Module Handbook

Master´s degree program

Pharmaceutical Biotechnology

Hamburg University of Applied Sciences

Faculty of Life Sciences

Department of Biotechnology

Ulmenliet 20, 21033 Hamburg, Germany

www.haw-hamburg.de

Approved by the Faculty Council 30.06.2023

Last updated 30.06.2023

Table of contents

Objectives

The M.Sc. program “Pharmaceutical Biotechnology” is a 1.5 years engineering course for biotechnology graduates. The focus is on technical aspects concerning the production, purification and analysis of biopharmaceuticals. In this context relevant technical, biological, pharmaceutical and regulatory aspects are addressed. The program has high practical relevance and is embedded in the research activities of the biotechnology department. The first and second semester are comprised of course work, lab projects and seminars. The third semester is dedicated to the master´s thesis which can be done within the department or externally (e.g. industry, academic research facilities).

Our master degree qualifies for a variety of careers in industry and for further scientific work (i.e. PhD-programs). Besides expert knowledge we teach analytical and personal skills that allow graduates to quickly adapt to changes in their professional life.

Modular structure of studies

Module	Name	CP
M1	Biopharmaceutical Engineering I	6
M2	Biopharmaceutical Engineering II	6
M3	Purification Techniques	9
M4	Pharmaceutical Technology	6
M5	Cell Culture Systems	6
M6	Immunobiotechnology	6
M7	Bioanalytics	6
M8	Process Simulation	6
M9	Biopharmaceutical Research	9
M10	Master Thesis	30
		90

Module	Corresponding courses
M1	Process Development and Automation Process Analysis and Optimization
M2	Biopharmaceutical Engineering Practice Course Bioprocess Automation Special Course
M3	Purification Techniques Purification Techniques Special Course Good Manufacturing Practice Course
M4	Pharmacology Drug Development and Formulation
M5	Cell Culture Techniques Cell Culture Techniques Special Course
M6	Immunology: basis and biotechnological applications Frontiers in Cell and Molecular Biotechnology
M7	Biochemical Analytics Bioassays
M8	Analysis, Modeling and Simulation of Bioprocesses Analysis, Model. and Sim. of Biopr. Practice Course
M9	Lab Project Research Seminar
M10	Master Thesis

Semester schedule

Start in winter term

Semester	Courses
1	Process Development and Automation Bioprocess Automation Special Course* Biopharmaceutical Engineering Practice Course* Purification Techniques Purification Techniques Special Course Good Manufacturing Practice Course Pharmacology Drug Development and Formulation Immunology: basis and biotechnological applications Frontiers in Cell and Molecular Biotechnology Lab Project** Research Seminar*
2	Process Analysis and Optimization Bioprocess Automation Special Course* Biopharmaceutical Engineering Practice Course* Cell Culture Techniques Cell Culture Techniques Special Course Biochemical Analytics Bioassays Analysis, Modeling and Simulation of Bioprocesses Analysis, Model. and Sim. of Biopr. Practice Course Lab Project** Research Seminar*
3	Master Thesis

* must be taken continuously for two semesters

** completed in one semester; offered each semester

Semester schedule

Start in summer term

Semester	Courses
1	Process Analysis and Optimization Bioprocess Automation Special Course* Biopharmaceutical Engineering Practice Course* Cell Culture Techniques Cell Culture Techniques Special Course Biochemical Analytics Bioassays Analysis, Modeling and Simulation of Bioprocesses Analysis, Model. and Sim. of Biopr. Practice Course Lab Project** Research Seminar*
2	Process Development and Automation Bioprocess Automation Special Course* Biopharmaceutical Engineering Practice Course* Purification Techniques Purification Techniques Special Course Good Manufacturing Practice Course Pharmacology Drug Development and Formulation Immunology: basis and biotechnological applications Frontiers in Cell and Molecular Biotechnology Lab Project** Research Seminar*
3	Master Thesis

* must be taken continuously for two semesters

** completed in one semester; offered each semester

Assessments: types and forms

1. Case study (CS) (FS)
A case study is a piece of written work presenting a solution to a set problem and the rationale for the solution proposed. It may be completed individually or in a group and involves the identification, analysis and solution of specific problems from a relevant professional field via the application of academic/scientific methods and findings. Case studies shall be undertaken alongside a particular class and must be completed in the same semester as the class and by the time the class ends. The relevant Course-Specific Course and Examination Regulations may contain more detailed provisions on the time available for the completion of case studies.

2. Written paper (WP) (H)
A written paper is a piece of written work to be produced independently by the student outside class hours, in which the student demonstrates their ability to investigate and analyse a set question or subject independently. A maximum of three months is allowed for completion. Where a written paper constitutes a Prüfungsleistung, the relevant Course-Specific Course and Examination Regulations may specify whether or not a colloquium is to be held once the written project has been submitted. Colloquia should last between 15 and 45 minutes, and are generally to be held within one month of submission of the written paper.

3. Written examination (WE) (K)
A written examination is completed under supervision. Students must complete the questions set on their own, either without the use of study aids or with the use of specified study aids only. Written examinations last at least 60 and no longer than 240 minutes. In cases in which a written examination takes place as an online examination under remote (video) invigilation in accordance with Section 14 d, the student taking the examination shall, upon submission of the completed examination, give a declaration in written or electronic form that they have completed the examination on their own, within the time period allowed, and without the use of any aids except those explicitly permitted.

4. Colloquium (CO) (KO)
A colloquium may be required as part of certain types of assessment, or in combination with the Bachelor or Master thesis. A colloquium is an oral examination in which students must demonstrate their knowledge of the material examined, speaking and responding without the use of a script. A further purpose of a colloquium is to establish that written work previously submitted for assessment was all the student's own work. Colloquia last at least 15 and no more than 45 minutes,

and may take place as individual or group examinations. In the case of group colloquia, the size of the group should be taken into consideration when setting the length of the colloquium.

5. Engineering design task (EDT) (KN)
An engineering design task is a piece of written work in which students demonstrate their design skills by solving practical tasks. A maximum of three months is allowed for completion.

6. Lab work completion (LWC) (LA)
Laboratory work is successfully completed when students have successfully conducted the experiments set by the examiner during the semester and have demonstrated their knowledge by taking part in associated colloquia and/or by submitting written records of their experimental work and/or by completing set written tasks. Colloquia last for a minimum of 15 and a maximum of 45 minutes. The written work must be submitted by a deadline set by the examiner; the latest deadline is the end of the semester in which the class in question was taken.

7. Lab work examination (LE) (LR)
The lab work examination consists of the lab work completion as outlined above and an additional final examination at the end of the class, which shall require the student to carry out an experiment independently. This examination shall last at least 60 and no more than 240 minutes.

8. Oral examination (OE) (M)
In an oral examination, a student must demonstrate in discussion with the examiner that they have fully learned and understood the material on which they are being examined. Oral examinations generally last at least 15 and no more than 45 minutes, and may be conducted as individual or group examinations. They shall be conducted by one examiner and one supplementary assessor (Beisitzer*in) in accordance with Section 13 subsection 4 above. An oral examination may alternatively be conducted by two or more examiners instead of one, i.e. by a panel of examiners; in such a case, one examiner only shall be responsible for conducting the examination for each examination subject. Oral examinations are always assessed and graded by one examiner [the principal examiner, in the case of panel examinations] only, no matter whether they are conducted by several examiners or by an examiner and a supplementary assessor. The examiner responsible for grading in each case shall consider the views of the other examiners/the supplementary assessor before deciding on the grade to be awarded. A written record shall be made of the principal topics covered in each examination and its result. The record shall be signed by the examiner(s) and supplementary assessor and filed with the examination documents.

9. Project (Pro) (Pj)
A project is an interdisciplinary task relating to the professional field towards which the degree course is principally oriented. The results/findings of projects must be documented. At least 6 and no more than 26 weeks are allowed for projects. A project generally concludes with a colloquium. The relevant Course-Specific Course and Examination Regulations may specify additional requirements in relation to a project's form, content and objective and an alternative form of final assessment instead of a colloquium.

10. Presentation (Pres) (R)
A presentation is an oral talk lasting between 15 and 45 minutes, given on the basis of a written outline prepared by the student and followed by a facilitated discussion. Presentations should not be read out from a script; students should be able to speak spontaneously. Students must submit digital or hard copies of any presentation slides and diagrams/charts/images used to the examiner. Their written outline, which they must also submit to the examiner, should summarise their key findings and conclusions.

11. Test (T)
Tests are pieces of written work in which students demonstrate their ability to solve set tasks in a clearly defined subject area under examination conditions. Tests last at least 15 and no more than 90 minutes. Course-Specific Course and Examination Regulations may stipulate that the results of individual tests shall be included in the overall grade for written examinations.

12. Certificate for exercises (CfE) (ÜT)
A certificate for exercises is awarded once a student has successfully solved theoretical tasks set by the examiner in written form and has demonstrated their knowledge of the subject in a colloquium or presentation. Colloquia shall last at least 15 and no more than 45 minutes. The written work must be submitted by a deadline set by the examiner; the latest deadline shall be the end of the semester in which the student took the class (exercise/Übung). The relevant Course-Specific Course and Examination Regulations may stipulate other forms of assessment where useful and necessary.

13. Portfolio examination (PP)
A portfolio examination is a type of assessment consisting of not more than ten distinct components, in at least two different forms of assessment chosen from the forms of assessment listed here; practice tasks set during the semester may also be one of the components. At the beginning of the class or course, the member of academic staff in charge of delivering it shall determine and announce which components will comprise the portfolio examination and their weightings.

Where the class concludes with a Prüfungsleistung, the overall grade for the portfolio examination shall be calculated from each individual component, weighted in accordance with the weighting announced at the outset of the course. The total workload and the difficulty level of a portfolio examination shall not exceed the workload or difficulty level that would pertain to each form of assessment used were they to be used as the sole component of the examination.

14. Take-home examination (THP)

A take-home examination consists in the student's completion of an examination paper, comprising one or more tasks, at their home, or in another location, using only such aids as are specifically permitted and within a specified period of time. Issuance of examination papers and submission of completed examinations take place electronically. The time allowed for completion shall be at least 60 and not more than 300 minutes, and shall include the period of time during which students complete the examination and the time required for downloading and uploading the papers. The examination shall take place using software, videoconferencing or online collaboration systems, or teaching and learning platforms provided by HAW Hamburg. During the class, course or module to which the examination pertains, students shall receive the opportunity to familiarise themselves with the software, videoconferencing or online collaboration systems, or teaching and learning platforms to be used for the examination. Students shall submit, with their completed examination, a written or electronic declaration that they have completed the examination on their own, within the time period allowed, and without the use of any aids except those explicitly permitted.

Module description

Master Pharmaceutical Biotechnology	
Biopharmaceutical Engineering I	
Module number	M1
Module coordinator	Prof. Dr. Gesine Cornelissen
Duration of the module	Two semesters
Semester	1st and 2nd semester
Frequency	Yearly
Credit points (CP)	6 CP
Semester hours / week (SHW)	4 SHW
Workload	180 h (contact hours: 68 h; self-study: 112 h)
Type of module	Compulsory module
Mandatory requirements	None
Recommended requirements	Knowledge in basics of electrical engineering, measuring techniques, automatic control, heat and mass transfer, bioreactor and fermentation technology
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** The students are able to... • describe exclusive functional units and control loops of bioreactors. • develop open-loop and closed-loop control procedures • describe the cell reaction behaviour and cell physiological parameters. • develop process strategies, set up corresponding system instrumentation and analytical tools. • transform mathematical system approaches in normalized control theory form. • benchmark dynamic behaviour of bioprocess control loops and to find appropriate control parameters. **Methodological competency (use, application and generation of knowledge)** The students are able to independently interpret cultivation experiments, develop process strategies as well as control loops and integrate analytical tools and approaches. **Social competency (communication and cooperation)**

	The students are able to coordinate work content. **Self-competency (scientific self-image, professionalism)** The students will be able to formulate their own position on a particular approach and supplement their argument with meaningful facts. They will be able to assume responsibilities in a production facility.
Content of the module	The module communicates • (integrated) bioprocesses for the production of pharmaceutical products. • development, balancing and analysis of bioreaction processes. • bioprocess technology, automation, optimization, and monitoring. • system theoretical description of functional units as well as exclusive control loops (e.g. level and temperature). • the model description of cell growth and reaction kinetics. • the model of oxygen supply, transfer and uptake.
Applicability of the module	Bioprocessing and automation knowledge and tools are mandatory in all areas around production processes in (pharmaceutical) biotechnology including Purification Techniques (M3) and the module BPE I (M1) is directly connected to BPE II (M2). Furthermore, the module Analysis, Modeling and Simulation of Bioprocesses (M8) is strongly related to BPE I and II.
Requirements for the award of credit points (study and exam requirements)	The courses Process Development and Automation and Process Analysis and Optimization will be finished with one controlled written examination at the end of the 2nd semester (graded). Further possible examination types: written paper or oral examination. Where more than one possible examination type is used in the module, the examination type to be used is to be made known by the responsible lecturer at the start of the course.
Corresponding courses	Process Development and Automation Process Analysis and Optimization
Learning and teaching types/ methods/ media types	Seminaristic lectures, presentations via slides, derivations at the panel, short video sequences
Literature	All references are used in the current edition • Bailey and Ollis, Chemical Engineering Fundamentals (Mc Graw Hill) • Gellissen, Production of Recombinant Proteins (Wiley VCH) • Chmiel and Takors, Bioprozesstechnik (Springer) • Storhas, Bioreaktoren und periphere Einrichtungen (vieweg) • Lindfield and Penny, Numerical methods using MatLab (Prentice Hall) • Specific method manuals, scientific original papers, and reviews

Master Pharmaceutical Biotechnology	
Biopharmaceutical Engineering II	
Module number	M2
Module coordinator	Prof. Dr. Gesine Cornelissen
Duration of the module	Two semesters
Semester	1st and 2nd semester
Frequency	Yearly
Credit points (CP)	6 CP
Semester hours / week (SHW)	4 SHW
Workload	180 h (contact hours: 68 h; self-study: 112 h)
Type of module	Compulsory module
Mandatory requirements	None
Recommended requirements	Knowledge in basics of electrical engineering, measuring techniques, automatic control, heat and mass transfer, bioreactor and fermentation technology
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** The students are able to... • describe and handle exclusive functional units and control loops of bioreactors. • transform mathematical system approaches in normalized control theory form for the application at a real system. • benchmark dynamic behaviour of bioprocess control loops and to find appropriate control parameters at a real system. • handle process data for visualization, analysis and determination of specific parameters with e.g. MATLAB. • describe the cell reaction behaviour and cell physiological parameters during simulation processes. **Methodological competency (use, application and generation of knowledge)** The students are able to... • evaluate the automation functionality of bioreactors and to complete available equipment meaningfully. • describe mathematically functionalities of bioreaction processes and to adapt bioreactor control parameters appropriately. • scrutinize controlled fed batch processes and to configure the essential instrumental engineering. • use MATLAB to solve the given problems and to visualize the results. • judge about the quality of results.

	Social competency (communication and cooperation) The students are able to… • work in a team of students on a task (e. g. lab experiment). • help each other in elimination of programming errors **Self-competency (scientific self-image, professionalism)** The students are able to… • evaluate experimental results and present them to a group of people • study relevant materials autodidactically
Content of the module	The module communicates • practical analysis and simulation of bioprocesses for the production of pharmaceutical products • development, balancing and analysis of bioreaction processes • bioprocess technology, automation, optimization, and monitoring • system theoretical description of functional units as well as exclusive control loops (e.g. level and temperature) • the model description of cell growth and reaction kinetics • the model of oxygen supply, transfer and uptake
Applicability of the module	Bioprocessing and automation knowledge and tools are mandatory in all areas around production processes in (pharmaceutical) biotechnology including Purification Techniques (M3) and the module BPE II (M2) is directly connected to BPE I (M1). Furthermore, the module Analysis, Modeling and Simulation of Bioprocesses (M8) is strongly related to BPE I and II.
Requirements for the award of credit points (study and exam requirements)	The module will be finished with one lab work completion (not graded).
Corresponding courses	Biopharmaceutical Engineering Practice Course (not graded) Bioprocess Automation Special Course (not graded)
Learning and teaching types/ methods/ media types	Seminaristic lectures, reports and group work according to the computer tasks and lab experiments
Literature	All references are used in the current edition • Bailey and Ollis, Chemical Engineering Fundamentals (Mc Graw Hill) • Gellissen, Production of Recombinant Proteins (Wiley VCH) • Chmiel and Takors, Bioprozesstechnik (Springer) • Storhas, Bioreaktoren und periphere Einrichtungen (vieweg) • Lindfield and Penny, Numerical methods using MatLab (Prentice Hall) • Specific method manuals, scientific original papers, and reviews

Master Pharmaceutical Biotechnology **Purification Techniques**	
Module number	M3
Module coordinator	Prof. Dr. Daniela Prochaska
Duration of the module	One semester
Semester	1st or 2nd semester
Frequency	Yearly (winter term)
Credit points (CP)	9 CP
Semester hours / week (SHW)	5 SHW
Workload	270 h (contact hours: 85 h; self-study: 185 h)
Type of module	Compulsory module
Mandatory requirements	None
Recommended requirements	None
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** The students are able to identify and evaluate complex issues of integrated processes. They understand the special aspects of biopharmaceutical production with regard to employee qualifications, production plant requirements and process safety. **Methodological competency (use, application and generation of knowledge)** The students will be able to independently develop and interpret experiments on a specific procedure based on a solution at hand. **Social competency (communication and cooperation)** The students are able to work in a team on a given assignment, distribute tasks among themselves, and coordinate work content. **Self-competency (scientific self-image, professionalism)** The students will be able to formulate their own position on a particular approach and supplement their argument with meaningful facts. They will be able to assume responsibilities in a pharmaceutical facility.
Content of the module	**Purification Techniques** • Overview about common downstream unit operations • Integrated processes: Aqueous 2-Phase-Partitioning, Expanded Bed Adsorption, Extractive Fermentation, Big Beads, Affinity Membranes, Magnetic Beads, Plasmid DNA Purification, Pervaporation **Purification Techniques Special Course**

	• Application of Downstream Processing skills in the lab on a specific project **Good Manufacturing Practice** • Quality management for the production of pharmaceuticals: human resources, operation, facility, documentation, quality safety • Overview about important regularities: national, EU, USA/FDA, WHO
Applicability of the module	Purification tools are mandatory in all areas of pharmaceutical biotechnology and natural sciences, including production (modules M1 and M2) as well as drug development and formulation (module M4).
Requirements for the award of credit points (study and exam requirements)	Regular examination type for Purification Techniques: written examination with separation problems to be solved as well as specific questions (100% of module score; graded) Further possible examination types: written paper or oral examination. Where more than one possible examination type is used in the module, the examination type to be used is to be made known by the responsible lecturer at the start of the course. Purification Technique - Special Course: Lab work completion (not graded), participation certificate Good Manufacturing Practice: Case studies (course achievement; not graded)
Corresponding courses	Purification Techniques Purification Techniques Special Course Good Manufacturing Practice
Learning and teaching types/ methods/ media types	Presentation of downstream as well as pharmaceutical processes and their technical organisation. Lectures on E-learning platform for self-study in case of missing competences in downstream processes of bioproducts. The students have to independently elaborate sub problems and present them by use of work sheets. Independent elaboration of chapters, i.e. of a site master file, as well as summaries in a group of two or individually about special problems.
Literature	• Anspach: Lecture notes about all presentations as PDF • Presentations on E-Learning platform, including exercises • Various sorted literature regarding specific problems as PDF • European Commission: EU Guidelines to Good Manufacturing Practice - Medicinal Products for Human and Veterinary Use. 2005 and later • PIC/S Secretariat (Eds.): Explanatory Notes for Industry on the Preparation of a Site Master File. 2004 • U.S. Department of Health and Human Services: Guidance for Industry. Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice. 2004

	• International Conference or Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): the Quality related Guidelines • Pharmaceutical Inspection Convention, Pharmaceutical Inspection Cooperation Scheme (PIC/S): Guidelines and Notes

Master Pharmaceutical Biotechnology	
Pharmaceutical Technology	
Module number	M4
Module coordinator	Prof. Dr. Daniela Prochaska
Duration of the module	One semester
Semester	1st or 2nd semester
Frequency	Yearly (winter term)
Credit points (CP)	6 CP
Semester hours / week (SHW)	4 SHW
Workload	180 h (contact hours: 68 h; self-study: 112 h)
Type of module	Compulsory module
Mandatory requirements	None
Recommended requirements	None
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** After an introduction to a topic, students are able to handle application-related tasks based on basic lecture content. **Methodological competency (use, application and generation of knowledge)** Students will be able to develop and evaluate solutions and present a critical and comprehensive conclusion to an audience. **Social competency (communication and cooperation)** Students are able to work in a team of students on a task as well as to divide tasks and make agreements on task contents between students. **Self-competency (scientific self-image, professionalism)** Students will be able to formulate their own statement on a particular approach and add relevant evidence to the argument.
Content of the module	**Drug Development and Formulation** • Biologicals / Drugs / Drug Discovery, Drug Development, Clearance and Metabolism, Protein and Peptide Stability, Preformulation, Formulation, Drug Vehicles, Drug Conjugates **Pharmacology** • Pharmacokinetics, Pharmacodynamics, Toxicity Studies, Preclinical Studies, Clinical Trials
Applicability of the module	Regarding the product, biopharmaceuticals, there are linkages with the modules Biopharmaceutical Engineering (M1 and M2), Purification Techniques (M3) and Bioanalytics (M7).

Requirements for the award of credit points (study and exam requirements)	Regular examination type for module testing: portfolio examination (graded). Further possible examination types: controlled written examination or oral examination. Where more than one possible examination type is used in the module, the examination type to be used is to be made known by the responsible lecturer at the start of the course.
Corresponding courses	Drug Development and Formulation Pharmacology
Learning and teaching types/ methods/ media types	PowerPoint presentations (also students to special topics) Lectures on E-learning platform for self-study
Literature	Print-outs and PDFs of all presentations of the lecture E-Learning platform Moodle with all presentation from lecturers and students, including exercises Different specialised literature and publications as PDF for introduction in special themes and problems

Master Pharmaceutical Biotechnology	
Cell Culture Systems	
Module number	M5
Module coordinator	Prof. Dr. Julien Béthune
Duration of the module	One semester
Semester	1st or 2nd semester
Frequency	Yearly
Credit points (CP)	6 CP
Semester hours / week (SHW)	4 SHW
Workload	180 h (contact hours: 68 h; self-study: 112 h)
Type of module	Compulsory module
Mandatory requirements	None
Recommended requirements	Background knowledge of molecular biology. Having attended the cell culture techniques lecture or having first experience with cell culture work is strongly recommended for the cell culture techniques special course.
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** On successful completion of this module, students will be able to… • describe the main components of eukaryotic cells and explain their functions. • comprehend how animal cells integrate into organs and how organs are formed and maintained. • comprehend and explain the significance of cell culture techniques for applications such as protein expression, tissue engineering, primary cell culture, stem cell culture and cell-based bioassays (lecture Cell Culture Techniques). • Interpret the data from cell-based bioassays and analyses by light and fluorescent microscopy, western blot or flow cytometry. **Methodological competency (use, application and generation of knowledge)** On successful completion of this module, students will be able to… • set up and manage a cell culture lab. • cultivate different mammalian cell lines under sterile conditions and perform basic quality control experiments. • synthesize mRNA in vitro for transfection experiments. • transfect eukaryotic cells in culture and use them for bioassays. • perform flow cytometry and microscopy analyses.

	Social competency (communication and cooperation) On successful completion of this module, students will be able to… • work as a team to perform lab experiments and write a scientific report, autonomously distribute assignments within the team for data analysis and visualization and writing strategies. • discuss the current cutting-edge applications of cell culture techniques, informed by discussions with peers and lecturers and the scientific literature. **Self-competency (scientific self-image, professionalism)** On successful completion of this module, students will be able to… • contribute to the scientific discussion in a public or professional context and argue from a molecular cell biology perspective. • follow the latest biotechnological advances in the field of cell culture techniques and reflect critically.
Content of the module	**Cell Culture Techniques (CCT)** • Structure and function of the eukaryotic cell • Microscopy techniques • Membrane trafficking and secretion • Structure and function of the cytoskeleton • Integration of cells in tissues • Design and organisation of a cell culture lab • Cultivating cells • Primary cells and organ cultures • Tissue engineering • Stem cells and induced pluripotent stem cells • Cell-based therapies • Protein production from mammalian cells **Cell Culture Techniques Special Course (CCT-P)** • Handling of cells in culture in a biosafety cabinet • Mycoplasma contamination monitoring • In vitro transcription and transfection of an mRNA • Flow cytometry analysis • Protein production in mammalian cells • Fluorescence-based western blot • Preparation of cells for indirect immunofluorescence microscopy • Fluorescence microscopy
Applicability of the module	Cell culture techniques and cell-based assays are key in all areas of pharmaceutical biotechnology and life sciences, including drug development, production, and characterization. Knowledge gained in this module is particularly relevant for the modules Purification Techniques (M3), Immunobiotechnology (M6) and Bioanalytics (M7).
Requirements for the award of credit points (study and exam requirements)	Standard form of assessment: • CCT: Regular examination type: written paper (graded). Further possible examination types: written or oral examination. Where

	more than one possible examination type is used in the module, the examination type to be used is to be made known by the responsible lecturer at the start of the course. • CCT-P: Lab work completion (not graded)
Corresponding courses	Cell Culture Techniques Cell Culture Techniques Special Course
Learning and teaching types/ methods/ media types	Seminar-style class + Lab: • Discussion • Self-directed study of literature • Group work • Lecturer presentations • Electronic platform • Wet-lab practice
Literature	All references are used in the current edition • Lodish, Molecular Cell Biology (Macmillan) • Alberts, Molecular Biology of the Cell (Norton) • Minuth, Tissue Engineering (Wiley-VCH) • Specific papers from the current scientific literature (will be communicated during the lectures) • Cell Culture Techniques Special Course: script for the practical course

Master Pharmaceutical Biotechnology	
Immunobiotechnology	
Module number	M6
Module coordinator	Prof. Dr. Julien Béthune
Duration of the module	One semester
Semester	1st or 2nd semester
Frequency	Yearly
Credit points (CP)	6 CP
Semester hours / week (SHW)	4 SHW
Workload	180 h (contact hours: 68 h; self-study: 112 h)
Type of module	Compulsory module
Mandatory requirements	None
Recommended requirements	Basic knowledge of cell biology and biochemistry
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** On successful completion of this module, students should… • understand the basics of immunology, including the function and interaction of immune cells and the molecular mechanisms of an immune response. • know the structure and function of antibodies and their main applications in immunological techniques. • be familiar with current research trends and advances in immunology and biotechnology, including the development of new immunotherapies and cell-based therapies. **Methodological competency (use, application, and generation of knowledge)** On successful completion of this module, students will be able to… • design antibody-based assays, including the selection of appropriate analytical methods, sample preparation, and data analysis. • critically evaluate scientific literature and design and execute experiments based on current research trends and advances in immunology and biotechnology **Social competency (communication and cooperation)** On successful completion of this module, students will be able to… • work as a team to select and analyse a scientific paper, extract the relevant information to present it to the group, autonomously distribute assignments and timelines within the team for

	literature research, data visualization and presentation strategies. • effectively communicate scientific ideas and results to a diverse audience, including peers, instructors, and industry professionals. **Self-competency (scientific self-image, professionalism)** On successful completion of this module, students will be able to… • contribute to the scientific discussion in a public or professional context and argue from a cell biology/immunology perspective. • behave professionally and ethically in a scientific setting, including adhering to research integrity standards, communicating clearly and respectfully with colleagues, and presenting their work in a polished and professional manner. • cultivate a mindset of lifelong learning and professional development, including seeking out new knowledge and skills, staying current with scientific advances, and networking with colleagues in their field.
Content of the module	**Immunology: basis and biotechnological applications** • Innate vs adaptive immunity, the cells of the immune system and their interactions, antibody's structure and function, production of antibodies, antibody-based technologies, immunology-based therapy of diseases **Frontiers in Cell and Molecular Biotechnology** • Current topics from the scientific literature related to different host and expression systems for protein production, antibody engineering and to cell-based biotechnological approaches to cure diseases.
Applicability of the module	Immunotherapies and cell-based technologies are at the forefront of pharmaceutical biotechnology research and development to provide novel approaches to cure diseases. Knowledge gained in this module is particularly relevant for the modules Purification Techniques (M3), Cell Culture Systems (M5) and Bioanalytics (M7).
Requirements for the award of credit points (study and exam requirements)	Regular examination type for module testing: portfolio examination (graded) Further possible examination types: written paper, written or oral examination. Where more than one possible examination type is used in the module, the examination type to be used is to be made known by the responsible lecturer at the start of the course.
Corresponding courses	Immunology: basis and biotechnological applications Frontiers in Cell and Molecular Biotechnology
Learning and teaching types/ methods/ media types	Seminaristic lectures, presentations of students, group work about specific problems
Literature	All references are used in the current edition.

	• Sam-Yellowe, Tobili, Immunology: Overview and Laboratory Manual (Springer) • Alberts, Molecular Biology of the Cell (Norton) • Specific scientific original papers, and reviews (will be communicated during the lectures)

Master Pharmaceutical Biotechnology	
Bioanalytics	
Module number	M7
Module coordinator	Prof. Dr. Jörg Andrä
Duration of the module	One semester
Semester	1st or 2nd semester
Frequency	Yearly
Credit points (CP)	6 CP
Semester hours / week (SHW)	4 SHW
Workload	180 h (contact hours: 68 h; self-study: 112 h)
Type of module	Compulsory module
Mandatory requirements	None
Recommended requirements	Basic knowledge of biochemistry and cell biology
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** On successful completion of this module, students will be able to… • list and explain the principle of current analytical methods used in pharmaceutical biotechnology. • understand and explain the strengths, limitations, and scope of use of these methods. • critically assess the use of these methods to solve scientific problems. **Methodological competency (use, application, and generation of knowledge)** On successful completion of this module, students will be able to… • design experiments in bioanalytics, including the selection of appropriate analytical methods, sample preparation, and statistical analysis. • analyse and interpret data obtained from bioanalytical experiments. • design quality control routines in bioanalytics, including the use of appropriate controls, calibration standards, and validation procedures. **Social competency (communication and cooperation)** On successful completion of this module, students will be able to… • work as a team to select a scientific topic to present to the group, autonomously distribute assignments and timelines within the team for literature research, data visualization and presentation strategies.

	• effectively communicate scientific ideas and results to a diverse audience, including peers, instructors, and industry professionals. **Self-competency (scientific self-image, professionalism)** On successful completion of this module, students will be able to... • contribute to the scientific discussion in a public or professional context and argue from a bioanalytical perspective. • behave professionally and ethically in a scientific setting, including adhering to research integrity standards, communicating clearly and respectfully with colleagues, and presenting their work in a polished and professional manner. • cultivate a mindset of lifelong learning and professional development, including seeking out new knowledge and skills, staying current with scientific advances, and networking with colleagues in their field.
Content of the module	The module communicates basic knowledge to gain quantitative and qualitative analytical characteristics of a sample as well as special knowledge in view of novel analytical techniques to find and to confirm the biological activity of new drug. **Biochemical Analytics** • Analytical characteristics (LoD, resolution), chemistry and spectroscopy of proteins and nucleic acids, detection methods (fluorescence, label-free detection), sequence and structure analysis, mass spectrometry and proteomics, nanoscopy, atomic force microscopy, molecular interactions **Bioassays** • Biosensors, toxicity monitoring, immunoassays, endotoxin detection, introduction to biostatistics, cell-based assays, incl. 3D cell culture, GPCR-based assays
Applicability of the module	Analytical tools are mandatory in all areas of pharmaceutical biotechnology and natural sciences, including Purification Techniques (M3), Pharmaceutical Technology (M4), Cell Culture Systems (M5), Biopharmaceutical Research (M9).
Requirements for the award of credit points (study and exam requirements)	Examination type for module testing: portfolio examination (graded)
Corresponding courses	Biochemical Analytics Bioassays
Learning and teaching types/ methods/ media types	Seminaristic lectures, short presentations of students (oral and posters), group work about specific problems, online tests
Literature	All references are used in the current edition. • Lottspeich and Engels, Bioanalytics (Wiley-VCH) • Alberts, Molecular Biology of the Cell (Norton & Company)

	• Specific method manuals, scientific original papers, and reviews (will be communicated during the lectures)

Master Pharmaceutical Biotechnology	
Process Simulation	
Module number	M8
Module coordinator	Prof. Dr. Anna Rodenhausen
Duration of the module	One semester
Semester	1st or 2nd semester
Frequency	Yearly (summer term)
Credit points (CP)	6 CP
Semester hours / week (SHW)	4 SHW
Workload	180 h (contact hours: 68 h; self-study: 112 h)
Type of module	Compulsory module
Mandatory requirements	None
Recommended requirements	Basic skills in mathematics and programming (e.g., acquired in a Bachelor program)
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** • The students understand the process of modelling. • They know a spectrum of mathematical methods for modelling, simulation and for the analysis of models. • They understand the fundamental ideas, possibilities of application, benefits and limitations of the discussed methods. **Methodological competency (use, application and generation of knowledge)** • The students are able to use the MATLAB environment to implement the discussed methods and to visualize the results. • They are able to apply the discussed methods in practical problems and to judge about the quality of result. **Social competency (communication and cooperation)** • The students are able to help each other in elimination of programming errors. • They are able to discuss computational results in order to judge their quality, improve the quality and to rank their scientific relevance. **Self-competency (scientific self-image, professionalism)** • The students are able to study relevant materials autodidactically. • They are able to help themselves in MATLAB programming by using the help menu.
Content of the module	• Introduction to MATLAB

	• Modelling with ordinary differential equations (ODEs) and systems of ODEs • Numerical solution of ODEs • Linear equation systems • Curve fitting and interpolation • Optimization and parameter estimation
Applicability of the module	M8 is applied in modules Biopharmaceutical Engineering I and II.
Requirements for the award of credit points (study and exam requirements)	Credit points are obtained on the basis of a graded module examination. The standard format of the exam is a written examination including programming problems. It might be replaced by an oral examination or a presentation.
Corresponding courses	• Analysis, Modelling and Simulation of Bioprocesses (AMS) • AMS Practice Course (AMSU).
Learning and teaching types/ methods/ media types	• The AMS course is based on lectures, self-study and exercises. • The AMSU practice course is based on self-study and programming problems.
Literature	Comprehensive script material provided by the lecturer in the current edition.

Master Pharmaceutical Biotechnology	
Biopharmaceutical Research	
Module number	M9
Module coordinator	Prof. Dr. Stephan Noll
Duration of the module	Two semesters
Semester	1st and 2nd semester
Frequency	Biannual
Credit points (CP)	9 CP
Semester hours / week (SHW)	5 SHW
Workload	270 h (contact hours: 85 h; self-study: 185 h)
Type of module	Compulsory module
Mandatory requirements	None
Recommended requirements	None
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** On successful completion of this module students will be able to… • master lab-specific techniques and applications. **Methodological competency (use, application and generation of knowledge)** On successful completion of this module students will be able to… • develop a research strategy and design experiments. • perform data evaluation/interpretation and literature analysis. • write a scientific report. **Social competency (communication and cooperation)** On successful completion of this module students will be able to… • acquire oral skills through public speaking. • participate in scientific discussions. • engage and co-work with professionals and students in the lab. **Self-competency (scientific self-image, professionalism)** On successful completion of this module students will… • develop a deeper understanding of a specific research area. • improve their problem solving skills and critical thinking.
Content of the module	Lab Project: independent work on a laboratory project within the BT-department (date and topic need to be agreed with the respective laboratory head.) Research Seminar: active participation
Applicability of the module	M9 prepares for the master thesis and a future profession in the technical/scientific field.

Requirements for the award of credit points (study and exam requirements)	Lab project: continuous work in the lab; graded project report Research Seminar: attendance; ungraded oral presentation
Corresponding courses	Lab Project Research Seminar
Learning and teaching types/ methods/ media types	Lab Project: practical work, self-study/organisation, teamwork Research Seminar: presentation and discussion skills
Literature	Project-specific

Master Pharmaceutical Biotechnology	
Master Thesis	
Module number	M10
Module coordinator	Prof. Dr. Stephan Noll
Duration of the module	One semester
Semester	3rd semester
Frequency	Biannual
Credit points (CP)	30 CP
Semester hours / week (SHW)	not specified
Workload	900 h
Type of module	Compulsory module
Mandatory requirements	Acquisition of 45 CP from the first study year; exceptions require approval by the Examination Board.
Recommended requirements	Contents of the Master´s program
Teaching language	English
Competencies gained / Learning Outcome	**Specialist competency (knowledge and understanding)** On successful completion of this module students will be able to… • conduct scientific experiments and/or data analyse in the field of biotechnology. **Methodological competency (use, application and generation of knowledge)** On successful completion of this module students will be able to… • systematically approach and analyse academic topics. • schedule experimental procedures. **Social competency (communication and cooperation)** On successful completion of this module students will be able to… • present work according to academic standards. • communicate with an academic audience/readership. **Self-competency (scientific self-image, professionalism)** On successful completion of this module, students will be able to develop and present their own professional point of view.
Content of the module	The Master Thesis is a comprehensive theoretical, empirical and/or experimental exploration in the field of biotechnology. The specific topic requires prior approval by the Head of the Examination Board.
Applicability of the module	M10 completes the master's degree.
Requirements for the award of credit points (study and exam requirements)	Master Thesis (graded) A grade of 4.0 or above is a pass.

Corresponding courses	None
Learning and teaching types/ methods/ media types	Scientific (experimental) work Scientific writing
Literature	Project-specific