Handbook for Master of Science Course „Industrial Pharmacy“ at the Faculty of Mathematics and Natural Sciences at the Heinrich-Heine-University Düsseldorf

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 to participate in various emerging careers in the pharmaceutical industry and related areas. Graduates may be employed for 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) on 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 study course 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 46 credit points of optional-compulsory (“O-modules”) and 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, eight optional compulsory modules, eight elective modules and the work on the master thesis. The program's setup enables pharmacists, natural scientists and engineers to learn basic knowledge from the different areas and focus on specific areas in the electives.

Course completion compulsory modules ("C-modules")

MIP-C01 Pharmaceutical Development[1]	10 cp
MIP-C02 Pharmaceutical Manufacturing[2]	10 cp
MIP-C03 Quality Control[2]	10 cp
MIP-C04 Quality Management[1]	4 cp
MIP-C05 Drug Regulatory Affairs[1]	10 cp
Total	**44 cp**
MIP-CT Master thesis	**30 cp**

Course completion optional compulsory modules ("O-modules")

MIP-O01 Drug Discovery[1]	8 cp
MIP-O02 Drug Synthesis[1]	8 cp
MIP-O03 Medicinal Chemistry[2]	8 cp
MIP-O04 Natural Products[2]	8 cp
MIP-O05 Pharmaceutical Biotechnology[1]	8 cp
MIP-O06 Pharmaceutical Engineering[1]	8 cp
MIP-O07 Biopharmaceutics & Pharmacokinetics[2]	6 cp
MIP-O08 Statistics and DoE[1]	8 cp
MIP-O09 Stability Testing[2]	8 cp
Optional (O-modules)	**min. 24 cp** (out of 58 cp in total)

Course completion elective modules ("E-modules")

MIP-E01 Regulatory Framework[1]	4 cp
MIP-E02 Process and Plant Design[1]	4 cp
MIP-E03 Medical Devices[2]	2 cp
MIP-E04 is now **MIP-O09**	---
MIP-E05 Design and Supply of Clinical Studies[2]	2 cp
MIP-E06 Project Management[1]	4 cp
MIP-E07 Intellectual Properties[1]	2 cp
MIP-E08 International Pharma Business[2]	2 cp
MIP-E09 Continuous Manufacturing[2]	2 cp

Optional (sum of O- and E-modules)	**min. 46 cp** (out of 88 cp in total)
Total (C-, O-, E-modules and master thesis)	**min. 120 cp**

[1]*Offered every fall/winter semester*
[2]*Offered every spring/summer semester*

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

Year 1

Fall/Winter semester

MIP-C01 Pharmaceutical Development		10 cp
MIP-O01 Drug Discovery		8 cp
MIP-O05 Pharmaceutical Biotechnology		8 cp
MIP-O08 Statistics and DoE		4 cp
	Total:	**30 cp**

Spring/Summer semester

MIP-C02 Pharmaceutical Manufacturing		10 cp
MIP-C03 Quality Control		10 cp
MIP-O09 Stability Testing		8 cp
MIP-E05 Design and Supply of Clinical Studies		2 cp
	Total:	**30 cp**

Year 2

Fall/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**

Spring/Summer semester

MIP-CT Master thesis		**30 cp**
	Overall:	**120 cp**

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

Year 1

Fall/Winter semester

MIP-C01 Pharmaceutical Development		10 cp
MIP-O01 Drug Discovery		8 cp
MIP-O02 Drug Synthesis		8 cp
MIP-E01 Regulatory Framework		4 cp
	Total:	**30 cp**

Spring/Summer semester

MIP-C02 Pharmaceutical Manufacturing		10 cp
MIP-C03 Quality Control		10 cp
MIP-O07 Biopharmaceutics & Pharmacokinetics		6 cp
MIP-E03 Medical Devices		2 cp
MIP-E05 Design and Supply of Clinical Studies		2 cp
	Total:	**30 cp**

Year 2

Fall/Winter semester

MIP-C04 Quality Management		4 cp
MIP-C05 Drug Regulatory Affairs		10 cp
MIP-O05 Pharmaceutical Biotechnology		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**

Spring/Summer semester

MIP-CT Master thesis		**30 cp**
	Overall:	**120 cp**

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

Year 1

Fall/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**

Spring/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

Fall/Winter semester

MIP-C04 Quality Management		4 cp
MIP-C05 Drug Regulatory Affairs		10 cp
MIP-O06 Pharmaceutical Engineering		8 cp
MIP-E02 Process and Plant Design		4 cp
MIP-E07 Intellectual Properties		2 cp
MIP-E08 International Pharma Business		2 cp
	Total:	**30 cp**

Spring/Summer semester

MIP-CT Master thesis		**30 cp**
	Overall:	**120 cp**

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

Year 1

Fall/Winter semester

MIP-C01 Pharmaceutical Development		10 cp
MIP-O01 Drug Discovery		8 cp
MIP-O02 Drug Synthesis		8 cp
MIP-E01 Regulatory Framework		4 cp
	Total:	**30 cp**

Spring/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

Fall/Winter semester

MIP-C04 Quality Management		4 cp
MIP-C05 Drug Regulatory Affairs		10 cp
MIP-O05 Pharmaceutical Biotechnology		8 cp
MIP-O08 Statistics and DoE		4 cp
MIP-E06 Project Management		4 cp
	Total:	**30 cp**

Spring/Summer semester

MIP-CT Master thesis		**30 cp**
	Overall:	**120 cp**

MIP-C01 (winter)	Pharmaceutical Development	Credit points: 10
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz, JProf. Dr. M. Hacker, Prof. A. Seidlitz, Dr. S. Braun (all HHU), various industrial lecturers, e.g. Dr. A. Dischinger, Dr. S. Page, Dr. F. Ditzinger (all Roche), Dr. K. Bart-scher, Dr. V. Pounti, Dr. H.J. Hamann (all NextPharma), Dr. M. Bultmann (Ab-bVie), Dr. W. Hoheisel (Invite), Dr. S. Dr. G. Hebbink (DFE Pharma), Dr. F. Hofmann (Evonik), Dr. C. Mühlenfeld (Ashland)	
Assignment	M.Sc. Industrial Pharmacy Compulsory course	
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	
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) • Contemporary work: QTTP set-up (group of 2 students)	
Examination	a) Oral presentation on specific drug project (20%) b) Written examination at the end of the semester (80%)	
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 (summer)	Pharmaceutical Manufacturing	Credit points: 10
Person-in-charge	Prof. Dr. Peter Kleinebudde	
Lecturers	Prof. Dr. P. Kleinebudde Various industrial lecturers, e.g. Dr. C. Bothe, Dr. C. Graneis, Dr. A. Hertrampf, Dr. S. Holzschuh, Dr. K. Hückstädt, Dr. M. Krumme, Dr. V. Pauli, Dr. O. Reer, Dr. F. Röder, Dr. B. Roessler, Dr. T. Struller, Dr. D. Wothe, Dr. F. Wetterich	
Assignment	M.Sc. Industrial Pharmacy Compulsory course	
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	
Requirements	Successful completed module MIP-C01 (10 CP) for participation in the course MIP-C02 and examination MIP-C02.	
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	a) Oral examination of project progress (20 %) b) Written tasks (20 %) c) Written examination at the end of the semester (60 %)	
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 (summer)	**Quality Control**	**Credit points: 10**
Person-in-charge	Prof. Dr. Holger Stark	
Lecturers	Prof. Dr. H. Stark, various industry lecturers, e.g. Dr. T. Lauterbach (formerly UCB), Dr. R. Bollig (Neuraxpharm),	
Assignment	M.Sc. Industrial Pharmacy Compulsory course	
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	
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	a) Oral and written seminar work-out (30 %) b) Written examination at the end of the module (70 %)	
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 (winter)	**Quality Management**	**Credit points: 4**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz, Dr. T. Knaab, Dr. S. Braun (all HHU), Dr. R. Bollig (Neuraxpharm)	
Assignment	M.Sc. Industrial Pharmacy Compulsory course	
Components	Lecture: ---- Seminar: 4 SWS Exercise: ---	
Work load	120 h, thereof 45 h presence and 75 h individual study	
Language	English	
Requirements	Successfully completed module MIP-C01 for participation in the course and the examination of MIP-C04.	
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 Preparation and use of several 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 An example of an organisational structure of a quality management unit	
Examination	a) Written quality documents and oral seminar work-out (30%) b) Written examination at the end of the semester (70%)	
Literature	EudraLex Vol 4 ICH Q9 Quality Risk Management ICH Q10 Pharmaceutical Quality System	

MIP-C05 (winter)	**Drug Regulatory Affairs**	**Credit points: 10**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz, Dr. T. Knaab (both HHU), various industrial lecturers, e.g. Dr. A. Baumann (NextPharma), Dr. E. Yildir (AdhexPharma)	
Assignment	M.Sc. Industrial Pharmacy Compulsory course	
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	
Requirements	Successfully completed module MIP-C01 (10 CP) for participation in the course MIP-C05 and examination MIP-C05. 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 Individual project on writing a regulatory document	
Examination	a) Written regulatory document (40%) b) Written examination at the end of the semester (60%)	
Literature	ICH, EMA and FDA guidelines (available by internet)	

MIP-CT (all time)	**Master Thesis**	**Credit points: 30**
Person-in-charge	Head of audit committee	
Examiners	Prof. Dr. J. Breitkreutz, Prof. Dr. H. Gohlke, JProf. Dr. M. Hacker, Kalscheuer, Prof. Dr. M. Kassack, Prof. Dr. Dr. h.c. P. Kleinebudde, Prof. Dr. T. Kurz, Prof. Dr. C. Passreiter, Prof. Dr. A. Seidlitz, Prof. Dr. Dr. h.c. H. Stark, Prof. Dr. N. Teusch	
Assignment	M.Sc. Industrial Pharmacy Compulsory course	
Components	Lecture: --- Seminar: --- Exercise: 35 SpS	
Work load	900 h, thereof 600 h presence max. 780 h at the host institution for experimental work of the master thesis	
Language	English	
Requirements	At least 75 credit points from previous MIP courses	
Learning targets	Independent scientific work under the guidance of an experienced host. 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	a) Written thesis, evaluation by 2 reviewers (75 %) b) Oral defense, evaluation by 3 reviewers, max. 30 min incl. 15 min presentation (25 %)	
Literature	No specific literature, may vary depending on the chosen topic.	

MIP-O01 (winter)	**Drug Discovery: Target and Hit Identification**	**Credit points: 8**
Person-in-charge	Prof. Dr. Matthias Kassack	
Lecturers	Prof. Dr. M. Kassack, Dr. S. Brands, Dr. A. Hamacher, Prof. Dr. H. Gohlke (all HHU), Dr. T. Lauterbach (formerly UCB),Prof. Dr. B. Riedl (Bayer), Dr. H.-G. Lerchen (Vincerx)	
Assignment	M.Sc. Industrial Pharmacy Optional compulsory course	
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	
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	a) Written examination (70%) b) Oral seminar work-out (written version, presentation and discussion) (30%)	
Literature	Wermuth, Aldous, Raboisson, Rognan, “The Practice of Medicinal Chemistry”, 4th ed. (2015), Academic Press	

MIP-O02 (winter)	**Drug Synthesis**	**Credit points: 8**
Person-in-charge	Prof. Dr. Thomas Kurz	
Lecturers	Prof. Dr. T. Kurz, Prof. Dr. M. Pein-Hackelbusch (TH OWL), Dr. T. Lauterbach (formerly UCB), Dr. B. Riedl (Bayer) Dr. H.-G. Lerchen (Vincerx), Dr. L. Spanier (Aesica)	
Assignment	M.Sc. Industrial Pharmacy Optional compulsory course	
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	
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)	
Examination	a) Oral seminar work-out (written version, presentation, and discussion (25%) b) Written examination (75%)	
Literature	Johnson, Li “The Art of drug synthesis”, Wiley, ISBN: 978-0-471-75215-8 Joules, Mills “Heterocyclic Chemistry”, 5th ed. Wiley, ISBN: 978-1-405-13300-5 Brown “Bioisosteres in Medicinal Chemistry”, 2012, Wiley, ISBN: 978-3-527-33015-7, Vol 54	

MIP-O03 (summer)	**Medicinal Chemistry: From Hit to Clinical Candidate**	**Credit points: 8**
Person-in-charge	Prof. Dr. Holger Gohlke	
Lecturers	Prof. Dr. H. Gohlke (HHU), 2 x scientists from the pharmaceutical industry	
Assignment	M.Sc. Industrial Pharmacy Optional compulsory course	
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	
Requirements / Note	Successfully completed module MIP-O01 for participation in the course and examination of MIP-O03. 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 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 modeling, molecular docking, molecular similarity, affinity prediction, and QSAR models) Physiological aspects of pharmacokinetic properties Biotransformations and drug transport Strategies for improving bioavailability	
Examination	a) Written or oral examination at the end of the semester (70%) b) Oral presentation during the seminar (30%)	
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 (summer)	**Natural Products**	**Credit points: 8**
Person-in-charge	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 course	
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	
Requirements	Successfully completed modules MIP-C01 and O01 for participation in the course and examination of MIP-O04.	
Learning targets	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	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	a) Oral examination (80%) b) Written scientific documentation and evaluation of experiments (20%)	
Literature	Selected peer-reviewed publications from the field	

MIP-O05 (winter)	**Pharmaceutical Biotechnology**	**Credit points: 8**
Person-in-charge	Prof. Dr. R. Kalscheuer	
Lecturers	Prof. Dr. R. Kalscheuer	
Assignment	M.Sc. Industrial Pharmacy Optional compulsory course	
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	
Requirements / Note	--- 9 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 lecture-free time	
Examination	a) Oral examination (80%) b) Written scientific documentation and evaluation of experiments (20%)	
Literature	Crommelin, Sindelar, Meibohm: “Pharmaceutical Biotechnology. Fundamentals and Applications”. 3rd ed. (2007), Springer	

MIP-O06 (winter)	**Pharmaceutical Engineering**	**Credit points: 8**
Person-in-charge	Prof. Dr. Peter Kleinebudde	
Lecturers	Prof. Dr. Dr. h.c. P. Kleinebudde (HHU), Dr. J. Quodbach (Utrecht University), A. Altmeyer (L.B. Bohle), Dr. H. Gieseler (Gilyos), Dr. Butt (Retsch), Dr. S. Dohrn (Abbvie), Dr. C.-H. Coulon (Invite), C. Nüboldt, Dr. R Sivanesapillai, Dr. R. Sibanc, Dr. J. Maggioni (all Bayer)	
Assignment	M.Sc. Industrial Pharmacy Optional compulsory course	
Components	Lecture: 2 SWS Seminar: 3 SWS Exercise: 2 SpS	
Work load	240 h, thereof 86.25 h presence and 153.75 h individual study	
Language	English	
Requirements	Successfully completed module MIP-C02 (10 CP) for participation in the course MIP-O06 and examination MIP-O06.	
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 The theoretical parts are combined with exercises in groups.	
Examination	a) Successful participation in exercises (40%) b) Written examination at the end of the module (60%)	
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 (summer)	**Biopharmaceutics & Pharmacokinetics**	**Credit points: 6**
Person-in-charge	Prof. Dr. Anne Seidlitz	
Lecturers	Prof. Dr. A. Seidlitz (HHU), Dr. M. Herbig (RaDes), Dr. S. Willmann (Bayer)	
Assignment	M.Sc. Industrial Pharmacy Optional compulsory course	
Components	Lecture: -- Seminar: Biopharmaceutics & Pharmacokinetics 2 SWS Exercise: Biopharmaceutics & Pharmacokinetics 3 SpS	
Work load	180 h, thereof 67.5 h presence and 112.5 h individual study	
Language	English	
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	a) Written examination at the end of the semester (80%) b) Excercises (20%)	
Literature	Skriptum Schmidt, Derendorf „Applied Pharmacometrics“, ebook (2014), aapspress / Springer	

MIP-O08 (winter)	**Statistics and DoE**	**Credit points: 8**
Person-in-charge	Prof. Dr. Peter Kleinebudde	
Lecturers	Prof. Dr. Dr. h.c. P. Kleinebudde, S. Klinken (both HHU)	
Assignment	M.Sc. Industrial Pharmacy Optional compulsory course	
Components	Lecture: --- SWS Seminar: 2 SWS Exercise: 2 SpS	
Work load	240 h, thereof 52.5 h presence and 187.5 h individual study	
Language	English	
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	a) Success in solving exercises (50%) b) Written examination at the end of the module (50%)	
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 (summer)	**Stability Testing**	**Credit points: 8**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz, Dr. S. Braun, Dr. T. Knaab (all HHU), C. Nüboldt (Bayer)	
Assignment	M.Sc. Industrial Pharmacy Optional compuslory course	
Components	Lecture: 0 SWS Seminar: 2 SWS Exercise: 5 SpS	
Work load	240 h, thereof 97.5 h presence and 142.5 h individual study	
Language	English	
Requirements	--	
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	a) Written and oral presentation of semester task (stability study) (50%) b) Written examination at end of semester (50%)	
Literature	ICH, EMA and FDA guidelines (available via internet) Bajaj, Singh, “Methods for Stability Testing of Pharmaceuticals”, 1st ed. (2018), Humana Press	

MIP-E01 (winter)	**Regulatory Framework**	**Credit points: 4**
Person-in-charge	Prof. Dr. Anne Seidlitz	
Lecturers	Prof. Dr. A. Seidlitz (HHU)	
Assignment	M. Sc. Industrial Pharmacy Elective course	
Components	Lecture: 1 SWS Seminar: 2 SWS Exercise: 1 SpS	
Work load	120 h, thereof 48.75 h presence and 71.25 h individual study	
Language	English	
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	a) Written examination at the end of the semester (50%) b) Exercises / Presentations (50%)	
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 (winter)	**Process and Plant Design**	**Credit points: 4**
Person-in-charge	JProf. Dr. Michael Hacker (HHU)	
Lecturers	JProf. Dr. M. Hacker (HHU) various lecturers from industry	
Assignment	M.Sc. Industrial Pharmacy Elective course	
Components	Lecture: -- SWS Seminar: 1 SWS Exercise: 2 SpS	
Work load	120 h, thereof 41.25 h presence and 78.75 h individual study	
Language	English	
Requirements	Successfully completed module MIP-C02 (10 CP) for participation in the course MIP-E02 and examination MIP-E02.	
Learning targets	• Overview of relevant aspects in plant design • Basic knowledge of concepts in process and plant design • Hands-on experience to perform a plant design	
Contents	• Process flowsheet modeling • 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 Group work in exercises on case studies: the concept of a production plant or development facility for defined products	
Examination	a) Individual and group exercises and presentations (55%) b) Written examination at the end of the module (45%)	
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 (summer)	**Medical Devices**	**Credit points: 2**
Person-in-charge	JProf Dr. Michael Hacker	
Lecturers	JProf Dr. M. Hacker, Dr. S. Braun (both HHU)	
Assignment	M.Sc. Industrial Pharmacy Elective course	
Components	Lecture: 1 SWS Seminar: 1 SWS Exercise: -- SpS	
Work load	60 h, thereof 22.5 h presence and 37.5 h individual study	
Language	English	
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 drug, food stuff etc.) Drug-Device Combinations EMA (Combination Products FDA) Distinguishing medical devices vs medicinal products, food stuff 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	Written examination at the end of the course (no quantitative assessment; pass/not-passed grading)	
Literature	Amato „ Regulatory Affairs for Biomaterials and Medical Devices", 1st ed. (2014), Woodham Publishers	

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

MIP-E05 (summer)	**Design and Supply of Clinical Studies**	**Credit points: 2**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz (HHU) Dr. V. Klingmann (University Childrens' Hospital Duesseldorf) Dr. T. Lauterbach (formerly UCB) Dr. J. Abrantes (Roche)	
Assignment	M.Sc. Industrial Pharmacy Elective course	
Components	Lecture: --- SWS Seminar: 2 SWS Exercise: --- SpS	
Work load	60 h, thereof 22.5 h presence and 37.5 h individual study	
Language	English	
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	Written examination at the end of the semester (no quantitative assessment; passed or non-passed)	
Literature	ICH, EMA and FDA guidelines (available by internet)	

MIP-E06 (winter)	Project Management	Credit points: 4
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz, Dr. T. Knaab (both HHU) Dr. M. Elek (Takeda), Dr. J. Peters (Evonik)	
Assignment	M.Sc. Industrial Pharmacy Elective course	
Components	Lecture: --- SWS Seminar: 1 SWS Exercise: 2 SpS	
Work load	120 h, thereof 41.25 h presence and 78.75 h individual study	
Language	English	
Requirements	---	
Learning targets	Efficient work organization in the pharmaceutical industry Project planning Project management and maintenance Reporting of project results	
Contents	Departments and responsibilities in the pharmaceutical industry Basics of project management Tools for project management - Project structure plan (PSP) - Critical path analysis/network analysis - Trend analysis, milestone structures - Lean project management - Fishbone (Ishikawa) and Wishbone diagrams - others Examples from practice Reporting	
Examination	a) Exercises (50%) b) Written examination (50%)	
Literature	Braun, Grundy “Project management for the pharmaceutical industry”2nd ed. (2011), Gower	

MIP-E07 (winter)	**Intellectual Properties**	**Credit points: 2**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz (HHU) Dr. D. Bröcher (Gille Hrabal Patent Attorneys)	
Assignment	M.Sc. Industrial Pharmacy Elective course	
Components	Lecture: --- SWS Seminar: 2 SWS Exercise: --- SpS	
Work load	60 h, thereof 22.5 h presence and 37.5 h individual study	
Language	English	
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	Written examination at the end of the course (no quantitative assessment; passed or non-passed)	
Literature	Skriptum Aerts “Pharmaceutical Patents”, 1st ed. (2013), Nova Science	

MIP-E08 (winter)	**International Pharma Business**	**Credit points: 2**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz (HHU) M. Inoue (Meiji Univ., Tokyo), Y. Miyazaki (Ono Pharmaceuticals) Dr. K. Bartscher (NextPharma), X. Jiang (CosSciMed Bejing)	
Assignment	M.Sc. Industrial Pharmacy Elective course	
Components	Lecture: --- SWS Seminar: 2 SWS Exercise: --- SpS	
Work load	60 h, thereof 22.5 h presence and 37.5 h individual study	
Language	English	
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	Written examination at the end of the course (no quantitative assessment; passed or non-passed)	
Literature	Skriptum	

MIP-E09 (winter)	Continuous Manufacturing	Credit points: 2
Person-in-charge	Prof. Dr. Peter Kleinebudde	
Lecturer	Dr. M. Krumme (Novartis)	
Assignment	M.Sc. Industrial Pharmacy Elective course	
Components	Lecture: --- SWS Seminar: 2 SWS Exercise: --- SpS	
Work load	60 h, thereof 22.5 h presence and 37.5 h individual study	
Language	English	
Requirements	Should be booked together with MIP-O06 Pharmaceutical Engineering	
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	Written examination at the end of the semester (no quantitative assessment; passed or non-passed)	
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	