



Module Compendium
for the
Master's Degree Program

Pharmaceutical Science & Business

Status September, 2022

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Status: September 29, 202

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Introductory Remarks

This module compendium has been written and the competence profiles (K1-K6) have been defined in accordance with module description principles of the Technical University of Munich (see for this https://www.ei.tum.de/fileadmin/tueifei/www/Studium_Pruefer/EN_Wegweiser_Modulbeschreibungen_Stand_November_2014-1.pdf).

Competence profiles (according to Anderson and Krathwohl's Taxonomy) :

K1	remembering	recognize, remember, identify, recall, define, state, name, reproduce, list, repeat, explain...
K2	understanding	compare, explain, present, translate, illustrate, classify, argue, adapt, describe, extrapolate, illuminate, discuss...
K3	applying	carry out, demonstrate, execute, measure, solve, conduct, predict, modify, operate, use, implement...
K4	analyzing	comparing, organizing, deconstructing, attributing, outlining, structuring, integrating...
K5	evaluating	checking, hypothesizing, critiquing, experimenting, judging, testing, detecting, monitoring, differentiating...
K6	creating	designing, constructing, planning, producing, inventing, devising, making, generating...

Fig. 1: Competence profiles according to Anderson and Krathwohl's taxonomy; taxonomy and format derived from

https://www.ei.tum.de/fileadmin/tueifei/www/Studium_Pruefer/EN_Wegweiser_Modulbeschreibungen_Stand_November_2014-1.pdf

The module compendium serves the purpose of providing participants and lecturers a detailed and comprehensive description of the curriculum of the degree program M.Sc. *Pharmaceutical Science & Business*. In addition to language and type of course, it presents the module goals and desired outcomes as well as details the content of the individual courses. Furthermore, it describes the examination type and duration as well as the literature recommended.

1. Qualification Profile

1.1 Aim of the program

The study program is designed to qualify graduates for various functions and roles in the pharma and biotech industry. It aims at developing pharma generalists with

- a profound understanding of the pharma and biotech industry and its principles,
- specialized knowledge of the various concepts, methods and regulations of pharmaceutical product development and manufacturing,
- a profound skill set and practice-oriented competencies to work in agile and project-driven organizations,
- an international and integrative mindset, and
- an understanding of technological trends and future directions in the life science sector.

1.2 Target group of the program

- Graduates of bachelor programs (or comparable degrees) who want to start their professional career in the pharma and biotech sector.
- Experienced professionals with an academic background (minimum bachelor degree), who are seeking new career paths and that have identified the pharma and biotech sector as an attractive branch for their professional goals.
- Future managers who want to shape their professional career in a growth industry.

1.3 Degree awarded

Master of Science (M.Sc.)

1.4 Concept of the program and duration of studies

The program is conceptualized to be studied in 4 semesters (90 ECTS) while working in a pharma, biotech or life science-related company.

1.5 Learning goals and objectives

Graduates of the M.Sc. *Pharmaceutical Science & Business* will have acquired

- academically well-founded professional competencies enabling them to perform in the science-driven pharma and biotech industry,

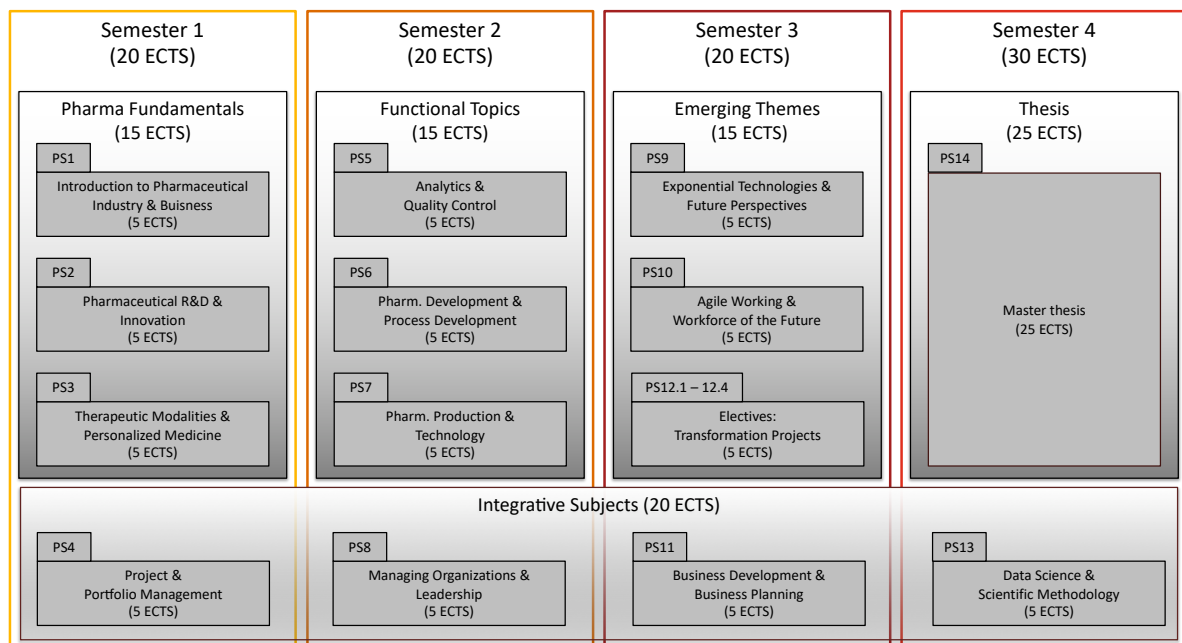
- a wide range of professional, personal and social skills to successfully interact in an international environment,
- an understanding of the significance of quality standards and the impact of personal commitment thereto,
- profound presentation and communication skills to behave in a way appropriate to a professional environment, and
- intercultural competencies to reflect upon the cultural context of risk-adjusted and sustainable corporate decisions.

2. Structure of the study program

The study program consists of fourteen modules. Each module is composed of various courses contributing to the learning outcome of the module. The curriculum comprises four core areas:

- **Pharma fundamentals (modules PS1-3):** introduction to pharmaceutical industry and business; pharmaceutical R&D and innovation; therapeutic modalities and personalized medicine
- **Functional themes (modules PS5-7):** analytics and quality control; pharmaceutical development and process development; pharmaceutical production and quality management
- **Emerging themes (modules PS9, PS10, PS12):** exponential technologies and future perspectives; agile working and workforce of the future; transformation projects (elective, international module)
- **Integrative subjects (modules PS4, PS8, PS11 and PS13):** project and portfolio management; managing organizations and leadership; business development and business planning; data science and scientific working.
- **Master thesis (module PS14)**
- **Research project, internship practical experience (optional module PS15)¹**

The following figure provides an overview of the program structure and sequence:



¹ Mandatory for students with a bachelor degree of less than 180 ECTS

3. Overview of modules, courses and abbreviations

Modulnummer	Modulbezeichnung	Summe ECTS	Vorlesungstage	Prüfungsform	Gewichtung der Module	
PS1	Introduction to pharmaceutical industry & business	5	5	RE, KL	4/90	
	General considerations to pharma business models		1,5			
	Basics in chemistry (SMOLs) and drug delivery		1			
	Basics in (molecular) biology		1			
	Basics in biologics		1			
	Excursion: NMI Reutlingen		0,5			
PS2	Pharmaceutical R&D & Innovation	5	6	KL	5/90	
	Basics in pharmaceutical R&D and R&D process		1			
	Basics in regulatory affairs		1			
	Basic in drug discovery		1			
	Basic in drug discovery		1			
	Basics in drug development		1			
PS3	Therapeutic Modalities & Personalized Medicine	5	6	RE, KL	5/90	
	Basics in pharmacology and drug targets		1			
	Basics in pharmacology and drug targets		1			
	Principles of personalized medicine and related technologies		1			
	Pharmaceuticals and breakthrough therapies		1			
	Breakthrough biologics		1			
PS4	Project, Risk and Portfolio Management	5	5	KL	4/90	
	Basics in project management and portfolio management		1			
	Case studies: Project management in Pharma and Biotech		1			
	Case study: Project management at Vetter Pharma		1			
	Basics in risk and resiliencemanagement		1			
	Case-in-points: Risk management		1			
PS5	Analytics & Quality Control	5	7	KL	6/90	
	Basic in chemical analytics		1			
	Basic in bioanalytics		1			
	Basics in process analytics		1			
	Insight into the regulatory framework		1			
	Quality control		1			
PS6	Pharmaceutical Development & Process Development	5	7	KL	6/90	
	Basics and principles of pharmaceutical development		1			
	Basics and principles of pharmaceutical development		1			
	Quality by design		1			
	Basics and principles of drug-device combinations		1			
	Basics and principles of pharmaceutical process development		1			
PS7	Pharmaceutical Production & Technology	5	7	KL	6/90	
	Basics in production technologies		1			
	Basics in Supply Chain Management		1			
	Basics in Supply Chain Management		1			
	Basics of Lean Enterprise Management		1			
	Principles of pharmaceutical manufacturing		1			
PS8	Managing Organizations & Leadership	5	6	KL	4/90	
	Corporate governance		1			
	Managing organizations		1			
	Case Study: Corporate values and pharma leadership principles		1			
	Leading myself and others		1			
	Leading myself and others		1			
PS9	Exponential Technologies & Future Perspectives	5	6	RE, KL	5/90	
	Principles and application of emerging biomedical technologies		1			
	Principles and application of new microtechnologies		1			
	Excursion: MPI Heidelberg		1			
	Principles of artificial intelligence and applications in pharma		1			
	Principles and applications of emerging materials		1			
PS10	Agile Working & Workforce of the Future	5	6	PA, KL	4/90	
	Principles business model innovation		1			
	Principles of open innovation		1			
	Case-in-point: Open innovation in pharma R&D		1			
	Agile organization and processes		1			
	Administrative process excellence		1			
PS11	Business Development & Business Planning	5	7	KL	5/90	
	Basics in business development		1			
	Biotech entrepreneurship		1			
	Basics in health economics		1			
	Basics in pharma economics		1			
	Financial management and accounting		1			
PS12.1	Electives: Transformation Project	5	5	PA	6/90	
	"Business & Innovation"					
	Electives: Transformation Project	5	5	PA	6/90	
	"Science & Technology"					
	Electives: Transformation Project	5	5	PA	6/90	
	"Pharmaceutical Development & Process Development"					
PS12.4	Electives: Transformation Project	5	5	PA	6/90	
	"Pharmaceutical Production & Technology"					
	PS13	Data Science & Scientific Working	5	6	KL	5/90
		Literature search and review		1		
		Basics in patent search and analysis		1		
		Qualitative research and design science research		1		
Scientific methods and writing			1			
Descriptive statistics			1			
PS14	Master Thesis	25	79	MT	25/90	

4. Module Description

PS1 – Introduction to pharmaceutical industry & business

Studienprogramm / Course of studies:	Pharmaceutical Science & Business (M.Sc.)		Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer/Prof. Dr. Alexander Schuhmacher				
Modul / Module:	Introduction to pharmaceutical industry and business		Dozent(en) / Lecturer(s):	1.	Prof. Dr. Alexander Schuhmacher			
Code:	PS1			2.	Prof. Dr. Günter Lorenz			
Semester:	1			3.	Prof. Dr. Ralf Kemkemer			
Sprache / Language:	DE/EN			4.	Prof. Dr. Ralf Kemkemer			
Status:	Pflicht / Mandatory			5.	Prof. Dr. Rumen Krastev			
Veranstaltungsart / Type of course	Kurs / course:			V	U	E	C	CO
	1.	General considerations to pharma business models		X				
	2.	Basics in chemistry (SMOLs) and drug delivery		X	X		X	
	3.	Basics in (molecular) biology		X	X		X	
	4.	Basics in biologics		X	X			
	5.	Excursion: NMI Reutlingen				X		
Arbeitsaufwand / workload (h)	Kurs / course:		Unterricht / class:	Selbststudium / Self-study:	Gesamt / total:			
	1.	General considerations to pharma business models	18,25	18,25	37,5			
	2.	Basics in chemistry (SMOLs) and drug delivery	12,5	12,5	25			
	3.	Basics in (molecular) biology	12,5	12,5	25			
	4.	Basics in biologics	12,5	12,5	25			
	5.	Excursion: NMI Reutlingen	6,25	6,25	12,5			
	Gesamt / total:		62,5	62,5	125			
ECTS-Punkte/ ECTS-Credits:	5							
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None							
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...							
	Professional competencies							
	... to understand how pharmaceutical business works and how it changes. (K2)							
	... to analyze the pharmaceutical industry and its key players. (K4)							
	... to evaluate the key challenges that are driving the industry. (K5)							
	... to outline the pharmaceutical value chain (from idea to market). (K4)							
	... to understand the basic principles of SMOLs. (K2)							
	... to understand the basic principles of biologics. (K2)							
	... to compare pharma business models. (K4)							
	Methodological competencies:							
	... to discuss scientific information. (K2)							
	... to discuss business model tools. (K2)							
	... to apply the business model navigator. (K3)							
	Social competencies:							
	... to execute team work. (K3)							
	... to build relationship with an open mind. (K3)							
	Personal competencies:							
	... to compare the various concepts and combine it with practical thinking. (K2)							
	... to argue with integrative ability. (K2)							
	... to argue objectively. (K2)							
	... to discuss potential problems. (K2)							

PS1 – Introduction to pharmaceutical industry & business (cont.)

Inhalt / content:	<p>General considerations to pharma and pharma business models: Role of pharmaceutical and biotech industries, economics, development of pharmaceutical sector, key trends and growth drivers, basics in business models (who/what/how/value) and business models in pharma, ethical vs. generics, leading pharma companies, FIPnet vs. other models</p> <p>Basics in chemistry (SMOLs) and drug delivery: Small molecules and their impact in drug discovery, Physical and chemical properties, Lipinski's rule of five, galenic aspects, dosage forms, drug administration - routes; drug delivery trends</p> <p>Basics in (molecular) biology: Biological macromolecules, their interaction principles and systemic functions in cells as basis for life processes. Basic principles of signal transduction and genetics for generating cell and tissue functionality.</p> <p>Basics in biologics: Basics about biological molecules used for therapeutic and diagnostic applications (basic chemistry, biological function, applications)</p> <p>Excursion: Pharma research center or pharmaceutical company Visiting a pharma research center or a pharma company, such as the NMI Reutlingen</p>
Prüfungsform und Dauer / examination type and duration:	<p>Presentation (50%) Written examination (50%), 1h</p>
Mediennutzung / media used:	<p>Script to download, student presentation, digital projector, handouts, flip chart</p>
Lehr- und Lernmethodik / teaching and learning methodology:	<p>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works, case-in-points and an excursion; students need to write a term paper in preparation of this module</p>
Empfohlene Literatur / recommended literature:	<p>Hinder M, Schuhmacher A, Goldhahn J, Hartl D (2022) Principles of Biomedical Science and Industries. In: Wiley-VCH. ISBN: 978-3527345717</p> <p>Oliver Gassmann, Alexander Schuhmacher, Max Zedtwitz, Gerrit Reepmeyer. Leading pharmaceutical Innovation. How to Win the Life Science Race. Springer. 2018. ISBN 978-3-319-66833-8</p>

PS2 – Pharmaceutical R&D & innovation

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)		Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer/Prof. Dr. Alexander Schuhmacher						
Modul / Module:	Pharmaceutical R&D & Innovation		Dozent(en) / Lecturer(s):	1.	Prof. Dr. Alexander Schuhmacher					
Code:	PS2			2.	Prof. Dr. Alexander Schuhmacher					
Semester:	1			3.	Prof. Dr. Ralf Kemkemer/ Prof. Dr. Alexander Schuhmacher					
Sprache / Language:	DE/EN			4.	Prof. Dr. Markus Hinder					
Status:	Mandatory			5.	Prof. Dr. Markus Hinder					
Veranstaltungsart / type of course	Kurs / course:			V	U	E	C	CO		
	1.	Basics in pharmaceutical R&D and R&D process		X	X		X			
	2.	Basics in regulatory affairs		X	X		X			
	3.	Basic in drug discovery		X	X		X			
	4.	Basics in drug development		X	X		X			
	5.	Clinical trials, clinical efficacy/safety and translational medicine		X	X		X			
Arbeitsaufwand / workload (h)	Kurs / course:		Unterricht / class:	Selbststudium / self-study:	Gesamt / total:					
	1.	Basics in pharmaceutical R&D and R&D process	12,5	12,5	25					
	2.	Basics in regulatory affairs	12,5	12,5	25					
	3.	Basic in drug discovery	25	12,5	37,5					
	4.	Basics in drug development	12,5	6,25	18,75					
	5.	Clinical trials, clinical efficacy/safety and translational medicine	12,5	6,25	18,75					
	Gesamt / total:		75	50	125					
ECTS-Punkte/ ECTS-Credits:	5									
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None									
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...									
	Professional competencies									
	... to outline how pharmaceutical R&D works principally. (K4)									
	... to outline the relevance of innovation for the pharmaceutical industry. (K4)									
	... to outline the pharmaceutical R&D process, its probabilities of success, timing and costs. (K4)									
	... to describe the scientific principles of drug discovery and development. (K2)									
	... to describe the role of translational medicine in context of drug development. (K2)									
	Methodological competencies:									
	- ... to apply the systems of drug classification and drug names. (K3)									
	- ... to understand the prototypic drug discovery technologies. (K2)									
	- ... to understand the clinical trial management principles. (K2)									
	Social competencies:									
	... to execute team work. (K3)									
	... to build relationship with an open mind. (K6)									
	Personal competencies:									
	... to apply conceptual thinking. (K3)									
	... to discuss with integrative ability. (K2)									
	... to judge objectively. (K5)									

PS2 – Pharmaceutical R&D & innovation (cont.)

<p>Inhalt / content:</p>	<p>Basic principles of pharma R&D and R&D process: Basic terms and basic principles of innovation/innovation management, such as idea, innovation, invention, innovation process, key drivers of innovation, innovation trends, product innovation, pharma R&D process (phases, stages, key milestones, timing, probabilities, costs), basics are supplemented by pharma-specific case-in-points and specific examples</p> <p>Basics in regulatory affairs: Basics principles of drug regulations, FDA vs. EMA, IND, INDA, and MA criteria, ICH guidelines and regulations to bring a new drug to market</p> <p>Basics in drug discovery: Principles, process, content, milestones and deliverables of target identification, target validation, lead finding, and lead optimization; drug discover of SMOLs vs. biologics; basics are supplemented by pharma-specific examples and case-in-points</p> <p>Clinical trials, clinical efficacy and safety and translational medicine: Clinical trials types, clinical endpoints, outcomes, clinical trial management, regulatory basic principles, clinical efficacy and safety guidelines, role of translational medicine; basics are supplemented by pharma-specific examples and case-in-points</p>
<p>Prüfungsform und Dauer / examination type and duration:</p>	<p>Written examination (100%), 1h</p>
<p>Mediennutzung / media used:</p>	<p>Script to download, student presentation, digital projector, handouts, flip chart</p>
<p>Lehr- und Lernmethodik / teaching and learning methodology:</p>	<p>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works, case-in-points and an excursion; students need to write a term paper in preparation of this module</p>
<p>Empfohlene Literatur / recommended literature:</p>	<p>Hinder M, Schuhmacher A, Goldhahn J, Hartl D (2022) Principles of Biomedical Science and Industries. In: Wiley-VCH. ISBN: 978-3527345717</p> <p>Alexander Schuhmacher, Markus Hinder, Oliver Gassmann. Value Creation in the Pharmaceutical Industry. The Critical Path to Innovation. Wiley-VCH. 2016</p> <p>Ena Ray Banerjee. Perspectives in Translational Research in Life Sciences and Biomedicine: Translational Outcomes Research in Life Sciences and Translational Medicine. Springer. 2018</p> <p>Littman, Bruce H. Translational Medicine and Drug Discovery. Cambridge University Press. 2014</p> <p>Recent scientific publications in the respective field</p>

PS3 – Therapeutic Modalities & Personalized Medicine

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)		Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer/Prof. Dr. Alexander Schuhmacher					
Modul / Module:	Therapeutic Modalities & Personalized Medicine		Dozent(en) / Lecturer(s):	1.	Prof. Dr. Dominik Hartl				
Code:	PS3			2.	Prof. Dr. Dominik Hartl				
Semester:	1			3.	Prof. Dr. Günter Lorenz				
Sprache / Language:	DE/EN			4.	Prof. Dr. Ralf Kemkemer				
Status:	Mandatory			5.	Prof. Dr. Alexander Schuhmacher				
Veranstaltungsart / type of course:	Course:				V	U	E	C	CO
	1.	Basics in pharmacology and drug targets			X			X	
	2.	Principles of personalized medicine and related technologies			X				
	3.	Pharmaceuticals and breakthrough therapies			X			X	
	4.	Breakthrough biologics							
	5.	Gene therapy and genome editing			X			X	
Arbeitsaufwand / workload (h):	Course:			Unterricht / class:	Selbststudium / self-study:	Gesamt / total:			
	1.	Basics in pharmacology and drug targets		12,5	12,5	25			
	2.	Principles of personalized medicine and related technologies		12,5	12,5	25			
	3.	Pharmaceuticals and breakthrough therapies		12,5	12,5	25			
	4.	Breakthrough biologics		12,5	12,5	25			
	5.	Gene therapy and genome editing		12,5	12,5	25			
	Total:			62,5	62,5	125			
ECTS-Punkte/ ECTS-Credits:	5								
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None								
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...								
	Professional competencies								
	... to outline the various drug target classes. (K4)								
	... to discuss drug formats and the basics of the underlying pharmacology. (K2)								
	... to understand therapeutic modalities. (K2)								
	... to outline the principles and options of personalized medicine and to illustrate the underlying paradigms and technologies. (K4)								
	... to understand and discuss new therapeutic breakthrough (K2)								
	... to outline the up- and downsides of gene therapy and genome editing (K4).								
	Methodological competencies:								
	... to describe technical depth and breadth in the field of therapeutic modalities. (K2)								
... to describe principles of drug targets. (K2)									
... to explain "the rule of five". (K2)									
... to classify physicochemical properties with respect to ADME parameters. (K2)									
Social competencies:									
... to execute team work. (K3)									
Personal competencies:									
... to apply conceptual thinking. (K3)									
... to demonstrate analytical thinking. (K3)									
... to demonstrate the ability to read and understand scientific publications. (K3)									
... to demonstrate the ability to do scientific research and to present scientific findings. (K3)									

PS3 – Therapeutic Modalities & Personalized Medicine (cont.)

<p>Inhalt / content:</p>	<p>Basics in pharmacology and drug targets: Mechanism-of-action, receptors, agonism/antagonism, pharmacodynamics, pharmacokinetics, efficacy, safety, target classes, G-protein-coupled receptors, ion channels, kinases, proteases, drug/ligand interaction, drug-drug interactions, metabolism, clearance, pharmacogenetics, therapeutic index, therapeutic window, therapeutic monitoring</p> <p>Principles of personalized medicine and related technologies: Disease stratification, disease subtypes, endotypes, enrichment, prediction, surrogate markers, genomics, genetics, epigenetics, transcriptomics, proteomics, metabolomics, microbiomics, radiomics, imaging, diagnostics, companion diagnostics, complementary diagnostics, digitals, disease-risk assessment, drug development process, population screening, reimbursement</p> <p>Pharmaceuticals and breakthrough therapies: Drug classification, drug nomenclature, chemical names, non-proprietary names, generic naming system, drug classes, The first blockbuster Tagamet, proton pump inhibitors, antihistamines as allergy drugs, blood thinners - Heparin, Plavix, Analgesics - Morphine, Lyrica, beta-blockers, What makes a block buster drug?</p> <p>Basics of biologicals: Recombinant DNA, biology of biologicals (recombinant proteins, peptides, monoclonal antibodies, nucleic acids (siRNA), vaccines, hormones), drug formats, therapeutic uses of biologicals (e.g. cancer treatments, treatments of autoimmune diseases), breakthrough therapies (Rituximab, Trastuzumab, adalimumab)</p> <p>Gene therapy and genome editing: Basic technologies in gene therapy, in vivo vs. ex vivo, autologous vs. allogenic therapy, approved gene therapies/underlying technologies and market potentials, future of gene therapies, basics of genome editing, pipeline of</p>
<p>Prüfungsform und Dauer / examination type and duration:</p>	<p>Presentation (50%) Written examination (50%), 1h</p>
<p>Mediennutzung / media used:</p>	<p>Script to download, student presentation, digital projector, handouts, flip chart</p>
<p>Lehr- und Lernmethodik / teaching and learning methodology:</p>	<p>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works and case-in-points; students need to write a term paper in preparation of this module</p>
<p>Empfohlene Literatur / recommended literature:</p>	<p>Jagschies, Gunter et al. (2018) Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes. Elsevier</p> <p>Cullis, Peter (2015) The Personalized Medicine Revolution: How Diagnosing and Treating Disease Are About to Change Forever. Greystone Books Ltd.</p> <p>Snycer, Michael (2016) Genomics and Personalized Medicine. Oxford University Press</p> <p>Doudna, J., Sternberg, S. (2018) A crack in creation. Vintage</p> <p>Recent scientific publications in the respective field</p>

PS4 – Project & Portfolio Management

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)		Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer/Prof. Dr. Alexander Schuhmacher					
Modul / Module:	Project & Portfolio Management		Dozent (en) Lecturer(s):	1.	Prof. Dr. Alexander Schuhmacher				
Code:	PS4			2.	Prof. Dr. Kathrin Tissot				
Semester:	1			3.	Armin Bareth				
Sprache / Language:	DE/EN			4.	Doris Honold				
Status:	Mandatory			5.	Doris Honold				
Veranstaltungsart / type of course:	Course:				V	U	E	C	CO
	1.	Basics in project management and portfolio management			X	X			
	2.	Case studies: Project management in Pharma and Biotech			X	X		X	
	3.	Case study: Project management at Vetter Pharma			X	X		X	
	4.	Basics in risk and resilience management			X	X		X	
	5.	Case-in-points: Risk management							
Arbeitsaufwand / workload (h):	Course:		Unterricht / class:	Selbststudium / self-study:	Gesamt / total:				
	1.	Basics in project management and portfolio management		12,5	12,5	25			
	2.	Case studies: Project management in Pharma and Biotech		12,5	12,5	25			
	3.	Case study: Project management at Vetter Pharma		12,5	12,5	25			
	4.	Basics in risk and resilience management		12,5	12,5	25			
	5.	Case-in-points: Risk management		12,5	12,5	25			
Total:			62,5	62,5	125				
ECTS-Punkte/ ECTS-Credits:	5								
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None								
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...								
	Professional competencies								
	... to discuss the principles of portfolio and product life cycle management. (K2)								
	... to execute the principles of project management. (K3)								
	... to use the principles of risk management. (K3)								
	... to structure project work and tasks. (K4)								
	Methodological competencies:								
... to carry out a SWOT analysis (K3)									
... to execute a risk analysis (K3)									
... to conduct a stakeholder analysis (K3)									
... to conduct a NPV calculation. (K3)									
... to organize a project team. (K4)									
... to monitor the project progress. (K5)									
... To plan a project. (K6)									
Social competencies:									
... to communicate with impact. (K5)									
... to build relationship with an open mind. (K3)									
... to organize team work. (K4)									
... to personally compare with the pharmaceutical industry. (K4)									
Personal competencies:									
... to develop a result-oriented and creative working culture. (K6)									

PS4 – Project & Portfolio Management (cont.)

<p>Inhalt / content:</p>	<p>Basics in project and portfolio management and case study "project management in pharma & biotech": Project, exemplary projects, basic considerations, guidance to project management, ISO21500, scope, terms and definitions, project management concepts, project management process, project process groups, project planning, project progress, monitoring, resolving issues, PMI triangle, SWOT analysis, SMART method, risk analysis, risk response plan, stakeholder analysis, project phases and milestones, work breakdown structure (WBS), project team, team composition, team meetings, project team leadership, role of the project leader, role of the team members, stage-gate-model, portfolio analysis, evaluation criteria (drugability, patentability, freedom-to-operate, technical feasibility, market share), portfolio management, costs, time, probabilities, cost of goods (COGS), pricing, net present value (NPV), project prioritization, resource allocation, portfolio optimization</p> <p>Case study project management at Vetter Pharma: Organizational structures (matrix types), Project types, project governance, project committees, project decision-making, project as social system, project crisis and escalation, lessons learnt from historical projects, project management standards in pharma, project life cycle, stakeholder management (internal and external / customers) and communication</p> <p>Risk management: Introduction to Risk Management: Principles of Risk Management, Risk Management Standards, Enterprise Risk Management, Risk Management Process: Risk Assessment, Identification, Analysis and Evaluation, Risk Treatment, Reporting, Monitoring, Risk Types, Impact of Risk on Organisations Specialist areas of Risk Management</p> <p>Case-in-points risk management: Risk Management in the Pharma Industry: example Novartis, BioNTech Approaches to defining risk, risk description, inherent risk: practical example from Pharma industry Designing a risk register for Pharma Industry</p>
<p>Prüfungsform und Dauer / examination type and duration:</p>	<p>Written examination (100%), 1h</p>
<p>Mediennutzung / media used:</p>	<p>Script to download, student presentation, digital projector, handouts</p>
<p>Lehr- und Lernmethodig / teaching and learning methodology:</p>	<p>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works and case-in-points</p>
<p>Empfohlene Literatur / recommended literature:</p>	<p>Hinder M, Schuhmacher A, Goldhahn J, Hartl D (2022) Principles of Biomedical Science and Industries. In: Wiley-VCH. ISBN: 978-3527345717</p> <p>S. Nokes and S. Kelly (2003) Guide to Project Management. FT Press</p> <p>Brown L. and Grundy T. (2011) Project Management in the Pharmaceutical Industry. Gower Verlag</p> <p>Kuster Jürg et al. (2018) Handbuch Projektmanagement. Springer</p> <p>ISO 21500. Guidance on project management. ISO 21500:2012</p> <p>Cohn, M. (2006). Agile estimating and planning. Upper Saddle River, NJ: Pearson Education, Inc.</p> <p>Project Management Institute. (2008). A guide to the project management body of knowledge (PMBOK® Guide) (4th ed.). Newtown Square, PA: Project Management Institute.</p> <p>Schwaber, K. (2004). Agile project management with Scrum. Redmond, WA: Microsoft Press.</p> <p>Brown, Laure (2016) Project Management for the Pharmaceutical Industry. Gower Publishing</p>

PS5 – Analytics & Quality Control

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)		Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Günter Lorenz / Prof. Dr. Alexander Schuhmacher						
Modul / Module:	Analytics & Quality Control		Dozent / Lecturer(s):	1.	Prof. Dr. Günter Lorenz					
Code:	PS5			2.	Prof. Dr. Ralf Kemkemer					
Semester:	2			3.	Prof. Dr. Günter Lorenz					
Sprache / Language:	DE/EN			4.	Kattja Kotter					
Status:	Mandatory			5.	Oliver Kurz					
				6.	Dr. Anne Kuhlmann					
				7.	Dr. Anne Kuhlmann					
Veranstaltungsart / type of course:	Kurs / course:			V	U	E	C	CO		
	1.	Basic in chemical analytics		X			X			
	2.	Basic in bioanalytics		X	X					
	3.	Basics in process analytics		X						
	4.	Insight into the regulatory framework		X	X		X			
	5.	Quality control		X	X		X			
	6.	Quality assurance								
	7.	Quality management systems								
Arbeitsaufwand / workload (h):	Kurs / course:		Unterricht / class:	Selbststudium / self-study:	Gesamt / total:					
	1.	Basic in chemical analytics	12,5	6,25	18,75					
	2.	Basic in bioanalytics	12,5	6,25	18,75					
	3.	Basics in process analytics	12,5	6,25	18,75					
	4.	Insight into the regulatory framework	12,5	6,25	18,75					
	5.	Quality control	12,5	3,125	18,75					
	6.	Quality assurance	12,5	3,125	18,75					
	7.	Quality management systems	12,5	6,25	18,75					
	Gesamt / total:		87,5	37,5	125					
ECTS-Punkte/ ECTS-Credits:	5									
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None									
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...									
	Professional competencies									
	... to illustrate chemical and bio-analytical methods used in pharmaceutical development and manufacturing. (K2)									
	... to outline analytical questions and suggest appropriate analytical methods. (K4)									
	... to describe the various guidelines relevant for pharmaceutical development and manufacturing. (K2)									
	... demonstrate a profound understanding of QC- and QA-systems and processes including the GMP-QC lab responsibility. (K3)									
	... to compare the strategic and operational impact of regulatory affairs in the drug R&D and production process. (K4)									
	... to analyzing the various regulations relevant for developing and manufacturing drugs. (K4)									
	Methodological competencies:									
	... to understand the various analytical methods underlying regulatory rules and quality standards. (K2)									
	... to compare and differentiate regulatory standards and practices. (K4, K5)									
	Social competencies:									
	... to demonstrate accountability for other. (K3)									
	Personal competencies:									
	... to demonstrate customer-orientation. (K3)									
	... to demonstrate commitment to job and responsibility. (K3)									
	... to demonstrate personal accountability. (K3)									
	... to integrate pro-active quality thinking. (K4)									

PS5 – Analytics & Quality Control (cont.)

Inhalt / content:	<p>Basics in chemical analytics: Basics in instrumental analytics, physical and chemical analytics: Analytical techniques for drug substance and drug product release. Identity and evidence of chemical structure: optical spectroscopy, e.g. UV/VIS and IR; mass and NMR spectrometry. Purity analysis, stability testing of drug substance and drug product as well as metabolism studies: HPLC, GC, electrophoresis</p> <p>Basics in bioanalytics: Basics of bioanalytical methods and techniques as an essential tool in diagnostics, QM, drug discovery and development (sampling, analysis techniques and their working principle, data analysis, regulations, challenges)</p> <p>Basics in process analytical technology (PAT): strategies for knowledge-based products and processes, chemometrics in the PAT, spectroscopic methods, regulatory framework, applications in bioprocess measurement and control</p> <p>Insight into the regulatory framework: Good laboratory practice (GLP), good manufacturing practice (GMP) - requirements in Germany, Europe and the US, International conference on harmonization of technical requirements for pharmaceuticals for human use (ICH), World Health Organization (WHO), Pharmaceutical Inspection Co-operation Scheme (PIC/S), authority inspections, documentation needed for drug approval (CMC documentation) EU and US, drug master files, site master files</p> <p>Quality control, quality assurance and quality management: (1) Basics and principles of quality control and quality assurance: Basic terms and concepts, such as pharmaceutical quality system (PQS), quality assurance and quality control functions, key personnel (Head of QC, Head of Production, QP), relationship between quality management and Good Manufacturing Practice (GMP). Basics are supplemented by pharma-specific case-in-points and specific examples. (2) Case study: Pharma quality control Microbiological quality control, Sterility Testing, Regulatory framework (pharmacopoeia USP, EP, JP, guidelines, etc.), isolators for sterility testing and the surrounding, suitability testing, challenging products, RMM, microbiological growth detected during sterility test read out, method performance, test result relevance for batch release decision, impact of a sterility test non-conformity, investigation process, sterility test invalidation, OOS-procedure, lab investigation, CAPA definition. Understanding of the relevance and related processes of QC-release testing of aseptically filled</p>
Prüfungsform und Dauer / examination type and duration:	Written examination (100%), 1h
Mediennutzung / media used:	Script to download, student presentation, digital projector, handouts, flip chart
Lehr- und Lernmethodik / teaching and learning methodology:	A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works and an on-site training
Empfohlene Literatur / recommended literature:	<p>Hansen SH (2011) Introduction to Pharmaceutical Chemical Analysis. Wiley</p> <p>Watson DG. (2016) Pharmaceutical Analysis: A Textbook for Pharmacy Students and Pharmaceutical Chemists. Elsevier</p> <p>Lottspeich, F, Engels, JW. Bioanalytics (2018) Analytical Methods and Concepts in Biochemistry and Molecular Biology. Wiley</p> <p>ICHQ9 - https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-3.pdf</p> <p>AMWHV – Arzneimittel und Wirkstoffherstellungsverordnung; https://www.gesetze-im-internet.de/amwhv/</p> <p>AMG – Arzneimittelgesetz; https://www.gesetze-im-internet.de/amwhv/</p> <p>EU-GMP Leitfaden Teil I, II, III inkl. Anhänge: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Statistiken/GKV/Bekanntmachungen/GMP-Leitfaden/GMP-Leitfaden-1.pdf http://academy.gmp-compliance.org/guidemgr/files/GMP-LEITFADEN_TEIL%20%20WIRKSTOFFE_ERGAENZT.PDF https://www.gmp-berater.de/showdoc/GMP-BERATER/GMP-Regulieren/H-EU-GMP-Leitfaden/H33-EU-GMP-Leitfaden-Teil-III-8211-GMP-bezogene-Dokumente?docId=docs/h03_3.html&alias=GMPReg_H_3_3_EndAli&activeToolBarTab=document&startSite=false&fdl=false&event=navigation&from=tree</p> <p>21 CFR 211 Aktuelle Gute Herstellungspraxis für Fertigarzneimittel https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211</p> <p>21 CFR 11 Elektronische Dokumente; Elektronische Unterschriften https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211</p> <p>21 CFR 820 Regelwerk zum Qualitätssystem https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820</p> <p>21 CFR 4 Regelungen für Kombinationsprodukte https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=4</p> <p>ICH Q9 Quality Risk Management https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Statistiken/GKV/Bekanntmachungen/GMP-Leitfaden/Anhang-20-EG-GMP-Leitfaden.pdf</p> <p>ICH Q10 Pharmazeutisches Qualitätssystem https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human_en.pdf</p> <p>Amborn, J et al. (2009) GMP-/FDA-Anforderungen an die Qualitätssicherung - Qualitätssicherungssystem, GMP-Compliance, Lieferantenqualifizierung, GMP-relevante Verträge. Editio Cantor Verlag</p>



PS6 – Pharmaceutical Development & Process Development

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Günter Lorenz / Prof. Dr. Alexander Schuhmacher
Modul / Module:	Pharmaceutical Development and Process Development	Dozent (en) / Lecturer(s):	1. Prof. Dr. Günter Lorenz
Code:	PS6		2. Prof. Dr. Andreas Kandelbauer
Semester:	2		3. Tilman Roedle
Sprache / Language:	DE/EN		4. Jörg Zimmermann
Status:	Mandatory		5. Jörg Zimmermann
			6.

Veranstaltungsart / type of course:	Kurs / course:					V	U	E	C	CO
	1.	Basics and principles of pharmaceutical development				X	X			
	2.	Quality by design				X				
	3.	Basics and principles of drug-device combinations				X				
	4.	Basics and principles of pharmaceutical process development				X	X			
	5.	Case studies: Lyophilization and pharma project review				X	X		X	

Arbeitsaufwand / workload (h):	Kurs / course:		Unterricht /	Selbststudium /	Gesamt /
	1.	Basics and principles of pharmaceutical development	25	12,5	37,5
		Quality by design	12,5	6,25	18,75
	2.	Basics and principles of drug-device combinations	12,5	3,125	15,625
	3.	Basics and principles of pharmaceutical process development	25	12,5	37,5
	4.	Case studies: Lyophilization and pharma project review	12,5	3,125	15,625
	5.				
	Gesamt / total:		87,5	37,5	125

ECTS-Punkte/ ECTS-Credits:	5
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Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None
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Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...
	Professional competencies
	... to outline the principles of pharmaceutical development and pharmaceutical process development. (K4)
	... to describe quality by design. (K2)
	... to understand how pharmaceutical dosage forms are developed and qualified. (K2)
	... to understand the principles of process validation. (K2)
... to outline QC method development and transfer. (K4)	
... to understand pharmaceutical unit-operations including lyophilization. (K2)	
... to understand the setting of analytical product specifications. (K2)	
... to outline devices and drug device combinations. (K4)	
... to understand the principles of lyophilization, its principles, technologies and applications. (K2)	
Methodological competencies:	
- ... to outline the different steps of pharmaceutical development. (K4)	
- ... to assess which physicochemical criteria the active product ingredient need to meet. (K3)	
- ... to develop solution concepts for bioavailability problems. (K3)	
- ... to adhere to regulatory rules and quality standard practices. (K3)	
- ... to understand the method of continuous process verification. (K2)	
Social competencies:	
... to execute team work. (K3)	
... to build relationship with an open mind. (K3)	
Personal competencies:	
... to apply conceptual and practical thinking. (K3)	
... to develop commitment to job. (K6)	

PS6 – Pharmaceutical Development & Process Development (cont.)

<p>Inhalt / content:</p>	<p>Basic principles of pharmaceutical development: Pharma R&D process and context of pharmaceutical development, principles of preclinical development, basics in physicochemistry and biopharmacy, basics of Quality by Design (QbD), drug administration forms, analytical procedures and validation, regulatory rules in context of pharmaceutical development (e.g. ICH Q2 Validation of Analytical Procedures, ICH Q8 Pharmaceutical Development, ICH Q9 Quality Risk Management, ICH Q10 Pharmaceutical Quality System), GLP quality requirements, EU legal framework, Directives 2004/9/EC and 2004/10/EC</p> <p>Quality by design - Design of Experiments: General aspects of experimental design, thinking and working in experimental spaces, calculation of effects, factorial experimental designs, complete and incomplete designs, screening and optimisation experimental designs, applications of DoE in quality management and in research and development, special Topics (Box-Behnken, Plackett-Burman, Taguchi and other designs) Design of multifactorial property profiles and determination of process windows</p> <p>Basics and principles of drug-device combinations: material science, components, regulations - Components: glas, rubber, polymers and others - How are they made? How are combinations developed? - Regulatory framework for medical devices and combination products - Qualification and functional testing of combination products - Device development: pens, autoinjectors, wearable injectors etc.</p> <p>Basics and principles of pharmaceutical process development: - Development of qualified processes according to ICH Q8 and other guidelines - Quality by design, risk-based approaches with bracketing and matrixing, and examples. Also examples on abridged development for orphan drugs. Also examples of authorities not accepting ICH Q8 and how to deal with this - Continuous process verification (CPV): data monitoring and evaluation on a continuous basis.</p> <p>Case studies: Lyophilization and pharma project review (1) Lyophilization (principles, technologies and applications) Physical principles for lyophilisation, lyophilisation technology, process development for state-of-the-art drying processes based on physical formulation properties, lab-scale work, at-scale work including robustness-runs and multi-dosage, multi-lyo qualification (2) Pharma project review from the pharmaceutical-technical and product perspective Review of an executed final dosage form project from start to commercialization including adaptations to the original plan, learnings and how they will be applied to future projects</p>
<p>Prüfungsform und Dauer / examination type and duration:</p>	<p>Written examination (100%), 1h</p>
<p>Mediennutzung / media used:</p>	<p>Script to download, student presentation, digital projector, handouts, flip chart</p>
<p>Lehr- und Lernmethodik / teaching and learning methodology:</p>	<p>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works and an excursion</p>
<p>Empfohlene Literatur / recommended literature:</p>	<p>Bauer, Frömmig, Führer (2016) Lehrbuch der Pharmazeutischen Technologie: Mit Einführung in die Biopharmazie und Biotechnologie. WVG mbh Stuttgart</p> <p>Agalloco, James; Akers, James (2010) Advanced Aseptic Processing Technology (Drugs and the Pharmaceutical Sciences). Informa Healthcare</p> <p>Akers Michael (2010) Sterile Drug Products: Formulation, Packaging, Manufacturing and Quality. Informa Healthcare</p> <p>Rey, Louis; May, Joan (2010) Freeze-Drying/Lyophilization of Pharmaceutical and Biological Products. Informa Healthcare</p> <p>Recent scientific publications in the respective field</p>

PS7 – Pharmaceutical Production & Technology

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Günter Lorenz / Prof. Dr. Alexander Schuhmacher
Modul / Module:	Pharmaceutical Production and Technology	Dozent / lecturer(s):	1. Prof. Dr. Günter Lorenz
Code:	PS7		2. Prof. Dr. Stefan Höfer
Semester:	2		3. Prof. Dr. Stefan Höfer
Sprache / Language:	DE/EN		4. Uwe Remminghorst, Gabriele Maier
Status:	Mandatory		5. Uwe Remminghorst, Gabriele Maier
			6. Uwe Remminghorst, Gabriele Maier

Veranstaltungsart / type of course:	Course:		V	U	E	C	CO
	1. Basics in production technologies		X				
	2. Basics in Supply Chain Management		X	X		X	
	3. Basics of Lean Enterprise Management		X	X		X	
	4. Principles of pharmaceutical manufacturing		X		X	X	
	5. Principles and processes of aseptic filling		X		X	X	
	6. Production systems and technologies		X		X	X	

Arbeitsaufwand / workload (h):	Kurs / course:	Unterricht / class:	Selbststudium / self-study:	Gesamt / total:
	1. Basics in production technologies	12,5	6,25	25
	2. Basics in Supply Chain Management	18,75	3,125	21,875
	3. Basics of Lean Enterprise Management	18,75	3,125	21,875
	4. Principles of pharmaceutical manufacturing	12,5	6,25	18,75
	5. Principles and processes of aseptic filling	12,5	6,25	18,75
	6. Production systems and technologies	12,5	6,25	18,75
Gesamt / total:	87,5	37,5	125	

ECTS-Punkte/ ECTS-Credits:	5
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Voraussetzungen für	None
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Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...
	Professional competencies
	... to outline the principles of supply chain management. (K4)
	... to understand the principles of lean enterprise management. (K2)
	... to outline the pharmaceutical production process. (K4)
	... to outline production process control systems. (K4)
... to outline aseptic manufacturing and differentiate the respective processes/principles. (K4, K5)	
... to adhere to regulatory rules and quality standards (K4).	
... to apply lean thinking. (K3)	
... to apply the principles of production processing and production management. (K3)	
Social competencies:	
... to demonstrate accountability for others. (K3)	
... to apply conceptual and practical thinking. (K3)	
... to differentiate customer and other stakeholder's needs. (K5)	
... to develop commitment to job. (K6)	

PS7 – Pharmaceutical Production & Technology (cont.)

<p>Inhalt / content:</p>	<p>Basics in production technology: The pharmaceutical manufacturing process, steps, tools, technologies, regulations.</p> <p>Basics in supply chain management: The complexity of supply chains, international procurement, synchronized production, distribution</p> <p>Basics in Lean Enterprise Management: Lean Thinking, Learning to see and eliminate waste in production and administration, Business simulation game synchronized production</p> <p>Principles of pharmaceutical manufacturing: Introduction to drug product development, active pharmaceutical ingredients (APIs), basic technologies and unit operations, regulatory aspects of pharmaceutical production, principles of Quality by Design (QbD) and knowledge-based production, scale-up considerations and economical aspects, supplemented by case studies</p> <p>Basics and processes of aseptic filling: demonstration of complete production process including compounding, material preparation and aseptic filling, various compounding systems and processes, material preparation processing including equipment and primary packaging materials, sterilization, processing of bulk and pre-sterilized primary packing material, use of different dosing and stoppering techniques, inline and offline filtration processes, liquid and freeze-dried formulated drug products, process flow (material, operator, equipment, product)</p> <p>Basics of production systems and technologies: production systems: master batch record handling, application systems (electronic weighing system, material tracking systems, in process control systems), production excellence processes (human error avoiding, process optimization, KPIs), technologies: Vetter clean room technology, utilities (HVAC, water, power, gases, etc), function and setup of major primary equipment (equipment washer, glass barrel washer, autoclave and dry heat tunnel, filling machines), flexible production cells (filling cells, co-robot assisted processes), smart production technologies (Industry 4.0)</p> <p>including Packaging and packaging processes: demonstration of complete secondary packaging processes, labeling, assembly of safety devices and tools, blistering, cartoning, serialization and track&trace, autoinjectors and pen systems and assembly, anti-counterfeiting systems, manual and automated packaging processes</p> <p>Visual inspection: Methods and processes of manual and automated VI processes, AQL-approaches, validation of manual and automated systems, training and qualification programmes including test-kit handling, VI special qualities (japanese quality), automated camera systems and defect recognition</p>
<p>Prüfungsform und Dauer / examination type and duration:</p>	<p>Written examination (100%), 1h</p>
<p>Mediennutzung / media used:</p>	<p>Script to download, student presentation, digital projector, handouts, flip chart</p>
<p>Lehr- und Lernmethodik / teaching and learning methodology:</p>	<p>A mixture of methodologies is applied, e.g. primarily lecture and interactive teaching with discussions, combined with team works, case-in-points and an excursion</p>
<p>Empfohlene Literatur / recommended literature:</p>	<p>Bertagnolli, F. (2018): Lean Management. Springer Gabler Verlag</p> <p>Erßig, M. et al (2013): Supply Chain Management. Vahlen Verlag</p> <p>Aulton's Pharmaceutics: The Design and Manufacture of Medicines, Churchill Livingstone Elsevier. 2013, ISBN 978-0-7020-4290-4.</p> <p>P. Hitzer et al., (2017) Process analytical techniques for hot-melt extrusion and their application to amorphous solid dispersions, Anal. Bioanal. Chem., 409, 2017, 4321-4333.</p> <p>Gintaras V. Reklaitis, Christine Seymour et. Al (2017) Comprehensive Quality by Design for Pharmaceutical Product Development and Manufacture. Wiley</p> <p>Qiu, Chen, Zhang (2009) Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice. Academic Press</p> <p>Recent scientific publications in the respective field</p>

PS8 – Managing Organizations & Leadership

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Günter Lorenz / Prof. Dr. Alexander Schuhmacher
Modul / Module:	Managing Organizations and Leadership	Dozent(en) / Lecturer(s):	1. N.N.
Code:	PS8		2. Prof. Dr. Thomas Beckers
Semester:	2		3. Markus Maiwald, Claudia Roth
Sprache / Language:	DE/EN		4. Prof. Dr. Arjan Kozica
Status:	Mandatory		5.
			6.

Veranstaltungsart / type of course:	Kurs / course:		V	U	E	C	CO
	1. Corporate governance		X	X		X	
	2. Managing organizations		X	X		X	
	3. Case Study: Corporate values and pharma leadership principles		X			X	
	4. Leading myself and others		X	X		X	
	5.						

Arbeitsaufwand / workload (h):	Kurs / course:	Unterricht / class:	Selbststudium / self-study:	Gesamt / total:
	1. Corporate governance	12,5	12,5	25
	2. Managing organizations	12,5	12,5	25
	3. Case Study: Corporate values and pharma leadership principles	12,5	12,5	25
	4. Leading myself and others	37,5	12,5	50
	5.			
	Gesamt / total:	75	50	125

ECTS-Punkte/ ECTS-Credits:	5
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Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None
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Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...
	Professional competencies
	... to apply the key approaches of leadership especially and build profound leadership competencies. (K3)
	Methodological competencies:
	... to carry out leadership tools, such as the Eisenhower matrix or specific leadership styles, in order to solve leadership tasks. (K3)
	... to methodologically operate the single phases of change management. (K3)
	... to apply change management tools such as Kotters 8 steps of change in organisational change projects. (K3)
	Social competencies:
	... to engage productively in complex and changing environments. (K3)
	... to create value through generating a variety of perspectives and solutions. (K6)
... to improve their communicative skills, specifically for communicating in leadership situations. (K6)	
... to develop a sense for leadership during changes. (K6)	
... to know how to communicate and persuade people to be part of the change and managed challenging situations. (K5)	
Personal competencies:	
... to develop accountability for others. (K6)	
... to generate self management. (K6)	
... to handle stress. (K6)	
... to make realistic expectations,	
... to develop role awareness and sensitivity to others. (K6)	
... enhance their personal competencies by increasing reflexivity about their influence on others (self and role awareness) in social situations. (K6)	
... to understand how they can leverage their competencies in order to positively influence others (i.e. applying leadership; change management). (K2)	
... to reflect on oneself. (K5)	

PS8 – Managing Organizations & Leadership (cont.)

Inhalt / content:	<p>Corporate governance: Basic principles of corporate governance. Structure of rules, practices, and processes used to direct and manage a company - including environmental awareness, ethical behavior, corporate strategy, compensation, and risk management. Corporate governance and structure, strategy, corporate functions, board structure and leadership.</p> <p>Managing organizations: Basics of managing an organization. Translating the corporate strategy into action and getting people together on the common platform of strategy, structure, processes, and values to make them work towards a common predefined goal.</p> <p>Leading myself and others: Students understand that leadership is a crucial variable for achieving sustainable competitive advantage. The module focusses on skills for doing leadership. It focusses on specific leadership behavior and the individual preferences, abilities and professional skills of leaders. The course interactively elaborates contemporary leadership behavior and introduces students into current debates on sustainable leadership.</p> <p>Case study: Corporate values and pharma leadership principles Apply the lessons learnt from leading business, leading myself and leading others on the specific situation of a pharmaceutical company with its highly regulated environment and its science-driven culture.</p> <p>Personal development and coaching: Students experience the power of targeted development. They learn to find a starting point for personal development (define + measure), identify key development objectives and create a personal development plan for themselves. They understand the methodology and systematic behind combined with personal insight and reflection offered in the course. The course provides some theoretical background but focuses primarily on opportunities for growth and personal development such as self reflection, feedforward, peer consulting, coaching and mentoring.</p>
Prüfungsform und Dauer / examination type and duration:	Written examination (100%), 1h
Mediennutzung / media used:	Script to download, student presentation, digital projector, handouts, flip chart
Lehr- und Lernmethodik / teaching and learning methodology:	A mixture of methodologies is applied, e.g. lecture with interactive teaching and discussions, combined with team works, trainings and a personal coaching session
Empfohlene Literatur / recommended literature:	<p>Weige, MK; Eulerich, M. (2014) Corporate-Governance-Management: Theorie und Praxis der guten Unternehmensführung. Springer</p> <p>Northouse, Peter G. (2016): Leadership. Theory & Practice (7. Aufl.). Thousand Oaks, California: Sage Publications, Inc.</p> <p>Hayes, J. (2018). The Theory and Practice of Change Management, 5th Edition, Palgrave MacMillan, New York.</p> <p>Kotter, John P. (2012). Leading Change. Wie Sie Ihr Unternehmen in acht Schritten erfolgreich verändern. Verlag Franz Vahlen, München.</p> <p>Northouse, Peter G. (2016): Leadership. Theory & Practice (7. Aufl.). Thousand Oaks, California: Sage Publications, Inc.</p> <p>Graf-Götz, Friedrich u. Glatz, Hans (2018). Organistaion gestalten. Handbuch. Beltz Verlag, Weinheim</p>

PS9 – Exponential Technologies & Future Perspectives

Studienprogramm / Course of studies:	Pharmaceutical Sciences (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer / Prof. Dr. Alexander Schuhmacher
Modul / Module:	Exponential Technologies and Future Perspectives	Dozent(en) / lecturer(s):	1. Prof. Dr. Ralf Kemkemer
Code:	PS9		2. Prof. Dr. Ralf Kemkemer
Semester:	3		3. Prof. Dr. Ralf Kemkemer
Sprache / Language:	DE/EN		4. Prof. Dr. Naomi Häfner
Status:	Mandatory		5. Prof. Dr. Günter Lorenz
			6. Prof. Dr. Alexander Schuhmacher

Veranstaltungsart / type of course:	Course:		V	U	E	C	CO
	1. Principles and applications of emerging biomedical technologies		X			X	
	2. Principles and application of new microtechnologies		X			X	
	3. Excursion: MPI Heidelberg				X		
	4. Principles of artificial intelligence and applications in pharma		X			X	
	5. Principles and applications of emerging materials		X				
	6. BioRevolution - a future driven by digital and biotech		X			X	

Arbeitsaufwand / workload (h):	Kurs / course:	Unterricht / class:	Selbststudium / self-study:	Gesamt / total:
	1. Principles and applications of emerging biomedical technologies	12,5	12,5	25
	2. Principles and application of new microtechnologies	12,5	6,25	18,75
	3. Excursion: MPI Heidelberg	12,5		12,5
	4. Principles of artificial intelligence and applications in pharma	12,5	12,5	25
	5. Principles and applications of emerging materials	12,5	6,25	18,75
	6. BioRevolution - a future driven by digital and biotech	12,5	12,5	25
	Total:	75	60	125

ECTS-Punkte/ ECTS-Credits:	5
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Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None
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Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...
	Professional competencies ... to outline the various emerging technologies (K4) ... to differentiate the various technology and their impact on the pharmaceutical sector and the business of the future. (K6) ... to compare the new breakthrough biomedical technologies. (K4)
	Methodological competencies: ... to carry out a technology assessment. (K3) ... to systematically review the impact of new technologies on the pharma business. (K4) ... to execute team work. (K3) ... to leverage from a diverse team. (K6) ... to generate new technical depth and breadth in the field of new therapeutic modalities. (K6) ... analyze scientific information systematically (K4)
	Social competencies: ... to communicate with impact. (K5) ... to build relationship with an open mind. (K3)
	Personal competencies: ... to apply analytical thinking. (K3) ... to analyze various scenarios and judge proactively. (K4, K5) ... to monitor scientific publications. (K5) ... to evaluate scientific information in a business context. (K5)

PS9 – Exponential Technologies & Future Perspectives (cont.)

Inhalt / content:	<p>Principles and applications of emerging biomedical technologies: Design and function of artificial cells and biohybrid systems Design, function and applications of synthetic micro-robots for health applications Engineering and application of in-vitro and in-vivo chip technologies (organ on a chip) for diagnostics and therapies</p> <p>Principles and applications of emerging microtechnologies: Micro- and nanotechnology as a one of keys driving motors of future developments in life sciences and biomedical technologies; basics to production of microtechnology and applications from various fields.</p> <p>Excursion MPI Heidelberg: Visit Max Planck Institute for Medical Research and DKFZ</p> <p>Principles of artificial intelligence and applications in pharma: Artificial intelligence (AI) technologies, machine learning, neural networks, deep learning, natural language processing, chatbots, AI applications in healthcare, AI application in pharmaceutical R&D, AI application in project management, manufacturing and marketing/sales, changing business models, appropriability of AI-based innovations</p> <p>Principles and applications of emerging materials: Functional materials and structures; Polymeric materials in pharmaceutical designs and applications; Nanotechnology in pharmaceutical applications</p> <p>Biorevolution - digital and biotech revolution: Basics and principles of emerging digital technologies and applications as well as breakthrough biotech technologies, such as CRISPR-Cas, and their impact on societies, businesses and companies.</p>
Prüfungsform und Dauer / examination type and duration:	<p>Presentation (50%) Written examination (50%), 1h</p>
Mediennutzung / media used:	<p>Script to download, student presentation, digital projector, handouts, flip chart</p>
Lehr- und Lernmethodik / teaching and learning methodology:	<p>A mixture of methodologies is applied, e.g. lecture with interactive teaching and discussions, combined with team works and case-in-points</p>
Empfohlene Literatur / recommended literature:	<p>Agrawal, A., Gans, J., & Goldfarb, A. (2018). Prediction Machines: The Simple Economics of Artificial Intelligence. Cambridge, MA: Harvard Business Review Press.</p> <p>Brynjolfsson, E., & McAfee, A. (2017). The business of artificial intelligence: What it can - and cannot - do for your organization. Harvard Business Review, Jul (1), 10. Retrieved from https://hbr.org/cover-story/2017/07/the-business-of-artificial-intelligence</p> <p>Chui, M., Manyika, J., & Miremadi, M. (2018). What AI can and can't do (yet) for your business. McKinsey Quarterly, 2018 (1), 96-108. Retrieved from https://www.mckinsey.com/business-functions/mckinsey-analytics/our-insights/what-ai-can-and-cant-do-yet-for-your-business</p> <p>Chui, M., Manyika, J., Miremadi, M., Henke, N., Chung, R., Nel, P., & Malhotra, S. (2018). Notes from the AI frontier: Insights from hundreds of use cases. McKinsey Global Institute. Washington, DC. Retrieved from https://www.mckinsey.com/featured-insights/artificial-intelligence/notes-from-the-ai-frontier-applications-and-value-of-deep-learning</p> <p>Ng, A. 2018. AI Transformation Playbook. Landing AI. Palo Alto, CA. Retrieved from https://landing.ai/ai-transformation-playbook/</p> <p>Forbes. (2018). Behind every AI strategy is a data strategy. Retrieved September 9, 2019, from https://www.forbes.com/sites/insights-delltechnologies/2018/12/04/behind-every-ai-strategy-is-a-data-strategy/</p> <p>Forbes. (2019). What's your AI data strategy? Retrieved September 9, 2019, from https://www.forbes.com/sites/intelai/2019/05/22/whats-your-ai-data-strategy</p> <p>Tony J. Prescott et al. (2018) Living machines: A handbook of research in biomimetics and biohybrid systems Published to Oxford Scholarship Online: June 2018; DOI: 10.1093/oso/9780199674923.001.0001</p> <p>Julia Hoeng et al. (2019) Organ-on-a-chip, 1st Edition, Academic Press, Paperback ISBN: 9780128172025 Academic Press</p> <p>Metin Sitti (2017) Mobile Microrobotics - Intelligent Robotics and Autonomous Agents series. MIT Press, ISBN 0262036436, 9780262036436</p> <p>Rabus, Rebner, Sada: Optofluidics, Process Analytical Technology, De Gruyter, 2018</p> <p>Kessler RW (Ed.): Prozessanalytik Strategien und Fallbeispiele aus der industriellen Praxis, Wiley-VCH, 2006</p> <p>Bakeev: Process Analytical Technology: Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries, Wiley-VCH, 2010.</p>

PS10 – Agile Working & Workforce of the Future

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer / Prof. Dr. Alexander Schuhmacher
Modul / Module:	Agile Working & Workforce of the Future	Dozent(en) / lecturer(s):	1. Prof. Dr. Alexander Schuhmacher
Code:	PS10		2. Prof. Dr. Alexander Schuhmacher
Semester:	3		3. Prof. Dr. Alexander Schuhmacher
Sprache / Language:	DE/EN		4. Prof. Dr. Thomas Beckers
Status:	Mandatory		5. Prof. Dr. Stephan Höfer
			6.

Veranstaltungsart / type of course:	Kurs / course:		V	U	E	C	CO
	1. Principles business model innovation		X	X		X	
	2. Principles of open innovation		X	X		X	
	3. Case-in-point: Open innovation in pharma R&D		X	X		X	
	4. Agile organization and processes		X	X		X	
	5. Administrative process excellence		X	X		X	

Arbeitsaufwand / workload (h):	Kurs / course:	Unterricht / class:	Selbststudium / self-study:	Gesamt / total:
	1. Principles business model innovation	12,5	12,5	25
	2. Principles of open innovation	12,5	12,5	25
	3. Case-in-point: Open innovation in pharma R&D	12,5	12,5	25
	4. Agile organization and processes	12,5	12,5	25
	5. Administrative process excellence	12,5	12,5	25
Total:	75	50	125	

ECTS-Punkte/ ECTS-Credits:	5
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Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None
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Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...
	Professional competencies ... to apply the key approaches of design thinking and agile working. (K3) ... evaluate the various business options provided by the open innovation paradigm. (K5)
	Methodological competencies: ... to apply the 55 business model innovators to the pharmaceutical practice. (K3) ... to carry out design thinking principles. (K3) ... to methodologically operate the phases of design thinking. (K3) ... to apply agile tools in organisational transformation project. (K3)
	Social competencies: ... to engage productively in a business transformation. (K3) ... to create value through generating a variety of perspectives and solutions. (K6) ... to improve their communicative skills, specifically for communicating in a transformation. (K6) ... to develop a sense for business innovation. (K6) ... to know how to communicate and persuade people to be part of a business transformation. (K5)
	Personal competencies: ... to develop accountability for others. (K6) ... to generate self management. (K6) ... to handle stress. (K6) ... to develop proactive thinking. (K6) ... to develop conceptual thinking. (K6) ... to analyze, evaluate and create new business opportunities. (K3, K4, K6) ... to evaluate potential problems and future opportunities. (K5)

PS10 – Agile Working & Workforce of the Future (cont.)

Inhalt / content:	<p>Business model innovation: Basics principles in business models, management theories, e.g. absorptive capacity theory or evolutionary theory, how to improve the who/what/how/value, strategic management and change of business model</p> <p>Principles of open innovation: Innovation paradigms, closed innovation, open innovation, crowdsourcing, public-private-partnerships, innovation hubs, virtual R&D models, outsourcing, outcubation, off-shoring, and virtualization of R&D.</p> <p>Case-in-point: Open innovation in pharma: Pharma R&D models, traditional R&D, network-based R&D, R&D ecosystems, corporate strategies in R&D, open innovation models, such as outcubation, academic centers of excellence or crowdsourcing</p> <p>Agile organization and processes: Agile organizations, use cases, agile transformation, journey to an agile organization, building agile capabilities, new ways of working, agility in the daily business, agile culture, agile leadership</p> <p>Administrative process excellence: Learning to see, understand, and quantify waste in administrative processes, designing optimized workflows with Administrative Value Stream Design, implementing process changes sustainably</p>
Prüfungsform und Dauer / examination type and duration:	<p>Project report (50%) Written examination (50%), 1h</p>
Mediennutzung / media used:	<p>Script to download, student presentation, digital projector, handouts</p>
Lehr- und Lernmethodik / teaching and learning methodology:	<p>A mixture of methodologies is applied, e.g. lecture with interactive teaching and discussions, combined with team works and case-in-points, as well as a design thinking work shop; students need to write a term paper in preparation of this module</p>
Empfohlene Literatur / recommended literature:	<p>Chesbrough H. Open Innovation: The New Imperative for Creating and Profiting from Technology. Harvard Business School Press; 2003</p> <p>Oliver Gassmann, Alexander Schuhmacher, Max Zedwitz, Gerrit Reepmeyer. Leading pharmaceutical Innovation. How to Win the Life Science Race. Springer. 2018. ISBN 978-3-319-66833-8</p> <p>Oliver Gassmann, Karolin Frankenberger. Geschäftsmodelle entwickeln: 55 innovative Konzepte mit dem St. Galler Business Model Navigator. Hanser Verlag. 2017</p> <p>Michael Lewrick, Patrick Link, Larry Leifer: Das Design Thinking Playbook. Mit traditionellen, aktuellen und zukünftigen Erfolgsfaktoren. Verlag Franz Vahlen. 2018</p> <p>Hester Hilbrecht, Oliver Kempkens: Design Thinking im Unternehmen – Herausforderung mit Mehrwert. In: Digitalisierung und Innovation: Planung – Entstehung – Entwicklungsperspektiven. Springer. 2013</p> <p>Recent scientific publications in the respective field</p>

PS11 – Business Development & Business Planing

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Günter Lorenz / Prof. Dr. Alexander Schuhmacher
Modul / Module:	Business Development & Business Planning	Dozent(en) / Lecturer(s):	1. Monika Schüssler
Code:	PS11		2. Monika Schüssler
Semester:	3		3. Prof. Dr. Silke Wolfenstetter
Sprache / Language:	DE/EN		4. N.N.
Status:	Mandatory		5. Armin Rauch
			6. Oliver Watz

Veranstaltungsart / type of course:	Kurs / course:		V	U	E	C	CO
	1. Basics in business development		X			X	
	2. Biotech entrepreneurship		X	X		X	
	3. Basics in health economics		X	X			
	4. Basics in pharma economics						
	5. Financing Management and Accounting		X			X	
	6. Case-study: operational and strategic planning		X	X		X	

Arbeitsaufwand / workload (h):	Kurs / course:	Unterricht / class:	Selbststudium / self-study:	Gesamt / total:
	1. Basics in business development	12,5	6,25	18,75
	2. Biotech entrepreneurship	12,5	6,25	18,75
	3. Basics in health economics	12,5	6,25	18,75
	4. Basics in pharma economics	12,5	6,25	18,75
	5. Financing Management and Accounting	12,5	6,25	18,75
	6. Case-study: operational and strategic planning	25	6,25	31,25
Total:	87,5	37,5	125	

ECTS-Punkte/ ECTS-Credits:	5
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Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None
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Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...
	Professional competencies
	... to understand how business works and how it changes. (K2)
	... to understand the pharmaceutical business environment. (K2)
	... to analyze the peculiarities and challenges of corporate business development. (K4)
	... to differentiate between the challenges that corporate business development poses on the organisation's ability to optimise efficiency and outcome on the one hand and its ability to react to change in a flexible and agile manner on the other. (K5)
	... to judge the effect of change – especially disruptive technologies and scenarios have – on the organisational structure of corporations, the interaction of their employees and the ability to develop and/or grow business. (K5)
	... to identify and differentiate efficiency and outcome related success factors for internationally active companies. (K4, K5)
	Methodological competencies:
	... to evaluate operational and motivational effects of organisational structures and business models. (K5)
... analyze and evaluate stakeholders and generate a stakeholder analysis. (K5, K6)	
... to negotiate professionally. (K5)	
... to outline complex contexts and to present them professionally. (K4)	
Social competencies:	
... to integrate social responsibility towards customers and employees. (K4)	
... to communicate and lead small disparate teams they work with. (K4)	
... to communicate with impact. (K6)	
... to create value through generating a variety of perspectives and solutions. (K6)	
Personal competencies:	
... to reflect on oneself. (K5)	
... to lead and motivate teams. (K6)	
... to act proactively, result-oriented and customer-oriented. (K6)	
... to create sensitivity to others. (K6)	

PS11 – Business Development & Business Planing (cont.)

<p>Inhalt / content:</p>	<p>Business development: Basics in business development, such as types of collaborations, licensing agreements, commercial or distribution partnerships, research collaborations, tech transfer agreements, due diligence, letter of intent and term sheet, alliance management</p> <p>Biotech entrepreneurship: Biotech basic principles and business models, biotech start-up, biotech life cycle, seed funding, ideation, valuation, venture financing, initial public offering</p> <p>Health economics: Basics in health economics, health systems, healthcare players, legislation and basic principles (US, Europe, ROW)</p> <p>Pharma economics: Structure of the Pricing and Reimbursement Process, Analysis of Effects of the AMNOG Process on Drug Prices, market entry and reimbursement, market access, drug purchasing, payers and value assessment, pricing policies, value-based pricing</p> <p>Financial management and accounting: Management & controlling, financial accounting and management accounting, financial statement, profit, statement of income, cash outflow, expenditure, expenses, costs, basic figures for financial success, key performance indicators and cash cycle, cost structures, cost and activity accounting, full cost accounting vs. direct costing, business analytics in controlling</p> <p>Case study: Operational and strategic planing in pharma Basics of corporate planing, operational planing, strategic planing, balanced csorecard, value-driver models, pricing and reimbursement, change management and controlling, use case: planing and pricing excercise</p>
<p>Prüfungsform und Dauer / examination type and duration:</p>	<p>Written examination (100%)</p>
<p>Mediennutzung / media used:</p>	<p>Lecture, script to download, student presentation, digital projector, handouts</p>
<p>Lehr- und Lernmethodik / teaching and learning methodology:</p>	<p>A mixture of methodologies is applied, e.g. lecture with interactive teaching and discussions, combined with team works and case-studies</p>
<p>Empfohlene Literatur / recommended literature:</p>	<p>Galbraith, J.R. (2014): Designing Organisations: Strategy, Structure and Process at the Business Unit and Enterprise Levels, Jossey-Bass</p> <p>Davis, Roger: The relevance and importance of business development and licensing in the biopharmaceutical industry, in Journal of Commercial Biotechnology (2013) 19(3), 49–56</p> <p>Urbany, J., James, H.D. (2010): Grow by focusing on what matters: competitive strategy in 3 circles, Business Expert Press</p> <p>Horvath, Peter; Gleich, Ronald; Seiter, Mischa (2015) Controlling. Vahlen Verlag</p> <p>Coenenberg, Adolf; Fischer, Thomas; Günther, Thomas (2016) Kostenrechnung und Kostenanalyse. Schäffer Poeschel Verlag</p> <p>Schöffski, Oliver; Fricke, Frank; Guminski, Werner (2008) Pharmabetriebslehre. Springer Verlag</p> <p>Seliger, Ruth (2014) Positive Leadership: Die Revolution in der Führung. Schäffer Poeschel Verlag</p> <p>Kaplan & Norton (2018) Balanced Scorecard: Strategien erfolgreich umsetzen. Schäffer Poeschel Verlag</p> <p>Horvath & Partners (2004) Beyond Budgeting umsetzen: Erfolgreich planen mit Advanced Budgeting. Schäffer Poeschel Verlag</p> <p>Waniczek, Mirko; Ruthner, Raoul; Feichter, Andreas (2016) Unternehmensplanung und -steuerung: Von der Strategie zum Cashflow. Linde Verlag</p>

PS12.1 – Transformation Project „Business & Innovation“

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer / Prof. Dr. Alexander Schuhmacher				
Modul / Module:	Transformation project: "Business and Innovation"	Dozent(en) / Lecturer(s):	1. Prof. Dr. Alexander Schuhmacher				
Code:	PS12.1		2.				
Semester:	3		3.				
Sprache / Language:	DE/EN		4.				
Status:	Mandatory		5.				
			6.				
Veranstaltungsart / type of course:	Kurs / course:		V	U	E	C	CO
	1. Transformation project: "Business and Innovation"		X	X	X		X
	2.						
	3.						
	4.						
Arbeitsaufwand / workload (h):	Kurs / course:	Unterricht / class:	Selbststudium / self-study:	Gesamt / total:			
	1. Transformation project: "Business and Innovation"	25	100	125			
	2.						
	3.						
	4.						
Gesamt / total:	25	100	125				
ECTS-Punkte/ ECTS-Credits:	5						
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None						
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...						
	Professional competencies						
	... to understand how business transformation works. (K1)						
	... to analyze the specific business environment of the given case. (K4)						
	... to evaluate the given case and to create own concepts and business ideas. (K6)						
	Methodological competencies:						
	... to create a project proposal. (K6)						
... to plan a project and execute the plan. (K6, K3)							
Social competencies:							
... to leverage the potential of a cross-functional project team. (K6)							
... to create a network and to leverage it. (K6)							
Personal competencies:							
... to develop a global mindset. (K6)							
... to lead and motivate teams. (K6)							
... to act proactively, result-oriented and customer-oriented. (K6)							
... to create sensitivity to others. (K6)							
... to handle stress. (K6)							
... to develop proactive thinking. (K6)							
... to develop conceptual thinking. (K6)							
Inhalt / content:	Students can select between 4 different modules PS12.1 - 12.4: "Business and Innovation", "Science & Technology", "Pharmaceutical Development & Process Development" and "Pharmaceutical Production & Technology".						
	The modules are split in six section: (1) presentation of the case (incl. teaching) and coached preparation of the case, (2) coached team work to answer a RFI (request for information, around 20 questions to the case), (3) submission of RFI answers and feedback to the team, (4) business trip to the U.S., (5) RFP (request for project proposal) to the teams, (6) coached team work in the US and preparation of a project proposal.						
	Project proposals (to be drafted) refer to business transformation themes with relevance for the pharmaceutical industry, such as application of crowdsourcing to increase R&D effectiveness or use of artificial intelligence in pharma production.						
	The team work is (ideally) done on cross-functional teams (of at least 4 students) on a "real" business transformation project (real-life case). Students` performance is evaluated based on the written answers to RFI and RFP.						
Prüfungsform und Dauer / examination type and duration:	Answer to RFI (50%)						
	Project proposal and presentation (50%)						
Mediennutzung / media used:	Script/RFI/RFP to download, digital projector, handouts, flip charts						
Lehr- und Lernmethodik / teaching and learning methodology:	Team works and a real-life case (including coaching)						
Empfohlene Literatur / recommended literature:	Young Sop Ahn, Ten Megatrends Changing our Lives (2019)						
	Linz, Carsten; Müller-Stewens, Günter; Zimmermann, Alexander. Radical Business Model Transformation: Gaining the Competitive Edge in a Disruptive World. KoganPage. 2017						

PS12.2 – Transformation Project „ Science & Technology“

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer / Prof. Dr. Alexander Schuhmacher
Modul / Module:	Transformation project: "Science and Technology"	Dozent(en) / Lecturer(s):	1. Prof. Dr. Ralf Kemkemer
Code:	PS12.2		2.
Semester:	3		3.
Sprache / Language:	DE/EN		4.
Status:	Mandatory		5.
			6.

Veranstaltungsart / type of course:	Kurs / course:	V	U	E	C	CO
1.	Transformation project: "Science and Technology"	X	X	X		X
2.						
3.						
4.						

Arbeitsaufwand / workload (h):	Kurs / course:	Unterricht / class:	Selbststudium / self-study:	Gesamt / total:
1.	Transformation project: "Science and Technology"	25	100	125
2.				
3.				
4.				
	Gesamt / total:	25	100	125

ECTS-Punkte/ ECTS-Credits:	5
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Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None
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Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	<p>Upon successful completion of this module, students are able ...</p> <p>Professional competencies</p> <p>... to understand how business transformation works. (K1) ... to analyze the specific business environment of the given case. (K4) ... to evaluate the given case and to create own concepts and business ideas. (K6)</p> <p>Methodological competencies:</p> <p>... to create a project proposal. (K6) ... to plan a project and execute the plan. (K6, K3)</p> <p>Social competencies:</p> <p>... to leverage the potential of a cross-functional project team. (K6) ... to create a network and to leverage it. (K6)</p> <p>Personal competencies:</p> <p>... to develop a global mindset. (K6) ... to lead and motivate teams. (K6) ... to act proactively, result-oriented and customer-oriented. (K6) ... to create sensitivity to others. (K6) ... to handle stress. (K6) ... to develop proactive thinking. (K6) ... to develop conceptual thinking. (K6)</p>
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Inhalt / content:	<p>Students can select between 4 different modules PS12.1 - 12.4: "Business and Innovation", "Science & Technology", "Pharmaceutical Development & Process Development" and "Pharmaceutical Production & Technology".</p> <p>The modules are split in six section: (1) presentation of the case (incl. teaching) and coached preparation of the case, (2) coached team work to answer a RFI (request for information, around 20 questions to the case), (3) submission of RFI answers and feedback to the team, (4) business trip to the U.S., (5) RFP (request for project proposal) to the teams, (6) coached team work in the US and preparation of a project proposal.</p> <p>Project proposals (to be drafted) refer to business transformation themes with relevance for the pharmaceutical industry, such as application of crowdsourcing to increase R&D effectiveness or use of artificial intelligence in pharma production.</p> <p>The team work is (ideally) done on cross-functional teams (of at least 4 students) on a "real" business transformation project (real-life case).</p> <p>Students' performance is evaluated based on the written answers to RFI and RFP.</p>
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Prüfungsform und Dauer / examination type and duration:	<p>Answer to RFI (50%) Project proposal and presentation (50%)</p>
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Mediennutzung / media used:	Script to download, digital projector, handouts, flip charts
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Lehr- und Lernmethodik / teaching and learning methodology:	Team works and a real-life case (including coaching)
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Empfohlene Literatur / recommended literature:	<p>Young Sop Ahn, Ten Megatrends Changing our Lives (2019)</p> <p>Linz, Carsten; Müller-Stewens, Günter; Zimmermann, Alexander. Radical Business Model Transformation: Gaining the Competitive Edge in a Disruptive World. KoganPage. 2017</p>
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PS12.3 – Transformation Project „Pharmaceutical Development & Process Development“

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer/ Prof. Dr. Alexander Schuhmacher
Modul / Module:	Transformation project: Pharmaceutical Development & Process Development"	Dozent(en) / Lecturer(s):	1. Prof. Dr. Günter Lorenz
Code:	PS12.3		2.
Semester:	3		3.
Sprache / Language:	DE/EN		4.
Status:	Mandatory		5.
			6.
Veranstaltungsart / type of course:	Kurs / course:		V U E C CO
	1. Transformation project: Pharmaceutical Development & Process Development"		X X X X
	2.		
	3.		
	4.		
Arbeitsaufwand / workload (h):	Kurs / course:	Unterricht / class:	Selbststudium / self-study:
	1. Transformation project: Pharmaceutical Development & Process Development"	25	100
	2.		
	3.		
	4.		
	Gesamt / total:	25	100
			125
ECTS-Punkte/ ECTS-Credits:	5		
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None		
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	<p>Upon successful completion of this module, students are able ...</p> <p>Professional competencies ... to understand how business transformation works. (K1) ... to analyze the specific business environment of the given case. (K4) ... to evaluate the given case and to create own concepts and business ideas. (K6)</p> <p>Methodological competencies: ... to create a project proposal. (K6) ... to plan a project and execute the plan. (K6, K3)</p> <p>Social competencies: ... to leverage the potential of a cross-functional project team. (K6) ... to create a network and to leverage it. (K6)</p> <p>Personal competencies: ... to develop a global mindset. (K6) ... to lead and motivate teams. (K6) ... to act proactively, result-oriented and customer-oriented. (K6) ... to create sensitivity to others. (K6) ... to handle stress. (K6) ... to develop proactive thinking. (K6) ... to develop conceptual thinking. (K6)</p>		
Inhalt / content:	<p>Students can select between 4 different modules PS12.1 - 12.4: "Business and Innovation", "Science & Technology", "Pharmaceutical Development & Process Development" and "Pharmaceutical Production & Technology".</p> <p>The modules are split in six section: (1) presentation of the case (incl. teaching) and coached preparation of the case, (2) coached team work to answer a RFI (request for information, around 20 questions to the case), (3) submission of RFI answers and feedback to the team, (4) business trip to the U.S., (5) RFP (request for project proposal) to the teams, (6) coached team work in the US and preparation of a project proposal.</p> <p>Project proposals (to be drafted) refer to business transformation themes with relevance for the pharmaceutical industry, such as application of crowdsourcing to increase R&D effectiveness or use of artificial intelligence in pharma production.</p> <p>The team work is (ideally) done on cross-functional teams (of at least 4 students) on a "real" business transformation project (real-life case).</p> <p>Students' performance is evaluated based on the written answers to RFI and RFP.</p>		
Prüfungsform und Dauer / examination type and duration:	<p>Answer to RFI (50%) Project proposal and presentation (50%)</p>		
Mediennutzung / media used:	Script to download, digital projector, handouts, flip charts		
Lehr- und Lernmethodik / teaching and learning methodology:	Team works and a real-life case (including coaching)		
Empfohlene Literatur / recommended literature:	<p>Young Sop Ahn, Ten Megatrends Changing our Lives (2019)</p> <p>Linz, Carsten; Müller-Stewens, Günter; Zimmermann, Alexander. Radical Business Model Transformation: Gaining the Competitive Edge in a Disruptive World. KoganPage. 2017</p>		



PS12.4 – Transformation Project „Pharmaceutical Production & Technology“

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)		Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Ralf Kemkemer/ Prof. Dr. Alexander Schuhmacher	
Modul / Module:	Transformation project: "Pharmaceutical Production & Technology"		Dozent(en) / Lecturer(s):	1.	Prof. Dr. Naomi Häfner
Code:	PS12.4			2.	
Semester:	3			3.	
Sprache / Language:	DE/EN			4.	
Status:	Mandatory			5.	
				6.	
Veranstaltungsart / type of course:	Kurs / course:			V	U
	1. Transformation project: "Pharmaceutical Production & Technology"			X	X
	2.				
	3.				
	4.				
Arbeitsaufwand / workload (h):	Kurs / course:		Unterricht / class:	Selbststudium / self-study:	Gesamt / total:
	1. Transformation project: "Pharmaceutical Production & Technology"		25	100	125
	2.				
	3.				
	4.				
	Gesamt / total:		25	100	125
ECTS-Punkte/ ECTS-Credits:	5				
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None				
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Upon successful completion of this module, students are able ...				
	Professional competencies				
	... to understand how business transformation works. (K1)				
	... to analyze the specific business environment of the given case. (K4)				
	... to evaluate the given case and to create own concepts and business ideas. (K6)				
	Methodological competencies:				
	... to create a project proposal. (K6)				
	... to plan a project and execute the plan. (K6, K3)				
	Social competencies:				
	... to leverage the potential of a cross-functional project team. (K6)				
	... to create a network and to leverage it. (K6)				
	Personal competencies:				
	... to develop a global mindset. (K6)				
	... to lead and motivate teams. (K6)				
	... to act proactively, result-oriented and customer-oriented. (K6)				
	... to create sensitivity to others. (K6)				
	... to handle stress. (K6)				
	... to develop proactive thinking. (K6)				
	... to develop conceptual thinking. (K6)				
Inhalt / content:	Students can select between 4 different modules PS12.1 - 12.4: "Business and Innovation", "Science & Technology", "Pharmaceutical Development & Process Development" and "Pharmaceutical Production & Technology".				
	The modules are split in six section: (1) presentation of the case (incl. teaching) and coached preparation of the case, (2) coached team work to answer a RFI (request for information, around 20 questions to the case), (3) submission of RFI answers and feedback to the team, (4) business trip to the U.S., (5) RFP (request for project proposal) to the teams, (6) coached team work in the US and preparation of a project proposal.				
	Project proposals (to be drafted) refer to business transformation themes with relevance for the pharmaceutical industry, such as application of crowdsourcing to increase R&D effectiveness or use of artificial intelligence in pharma production.				
	The team work is (ideally) done on cross-functional teams (of at least 4 students) on a "real" business transformation project (real-life case).				
	Students' performance is evaluated based on the written answers to RFI and RFP.				
Prüfungsform und Dauer / examination type and duration:	Answer to RFI (50%) Project proposal and presentation (50%)				
Mediennutzung / media used:	Script to download, digital projector, handouts, flip charts				
Lehr- und Lernmethodik / teaching and learning methodology:	Team works and a real-life case (including coaching)				
Empfohlene Literatur / recommended literature:	Young Sop Ahn, Ten Megatrends Changing our Lives (2019) Linx, Carsten; Müller-Stewens, Günter; Zimmermann, Alexander. Radical Business Model Transformation: Gaining the Competitive Edge in a Disruptive World. KoganPage. 2017				

PS13 – Data Science & Scientific Working

Studienprogramm / Course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / Responsible person for the module:	Prof. Dr. Günter Lorenz / Prof. Dr. Alexander Schuhmacher
Modul / Module:	Data Sciences & Scientific Methodology	Dozent (en) / Lecturer(s):	1. Prof. Dr. Günter Lorenz
Code:	PS13		2. Prof. Dr. Alexander Schuhmacher
Semester:	4		3. Prof. Dr. Alexander Schuhmacher
Sprache / Language:	DE/EN		4. Prof. Dr. Ralf Kemkemmer
Status:	Mandatory		5. Prof. Dr. Marc Brecht
			6. Prof. Dr. Karsten Rebner
Veranstaltungsart / type of course:	Kurs / course:		V U E C OO
	1. Literature search and review		X X
	2. Basics in patent search and analysis		X X
	3. Qualitative research and design science research		X X
	4. Scientific methods and writing		X X
	5. Descriptive statistics		X X
	6. Data analytics and visualization		X X
Arbeitsaufwand / workload (h):	Kurs / course:	Unterricht / class:	Selbststudium / self-study:
	1. Literature search and review	12,5	12,5
	2. Basics in patent search and analysis	12,5	7,5
	3. Qualitative research and design science research	12,5	7,5
	4. Scientific methods and writing	12,5	7,5
	5. Descriptive statistics	12,5	7,5
	6. Data analytics and visualization	12,5	7,5
	Gesamt / total:	75	50
ECTS-Punkte/ ECTS-Credits:	5		
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	None		
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	<p>Upon successful completion of this module, students are able ...</p> <p>Professional competencies:</p> <p>... to outline the basics of the European data protection regulation and respective applications. (K4)</p> <p>... to carry out scientific searches and to use scientific data bases. (K3)</p> <p>... to understand the basics of quantitative models and statistical methods and to apply them respectively. (K2, K3)</p> <p>... to understand and apply the basic principles of macro programming. (K2, K3)</p> <p>... to understand the various strategies to retrieve information from complex data sets. (K2)</p> <p>... to apply a basic knowledge in multivariate statistical data evaluation. (K3)</p> <p>... to understand the principle limitations of various experimental design strategies in order to obtain scientifically valid data. (K2)</p> <p>... to apply the general principles of writing scientific data reports and publications. (K3)</p> <p>Methodological competencies:</p> <p>... to use software and tools for statistics, data and image analysis as well as data visualization. (K3)</p> <p>... to apply statistical methods and interpret test results. (K4)</p> <p>... to exploit statistical software tools to explore the design space (for product development and identification of causal relationships). (K5)</p> <p>... to write concisely and address selected target groups (scientific community, public, funding agencies, ...). (K2)</p> <p>Social competencies:</p> <p>... to work responsibly. (K2)</p> <p>Personal competencies:</p> <p>... to work target-oriented and systematically. (K3)</p> <p>... to work self-responsibly. (K3)</p>		
Inhalt / content:	<p>Literature search and review: Reference data bases, search engines, citation managers, literature search examples/exercises based on concrete scientific questions</p> <p>Basics in patent and patent search: Patent, patent application, structure of a patent document, international and European patent application process, priority date, patent term, patent claims, oppositions proceedings, Espacenet search, freedom-to-operate analysis</p> <p>Qualitative research and design science research: Core principles and practices of qualitative research, memo writing, coding, introduction to MaxQDA, grounded theory, narrative analysis, case studies, qualitative research design, basics in design science research, artefact design, action design science</p> <p>Scientific methods and writing: Target-group oriented writing; sections and their function; writing reports, scientific papers, project applications, reviews; using headlines, tables, figures and schematics</p> <p>Descriptive statistics: Mathematical and statistical fundamentals: Sequences, series and functions, interpretation of functions (including differential calculus and integral calculus, probability calculus, fundamentals of mathematical statistics</p> <p>Data analytics and data visualization: Terminology and classification; exploratory data analysis; statistical learning and model selection; dimensions reduction methods; variable selection; linear regression; modeling non-linear relationships</p>		
Prüfungsform und Dauer / examination type and duration:	Presentation (50%) / written examination (50%)		
Mediennutzung / media used:	Manuscripts (electronic and hardcopy), boards, overheads, and all other usual classroom appliances; student computer/laptop		
Lehr- und Lernmethodik / teaching and learning methodology:	A mixture of methodologies is applied, e.g. lecture with interactive teaching and discussions, combined with team work sessions, case-studies, and computer practicals		
Empfohlene Literatur / recommended literature:	<p>Caider/Watkins, IT Governance: An International Guide to Data Security and ISO 27001/ISO 27002 (7th edition) (Iannarelli/O'Shaughnessy, Information Governance and Security: Protecting and Managing your company's proprietary information (2014)</p> <p>Papula, L. Mathematik für Ingenieure und Naturwissenschaftler, Band 1 und 3</p> <p>Kessler (2006) Multivariate Datenanalyse für die Pharma-, Bio- und Prozessindustrie, Wiley</p> <p>Multivariate Data Analysis: An Introduction to Multivariate Analysis, Process Analytical Technology and Quality by Design (English Edition), 2018</p> <p>Bilo (2011) Excel for Chemists, Wiley</p> <p>Box, Hunter, Hunter (2008) Statistics for Experimenters, Wiley</p> <p>Danzer, Hobert, Fischbacher, Jagemann (2001) Chemometrik - Grundlagen und Anwendungen</p> <p>Alley (2018) The Craft of Scientific Writing, Wiley</p> <p>Deutsche Forschungsgemeinschaft (2019) Sicherung guter wissenschaftlicher Praxis, Denkschrift / Safeguarding Good Scientific Practice, Memorandum, Wiley/DFG</p>		

PS14 – Master Thesis

Studienprogramm / course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / responsible person for the module:	Prof. Dr. Ralf Kemkemer, Prof. Dr. Günter Lorenz, Prof. Dr. Karsten Rebner, Prof. Dr. Alexander Schuhmacher
Modul / module:	Master thesis	Dozent / lecturer(s):	Depending on the topic
Code:	PS14	Sprache / language	DE/EN
Semester:	4	Status:	Mandatory
Veranstaltungart / type of course	Research / scientific project with practical / professional background No courses included in the module		
Arbeitsaufwand / workload (hours)	625 h		
ECTS-Punkte/	25		
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending the course:	Application for the master thesis at the earliest possible with a deliverable of 50 ECTS (80 ECTS in case of a bachelor degree with 180 ECTS). Latest application required 2 months after successfully passing all modules of the study program.		
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	The thesis project usually is conducted on basis of a practical / professional projects in collaboration with the participant's employer. In-depth problem-solving competencies have to be applied by selecting and applying appropriate business research methods to solve project-related business problems in the domain of the pharma and biotech industry.		
Inhalt / content:	Content varies according to thesis project / subject		
Prüfungsform und Dauer / examination type and duration:	Master thesis with 25.000 - 30.000 words 6 months duration		
Lehr- und Lernmethodik / teaching and learning methodology:	Project and individual coaching		
Empfohlene Literatur / recommended literature:	Research methods - see module PS13 "data science and scientific working" Depending on the topic or issue		



PS15 – Research project, internship or practical experience

Studienprogramm / course of studies:	Pharmaceutical Sciences & Business (M.Sc.)	Modulverantwortlicher / responsible person for the module:	Prof. Dr. Günter Lorenz
Modul / module:	Research project, internship or practical experience	Dozent / lecturer(s):	Depending on the topic
Code:	PS15	Sprache / language	DE/EN
Semester:		Status:	Mandatory for candidates with a bachelor degree of 180 ECTS
Veranstaltungsart / type of course	Research project, internship or practical experience No courses included in the module		
Arbeitsaufwand / workload (hours)	up to 750 h		
ECTS-Punkte/ ECTS-Credits:	30		
Voraussetzungen für die Teilnahme am Kurs / prerequisites for attending	See hereto the explanatory note to this module.		
Modulziele bzw. erwünschte Ergebnisse / module goals and desired outcome:	Reaching a qualification / know-how / skill level of a 210 ECTS degree		
Inhalt / content:	Depending on the topic or issues of the module. See hereto the explanatory note to this module.		
Prüfungsform und Dauer / examination type and duration:	Term paper based on individual reyearch project, practical or progfessional experience. See hereto the explanatory note to this module.		
Lehr- und Lernmethodik / teaching and learning methodology:	Individual coaching		
Empfohlene Literatur / recommended literature:	Depending on the topic or issue		

