Modules for Pharmazie Pharmaceut.Biotech.MA120

Date 10/01/26

Pflichtmodule

PHA.03532.02 - Drug target identification and validation

PHA.03532.02	10 CP
Module label	Drug target identification and validation
Module code	PHA.03532.02
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	Prof. Dr. W. Sippl
Prerequisites	
Skills to be acquired in this module	• Basic understanding of drug substances and drug targets • Knowledge of methods and illustrative examples of drug target identification and valida-tion • Basic understanding of the connection between molecular and clinical effects of drug substances • Knowledge of bioanalytical tools for protein separation and ~identification • Ability to judge the quality of results, i.e., protein identification, protein quantitation • Ability to set up a proteomics workflow in industry • Application of proteomics methods to diseases • Knowledge of edible vaccine concepts • Knowledge of fusion protein strategies • Understanding of differences between stable and transient expression systems • Knowledge of the basic concepts of Computational Biology and Bioinformatics • A first and transparent introduction in comparative modeling and molecular dynamics simulations • Concepts of analyzing proteins/drug targets in 3D • Principles of modeling biological data
Module contents	Course B.1: General aspects of drug target identification and validation • Definition and characteristics of drug substances • Definition and characteristics of molecular drug targets • Interaction of drug substances and drug targets • Propagation of molecular drug effects • Methods and techniques for the identification and validation of drug targets • Correlation and causality of molecular and clinical drug effects Course B.2: Proteomics • Methods for separating complex protein mixtures (2-DE, LC) • Protein mass spectrometry (ionization methods; mass analyzers) • Protein sequencing • Quantitative proteomics (ICAT, iTRAQ) • Analysis of post-translational modifications (glycosylation, phosphorylation) • Protein-protein interactions • In-vivo proteomics • Proteome analysis for investigation of diseases • Automation of the proteomics workflow Course B.3: Molecular F(Ph)arming - Basics, Principles and Examples • General overview about expression of human proteins in transgenic organisms including microorganisms and mammalian cells. • Basics of intracellular sorting with special focus to plant cells. • N-glycosylation especially according the differences between plants and mammals. • Plantibody concept • Fusion protein strategies (expression enhancement, stability enhancement • Vaccines from plants including edible vaccine concepts. • Therapeutic antibodies from plants, different recombinant antibody formats. • Plant-based production of therapeutic proteins as human serum albumins and insulin as well as silk proteins for nanomedicine 4. Course B.4: Protein modeling and simulation • Introduction to Bioinformatics and comparative/homology modeling • Introduction in sequence alignment techniques • Analyzing protein structures • Commonly used force fields for protein simulations • Introduction to Molecular Dynamics • Introduction to docking simulations
Forms of instruction	Lecture (2 SWS) Lecture (2 SWS) Seminar (2 SWS) Lecture (1 SWS) Seminar (1 SWS) Lecture (1 SWS) Course
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Wintersemester

PHA.03532.02 10 CP

Module capacity	unrestricted
Time of examination	
Credit points	10 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %; Course 4: %; Course 5: %; Course 6: %; Course 7: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Course 4		
Course 5		
Course 6		
Course 7		
Final exam of module		Klausur
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Proteomics	2					0
Course 2	Lecture	Molecular F(Ph)arming - Basics, Principles and Examples	2					0
Course 3	Seminar	Protein modeling and simulation	2					0
Course 4	Lecture	General aspects of drug target identification and validation	1					0
Course 5	Seminar	General aspects of drug target identification and validation	1					0
Course 6	Lecture	Protein modeling and simulation	1					0
Course 7	Course	Selbststudium						0
Workload by module						300		300
Total module workload								300

PHA.03541.03 - Biopharmaceuticals in regenerative medicine

PHA.03541.03	10 CP
Module label	Biopharmaceuticals in regenerative medicine
Module code	PHA.03541.03
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	Prof. Dr. T. Groth
Prerequisites	
Skills to be acquired in this module	• Knowledge on the application of Biopharmaceuticals in `Regenerative Medicine`, Clarification of terms and definitions • Overview about biopharmaceuticals interesting for Regenerative Medicine • General techniques to embed or attach biopharmaceuticals to carriers or their single application • Preparation of carriers and scaffolds • Effects of biopharmaceuticals on mammalian cells and whole organism • Adverse reactions of organism on carriers and biopharmaceuticals • Selection and manipulation of cells • Selected examples of biopharmaceutical application in regenerative medicine
Module contents	1. Basic concepts of biopharmaceuticals application in regenerative medicine • Introduction to regenerative medicine • Biopharmaceuticals in regenerative medicine • Target validation and delivery of biopharmaceuticals • Cell adhesion, migration, and growth • Regulation of signal transduction, gene expression, differentiation • Blood compatibility of carriers and biopharmaceuticals • Immunocompatibility of carriers and biopharmaceuticals • Histocompatibility of carriers and biopharmaceuticals 2. Application of biopharmaceuticals in regenerative medicine • Preparation of carriers and scaffolds • Techniques to functionalize carriers and scaffolds • Concept of biomimetics • Techniques for immobilization and delivery of biopharmaceuticals • Cells in regenerative medicine • Adult and embryonic stem cells • Examples of biopharmaceutical application for regeneration of different tissues 3. Application of biopharmaceuticals for regeneration of bone • Preparation of model scaffold • Embedding of adhesive proteins and growth factors • Studies of mesenchymal stem cell adhesion and differentiation
Forms of instruction	Lecture (4 SWS) Seminar (1 SWS) Practical training (2 SWS) Course
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Wintersemester
Module capacity	unrestricted
Time of examination	
Credit points	10 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %; Course 4: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Course 4		
Final exam of module	Protocol on lab course	Klausur
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Biopharmaceuti	4					0

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
		cals in regenerative medicine						
Course 2	Seminar	Biopharmaceuticals in regenerative medicine	1					0
Course 3	Practical training	Biopharmaceuticals in regenerative medicine	2					0
Course 4	Course	Selbststudium						0
Workload by module						300		300
Total module workload								300

PHA.03531.03 - Introduction to Pharmaceutical Biotechnology

PHA.03531.03	5 CP
Module label	Introduction to Pharmaceutical Biotechnology
Module code	PHA.03531.03
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	Prof. Dr. M. Pietzsch
Prerequisites	
Skills to be acquired in this module	Knowledge of the basic concepts and technologies of Pharmaceutical Biotechnology: Terminology & Definitions Overview on industrial development and production processes Knowledge of product classes Insight to interdisciplinary cooperation in biopharmaceutical drug development and production Organizational structures and industries Interrelation of biotechnology & medicine Practical skills in biochemical methods Practical skills in chemical calculations
Module contents	A.1 Course A.1: Introduction to Pharmaceutical Biotechnology • General introduction and history of Pharmaceutical Biotechnology (PhBT) • Products of Pharmaceutical Biotechnology • Drug target identification, and validation • Selection and construction of production strains • Production aspects: Up- and Downstream Processing • Introduction to formulation • Analytical aspects • Clinical aspects • Regulatory aspects A.2 Course A.2: Basic lab course on biochemical methods • Chemical calculations (stoichiometry) • Weighing, Pipetting • Spectrophotometry • Centrifugation • Dialysis • Measurement of pH, preparation of buffer solutions, ionic strength. • Protein assay using BRADFORD and BCA-methods • Determination of enzyme activity, continuous and end point methods
Forms of instruction	Lecture (2 SWS) Practical training (2 SWS) Course
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Wintersemester
Module capacity	unrestricted
Time of examination	
Credit points	5 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Final exam of module	Examination on lab course contents, Protocol on lab course	Klausur
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Introduction to Pharmaceutical Biotechnology	2					0
Course 2	Practical training	Basic lab course on	2					0

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
		biochemical methods						
Course 3	Course	Selbststudium						0
Workload by module						150		150
Total module workload								150

PHA.03535.02 - Optimization of bioprocesses

PHA.03535.02	5 CP
Module label	Optimization of bioprocesses
Module code	PHA.03535.02
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	Dr. N. Volk
Prerequisites	Modul D: Introduction to Bioprocess Technology (Upstream Processing)
Skills to be acquired in this module	• Knowledge of mathematical modeling to optimization of bioprocesses • Foundations in the use of simulations languages • Using tools to identification, simulation and optimization • Application of models to optimization of bioprocesses • Knowledge of planning and preparation of bioreactor cultivations • Laboratory scale development of strategies for optimal bioprocessing technologies • Experience in the use of bioprocess cultivation techniques • Practical experience in the preparation and implementation of fermentations • Analyze and validate of results of fermentations
Module contents	Course E.1: Modeling and simulation • Principles of bioprocess modeling and optimization • Modeling concepts for biological systems and bioreactors • Dynamic modeling of bioreactors • Introduction in simulation language (MATLAB, Copasi, Celldesigner) • Case studies to simulation • Optimization of bioprocesses • Case studies to optimization Course E.2: Control of bioreactor cultivations • Planning of a bioreactor cultivation process • Mathematical simulation of the process • Preparation of the bioprocess techniques and analytics • Experimental realization of the cultivation process • Analyze and validate the results • Identification of a model from the results • Describe and analyze the process
Forms of instruction	Practical training (2 SWS) Lecture (1 SWS) Seminar (1 SWS) Seminar (1 SWS) Course
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Sommersemester
Module capacity	unrestricted
Time of examination	
Credit points	5 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %; Course 4: %; Course 5: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Course 4		
Course 5		
Final exam of module	1 attestation, 1 protocol, 5 exercises	Klausur
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Practical training	Control of bioreactor cultivations	2					0
Course 2	Lecture	Modeling and	1					0

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
		Simulation						
Course 3	Seminar	Modeling and Simulation	1					0
Course 4	Seminar	Control of bioreactor cultivations	1					0
Course 5	Course	Selbststudium						0
Workload by module						150		150
Total module workload								150

PHA.03542.02 - Project work

PHA.03542.02	5 CP
Module label	Project work
Module code	PHA.03542.02
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	Prof. Dr. M. Pietzsch
Prerequisites	Module D: Introduction to bioprocess technology; Module E: Optimization of bioprocesses; Module G: Purification of products from pharmaceutical biotechnology
Skills to be acquired in this module	• first independent research experience for the students • literature studies and experimental work • writing of reports • defending results
Module contents	• participation in a research group • introduction to independent research of the students • combining literature and experimental research • independent preparation of the research report • oral presentation of the results using Power Point; discussion of the results
Forms of instruction	Course (4 SWS) Course
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Wintersemester
Module capacity	unrestricted
Time of examination	
Credit points	5 CP
Share on module final degree	Course 1: %; Course 2: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Final exam of module		Lehrforschungsbericht, Mündliche Präsentation und Verteidigung
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Course	Project work	4					0
Course 2	Course	Selbststudium						0
Workload by module						150		150
Total module workload								150

PHA.03540.03 - Biopharmaceuticals

PHA.03540.03	5 CP
Module label	Biopharmaceuticals
Module code	PHA.03540.03
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	Prof. Dr. B. Dräger
Prerequisites	Module A: Optimization of bioprocesses; Module E: Introduction to pharmaceutical biotechnology
Skills to be acquired in this module	• Knowledge of the basic concepts of immune response • Overview on immunotherapeutics, vaccines, antibodies, fusion proteins, future develop-ments • Overview of the different types of monoclonal antibodies (mAbs) • Knowledge of the targets for mAbs • Knowledge of the PK and PD characteristics of mAbs • Insight into mAbs under clinical development • Insight into the currently approved mAbs • Understanding of antibody production: polyclonal antibodies from mice, monoclonal an-tibodies from hybridoma cells, recombinant antibodies from bacteria • Understanding of antibody action: specificity, affinity, avidity • Understanding the background and basics of different immunological tests: ELISA, Western blot and hemagglutination test, practical experience. • Understanding the production (phages, bacteria) and physical (Western blot) and func-tional (ELISA) characterization of different formats of recombinant antibodies: nanobod-ies, scFv. • Practical experience in the purification of antibodies from sera by affinity chromatography • Diseases relevant for DNA therapy • Functional aspects of therapeutic DNA • Delivery systems for DNA • Current therapy strategies
Module contents	Course K.1: Vaccines, Immunology • Basic immunology: innate and specific immune response • Basics of immune cell differentiation, B- and T-lymphocytes • Basics of immune system receptors and signaling • Basics of tumor immunology • Basics of allergy sand autoimmune disease • Vaccines in use and in development • Antibodies for therapy and diagnosis Course K.2: Clinical development of monoclonal antibodies • Basics of immunology • Technical and methodical basics of production/selection of monoclonal antibodies by classical methods and advanced modern technologies • The selection of monoclonal recombinant antibodies of different formats by Phage Dis-play, Screening • Production of monoclonal antibodies in CHO cells including optimization of cell lines, cul-tivation, media, scale up as well as purification strategies and methods. • Plant-based antibody production is generally explained with a specific focus to expres-sion enhancement, purification tags and glycol-engineering. • Mechanisms of action of therapeutic antibodies • Antibody optimization wrt pharmacokinetical half-life extension, ADCC and CDC • Development of therapeutic anti-tumour antibodies • Approval and necessary tests to perform phase I, II and II trials. • Bleeding of immunized mice, production of sera, characterization by ELISA and Western blot • Lab course: Observation of hybridoma cultures, harvest of supernantants, functional characterization by ELISA and Western blot • Production of specific display phages, nanobodies and scFv in E. coli, physical • characterization by Western blot and functional characterization by competitive ELISA • Characterization of potentially neutralizing anti H5N1 antibodies in an hemagglutination test with plant-derived Virus-Like-Particles (VLPs) Course K.3: DNA for gene therapy • DNA therapy: monogenic diseases, cancer • Therapeutic DNA: structure, preparation, quality control, biological requirements • Delivery systems: viral, liposomes, other - advantages/disadvantages • Experimental test systems, cell culture, animal model • Current therapy protocols
Forms of instruction	Lecture (2 SWS) Lecture (1 SWS) Lecture (1 SWS) Course Practical training (2 SWS)
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Wintersemester

PHA.03540.03 5 CP

Module capacity	unrestricted
Time of examination	
Credit points	5 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %; Course 4: %; Course 5: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Course 4		
Course 5		
Final exam of module	attestation on lab course contents, Protocol on lab course	Klausur
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Vaccines, Immunology	2					0
Course 2	Lecture	Clinical development of monoclonal antibodies	1					0
Course 3	Lecture	DNA for gene therapy	1					0
Course 4	Course	Selbststudium						0
Course 5	Practical training	Lab course on basics of immunological methods	2					0
Workload by module						150		150
Total module workload								150

PHA.03537.03 - Purification of products of pharmaceutical biotechnology (Downstream Processing)

PHA.03537.03	10 CP
Module label	Purification of products of pharmaceutical biotechnology (Downstream Processing)
Module code	PHA.03537.03
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	Prof. Dr. M. Pietzsch
Prerequisites	Module C: Construction of production organisms; Module D: Introduction to bioprocess technology
Skills to be acquired in this module	• Knowledge of the basic concepts of downstream processing • Foundations of protein purification • Knowledge on equipment and design parameters • Knowledge of scale-up parameters • Challenges in prevention or elimination of contaminants • Knowledge on process integration: Strain development, up- and downstream processing • Bbasics of technical/industrial purification of proteins • Know how to plan and perform the purification of a target protein from biomass
Module contents	Course G.1: Introduction to Downstream Processing • Overview on potential contaminations of target products and strategies for their removal • Equipment: Design and operation • Cell disintegration • Solid-Fluid separations • Liquid-Liquid extraction • Precipitation and crystallization • Chromatographic separations • Special applications: Purification of membrane proteins, inclusion bodies, antibodies, vi-ruses, DNA, etc. Course G.2: Practical course on Downstream Processing • Purity control by SDS-PAGE and determination of specific enzymatic activity • Cell disintegration • Solid / Liquid Separation • Protein precipitation • Preparative chromatography for the purification of proteins • Packing of chromatography columns • Generation of purification tables
Forms of instruction	Lecture (2 SWS) Seminar (1 SWS) Seminar (1 SWS) Practical training (4 SWS) Course
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Sommersemester
Module capacity	unrestricted
Time of examination	
Credit points	10 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %; Course 4: %; Course 5: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Course 4		
Course 5		
Final exam of module	1 attestation, 1 presentation, 1 protocol on lab course	Klausur
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Introduction to	2					0

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
		Downstream Processing						
Course 2	Seminar	Introduction to Downstream Processing	1					0
Course 3	Seminar	Practical course on Downstream Processing	1					0
Course 4	Practical training	Practical course on Downstream Processing	4					0
Course 5	Course	Selbststudium						0
Workload by module						300		300
Total module workload								300

PHA.03536.02 - Legal and economical aspects of pharmaceutical biotechnology

PHA.03536.02			5 CP
Module label		Legal and economical aspects of pharmaceutical biotechnology	
Module code		PHA.03536.02	
Semester of first implementation			
Module used in courses of study / semesters		• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule	
Responsible person for this module			
Further responsible persons		Prof. Dr. P. Imming	
Prerequisites			
Skills to be acquired in this module		• Understanding of drug quality requirements, pre-requisites and activities • Basic knowledge of the European drug quality system • Connection of the European system with international regulations, differences and over-laps • Knowledge of basic concepts for GMP and on differences between European and US regulations • Knowledge of the basic concepts of a) Strategic & business planning (corporate, marketing, financial, R&D) b) value assessment of developmental projects and intellectual properties with simple standard methods (NPV, double-sided NPV, benchmarking etc) c) portfolio strategy d) structuring cooperation agreements e) patent assessment and trading intellectual properties (licensing) f) alliances and joint ventures • Drafting and evaluation of different forms of cooperation agreements • Calculating value of a particular product in development • Understanding and drafting a commercial term sheet for licensing of a particular product from a development to a distributor company • Drafting a business plan	
Module contents		Course F.1: Drug quality control - European and international standards and regulations • Requirements for drugs: efficacy, safety, quality • Drug quality: definitions, legal requirements, standards, methods • Good Manufacturing Practices, emphasis on quality; CPMP and ICH guidelines on qual-ity • European, US, and other pharmacopoeiae of international importance Course F.2: Good Manufacturing Practice - European and international regulations • European GMP regulations • Application of GMP guidelines for biotechnology • Aseptic processing • Qualification of materials and devices for pharmaceutical manufacturing • Process validation • GMP compliant documentation • Qualified persons in GMP manufacturing • Modern concepts for `Quality by Design` and Process Analytical Technology Course F.3: Economical and marketing aspects, patents and licensing • Strategic planning • Business Plan • Value assessment • Important legal issues for structuring different cooperation agreements • Evaluation of Intellectual Properties • Trading with Intellectual Properties • Exercise Course based on a case study	
Forms of instruction		Lecture (2 SWS) Lecture (1 SWS) Lecture (1 SWS) Course	
Languages of instruction		German, English	
Duration (semesters)		1 Semester Semester	
Module frequency		jedes Sommersemester	
Module capacity		unrestricted	
Time of examination			
Credit points		5 CP	
Share on module final degree		Course 1: %; Course 2: %; Course 3: %; Course 4: %.	
Share of module grade on the course of study's final grade		1	
Examination	Exam prerequisites		Type of examination
Course 1			
Course 2			
Course 3			
Course 4			
Final exam of module			Klausur
Exam repetition information			

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Economical and marketing aspects, patents and licensing	2					0
Course 2	Lecture	Drug quality control - European and international standards and regulations	1					0
Course 3	Lecture	Good manufacturing practice - European and international regulations	1					0
Course 4	Course	Selbststudium						0
Workload by module						150		150
Total module workload								150

PHA.03538.03 - Validation of Process and Product

PHA.03538.03		10 CP
Module label	Validation of Process and Product	
Module code	PHA.03538.03	
Semester of first implementation		
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule	
Responsible person for this module		
Further responsible persons	Dr. M. Niepel	
Prerequisites	Module B: Drug target identification and validation	
Skills to be acquired in this module	• Basics of chromatographic separation and identification of small molecules • Basics of GC-MS and HPLC-MS • Understanding the role of computing in knowledge discovery and apply bioinformatics tools in data processing, workflow automation, and structure determination. • Ability to critically analyze and evaluate different approaches to generating models and simulations from biological databases. • Knowledge of the basic concepts of chromatography and mass spectrometry • Ability to set up a proteomics workflow in industry • Ability to judge the quality of results, i.e. protein identifications	
Module contents	Course H.1: Detection of potential contaminations • Sample preparation from biological matrices • Plant product chromatography • How to quantify, if there is no (standard) compound • Distinction of similar compounds • Labeling and spiking of samples • Practical examples and problems Course H.2: Structure analysis • Bioinformatics in large scale proteomics and lipidomics • Genome and proteome databases, annotations, and search engines • Preprocessing of mass spectra • Principles and algorithms for peptide and protein sequence analysis • Identification of PTMs: classic and blind mode • Determination of elemental compositions by mass spectrometry • Molecular profiling and imaging techniques, Ion Mobility Spectroscopy • Vibrational spectroscopy: FT-IR, NIR, Raman, and Terahertz spectroscopies • Multivariate analysis for qualitative (principal component analysis) and quantitative (partial least squares regression) analysis Course H.3: Protein analysis by mass spectrometry • Methods for separating complex protein and peptide mixtures (gel electrophoresis, HPLC) • In-gel and in-solution proteolysis of proteins • Protein mass spectrometry (ionization methods ESI and MALDI; mass analyzers TOF, LIT, , Orbitrap, hybrid instruments) • Peptide sequencing by mass spectrometry (MS/MS) • Database searches (Mascot) • Scoring algorithms for protein identification • Automation of the proteomics workflow	
Forms of instruction	Lecture (2 SWS) Seminar (1 SWS) Lecture (2 SWS) Practical training (1 SWS) Practical training (2 SWS) Course	
Languages of instruction	German, English	
Duration (semesters)	1 Semester Semester	
Module frequency	jedes Sommersemester	
Module capacity	unrestricted	
Time of examination		
Credit points	10 CP	
Share on module final degree	Course 1: %; Course 2: %; Course 3: %; Course 4: %; Course 5: %; Course 6: %.	
Share of module grade on the course of study's final grade	1	

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Course 4		
Course 5		

Examination			Exam prerequisites			Type of examination		
Course 6								
Final exam of module			attestation on lab course contents - Course H.2: Structure analysis, attestation on lab course contents - Course H.3: Protein analysis by mass spectrometry, Protocol on lab course			Klausur		
Exam repetition information								
Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Detection of potential contaminations	2					0
Course 2	Seminar	Detection of potential contaminations	1					0
Course 3	Lecture	Structure analysis	2					0
Course 4	Practical training	Structure analysis	1					0
Course 5	Practical training	Protein analysis by mass spectrometry	2					0
Course 6	Course	Private study						0
Workload by module						300		300
Total module workload								300

PHA.03539.02 - Technological and clinical aspects of biopharmaceuticals

PHA.03539.02	10 CP
Module label	Technological and clinical aspects of biopharmaceuticals
Module code	PHA.03539.02
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	Prof. Dr. M. Pietzsch
Prerequisites	Module D: Introduction to Bioprocess technology; Module H: Validation of process and product
Skills to be acquired in this module	• Knowledge of formulation principles for biotech products • Challenges of protein formulations • Knowledge of formulation processes and ingredients • Knowledge of drug delivery mechanisms and kinetics • Knowledge of parenteral controlled release formulations • Knowledge on posttranslational modifications of proteins in vivo • Rationale behind posttranslational modification of proteins • Know-how to synthetically modify proteins in vitro • Knowledge on the application of biocatalysts for the synthesis of drugs • Biosynthetic pathways of plant secondary metabolites • Regulatory mechanisms of metabolite production • Plant-derived pharmaceuticals • Strategies to produce metabolites in transgenic plants • Successful examples of pharmaceutical production in plants • Knowledge of the basic concepts of Pharmacokinetics • Overview on the pharmacokinetic models • Knowledge concerning the relevant pharmacokinetic parameters • Basics of the physiological background of the Pharmacokinetics • Application of the pharmacokinetic evaluation on selected drugs
Module contents	Course I.1: Drug delivery • Principles of protein formulation • Rational based formulation development / Formulation Screening • Stabilization principles for proteins • Controlled Release: Principles, Materials and Kinetics • In vitro - In vivo Correlation of Drug Release Course I.2: Covalent modifications of proteins • Posttranslational modifications found in nature, e. g. glycosylation, farnesylation, phos-phorylation, protein-protein cross-linking, protein splicing, oxidation, etc. • Enzymes involved in posttranslational modification • Bio and chemo catalysis for the in vitro modification of proteins, e. g. PEGylation, transglutaminase, lysyl oxidase. • Application of biocatalysts in drug synthesis and enzyme technology, e. g. synthesis of semi-synthetic penicillin's, synthesis of optically pure D-amino acids, regiospecific hy-droxylation of steroids, etc. Course I.3: Advanced course on plant cell technology • Induction and subcultivation of plant cell cultures • Induction and cultivation of organ cultures • Selection of cell strains by cell aggregat and protoplast cloning • Introduction of foreign genetic material into plant cells • Expression of foreign genetic material using plant cell and hairy root cultures • In vitro storage of plant cell culture and meristems by cryopreservation Course I.4: Pharmacokinetics • General Introduction and history of Pharmacokinetics • Pharmacokinetic concepts and models • Pharmacokinetic characterization of drug using relevant parameters • Physiological and physicochemical background • Application of the pharmacokinetic analysis on drugs and formulations • Relevant routes of administration
Forms of instruction	Lecture (2 SWS) Lecture (2 SWS) Lecture (2 SWS) Lecture (2 SWS) Course
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Wintersemester
Module capacity	unrestricted
Time of examination	
Credit points	10 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %; Course 4: %; Course 5: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Course 4		
Course 5		
Final exam of module	1 Protokoll	Klausur
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Drug delivery	2					0
Course 2	Lecture	Covalent modification(s) of proteins	2					0
Course 3	Lecture	Advanced course on plant cell technology	2					0
Course 4	Lecture	Pharmacokinetics	2					0
Course 5	Course	Selbststudium						0
Workload by module						300		300
Total module workload								300

PHA.03534.02 - Introduction to Bioprocess technology (Upstream Processing)

PHA.03534.02	5 CP
Module label	Introduction to Bioprocess technology (Upstream Processing)
Module code	PHA.03534.02
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	Dr. N. Volk
Prerequisites	
Skills to be acquired in this module	• Knowledge of the basic concept of bioprocess technology • Foundations of microbial growth and cultivation principles • Application of bioprocess engineering principles • knowledge of bioreactor operations and their industrial applications • Basics of technical/industrial fermentation processes
Module contents	• Basics of bioprocess technology • Microbial growth and cultivation principles • Reactor design and instrumentation • process control of bioreactors • balancing and design of bioreactors • Bioprocess scale-up • sterile technology • Application of fermentation processes • Bioprocess case studies
Forms of instruction	Lecture (3 SWS) Seminar (1 SWS) Course
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Wintersemester
Module capacity	unrestricted
Time of examination	
Credit points	5 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Final exam of module		Klausur
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Bioprocess technology	3					0
Course 2	Seminar	Bioprocess technology	1					0
Course 3	Course	Selbststudium						0
Workload by module						150		150
Total module workload								150

PHA.03543.02 - Master thesis

PHA.03543.02			30 CP
Module label		Master thesis	
Module code		PHA.03543.02	
Semester of first implementation			
Module used in courses of study / semesters		• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule	
Responsible person for this module			
Further responsible persons		Prof. Dr. M. Pietzsch	
Prerequisites		90 credit points	
Skills to be acquired in this module		• carrying out of independent research • literature studies and experimental work • writing of the thesis • defense of the thesis	
Module contents		• thesis related to the development, analytics, production, isolation, formulation, or appli-cation of biopharmaceuticals • carrying out literature research • collecting experimental data and doing of data evaluation • oral presentation of the final thesis including defense	
Form of instruction		Independent supervised work (30 SWS)	
Languages of instruction		German, English	
Duration (semesters)		1 Semester Semester	
Module frequency		jedes Sommersemester	
Module capacity		unrestricted	
Time of examination			
Credit points		30 CP	
Share on module final degree		Course 1: %.	
Share of module grade on the course of study's final grade		1	
Examination	Exam prerequisites		Type of examination
Course 1			
Final exam of module			written Master thesis, oral presentation and examination /
Exam repetition information			
Form of instruction	Independent supervised work		
Course name	MA-Arbeit		
SWS	30		
Workload of compulsory attendance			
Workload of preparation / homework etc			
Workload of independent learning			
Workload (examination and preparation)			
Workload total	0		
Workload self-arranged work (module-oriented	900		
Total module workload	900		
Type of examination			
Frequency	Summer semester		
Capacity	unrestricted		

PHA.03533.03 - Construction of production organisms: Hosts and vectors

PHA.03533.03	10 CP
Module label	Construction of production organisms: Hosts and vectors
Module code	PHA.03533.03
Semester of first implementation	
Module used in courses of study / semesters	• Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule
Responsible person for this module	
Further responsible persons	PD Dr. M. Brandsch
Prerequisites	
Skills to be acquired in this module	• To understand the basic principles of cell physiology. • To obtain solid knowledge on morphology and function of cell organelles. • To understand the basic techniques of in vitro animal cell cultures. • To know the problematic nature of stem cell research. • To obtain detailed knowledge on transfection of mammalian cells for biotechnological purposes. • To understand the basic principles of plant development • Knowledge of the basic concepts of in vitro plant cell, tissue and organ cultures • Insight into molecular techniques of plant cell transformation and regeneration • Overview of industrial application of plant tissue systems • Insight into biotechnological applications of transgenic plants • Survey of basic techniques of in vitro cultivation of plant cells • Skills of induction and cultivation of plant cells • Skills of handling agrobacteria in plant transformation procedures • Practical knowhow in analyzing genetically modified plants • Theoretical ability to construct a genetically modified organism by gene cloning und ex-pression in a final production host. • Advantages of bacteria, yeast and insect cells as gene expression systems. • Theoretical ability to cultivate bacteria and yeasts. • Overview over products of molecular and classic biotechnology. • Practical know-how for transformation/transfection and cultivation of plant and microbial cells
Module contents	Course C.1: Animal cell biology and technology • Animal cell morphology and biochemistry • Animal cell physiology • Animal cell lines: Adherent cells, cells in suspension • Basic cell culture techniques: Trypsinization, subculturing, proliferation and viability tests • Transfection techniques • Animal cell mass culture • Special cell types: hybridoma cells Course C.2: Plant cell technology • Plant meristems, vegetative growth and reproductive development • Basic plant regeneration and propagation procedures • Application of organ culture systems • In vitro storage and cryopreservation of plant tissues • Plant cell transformation techniques • Gene expression systems in plants • Molecular plant biotechnology: natural and novel products • Plant cell, tissue and organ cultures: initiation and maintenance • Monitoring of growth parameters and proliferation of plant cell cultures • Agrobacterium-mediated transient expression of reporter genes • Testing transgenic plants for the presence of foreign DNA by PCR • Monitoring of promoter activation based on reporter enzyme activity Course C.3: Molecular Biotechnology • Principal mechanisms of DNA synthesis in vitro and in vivo - use of enzymes for gene cloning. • Regulation of gene expression in prokaryotes and use for heterologous expression of proteins. • Methods of gene cloning and target gene isolation. • Theoretical ability to construct a genetically modified organism for heterologous protein expression. • Theoretical ability to cultivate bacteria and yeasts. • Advantages of bacteria and yeast as gene expression systems. Course C.4: Practical course on construction of hosts and vectors • Amplification of target DNA using PCR, restriction digest and vector ligation. • Transformation of E. coli with plasmid, selection, monitoring of the expression success.
Forms of instruction	Lecture (1 SWS) Seminar (1 SWS) Lecture (2 SWS) Lecture (2 SWS) Seminar (1 SWS) Practical training (3 SWS) Course
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester
Module frequency	jedes Wintersemester
Module capacity	unrestricted

PHA.03533.03 10 CP

Time of examination	
Credit points	10 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %; Course 4: %; Course 5: %; Course 6: %; Course 7: %.
Share of module grade on the course of study's final grade	1

Examination	Exam prerequisites	Type of examination
Course 1		
Course 2		
Course 3		
Course 4		
Course 5		
Course 6		
Course 7		
Final exam of module	examination on lab course contents part microorganisms, examination on lab course contents part plant cell technology, Protocol on lab course part microorganisms, Protocol on lab course part plant cell technology	Klausur
Exam repetition information		

Module course label	Course type	Course title	SWS	Workload of compulsory attendance	Workload of preparation / homework etc	Workload of independent learning	Workload (examination and preparation)	Sum workload
Course 1	Lecture	Animal cell biology and technology	1					0
Course 2	Seminar	Animal cell biology and technology	1					0
Course 3	Lecture	Plant cell technology	2					0
Course 4	Lecture	Molecular biotechnology	2					0
Course 5	Seminar	Practical course on construction of hosts and vectors	1					0
Course 6	Practical training	Practical course on construction of hosts and vectors	3					0
Course 7	Course	Selbststudium						0
Workload by module						300		300
Total module workload								300