

Modules for Pharmazie

Date 24/03/2

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	. 101.211 111.044
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
Module contents	simulations • Concepts of analyzing proteins/drug targets in 3D • Principles of modeling biological data Course B.1: General aspects of drug target identification and validation •
Forms of instruction	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



Time of examina Credit points Share on module Share of module Examination								
Share on module	e final degree							
Share of module	e final degree			10	CP			
					ourse 1: %; Course 2: %; Course 7: %.	%; Course 3: %;	Course 4: %; Cou	rse 5: %; Course
Evamination	e grade on the o	course of study's f	inal grade	1				
=xammanon			Exam prerequi	sites		Type of examir	nation	
Course 1								
Course 2								
Course 3								
Course 4								
Course 5								
Course 6								
Course 7								
Final exam of n	nodule					Klausur		
Exam repetition	n 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				
Course 2	Lecture	Molecular F(Ph)arming - Basics, Principles and Examples	:	2				
Course 3	Seminar	Protein modeling and simulation	:	2				
Course 4	Lecture	General aspects of drug target identification and validation		1				
Course 5	Seminar	General aspects of drug target identification and validation		1				
Course 6	Lecture	Protein modeling and simulation		1				
Course 7	Course	Selbststudium						
Workload by mo						300	 O	30



PHA.03541.03 - Biopharmaceuticals in regenerative medicine

Module label				Biopha	armaceuticals in re	generative medic	ine			
Module code				PHA.0	3541.03					
Semester of fire	st implementation	on								
Module used in	n courses of stud	dy / semesters		•		ech.MA120, Versi	MA120 LP) (Master ion of accreditation			
Responsible pe	erson for this mo	odule								
Further respon	sible persons			Prof. [Dr. T. Groth					
Prerequisites										
Skills to be acq	quired in this mo	dule		Medic biopha to emb Prepa mamn	• Knowledge on the application of Biopharmaceuticals in `Regenerative Medicine`, Clarification of terms and definitions • Overview about biopharmaceuticals interesting for Regenerative Medicine • General techniqu 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 •					
Module content	ts			Introde medic adhes expres biopha Histor 2. Ap carrier Conce biopha stem of differe 3. Ap model	ic concepts of biop action to regeneration. Target validation, migration, and sision, differentiation armaceuticals • Immo mompatibility of carri- bication of biophar s and scaffolds • T pt of biomimetics • armaceuticals • Cel tells • Examples of nt tissues blication of biophar scaffold • Embedd senchymal stem ce	ive medicine • Bidion and delivery of growth • Regulath • Blood compation of the second compatibility lers and biopharm maceuticals in respective to fund Techniques for in lis in regenerative biopharmaceuticals for reing of adhesive p	pharmaceuticals of biopharmaceuticion of signal trans ibility of carriers and binaceuticals generative medicictionalize carriers mmobilization and medicine • Adult al application of boroteins and growth	in regenerative cals • Cell duction, gene and opharmaceuticals one • Preparation of and scaffolds • delivery of and embryonic egeneration of the • Preparation of the • Preparati		
Forms of instru	uction			Semi	ire (4 SWS) nar (1 SWS) ical training (2 SW se	S)				
Languages of in	nstruction			Gern	nan, English					
Duration (seme	esters)			1 Sem	ester Semester					
Module frequer	ncy			jedes	Wintersemester					
Module capacit	ty			unlimi	ed					
Time of examin	nation									
Credit points				10 CP						
Share on modu	ıle final degree			Cour	se 1: %; Course 2:	%; Course 3: %;	Course 4: %.			
Citaro Cir inicac	le grade on the o	course of study's	inal grade	1						
			Exam prered	nuisites		Type of examin	notion			
				14.0.00		Type of examili	ialion			
Share of modul				14101100		туре от ехапш	lation			
Share of modul Examination			ZAMIII Prorot	14.01.00		туре от ехапіїї	iation			
Share of modul Examination Course 1						туре от ехапш	iation			
Share of modul Examination Course 1 Course 2						Type of exami	iauon			
Share of modul Examination Course 1 Course 2 Course 3	module		Protocol on			Klausur	iation			
Share of modul Examination Course 1 Course 2 Course 3 Course 4 Final exam of	module on information						iation			
Share of modul Examination Course 1 Course 2 Course 3 Course 4 Final exam of		Course title			Workload of preparation / homework etc		Workload (examination and preparation)	Sum workload		



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	Biopharmaceuti cals in regenerative medicine		1				0
Course 3	Practical training	Biopharmaceuti cals 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

Module label					Introdu	iction to Pharmace	utical Biotechnol	ogy	
Module code					PHA.0	3531.03			
Semester of fire	st implementation	on							
Module used in	courses of stud	dy / semesters			•		ech.MA120, Versi	MA120 LP) (Master ion of accreditation	
Responsible pe	erson for this mo	odule							
Further respon	sible persons				Prof D	r. M. Pietzsch			
Prerequisites									
Skills to be acquired in this module					Bioted Overv Know Insigh and pr Orgar Interre Practi	edge of the basic of nnology: Terminold iew on industrial d ledge of product cl t to interdisciplinar oduction izitational structure elation of biotechno- cal skills in biochecal skills in chemic	ogy & Definitions evelopment and passes y cooperation in I is and industries ology & medicine mical methods	production process	ses
Module contents						curse A.1: Introduction and history of aceutical Biotechn on and construction and construction are Processing I aspects • Regularurse A.2: Basic latitions (stoichiomet ugation • Dialysis trength. • Protein a nination of enzyme	of Pharmaceutical ology • Drug targ on of production s • Introduction to latory aspects or course on block by) • Weighing, Pie • Measurement olessay using BRAI	I Biotechnology (Piet identification, autrains • Production formulation • Analymemical methods • ipetting • Spectrop f pH, preparation of DFORD and BCA-	hBT) • Products on divalidation • naspects: Up-anotical aspects • Chemical hotometry • of buffer solutions, methods •
Forms of instru	ıction					re (2 SWS) ical training (2 SW se	S)		
Languages of i	nstruction				Germ	an, English			
Duration (seme	esters)				1 Sem	ester Semester			
Module frequer	псу				jedes \	Wintersemester			
Module capacit	y				unlimit	ed			
Time of examin	ation								
Credit points					5 CP				
Share on modu	le final degree				Cours	se 1: %; Course 2:	%; Course 3: %.		
Share of modu	le grade on the	course of study's f	inal grade		1				
Examination			Exam prere	quisit	es		Type of examir	nation	
Course 1									
Course 2									
Course 3									
Final exam of	module		Examination course	n on I	ab course conter	nts, Protocol on lab	Klausur		
Exam repetition	on 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					(
Course 2	Practical training	Basic lab course on		2					(



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 r	module					150		150
Total module	workload							150



PHA.03535.02 - Optimization of bioprocesses

PHA.03535.02									5 CF		
Module label					Optimiz	zation of bioproces	sses				
Module code					PHA.03	3535.02					
Semester of fir	st implementation	on									
Module used in	n courses of stud	ly / semesters			•	 Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule 					
Responsible pe	erson for this mo	odule									
Further respon	sible persons				Dr. N. V	/olk					
Prerequisites							Bioprocess Techr	nology (Upstream I	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 conten	ts				Course optimiz Dynam (MATL bioproc Course cultivat the bio cultivat	E.1: Modeling an ation • Modeling of ic modeling of bio AB, Copasi, Celldo esses • Case stude E.2: Control of bion process • Mathorocess technique	d simulation • Printer oncepts for biologone reactors • Introduces igner) • Case states to optimizationi or eactor cultivatione matical simulations and analytics • lyze and validate	nciples of bioproce gical systems and ction in simulation tudies to simulation ons • Planning of a ion of the process Experimental reali the results • Identi	ess modeling and bioreactors • language n • Optimization o a bioreactor • Preparation of zation of the		
Forms of instru	uction				Lectu Semir	cal training (2 SW re (1 SWS) nar (1 SWS) nar (1 SWS) e	S)				
Languages of i	nstruction				Germ	an, English					
Duration (seme	esters)				1 Seme	ester Semester					
Module freque	ncy				jedes S	Sommersemester					
Module capacit	ty				unlimite	ed					
Time of examir	nation										
Credit points					5 CP						
Share on modu	ıle final degree				Cours	e 1: %; Course 2:	%; Course 3: %;	Course 4: %; Cou	rse 5: %.		
Share of modu	le grade on the c	course of study's	final grade		1						
Examination			Exam prerec	quisit	es		Type of examin	ation			
Course 1											
Course 2											
Course 3											
Course 4											
Course 5											
Final exam of	module		1 attestation	, 1 p	rotocol, 5 exercis	es	Klausur				
Exam repetition	on 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					(
Course 2	Lecture	Modeling and		1					(



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 I	nodule					150		150
Total module	workload							150



PHA.03542.02 - Project work

PHA.03542.02									5 CP		
Module label					Projec	t work					
Module code					PHA.0	3542.02					
Semester of fire	st implementation	on									
Module used in	courses of stud	dy / semesters			•	Pharmaceutical Pharmaceut.Biote WS 2015/16) > P	ech.MA120, Versi	IA120 LP) (Master on of accreditation			
Responsible pe	erson for this mo	odule									
Further respon	sible persons				Prof. [Dr. M. Pietzsch					
Prerequisites					biopro	Module D: Introduction to bioprocess technology; Module E: Optimization of bioprocesses; Module G: Purification of products from pharmaceutical biotechnology					
Skills to be acq	uired in this mo	dule				ndependent resear mental work • writir	•		rature studies and		
Module contents						 participation in a research group • introduction to independent research of th students • combining literature and experimental research • independent preparation of the research report • oral presentation of the results using Pow Point; discussion of the results 					
Forms of instru	ıction					Course (4 SWS) Course					
Languages of i	nstruction				Germ	nan, English					
Duration (seme	esters)				1 Sem	ester Semester					
Module frequer	псу				jedes '	Wintersemester					
Module capacit	y				unlimit	ted					
Time of examin	ation										
Credit points					5 CP						
Share on modu	ile final degree				Cour	se 1: %; Course 2:	%.				
Share of modul	le grade on the	course of study's	final grade		1						
Examination			Exam prere	quisi	tes		Type of examin	ation			
Course 1											
Course 2											
Final exam of	module						Lehrforschungs Verteidigung	sbericht, Mündliche	e Präsentation und		
Exam repetition	on 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 m	odule						150)	150		
Total module w	orkload								150		

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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 developments • 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
Forms of instruction	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 • Lab course: Observation of phanes, 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, ani
	Lecture (1 SWS) Lecture (1 SWS) Course Practical training (2 SWS)
Languages of instruction	German, English
Duration (semesters)	1 Semester Semester



Module capacit	ty			unlimi	ited				
Time of examir	nation								
Credit points				5 CP					
Share on modu	ıle final degree		Course 1: %; Course 2: %; Course 3: %; Course 4: %; Course 5: %						
Share of modu	le grade on the	course of study's f	inal grade	1					
Examination			Exam prerequi	sites		Type of examir	nation		
Course 1									
Course 2									
Course 3									
Course 4									
Course 5									
Final exam of	module		attestation on l	ab course content	s, Protocol on lab	Klausur			
Exam repetition	on 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				(
Course 2	Lecture	Clinical development of monoclonal antibodies		1				(
Course 3	Lecture	DNA for gene therapy		1				(
Course 4	Course	Selbststudium						(
Course 5	Practical training	Lab course on basics of immunological methods		2				(
Workload by m	odule					150	0	150	
Total module w	vorkload							150	



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

PHA.03537.03									10 CP
Module label					Purifica Proces	•	f pharmaceutical	biotechnology (Do	ownstream
Module code					PHA.0	3537.03			
Semester of fir	st implementation	on							
Module used in	ocourses of stud	ly / semesters			•		ech.MA120, Versi	MA120 LP) (Master ion of accreditation	
Responsible pe	erson for this mo	odule							
Further respon	sible persons				D	. M Di-t			
Prerequisites						or. M. Pietzsch	of production orga	anisms; Module D:	Introduction to
Troroquiottoo						cess technology	or production orga	anomo, modulo D.	inii oddolloli to
Skills to be acc	uired in this mo	dule			protein Knowle contan downs	purification • Kno edge of scale-up p ninants • Knowled tream processing how to plan and p	wledge on equipn arameters • Chall ge on process inte • Bbasics of techr	nent and design pa lenges in prevention egration: Strain de	on or elimination of velopment, up- and fication of proteins
Module conten	ts				contant Design Liquid separat bodies Cours SDS-P disinte chroma	ninations of target and operation • C extraction • Precip titions • Special app , antibodies, vi-rus e G.2: Practical oc AGE and determing gration • Solid / Lice	products and stracell disintegration itation and crysta olications: Purificates, DNA, etc. ourse on Downstro nation of specific quid Separation • ourification of prot	Solid-Fluid sepa Ilization • Chromatation of membrane eam Processing • enzymatic activity Protein precipitations • Packing of controls	moval • Equipment: rations • Liquid- tographic proteins, inclusion Purity control by • Cell on • Preparative
Forms of instru	uction				Semi Semi	re (2 SWS) nar (1 SWS) nar (1 SWS) ical training (4 SW se	(S)		
Languages of i	nstruction				Germ	an, English			
Duration (seme						ester Semester			
Module freque	•				jedes S	Sommersemester			
Module capaci	-				unlimit	ed			
Time of examin	-								
Credit points					10 CP				
Share on modu	ıle final degree				Cours	se 1: %; Course 2:	%; Course 3: %;	Course 4: %; Cou	ırse 5: %.
Share of modu	le grade on the o	ourse of study's	final grade		1				
Examination			Exam prereq	uisites			Type of examir	nation	
Course 1									
Course 2									
Course 3									
Course 4									
Course 5									
Final exam of	module		1 attestation, course	, 1 presentat	tion, 1 pro	otocol on lab	Klausur		
Exam repetition	on information								
Module course label	Course type	Course title	SWS	Worklo compu attenda	lsory	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 I	module					30	0	300
Total module	workload							300



PHA.03536.02 - Legal and economical aspects of pharmaceutical biotechnology

PHA.03536.02 Pharmaceutical Biotechnology (MA120 LP) (Master) > Pharmazie Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule Prof. Dr. P. Imming Understanding of drug quality requirements, pre-requisites and activities Basic knowledge of the European drug quality system • Connection of the
Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule Prof. Dr. P. Imming • Understanding of drug quality requirements, pre-requisites and activities • Basic knowledge of the European drug quality system • Connection of the
Pharmaceut.Biotech.MA120, Version of accreditation (WS 2008/09 - WS 2015/16) > Pflichtmodule Prof. Dr. P. Imming • Understanding of drug quality requirements, pre-requisites and activities • Basic knowledge of the European drug quality system • Connection of the
Understanding of drug quality requirements, pre-requisites and activities Basic knowledge of the European drug quality system Connection of the
Understanding of drug quality requirements, pre-requisites and activities Basic knowledge of the European drug quality system Connection of the
Basic knowledge of the European drug quality system • Connection of the
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
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
Lecture (2 SWS) Lecture (1 SWS) Lecture (1 SWS) Course
German, English
1 Semester Semester
jedes Sommersemester
unlimited
5 CP
Course 1: %; Course 2: %; Course 3: %; Course 4: %.
1
Type of examination
Klausur



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 m	odule					150		150
Total module w	orkload							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. Nienel
Prerequisites	Dr. M. Niepel Module B: Drug target identification and validation
Skills to be acquired in this module	Basics of chromatographic separation and identification of small molecules •
okins to be acquired in this module	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, lon 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	unlimited
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	
Course 1	
Course 2	
Course 3	
Course 4	
Course 5	



Examination			Exam prerequis	sites		Type of examination			
Course 6									
Final exam of module		Structure analycontents - Cou	ab course content sis, attestation on rse H.3: Protein a Protocol on lab co	lab course nalysis by mass	Klausur				
Exam repetition	on 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 m	odule					300)	300	
Total module w	orkload							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 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	unlimited
Time of examination	
Credit points	10 CP
Share on module final degree	Course 1: %; Course 2: %; Course 3: %; Course 4: %; Course 5: %.
onare on module iniai degree	Course 1. 70, Course 2. 70, Course 3. 70, Course 4. 70, Course 5. 70.



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	on 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	Pharmacokineti cs		2					0	
Course 5	Course	Selbststudium							0	
Workload by m	odule						300)	300	
Total module w	vorkload								300	



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

Module label					Introd	uction to Bioproces	s technology (Lin	stream Processing	ı)		
Module code						Introduction to Bioprocess technology (Upstream Processing) PHA.03534.02					
	st implementation	on			11000	7,000 1.02					
Module used in courses of study / semesters						Pharmaceutical Pharmaceut.Bioto WS 2015/16) > P	ech.MA120, Versi	A120 LP) (Master on of accreditation			
Responsible pe	erson for this m	odule									
Further responsible persons						Volk					
Prerequisites											
Skills to be acquired in this module					microl engine	wledge of the basic pial growth and cul- eering principles • I ations • Basics of t	tivation principles	 Application of bis eactor operations 	oprocess and their industria		
Module contents				React and d	cs of bioprocess te or design and instr esign of bioreactor ation of fermentation	umentation • proc s • Bioprocess sca	ess control of bior ale-up • sterile tech	eactors • balancir nnology •			
Forms of instruction					Sem	Lecture (3 SWS) Seminar (1 SWS) Course					
Languages of i	nstruction				Gern	nan, English					
Duration (seme	esters)				1 Sen	1 Semester Semester					
Module frequer	псу				jedes	jedes Wintersemester					
Module capacit	ty				unlimi	ted					
Time of examin	ation										
Credit points					5 CP						
Share on modu	ıle final degree				Cour	se 1: %; Course 2:	%; Course 3: %.				
Share of modul	le grade on the	course of study's	final grade		1						
Examination			Exam prere	equisit	es		Type of examin	ation			
Course 1											
Course 2											
Course 3											
Final exam of	module						Klausur				
Exam repetition	on 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					ı		
Course 2	Seminar	Bioprocess technology		1					ı		
Course 3	Course	Selbststudium									
Workload by m	odule						150)	15		
Total module w	orkload								15		



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 / semeste	ers		Biotechnology (MA120 LP) (Master) > Pharmazie ech.MA120, Version of accreditation (WS 2008/09 - flichtmodule
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 independ work • writing of the thesi	dent research • literature studies and experimental s • defense of the thesis
Module contents		or appli-cation of biophar	relopment, analytics, production, isolation, formulation, maceuticals • carrying out literature research • ata and doing of data evaluation • oral presentation of defense
Form of instruction		Independent supervised	l work (30 SWS)
Languages of instruction		German, English	
Duration (semesters)		1 Semester Semester	
Module frequency		jedes Sommersemester	
Module capacity		unlimited	
Time of examination			
Credit points		30 CP	
Share on module final degree		Course 1: %.	
Share of module grade on the course of st	udy'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	unlimited		



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 Forms of instruction	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	unlimited



PHA.03533.03

11A.00000.00								100		
Time of examin	ation									
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 modul	le grade on the	course of study's f	inal grade	1						
Examination			Exam prerequ	iisites		Type of examin	nation			
Course 1										
Course 2										
Course 3										
Course 4										
Course 5										
Course 6										
Course 7										
Final exam of	module		microorganisr contents part	icroorganisms, P	•	Klausur				
Exam repetition	on 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						
Course 2	Seminar	Animal cell biology and technology		1						
Course 3	Lecture	Plant cell technology		2						
Course 4	Lecture	Molecular biotechnology		2						
Course 5	Seminar	Practical course on construction of hosts and vectors		1						
Course 6	Practical training	Practical course on construction of hosts and vectors		3						
Course 7	Course	Selbststudium								
Workload by m	odule					30	0	30		
Total module w	rorkload							30		

10 CP

