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 is a world-leading program of study in all aspects of pharmaceutical sciences in an industrial environment.

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

Career options

The course prepares students to participate in a variety of emerging careers in 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 both pharmaceutical and chemical industry and equipment manufacturers. This course provides an additional level of expertise, targeting professionals who have the desire to ultimately lead teams and organizations at the chief scientific or chief executive level.

Entry and admission requirements

Applicants must have completed 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.

As the admission to the master study course is limited to 40 students per year, an additional selection process may be needed.

International students

Visa requirements: To obtain a student visa to study in Germany, international students outside the European Union must enroll full time and on campus. Further information are available by 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-courses”), at least 46 credit points of optional compulsory modules (“O-courses”) and electives (“E-courses”) and 30 credit points for the master thesis.

Course program

The master program includes 5 mandatory courses for all students, 8 optional compulsory modules, 8 elective modules and the work on the master thesis. The set-up of the program enables pharmacists, natural scientists and engineers to catch up basic knowledge from the different areas and to focus on specific areas in the electives.

Course completion compulsory modules ("C-courses")

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

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

MIP-O01 Drug Discovery	8 cp
MIP-O02 Drug Synthesis	8 cp
MIP-O03 Medicinal Chemistry	8 cp
MIP-O04 Natural Products	8 cp
MIP-O05 Pharmaceutical Biotechnology	8 cp
MIP-O06 Pharmaceutical Engineering	8 cp
MIP-O07 Biopharmaceutics & Pharmacokinetics	6 cp
MIP-O08 Statistics and DoE	4 cp
Optional (O-courses)	**min. 24 cp** (out of 58 cp in total)

Course completion elective modules (“E-courses”)

MIP-E01 Regulatory Framework	4 cp
MIP-E02 Process and Plant Design	4 cp
MIP-E03 Medical Devices	2 cp
MIP-E04 Stability Testing	8 cp
MIP-E05 Design and Supply of Clinical Studies	2 cp
MIP-E06 Project Management	4 cp
MIP-E07 Intellectual Properties	2 cp
MIP-E08 International Pharma Business	2 cp

Optional (sum of O- and E-courses)	**min. 46 cp** (out of 86 cp in total)

Total (C-, O-, E-courses and master thesis)	**min. 120 cp**

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

Year 1

Autumn 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 semester

MIP-C02 Pharmaceutical Manufacturing		10 cp
MIP-C03 Quality Control		10 cp
MIP-E04 Stability Testing		8 cp
MIP-E05 Design and Supply of Clinical Studies		2 cp
	Total:	**30 cp**

Year 2

Autumn 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 semester

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

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

Year 1

Autumn 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 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

Autumn 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-E08 International Pharma Business		2 cp
	Total:	**30 cp**

Spring semester

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

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

Year 1

Autumn 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 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

Autumn 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 semester

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

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

Year 1

Autumn 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 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

Autumn 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 semester

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

MIP-C01	Pharmaceutical Development	Credit points: 10
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz n.n. (Junior Professor), Prof. Dr. O. Kayser (TU Dortmund) H. Ponsar, A. Wilms, Dr. W. Hoheisel (all DDIC), M. Müller (Invite), Dr. K. Bartscher (NextPharma) Dr. S. Page, Dr. A. Dischinger, Dr. A. Szepes (all Roche) Dr. H.J. Hamann, Dr. A. Breitenbach, Dr. B. Skalsky, Dr. K. Manhardt (both Evonik), Dr. C. Mühlenfeld (Ashland), Dr. K. Wening (Grünenthal), Dr. E. Janssen (DFE Pharma)	
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 function of excipients • Knowledge of industrial development strategies • Establishment of a Target product profile (TPP) • Practical development of solids, liquids, semi-solids, parenterals • Knowledge of practical solutions for special populations: paediatric, geriatric and veterinary patients	
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) • Practical work: specific drug project (group of 2 students)	
Examination	a) Oral presentation on specific drug project (20%) b) Written examination at the end of the semester (80%)	
Literature	Aulton, Taylor “Aulton’s Pharmaceutics”, 5th ed. (2018), Elsevier 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**	**Credit points: 10**
Person-in-charge	Prof. Dr. Peter Kleinebudde	
Lecturers	Prof. Dr. P. Kleinebudde Dr. A. Schweiger, A. Wilms, S. Pohl (all DDIC)	
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	Successfull 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 • Solid dosage forms: granules, pellets, different types of tablets, capsules • Liquid and semisolid forms: solutions, emulsions, suspensions, ointments, creams, gels • Drug delivery systems: e.g. liposomes, aerosols, micro- and nanoparticles, transdermal patches, controlled release dosage forms • Sterile product manufacturing • Production of Biopharmaceuticals • Packaging and labeling	
Examination	a) Oral examination on project progress (20%) b) Written examination at the end of the semester (80%)	
Literature	Kleinebudde, Khinast, Rantanen “Continuous Manufacturing of Pharmaceuticals” 1st ed. (2017), Wiley Florence, Siepmann “Modern Pharmaceutics Vol. 1 & 2”, 5th ed. (2009), Informa Healthcare	

MIP-C03	**Quality Control**	**Credit points: 10**
Person-in-charge	Prof. Dr. Holger Stark	
Lecturers	Prof. Dr. H. Stark Prof. Dr. T. Kurz Dr. T. Lauterbach (former UCB)	
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	
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	**Quality Management**	**Credit points: 4**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz Dr. T. Knaab Dr. P. Hasemann, Dr. K. Bartscher (both NextPharma)	
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	Successfull completed module MIP-C01 (10 CP) for participation in the course MIP-C04 and examination MIP-C04.	
Learning targets	How to establish and maintain a Quality Management System (QMS) Plant Master File (PMF) Master Plans: Validation Plan, Hygienic Master Plan etc. Standard Operating Procedures (SOPs) Manufacturing and Packaging Instructions Change Control	
Contents	ICH Q10 Quality assurance and Quality control Structure of QMS Data documentation and management Content and structure of PMF Structure and writing of SOPs Structure and writing of Manufacturing and Packaging Instructions Strategies for change control Continuous lifecycle improvement Batch control vs. process-analytical technologies Quality metrics Individual project on writing a quality document	
Examination	a) Written quality document (30%) b) Written examination at the end of the semester (70%)	
Literature	FDA Guidance for industry “Q10 Pharmaceutical quality system” WHO “Quality assurance of pharmaceuticals” EMA guidelines (available by internet)	

MIP-C05	**Drug Regulatory Affairs**	**Credit points: 10**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz Dr. T. Knaab, Sr. R. Wiedey M. Müller (Invite), H. Ponsar, J. Rahman (both DDIC) I. Bonnamour, A. Wischermann (both NextPharma)	
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	Successfull completed module MIP-C01 (10 CP) for participation in the course MIP-C05 and examination MIP-C05. Knowledge of regulatory framework	
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 (30%) b) Written examination at the end of the semester (70%)	
Literature	ICH, EMA and FDA guidelines (available by internet)	

MIP-CT	**Master Thesis**	**Credit points: 30**
Person-in-charge	Head of audit committee	
Lecturers	Prof. Dr. J. Breitkreutz, Prof. Dr. H. Gohlke, Prof. Dr. R. Kalscheuer, Prof. Dr. M. Kassack, Prof. Dr. P. Kleinebudde, Prof. Dr. T. Kurz, Prof. Dr. C. Passreiter, Prof. Dr. H. Stark, n.n. (Junior Professor)	
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 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	Drug Discovery: Target and Hit Identification	Credit points: 8
Person-in-charge	Prof. Dr. Matthias Kassack	
Lecturers	Prof. Dr. M. Kassack Prof. Dr. H. Gohlke, Dr. A. Hamacher Dr. T. Lauterbach (formerly UCB) Dr. Mück, Dr. A. Riedl (Bayer)	
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 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	Written examination (70% of final grade) Written scientific protocols and evaluation of experiments (30% of final grade)	
Literature	Wermuth, Aldous, Raboisson, Rognan, “The Practice of Medicinal Chemistry”, 4th ed. (2015), Academic Press	

MIP-O02	Drug Synthesis	Credit points: 8
Person-in-charge	Prof. Dr. Thomas Kurz	
Lecturers	Prof. Dr. T. Kurz Prof. Dr. H. Stark Prof. Dr. H. Gohlke Dr. Héctor Torres-Gómez, Dr. Thomas Lauterbach, Dr. Bernd Riedl, Dr. Hans-Georg Lerchen, Dr. Carsten Griebel	
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 strageties, implementation and analysis	
Contents	Synthesis and applications of heterocycles, prodrugs, peptidomimetics, bioisosteres, antibody-drug conjugates, fluorine-containing groups Protecting groups and functional group activation Selected reaction mechanism and name reactions Peptide synthesis and peptide drugs 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) Flow chemistry	
Examination	a) Oral seminar work-out (presentation and discussion) (10 %) b) Written examination at the end of the module (90 %)	
Literature	Johnson, Li “The Art of drug synthesis”, 2007, Wiley Johnson, Li “Innovative drug synthesis”, 2015, Wiley Graham “An introduction to drug synthesis”, 2015, Oxford University Press Wiles, Watts “Micro Reaction Technology in Organic Synthesis”, 1st ed. (2011), CRC Press Li “Name Reactions” 3rd ed. (2006), Springer Joules, Mills “Heterocyclic Chemistry”, 5th ed. (2010), Wiley Blackwell Brown “Bioisosteres in Medicinal Chemistry”, Vol.54 (2012), Wiley VCH	

MIP-O03	**Medicinal Chemistry: From Hit to Clinical Candidate**	**Credit points: 8**
Person-in-charge	Prof. Dr. Holger Gohlke	
Lecturers	Prof. Dr. H. Gohlke Prof. Dr. M. Kassack Prof. Dr. T. Kurz Prof. Dr. H. Stark	
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 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, 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% of final grade) b) Oral presentation during the seminar (30% of final grade)	
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**	**Credit points: 8**
Person-in-charge	Prof. Dr. Peter Proksch	
Lecturers	Prof. Dr. Peter Proksch Prof. Dr. Claus Passreiter	
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	Strategies for drug discovery from nature Biosynthesis of major groups of natural products in plants, micro-organisms and animals Principles of detection, separation and structure elucidation of natural products Role of plant derived drugs in modern phytotherapy	
Contents	Drug discovery from plants, microbes and animals anticancer drugs, antibiotics molecular targets and modes of action isolation of active compounds from complex extracts spectroscopic structure elucidation traditional therapy and modern phytotherapy biosynthesis of natural products	
Examination	Oral presentation (30%) and written examination (70%)	
Literature	Paul M. Dewick, “Medicinal Natural Products”, Wiley & Sons, ebook, 2011	

MIP-O05	**Pharmaceutical Biotechnology**	**Credit points: 8**
Person-in-charge	Prof. Dr. Rainer Kalscheuer	
Lecturers	Prof. Dr. Rainer 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	---	
Learning targets	- Broad overview over techniques involved in production of re-combinant pharmaceuticals - Knowledge of basic principles of biopharmaceuticals (vaccines, monoclonal antibodies, engineered T-cells) - Knowledge of and practical application of principles in antibacte-rial 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	Oral examination (80% of final grade) Written scientific documentation and evaluation of experiments (20%)	
Literature	Crommelin, Sindelar, Meibohm: “Pharmaceutical Biotechnology. Fundamentals and Applications”. 3rd ed. (2007), Springer	

MIP-O06	**Pharmaceutical Engineering**	**Credit points: 8**
Person-in-charge	Prof. Dr. Peter Kleinebudde	
Lecturers	Prof. Dr. P. Kleinebudde Dr. R. Wiedey Dr. M. Krumme (Novartis)	
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	Successfull 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, compactability, 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 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-O07	**Biopharmaceutics & Pharmacokinetics**	**Credit points: 6**
Person-in-charge	Prof. Dr. J. Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz Dr. R. Wiedey H. Ponsar, J. Rahman (both DDIC)	
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	Successfull completed module MIP-C01 (10 CP) for participation in the course MIP-O07 and examination MIP-O07.	
Learning targets	• Fundamental and applied knowledge on Pharmacokinetics (PK) and drug dissolution methods • Advanced PK modelling and profiling • Knowledge 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 optimization • 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) Computational excercises (20%) The detailed information on examinations will be provided prior to the start of the semester.	
Literature	Skriptum Schmidt, Derendorf „Applied Pharmacometrics“, ebook (2014), aapspress / Springer	

MIP-O08	Statistics and DoE	Credit points: 4
Person-in-charge	Prof. Dr. Peter Kleinebudde	
Lecturers	Prof. Dr. P. Kleinebudde	
Assignment	M.Sc. Industrial Pharmacy Optional compulsory course	
Components	Lecture: --- SWS Seminar: 2 SWS Exercise: 2 SpS	
Work load	120 h, thereof 52.5 h presence and 67.5 h individual study	
Language	English	
Requirements	---	
Learning targets	• Understanding of common designs of experiments • Competence to design and evaluate experiments based on statistical principles • Basic understanding of multivariate data analysis • Hands on experience with open access software and proprietary software	
Contents	• Samples and populations • Confidence intervals and tests • Correlation and (multiple) linear regression • Design of experiments (full factorial designs, fractional factorial designs, split plot designs, central composite designs, Box-Behnken designs, mixture designs) • Basics of multivariate data analysis (PCA, PLS) • Introduction into statistical software: R, Modde, SIMCA • Application to real life problems (exercises)	
Examination	a) success in solving exercises (50%) b) Written examination at the end of the module (50%)	
Literature	Lawson “Design and analysis of experiments with R” (2015) CRC Press Box, Hunter, Hunter “Statistics for Experimenters” 2nd ed. (2005) Wiley	

MIP-E01	**Regulatory Framework**	**Credit points: 4**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz Dr. T. Knaab M. Müller (Invite), H. Ponsar, A. Wilms (both DDIC) A. Wischermann (NextPharma)	
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 for non-pharmacists Introduction of institutions dealing with medicinal products Basic drug regulations Basics of current Good Manufacturing Practice (cGMP) Regulatory documents	
Contents	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 Validation, Qualification, Justification	
Examination	Written examination at the end of the semester (100%)	
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	Credit points: 4
Person-in-charge	Prof. Dr. Peter Kleinebudde	
Lecturers	Prof. Dr. P. Kleinebudde Dr. A. Schweiger (DDIC) Dr. M. Krumme (Novartis)	
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	Successfull 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 plantdesign • 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: concept of a production plant or development facility for defined products	
Examination	weekly group reports in exercises (50%) written examination at the end of the module (50%)	
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**	**Credit points: 2**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz Dr. R. Wiedey	
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 on medical devices (Definitions, types, development) 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 additive etc.) Drug-Device Combinations EMA (Combination Products FDA) Distinguishing medical devices vs. medicinal products, food additives etc. Development of medical devices vs. medicinal products Examples of medical devices for - parenteral delivery - insulin delivery - skin and wound healing - nasal delivery - pulmonal delivery - electronic drug delivery	
Examination	Written examination at the end of the course (no quantitative assessment; passed or non-passed)	
Literature	Amato „ Regulatory Affairs for Biomaterials and Medical Devices", 1st ed. (2014), Woodham Publishers	

MIP-E04	**Stability Testing**	**Credit points: 8**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz Dr. R. Wiedey M. Müller, H. Ponsar, J. Rahman (all DDIC)	
Assignment	M.Sc. Industrial Pharmacy Elective 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	Successfull completed module MIP-C01 (10 CP) for participation in the course MIP-E04 and examination E04.	
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	Reports on exercises (50%) 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-E05	**Design and Supply of Clinical Studies**	**Credit points: 2**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz Dr. R. Wiedey Dr. V. Klingmann (University Childrens‘ Hospital Duesseldorf)	
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 on 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	**Project Management**	**Credit points: 4**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz T. Knaab (3i coordinator) Dr. K. Bartscher, Dr. S. Meier (both NextPharma)	
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 pharmaceutical industry Project planning Project management and maintenance Reporting of project results	
Contents	Departments and responsibilities in 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	Exercises (50 %) and written examination (50 %)	
Literature	Braun, Grundy “Project management for the pharmaceutical industry”2nd ed. (2011), Gower	

MIP-E07	**Intellectual Properties**	**Credit points: 2**
Person-in-charge	Prof. Dr. Jörg Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz Dr. R. Wiedey (vice-coordinator) n.n. patent attorney	
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 Example for 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 based on Cremer, APV course documentation (basic and advanced) Aerts “Pharmaceutical Patents”, 1st ed. (2013), Nova Science	

MIP-E08	International Pharma Business	Credit points: 2
Person-in-charge	Prof. Dr. J. Breitkreutz	
Lecturers	Prof. Dr. J. Breitkreutz Dr. A. Rummelt (InterPharmaLink) Dr. K. Bartscher (NextPharma) Dr. P. Serno (Bayer)	
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 pharma industry Strategic planning and business optimization Life-cyle management Basic accounting rules Efficient reporting Outsourcing in 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	