISBN: 978-0-471-75215-8 Deutsche Gesetzliche Unfallversicherung, „Working Safely in Laboratories“, 2014, https://publikationen.dguv.de/regelwerk/dguv-informationen/2831/working-safely-in-laboratories?c=117 Schlemmer, Gerhard, „Instrumental analytics“, De Gruyter, 2022, ISBN: 978-3-11-068966-2 Ning, Yong-Cheng, „Interpretation of Ogranic Spectra”, Wiley, 2011, ISBN: 978-0-470-82517-4 The practice of medicinal chemistry 4th Edition, 2015, Editors**:** Camille Wermuth, David Aldous, Pierre Raboisson, Didier Rognan, ISBN: 9780124172050, eBook ISBN: 978012417213

MIP-O03 Medicinal Chemistry: From Hit to Clinical Candidate (8 CP)	
Responsible person	Prof. Dr. Holger Gohlke
Lecturers	Prof. Dr. H. Gohlke (HHU), 2 x scientists from the pharmaceutical industry
Assignment	M.Sc. Industrial Pharmacy Optional compulsory module
Term	Summer semester
Components	Lecture: 1 SWS Seminar: 1 SWS Exercise: 4 SpS
Workload	240 h, thereof 82,5 h presence and 157,5 h individual study
Language	English
Entry Requirements	Successfully completed MIP-O01 Drug Discovery module. 30 seats are offered per year
Learning targets	• Understanding structure-activity relationships and application to API development • Scope and limitations of methods in computer-aided drug design • Understanding pharmacokinetic properties and application of principles in API development
Contents	• Molecular interactions: What constitutes a *binding of small molecule ligands to macromolecular receptors* • *Molecular variations to influence* structure-activity relationships (including bioisosteric replacements, ring and group variations) • Compound properties aside from affinity • Computer-aided drug design: structure- and ligand-based (including target modelling, molecular docking, molecular similarity, affinity prediction, and QSAR models) • Physiological aspects of pharmacokinetic properties • Biotransformations and drug transport • Strategies for improving bioavailability
Examination	70% of the grade derives from a written exam at the end of the semester. 30% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	Wermuth, Aldous, Raboisson, Rognan, “The Practice of Medicinal Chemistry”, 4th ed. (2015), Academic Press Klebe, “Drug Design: Methodology, Concepts, and Mode-of-Action“, 1st ed. (2013), Springer-Verlag Gohlke, “Protein-Ligand Interactions”, 1st ed. (2012), Wiley

MIP-O04 Natural Products (8 CP)	
Responsible person	Prof. Dr. Nicole Teusch
Lecturers	Prof. Dr. N. Teusch Prof. Dr. M. Popp (Bionorica SE) Dr. T. Henkel (Axxam GmbH) Dr. D. Bredenbröker (Dr. Willmar Schwabe GmbH & Co.KG) Dr. M. Wiedmann (Vincerx Pharma GmbH) Dr. O. Kelber (Bayer Consumer Health)
Assignment	M.Sc. Industrial Pharmacy Optional compulsory module
Term	Summer semester
Components	Lecture: 1 SWS Seminar: 1 SWS Exercise: 4 SpS
Work load	240 h, thereof 82,5 h presence and 157,5 h individual study
Language	English
Entry Requirements	Successfully completed MIP-C01 Pharmaceutical Development and MIP-O01 Drug Discovery modules.
Learning targets	• Knowledge and practical application of principles in modern natural product-based drug discovery, including antibody-drug conjugates. • The industry perspective on strategies and challenges for drug discovery, development and market access from nature. • Overview of natural product groups from plants, microorganisms and animals relevant for market drugs. • Knowledge and practical application of principles of isolation, detection, separation and structure elucidation of natural products. • Bioactivity-guided state-of-the-art screening
Contents	• Drug discovery from plants, microbes, and animals. • Rational drug design compared to modern extract-based phytotherapy. • Mammalian tissue culture techniques for mode-of-action studies • Robotic-based compound screening • Chromatography techniques for isolation and purification of active compounds from complex extracts. • Spectroscopic structure elucidation • Pharma industry excursion
Examination	80% of the grade derives from an oral exam at the end of the semester. 20% of the grade derives from scientific documentation and evaluation of experiments.
Literature	Selected peer-reviewed publications from the field

MIP-O05 Pharmaceutical Biotechnology (8 CP)	
Responsible person	Prof. Dr. Rainer Kalscheuer
Lecturers	Prof. Dr. R. Kalscheuer
Assignment	M.Sc. Industrial Pharmacy Optional compulsory module
Term	Winter semester
Components	Lecture: 1 SWS Seminar: 1 SWS Exercise: 4 SpS
Workload	240 h, thereof 82.5 h presence and 157.5 h individual study
Language	English
Entry Requirements	--- (12 seats are offered per year)
Learning targets	• Broad overview of techniques involved in the production of recombinant pharmaceuticals. • Knowledge of basic principles of biopharmaceuticals (vaccines, monoclonal antibodies, engineered T-cells) • Knowledge of and practical application of principles in antibacterial drug discovery • Knowledge of and practical application of principles of molecular approaches in target identification and validation
Contents	• Generation of engineered hosts for recombinant drug production • High-throughput assays for antibacterial drug discovery • Reporter systems for mode-of-action studies • Molecular approaches in target identification • Resistance mechanisms • Cell culture techniques • Monoclonal antibody production and purification Exercise: 2 weeks during the lecture-free time
Examination	80% of the grade derives from an oral exam at the end of the semester. 20% of the grade derives from scientific documentation and evaluation of experiments.
Literature	Crommelin, Sindelar, Meibohm: “Pharmaceutical Biotechnology. Fundamentals and Applications”. 3rd ed. (2007), Springer

MIP-O06 Pharmaceutical Engineering (8 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz Various external lecturers from the pharmaceutical industry e.g. Bayer, L.B. Bohle, etc.
Assignment	M.Sc. Industrial Pharmacy Optional compulsory module
Term	Winter semester
Components	Lecture: 2 SWS Seminar: 3 SWS Exercise: 2 SpS
Workload	240 h, thereof 86.25 h presence and 153.75 h individual study
Language	English
Entry Requirements	Successfully completed MIP-C02 Pharmaceutical Manufacturing module.
Learning targets	• Basic understanding of engineering principles in pharmaceutical production • Fundamental understanding of unit operations • Knowledge of possible options in pharmaceutical process control • Hands on experience in evaluating and understanding different process steps
Contents	• Process design • Scale-up principles • Integrated theoretical and practical learning in continuous manufacturing principles: case study solid dosage forms • Feeders: principles, process variables, feed factors, refill • Blender: fundamentals of powder mixing, mass hold up, residence time distributions, feeder-blender pairing, critical blender variables • Roll compaction: types, process control, critical variables • Dry granulation: types, process control, critical variables • Tableting: compaction equipment, compaction equations • Material characterization: flowability, compressibility, compactibility, tabletability, surface charge, wettability • Process Analytical Technologies (PAT): process data, spectroscopic techniques, other probes, data treatment • Pharmaceutical process control: feed forward and feed backward controllers, design and evaluation of control systems, real-time monitoring, integration of unit operations, flowsheet modeling, implementation of control system and closed-loop operation
Examination	60% of the grade derives from a written exam at the end of the semester 40% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	Hickey, Ganderton “Pharmaceutical Process Engineering” 2nd ed. (2010), Informa Kleinebudde, Khinast, Rantanen “Continuous Manufacturing of Pharmaceuticals” 1st ed. (2017), Wiley Singh, Juan: “Process Systems Engineering for Pharmaceutical Manufacturing” (2018), Elsevier

MIP-O07 Biopharmaceutics & Pharmacokinetics (6 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz (HHU), Dr. M. Herbig (RaDes), Dr. S. Willmann (Bayer)
Assignment	M.Sc. Industrial Pharmacy Optional compulsory module
Term	Summer semester
Components	Lecture: --- Seminar: 2 SWS Exercise: 3 SpS
Workload	180 h, thereof 67.5 h presence and 112.5 h individual study
Language	English
Entry Requirements	---
Learning targets	• Fundamental and applied knowledge of Pharmacokinetics (PK) and drug dissolution methods • Advanced PK modelling and profiling • Knowledge of how to improve drug performance
Contents	• Mathematical PK modelling and profiling • Drug dissolution methods • Mechanisms of drug absorption and excretion • Drug administration sites and permeation pathways • In-vitro permeation models • PK/PD (pharmacokinetics/pharmacodynamics) modelling • Physiology-based PK modelling (PBPK) • Patient-specific PK profiling • Dose optimisation • Bioavailability (BA), relative BA • Bioequivalence (BE), data evaluation • Design and evaluation of BA and BE studies
Examination	80% of the grade derives from a written exam at the end of the semester 20% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	Skriptum Schmidt, Derendorf „Applied Pharmacometrics“, ebook (2014), aapspress / Springer

MIP-O08 Statistics and DoE (8 CP)	
Responsible person	JProf. Dr. Michael Hacker
Lecturers	JProf. Dr. M. Hacker, Dr. S. Klinken
Assignment	M.Sc. Industrial Pharmacy Optional compulsory module
Term	Winter semester
Components	Lecture: --- SWS Seminar: 2 SWS Exercise: 2 SpS
Workload	240 h, thereof 52.5 h presence and 187.5 h individual study
Language	English
Entry Requirements	---
Learning targets	• Understanding of basic statistical principles and of properties of experimental designs • Competence to design and evaluate experiments • Basic understanding of multivariate data analysis • Hands-on experience with open-access software and proprietary software
Contents	• Samples and populations • Statistical hypothesis testing and confidence intervals • Correlation, regression and clustering • Design of experiments (full factorial designs, fractional factorial designs, central composite designs, mixture designs, D-optimal designs) • Basics of multivariate data analysis (PCA, PLS) • Introduction into statistical software: Python and/or RStudio, Modde • Application to real-life problems (exercises)
Examination	50% of the grade derives from a written exam at the end of the semester 50% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	Kronthaler “Data Analysis with RStudio” (2021) Springer Nature Frost “Introduction to Statistics” (2020) Statistics By Jim Publishing Lawson “Design and analysis of experiments with R” (2015) CRC Press Box, Hunter, Hunter “Statistics for Experimenters” 2nd ed. (2005) Wiley

MIP-O09 Stability Testing (8 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz, Dr. B. Fischer, M. Klaßen (IUTA e.V.), C. Nüboldt (Bayer)
Assignment	M.Sc. Industrial Pharmacy Optional compulsory module
Term	Winter semester
Components	Lecture: 0 SWS Seminar: 2 SWS Exercise: 5 SpS
Workload	240 h, thereof 97.5 h presence and 142.5 h individual study
Language	English
Entry Requirements	Successfully completed MIP-C03 Quality Control module
Learning targets	• Identifying reasons for drug substance and drug product instability • How to evaluate drug stability • How to set up an efficient stability program • Regulatory dossier content of stability aspects

Contents	• Regulatory background for stability testing (ICH, EMA, FDA)
	• Long-term, short-term, in-use stability testing
	• Experimental investigations
	  ○ Forced (accelerated) stability testing
	  ○ Forced degradation testing
	  ○ Planning of stability testing
	  ○ Reporting of stability results
	• Data reporting and transfer into official documents

Examination	60% of the grade derives from a written exam at the end of the semester 40% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	ICH, EMA and FDA guidelines (available via Internet) Bajaj, Singh, “Methods for Stability Testing of Pharmaceuticals”, 1st ed. (2018), Humana Press

MIP-E01 Regulatory Framework (4 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz
Assignment	M. Sc. Industrial Pharmacy Elective module
Term	Winter semester
Components	Lecture: 1 SWS Seminar: 2 SWS Exercise: 1 SpS
Workload	120 h, thereof 48.75 h presence and 71.25 h individual study
Language	English
Entry Requirements	---
Learning targets	• Legal background of medicinal products and medical devices for non-pharmacists • Introduction of institutions dealing with medicinal products • Basic drug regulations • Basics of current Good Manufacturing Practice (cGMP) • Regulatory documents
Contents	• Understanding of pharmaceutical approach to manufacture of medicinal products • International drug laws (focus on Europe and USA) • Organisation of competent authorities (EMA, BfArM, PEI, MHRA, EDQM, FDA, WHO etc.) • Basic regulations and requirements Pharmacopoeias: Ph.Eur., DAB, BP, USP • cGMP regulations and related terms • Validation, Qualification, Justification
Examination	50% of the grade derives from a written exam at the end of the semester 50% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	ICH, EMA and FDA guidelines (available by internet) Harrison “Pharmaceutical Regulatory Affairs: An Introduction for Life Scientists”, 1st ed. (2016), Harrison Scientific / Kindle Eckstein „Arzneimittel - Entwicklung und Zulassung: Für Studium und Praxis“, 1st ed. (2016), Deutscher Apotheker Verlag

MIP-E02 Process and Plant Design (4 CP)	
Responsible person	JProf. Dr. Michael Hacker
Lecturers	JProf. Dr. M. Hacker Various external lecturers from the pharmaceutical industry
Assignment	M.Sc. Industrial Pharmacy Elective course
Term	Winter semester
Components	Lecture: --- Seminar: 1 SWS Exercise: 2 SpS
Workload	120 h, thereof 41.25 h presence and 78.75 h individual study
Language	English
Entry Requirements	Successfully completed MIP-C02 Pharmaceutical Manufacturing module.
Learning targets	• Overview of relevant aspects of plant design • Basic knowledge of concepts in process and plant design • Hands-on experience to perform a plant design
Contents	• Process flowsheet modelling • GMP-compliant plant design • Conceptual plant layout • Equipment selection, specification and design • Zoning concepts • Cleaning concepts • Water, steam, gases • HVAC installations • Waste management • Clean room concepts • Qualification • Automation • Logistics • Energy efficiency
Examination	45% of the grade derives from a written exam at the end of the semester 55% of the grade derives from additional tasks during the semester, e.g. presentations, quizzes, or other tasks.
Literature	Qiu, Chen, Zhang, Yu, Mantri “Developing solid oral dosage forms” 2nd ed. (2017), Academic Press Behme “Manufacturing of Pharmaceutical Proteins” (2009), Wiley

MIP-E03 Medical Devices (2 CP)	
Responsible person	JProf Dr. Michael Hacker
Lecturers	JProf Dr. M. Hacker, Dr. S. Braun
Assignment	M.Sc. Industrial Pharmacy Elective module
Term	Summer semester
Components	Lecture: 1 SWS Seminar: 1 SWS Exercise: ---
Workload	60 h, thereof 22.5 h presence and 37.5 h individual study
Language	English
Entry Requirements	---
Learning targets	• Fundamental and applied knowledge of medical devices (Definitions, types, development) • The legal background of medical devices • How to develop medical devices • How to bring medical devices to the market

Contents	• Legal background (focus on Europe)
	• Definition of medical devices (vs drugs, foodstuff etc.)
	• Drug-Device Combinations EMA (Combination Products FDA)
	• Distinguishing medical devices vs medicinal products, foodstuff etc.
	• Development of medical devices vs medicinal products
	• Examples of medical devices for
	  ○ parenteral delivery
	  ○ insulin delivery
	  ○ skin and wound healing
	  ○ fracture management, bone augmentation
	  ○ nasal delivery
	  ○ pulmonary delivery
	  ○ electronic drug delivery

Examination	100% of the grade derives from a written exam at the end of the semester (only pass/fail assessment)
Literature	Amato „ Regulatory Affairs for Biomaterials and Medical Devices”, 1st ed. (2014), Woodham Publishers

MIP-E04 is now **MIP-O09**

MIP-E05 Design and Supply of Clinical Studies (2 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz (HHU) Dr. V. Klingmann (University Childrens‘ Hospital Duesseldorf) Dr. T. Lauterbach (formerly UCB) T. Holzer (Desitin Arzneimittel)
Assignment	M.Sc. Industrial Pharmacy Elective module
Term	Summer semester
Components	Lecture: --- Seminar: 2 SWS Exercise: ---
Work load	60 h, thereof 22.5 h presence and 37.5 h individual study
Language	English
Entry Requirements	---
Learning targets	• Basic knowledge of regulations on clinical studies • How to plan and design a clinical study • Required regulatory documents • Requirements for market authorization application
Contents	• First-in-human, bioavailability/bioequivalence studies, phase II/III studies, post-marketing studies pharmacovigilance Setup and planning of clinical studies Required documents • Responsibilities and Liability • Monitoring • Good Clinical Practice / Good Clinical Laboratory Practice • Producing clinical batches Clinical trial supply Reporting and storage of personal data and clinical results Dossier content • Paediatric Investigation Plan (PIP) Investigational Medicinal Product Dossier (IMPD) Investigator Brochure (IB)
Examination	100% of the grade derives from a written exam at the end of the semester (only pass/fail assessment)
Literature	ICH, EMA and FDA guidelines (available by internet)

MIP-E06 Project Management (4 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz, Dr. S. Braun, Dr. J. Peters (Evonik)
Assignment	M.Sc. Industrial Pharmacy Elective course
Term	Winter semester
Components	Lecture: --- Seminar: 1 SWS Exercise: 2 SpS
Workload	120 h, thereof 41.25 h presence and 78.75 h individual study
Language	English
Entry Requirements	---
Learning targets	• Efficient work organization in the pharmaceutical industry • Project planning • Project management and maintenance • Reporting of project results
Contents	• Basics of project management • Tools for project management • Project structure plan (PSP) • Critical path analysis/network analysis Trend analysis, milestone structures • Roles in a project team • Communication • Stakeholder analysis • Examples from practice • Reporting
Examination	100% of the grade derives from a written exam at the end of the semester (only pass/fail assessment)
Literature	Braun, Grundy “Project management for the pharmaceutical industry”2nd ed. (2011), Gower

MIP-E07 Intellectual Properties (2 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz, Dr. D. Bröcher (Gille Hrabal Patent Attorneys)
Assignment	M.Sc. Industrial Pharmacy Elective module
Term	Winter semester
Components	Lecture: --- Seminar: 2 SWS Exercise: ---
Workload	60 h, thereof 22.5 h presence and 37.5 h individual study
Language	English
Entry Requirements	---
Learning targets	• How to search patent data • How to read a patent • How to write a patent • How to develop a patent strategy
Contents	• IP strategies • International patent regulations • Patent structure and content • Patent language • Alternatives to protection by patents • Examples of pharmaceutical patents and strategies • Patents for blockbusters • Patents for rare diseases • Life-cycle management by patent filing • Patent leaks • Patent defeats and referrals
Examination	100% of the grade derives from a written exam at the end of the semester (only pass/fail assessment)
Literature	Skriptum Aerts “Pharmaceutical Patents”, 1st ed. (2013), Nova Science

MIP-E08 International Pharma Business (2 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturers	Prof. Dr. J. Breitkreutz (HHU) Various external lecturers from the pharmaceutical industry
Assignment	M.Sc. Industrial Pharmacy Elective course
Term	Winter semester
Components	Lecture: --- Seminar: 2 SWS Exercise: ---
Workload	60 h, thereof 22.5 h presence and 37.5 h individual study
Language	English
Entry Requirements	---
Learning targets	• Organisation of Pharmaceutical Industry • Strategic Planning • Basic knowledge of international business skills • Cultural differences / Intercultural training • Human Resources / Job applications for industry
Contents	• Business models for the pharma industry • Strategic planning and business optimization • Life-cyle management • Basic accounting rules • Efficient reporting • Outsourcing in the pharmaceutical industry: view from MA holders and contract manufacturers • International Business Skills • Cultural Differences / Intercultural Training • Human Resources / Job Applications in Industry • Pharma 4.0 • Examples of various company models
Examination	100% of the grade derives from a written exam at the end of the semester (only pass/fail assessment)
Literature	Skriptum

MIP-E09 Continuous Manufacturing (2 CP)	
Responsible person	Prof. Dr. Jörg Breitkreutz
Lecturer	Prof. Dr. J. Breitkreutz, Dr. M. Krumme (Novartis)
Assignment	M.Sc. Industrial Pharmacy Elective module
Term	Winter semester
Components	Lecture: --- Seminar: 2 SWS Exercise: ---
Workload	60 h, thereof 22.5 h presence and 37.5 h individual study
Language	English
Entry Requirements	Successfully completed MIP-C02 Pharmaceutical Manufacturing module.
Learning targets	• Understanding of several exemplary CM unit operations • Meaningful characterization techniques • Critical understanding and interpretation of quality, relevant process management aspects • Process knowledge extraction in multidimensional noisy data scenarios • Similarities/differences between batch and CM processes
Contents	• Overview of continuous chemical unit operations (reactors, workup, crystallization, washing, DS drying) • Coupling techniques and discussion thereof • E2E continuous manufacturing • Alternative (non-OSD) CM technologies • Material diversion strategies • PAT techniques in the field of CM • Advanced process management with special emphasis on continuous pharmaceutical processes • Understanding of process characterization aspects and techniques to manage portfolios of processes in industrial settings • System dynamics of CM process trains and their detection • Regulatory expectations (ICH Q13) and ways to address them • Quality management in CM processes (discretized vs continuous processes)
Examination	100% of the grade derives from a written exam at the end of the semester (only pass/fail assessment)
Literature	Hickey, Ganderton “Pharmaceutical Process Engineering” 2nd ed. (2010), Informa am Ende (Ed.) “Chemical Engineering in the Pharmaceutical Industry: R&D to Manufacturing” (2011,) Wiley Kleinebudde, Khinast, Rantanen “Continuous Manufacturing of Pharmaceuticals” 1st ed. (2017), Wiley Singh, Juan: “Process Systems Engineering for Pharmaceutical Manufacturing” (2018), Elsevier

MIP-CT – Details concerning the Master's Thesis

General Comments

Prerequisites for a Master's Thesis

The master's thesis is the final module (MIP-CT) worth 30 credit points. The requirements for registration of a master's thesis are outlined in the current examination regulations, which are available online1. Students must have at least 75 credit points to register for a thesis. The missing 15 credit points must be accumulated when the master's thesis is prepared. Students can only register for their thesis defense with 90 credit points.

Enrollment

Students must be enrolled in the program for the entire master's thesis period until the day of the final presentation.

Content

In the master's thesis, the student must show that he/she can work independently on a scientific topic related to the M. Sc. Industrial Pharmacy study program over a more extended period (six months). The topic can come from fields related to the modules of the study program. The thesis needs to fulfill the standards of good scientific practice. It does not need to be published, which makes it a perfect candidate for confidential topics of pharmaceutical companies.

Finding a Topic and Selection of a Supervisor(s)

Finding a position to write a Master's Thesis

Students need to be proactive in finding a master's thesis position. In the first step, the student must decide in which field to write a thesis and whether the position should be at the university or in the industry. With its diverse modules, the MSc Industrial Pharmacy study program offers several fields to select from, like development, manufacturing, quality control, quality management, and regulatory affairs.

If the student decides to do the thesis in the industry, he/she needs to search for a position, e.g., by screening the websites of pharmaceutical companies, contacting external speakers, or searching commercial job application databases online. If they want to do their master's thesis at the university, they need to screen the working groups of the institutes and their notes of the modules they took to find an exciting field. The students need to contact the person responsible for the institute or working group to ask whether an open position as a master's thesis student is available.

Whether in the industry or at the university, the student must discuss the thesis's formalities, topic, and content with their contact person.

[1] *https://www.pharmazie.hhu.de/en/studium/master-of-science-industrial-pharmacy/examination-regulation*

Selecting a Supervisor

The first supervisor needs to be selected when there is a positive outcome from the topic and content discussion. In the case of the master's thesis at the university, the person responsible for the institute or working group is mostly the first supervisor (see Annex A). In the case of a master's thesis in the pharmaceutical industry, a first supervisor needs to be found based on the available supervisors (see Annex A) and the field of the thesis. The student needs to schedule a meeting with the industry's contact person and the potential university supervisor to present and discuss the topic. If the industry partner and the supervisor agree that this will be a feasible master's thesis, the student can register for the thesis online.

In the meeting, the first supervisor or the student can also make suggestions for the second supervisor.

The two supervisors need to be chosen and registered from the beginning. Both will grade the thesis independently. The final grade of your thesis will be the average of both examiners' grades. A third supervisor/examiner, appointed by the head of the Examination Board, will be present at the thesis oral defense. This may be an external supervisor (mentor) from the company the student did the thesis with.

Registration of a Master's Thesis

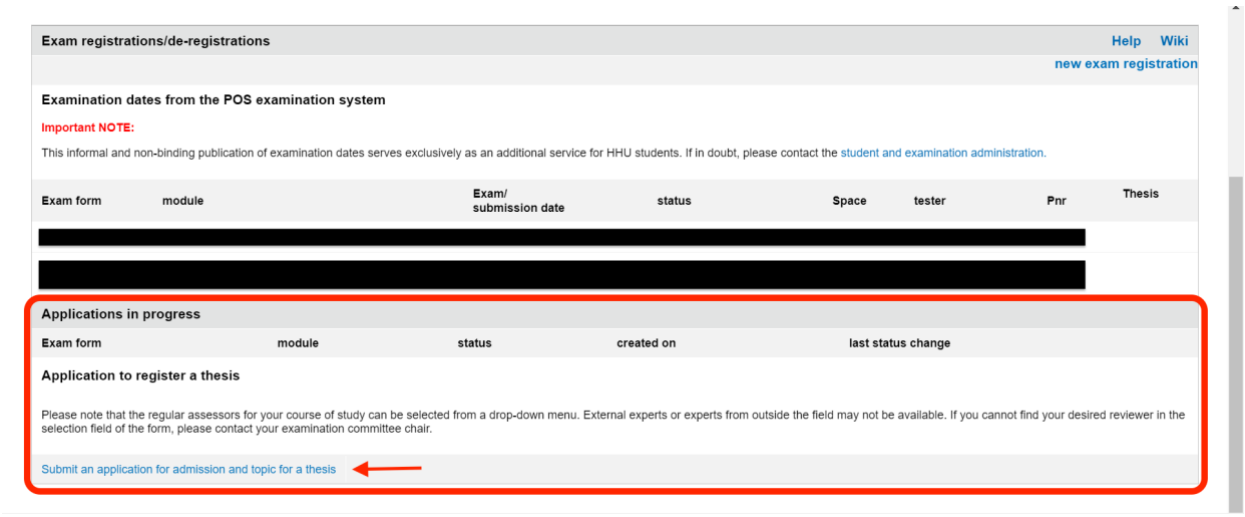
Master's Thesis Permission Form

As soon as the topic and both supervisors are fixed, fill in and sign the "Master's Thesis Permission" form, which you will get on request from the study coordinator. Send the form to the first supervisor and study coordinator (by email).[2] This is not the official registration. The official registration is done via the student portal.

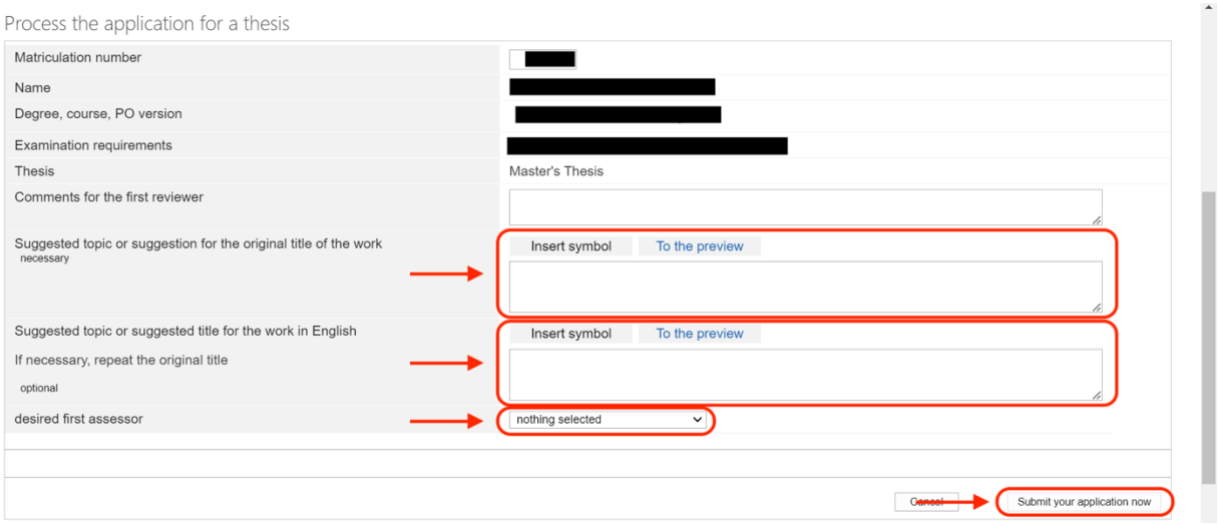
Online Registration via the Student Portal

The student applies for registration in the student portal under the menu item "Examination registration/de-registration" → "Application to register a thesis". See the following screenshot.

[2] *The submission of the document "Master thesis permission" to the first supervisor and to the study coordinator is essential in order to guarantee a smooth registration process.*



The student will be requested to enter a title or a topic and select a first supervisor (see screenshot).



After entering all data, the student submits the application and is reminded that information on the status of the application and the official issue of the topic will be sent by email (check your "@hhu.de" account!).

The application is sent automatically to the first supervisor and the head of the examination board. If accepted, the student will receive a confirmation email (no paper version!).

The processing period of 6 months begins with the sending of the confirmation email.

Submission and Presentation/Defense

Written Master's Thesis

The master module is the final module of the M. Sc. Industrial Pharmacy study program. It is divided into the master's thesis (practical work and written thesis) and the presentation, also called the defense of your thesis or the master seminar. The written thesis accounts for 26 credit points, while the presentation accounts for four.

The master's thesis must be submitted six months after the registration confirmation. This timeframe can only be extended by four weeks due to particular circumstances. Such circumstances include, e.g., a long-term illness (more than four weeks) or a defect of critical infrastructure, like a critically needed piece of equipment. The application for an extension can be filed up to two weeks before the deadline.

The master's thesis must be submitted as a PDF file via the student portal[3]. The first supervisor can request two printed versions in addition to the PDF file.

If the thesis is not uploaded in time, it is considered insufficient, with a grade of 5.0. This counts against your "one failed attempt" limit.

The first and second supervisors will examine the master's thesis within six to eight weeks after submission. One or both examiners can write an examination report and grade the thesis. The final grade of the written thesis is the mean grade of the two. The detailed grading process is described in the examination regulation[4]. A thesis with an external partner, e.g., from a pharmaceutical company, can have a third examiner. This examiner can hand in an examination report but is not part of the grading process. The grade of the written master's thesis will be 75% of the final grade of the thesis.

The written thesis should follow the specifications to conform to §16 (1) Examination Regulations. The two supervisors have the final say.

[3] *https://studierende.uni-duesseldorf.de/*
[4] *https://www.pharmazie.hhu.de/en/studium/master-of-science-industrial-pharmacy/examination-regulation*

Parameter	Specification
Format	PDF to be uploaded to the university platform (additional printed versions only if requested by the supervisors)
Length of the complete thesis	50-70 pages
Font style	Arial
Font size of text body	11
Structure	Title page Acknowledgements Declaration of Authorship Table of Contents Abbreviations Introduction Aim of the thesis Material and Methods Results and Discussion Conclusion References
Declaration of Authorship	Declaration of Authorship I hereby certify that this thesis has been composed by me and is based on my own work, unless stated otherwise. No other person's work has been used without due acknowledgement in this thesis. All references and verbatim extracts have been quoted, and all sources of information, including graphs and data sets, have been specifically acknowledged. Date: Signature:
References	first three author's name followed by et al. (if more than three authors) 'Title', *Journal or official journal abbreviation* (see CASSI), **year of publication**. Volume(*Issue*): page numbers. Example Hyvärinen, A., Oja, E. 'Independent Component Analysis: Algorithms and Applications', *Neural Networks*, **2000**. 13(*4-5*): pp. 411-430.

Presentation of the Thesis

After the examination reports are prepared and the grade is determined, the master's thesis has to be presented. The student must defend the results and interpretation before the first, second, and third examiners. The third examiner can be an external partner who can also discuss the defense's final grade. The defense will make up 25% of the thesis' grade.

The master's thesis presentation can be done in person or online. The student must discuss a date and time with the participating examiners. The duration will be 30 minutes, which are 15 minutes of presentation and 15 minutes of discussion. The presentation grade and the final grade will be announced at the end of the examination. The final grade of the study program will be announced within four weeks via the student portal.

Appendix

Examples of schedules

Pharmacist. The following example shows a typical full-time program for a graduate pharmacist.

Year 1 – Winter Semester		
MIP-C01	Pharmaceutical Development	10 CP
MIP-O01	Drug Discovery	8 CP
MIP-O08	Statistics and DoE	8 CP
MIP-E01	Regulatory Framework	4 CP
	Total:	**30 CP**
Year 1 – Summer Semester		
MIP-C02	Pharmaceutical Manufacturing	10 CP
MIP-C03	Quality Control	10 CP
MIP-O03	Medicinal Chemistry	8 CP
MIP-E05	Design and Supply of Clinical Studies	4 CP
	Total:	**30 CP**
Year 2 – Winter Semester		
MIP-C04	Quality Management	4 CP
MIP-C05	Drug Regulatory Affairs	10 CP
MIP-O06	Pharmaceutical Engineering	8 CP
MIP-E06	Project Management	4 CP
MIP-E07	Intellectual Properties	2 CP
MIP-E08	International Pharma Business	2 CP
	Total:	**30 CP**
Year 2 – Summer Semester		
MIP-CT	Master's Thesis	30 CP
	Total:	**30 CP**
	Overall:	**120 CP**

Engineer. The following example shows a typical full-time program for a graduate engineer.

Year 1 – Winter Semester		
MIP-C01	Pharmaceutical Development	10 CP
MIP-O01	Drug Discovery	8 CP
MIP-O05	Pharmaceutical Biotechnology	8 CP
MIP-E01	Regulatory Framework	4 CP
	Total:	**30 CP**
Year 1 – Summer Semester		
MIP-C02	Pharmaceutical Manufacturing	10 CP
MIP-C03	Quality Control	10 CP
MIP-O07	Biopharmaceutics and Pharmacokinetics	6 CP
MIP-E03	Medical Devices	2 CP
MIP-E05	Design and Supply of Clinical Studies	2 CP
	Total:	**30 CP**
Year 2 – Winter Semester		
MIP-C04	Quality Management	4 CP
MIP-C05	Drug Regulatory Affairs	10 CP
MIP-O02	Drug Synthesis	8 CP
MIP-E02	Process and Plant Design	4 CP
MIP-E07	Intellectual Properties	2 CP
MIP-E09	Continuous Manufacturing	2 CP
	Total:	**30 CP**
Year 2 – Summer Semester		
MIP-CT	Master's Thesis	30 CP
	Total:	**30 CP**
	Overall:	**120 CP**

Chemist. The following example shows a typical full-time program for a graduate chemist.

Year 1 – Winter Semester			
MIP-C01	Pharmaceutical Development		10 CP
MIP-O01	Drug Discovery		8 CP
MIP-O05	Pharmaceutical Biotechnology		8 CP
MIP-E01	Regulatory Framework		4 CP
		Total:	**30 CP**
Year 1 – Summer Semester			
MIP-C02	Pharmaceutical Manufacturing		10 CP
MIP-C03	Quality Control		10 CP
MIP-O03	Medicinal Chemistry		8 CP
MIP-E05	Design and Supply of Clinical Studies		2 CP
		Total:	**30 CP**
Year 2 – Winter Semester			
MIP-C04	Quality Management		4 CP
MIP-C05	Drug Regulatory Affairs		10 CP
MIP-O09	Stability Testing		8 CP
MIP-E02	Process and Plant Design		4 CP
MIP-E07	Intellectual Properties		2 CP
MIP-E09	Continuous Manufacturing		2 CP
		Total:	**30 CP**
Year 2 – Summer Semester			
MIP-CT	Master's Thesis		30 CP
		Total:	**30 CP**
		Overall:	**120 CP**

Biologist. The following example shows a typical full-time program for a graduate biologist.

Year 1 – Winter Semester			
MIP-C01	Pharmaceutical Development		10 CP
MIP-O01	Drug Discovery		8 CP
MIP-O05	Pharmaceutical Biotechnology		8 CP
MIP-E01	Regulatory Framework		4 CP
		Total:	**30 CP**
Year 1 – Summer Semester			
MIP-C02	Pharmaceutical Manufacturing		10 CP
MIP-C03	Quality Control		10 CP
MIP-O04	Natural Products		8 CP
MIP-E05	Design and Supply of Clinical Studies		2 CP
		Total:	**30 CP**
Year 2 – Winter Semester			
MIP-C04	Quality Management		4 CP
MIP-C05	Drug Regulatory Affairs		10 CP
MIP-O02	Drug Synthesis		8 CP
MIP-O09	Statistics and DoE		8 CP
		Total:	**30 CP**
Year 2 – Summer Semester			
MIP-CT	Master's Thesis		30 CP
		Total:	**30 CP**
		Overall:	**120 CP**

List of Supervisors

Tab. 1: Possible first (only Prof and JProf) and second supervisors

Supervisor	Department
Dr. Sebastian Braun	Institute of Pharmaceutics and Biopharmaceutics
Prof. Dr. Jörg Breitkreutz	Institute of Pharmaceutics and Biopharmaceutics
Dr. Björn Fischer	Institute of Pharmaceutics and Biopharmaceutics
Prof. Dr. Holger Gohlke	Institute of Pharmaceutical and Medicinal Chemistry
JProf. Dr. Michael Hacker	Institute of Pharmaceutics and Biopharmaceutics
Prof. Dr. Rainer Kalscheuer	Institute of Pharmaceutical Biology and Biotechnology
Prof. Dr. Matthias Kassack	Institute of Pharmaceutical and Medicinal Chemistry
Dr. Stefan Klinken-Uth	Institute of Pharmaceutics and Biopharmaceutics
Prof. Dr. Thomas Kurz	Institute of Pharmaceutical and Medicinal Chemistry
Prof. Dr. Dr. h.c. Holger Stark	Institute of Pharmaceutical and Medicinal Chemistry
Prof. Dr. Nicole Teusch	Institute of Pharmaceutical Biology and Biotechnology

Document History

Version	Comments	Date
01	Initial preparation and modifications. Last valid version Mar 29, 2023	Mar 29,2023
02	Design changes and addition of a detailed document history MIP-O02 Entry requirements removed MIP-E06 Examination changed to 100% for the written exam and only pass/fail assessment Addition of details regarding the MIP-CT Master's Thesis Change of various responsibilities and lecturers	Sep 24, 2024
03	MIP-O09 Stability Testing Term changed from summer to winter semester and associated examples Name change in supervisor table	Jan 24, 2025