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Module Handbook

Study program

Pharmaceutical Biotechnology (Bachelor)

Status: 10.05.2021

No responsibility is taken for the correctness of the WH and CP listed in the module handbook.
The study examination regulations are binding.

Table of contents

Modules in the 1st study stage (1st - 2nd semester)

Physics	
Code	(not yet provided)
Credit points according to ECTS	8
Attendance time (WH)	8
Course Language	German
Duration	2 semesters
Offered	Every semester
Module coordinator	Prof. Dr. Burghardt
Lecturers	Prof. Dr. Burghardt; Prof. Dr. Schafmeister
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 1st and 2nd semester
Prerequisites	**Mathematics I** Recommendation: Basic knowledge of higher mathematics (e.g. from high school or another type of school that qualifies to study at a university), preliminary course in mathematics. **Physics** Recommendation: Courses on the subject of mathematics; accompanying lectures Mathematics I and Mathematics II.
Learning Outcomes	Students who have successfully completed this module, **Mathematics I** • know the basics of higher mathematics that are required for application-based scientific and technical studies and can solve corresponding exercises. **Physics** • possess the theoretical and practical knowledge in the fields of physics relevant for technical applications in pharmaceutical biotechnology. This includes mechanics, electrical engineering, thermodynamics, optics and fluid dynamics. • know the physical basics of mechanics, electricity and thermodynamics. The theoretical knowledge is practiced in the form of exercises. • have an understanding of the principles of physical experimentation. • know different physical measurement methods and their

	limits and are able to deal critically with measurement errors and their influence on the result. • are able to interpret results within the framework of theoretical expectations.
Content	The following technical content is taught in this module: **Lecture Mathematics I:** • Basic concepts: Sets and set operations, sum and product signs, functions and inverse functions, polynomials and polynomial division. • Vector calculus: vectors, vector operations, scalar product • Limits: sequences and series, limits of sequences and functions, continuity, poles, asymptotes • Integral calculus: definite integral, integration rules **Lecture + Exercise Physics 1:** • Mechanics: Kinematics, Newtonian mechanics, conservation laws • Mechanics of liquids and gases: Density, pressure, fluid dynamics, laminar flows, Bernoulli's law, viscosity, Hagen-Poiseuille law. • Geometrical optics: imaging laws, telescope, microscope **Lecture + Exercise Physics 2:** • Heat transport: heat conduction, heat radiation • Thermodynamics: equations of state (ideal gas), circular processes, entropy, 1st and 2nd law, thermodynamic potentials and their extreme properties, chemical potential with applications (e.g. osmosis). • Electricity: current, voltage, charge, electric field, electric potential, Ohm's law, Kirchhoff's rules with applications **Practical Course in Physics:** • Kirchhoff's circuit laws (electrical engineering) • Thermal conduction (thermodynamics) • Laws of Lensing (optics) • Thermal expansion (thermodynamics) • Capillary viscometer (fluid dynamics) • Hagen- Poiseuille law (fluid dynamics)
Indicative bibliography	**Lecture Mathematics I:** L. Papula, Mathematik für Ingenieure und Naturwissenschaftler, Vieweg + Teubner, 2015--18, Bd. 1-3 Rießinger, T., Mathematik für Ingenieure, Springer Vieweg, 2017 Rießinger, T., Übungsaufgaben zur Mathematik für Ingenieure, Springer Vieweg, 2017 **Lecture + Exercise Physics:**

	Halliday, Resnick, Walker: Halliday Physics - Bachelor Edition, Wiley-VCH, 2013 P. A. Tipler & G. Mosca, Physik, Springer Spektrum, 2019 **Practical course in physics:** D. Meschede, Gerthsen Physik, Springer Verlag H. J. Eichler, H.-D. Kronfeldt & J. Sahm, Das neue Physikalische Grundpraktikum, Springer Spektrum**,** 2016
Teaching and learning methods	• Mathematics 1 (L+E), 2 WH, 2 CP • Physics 1 (L+E), 2 WH, 2 CP • Physics 2 (L+E), 2 WH, 2 CP • Practical course in physics (PC), 2 WH, 2 CP
Workload	**Lecture Mathematics 1** Lectures and exercises: 30 h Individual study time: 30 h **Lecture + Exercise Physics 1** Lectures and exercises: 30 h Individual study time: 30 h **Lecture + Exercise Physics 2** Lectures and exercises: 30 h Individual study time: 30 h **Practical course in physics** Lectures and exercises: 30 h Individual study time: 30 h **Total** Lectures and exercises: 120 h Individual study time: 120 h Total: 240 h
Form of examination and assessment	The examination performance is a written examination (90 minutes) covering the entire module. Only students who have successfully completed the entrance examinations for Mathematics I and Physics 1 as well as the Physics Practical and the prerequisite (wE) in the form of protocols for the Physics Practical course are admitted to this written examination.
Grading	The module grade corresponds to the result of the examination performance.

Fundamentals of Pharmaceutical Biotechnology	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	6
Course Language	German
Duration	2 semesters
Offered	Every semester
Module coordinator	Prof. Dr. Hannemann
Lecturers	Prof. Dr. Hannemann; M.A. Jutta Cook
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 1st + 2nd semester
Prerequisites	**Lecture Introduction to Biotechnology and Seminar GMP / GLP** No previous technical knowledge required **Scientific Presentation Technique** Recommendation: Basic knowledge of MS Office (Word, PowerPoint) and internet research
Learning Outcomes	Students who have successfully completed this module, **Lecture Introduction to Biotechnology** • know the subject-specific terminology of biotechnology. • know some basic terms of bioprocess engineering (mixing, temperature control, O_2 input), as well as the different bioreactors and methods (batch, perfusion, etc.), as well as the differences of bioreactors made out of different materials (glass versus steel versus plastic (single use)). • know the different types of expression systems (with organism-specific differences), production conditions of master and working cell banks, as well as their storage conditions in general and under GMP aspects. • know specifics of individual biotechnological products (L-glutamate, insulin). • know the basics of modern biopharmaceutical manufacturing processes (bacterial vaccines, cell therapeutics, Advanced Therapy Medicinal Product [=ATMP] such as tissue engineering (e.g. Autologous Chondrocyte Transplantation = ACT), stem cells, CAR-T cells. **Seminar GMP / GLP** • know terms and basics as well as reasons for

	pharmaceutical quality assurance (definitions, quality defects, drug scandals [Contergan]. • know the history of the development of GMP and GLP. • Know the basics of the drug development process (clinical phases, investigations (carcinogenicity, etc.). • Know the basic contents of various pharmaceutical regulations, such as AMG, EU GMP Guidelines, European Pharmacopoeia (Ph. Eur.), AMWHV, PICs and ICH. • know the basics of pharmaceutical qualification and validation. • know the basic pharmaceutical terms such as calibration, adjustment, risk assessment, etc. and are able to prepare simple instructions (SOP) for pharmaceutical production or quality control. • know the requirements for modern biopharmaceutical manufacturing processes (such as specifications, quality control testing, clean room requirements, etc.). • know the basic requirements for cleanroom technology with regard to particle counts and airborne germs. In the GMP-GLP seminar, the lecturer first gives approx. 6 introductory lectures (on the topics given above). Then the students can choose from suggested topics, based on articles in German and English (Pharmind) and various sets of rules. Then the students have approx. 4-5 weeks in groups (3-4 students) to prepare their seminar papers and discuss them with the lecturer. During the appointments in the last week of the semester, the students (in small groups) present their seminar papers in presentations (20-30 min.). **Seminar Scientific Presentation Technique** • know the basics of scientific work. • know presentation techniques for scientific questions in study and work. • can apply this knowledge in exercises, homework and their own presentations.
Content	The following technical content is taught in this module: **Lecture Introduction to Biotechnology** • Definitions of important terms in biotechnology • Historical development of biotechnology • Economic significance of various biotechnological products and development trends in biotechnological industrial sectors • Process stages in the biotechnological manufacturing process

	• Expression organisms used in biotechnological manufacturing processes • Expression types (transient and stable) • Bioreactors made of steel, glass or plastic • Process parameters (O_2 partial pressure, energy input, cell density, product quantity) and process control (batch, fed-batch and perfusion) • Cell banks ("master and working cell bank") and their importance in the production of biopharmaceutical products and their cryo-storage • Biotechnological products (glutamate, insulin) • Vaccine production and tissue engineering as biopharmaceutical manufacturing processes • Examples of Advanced Therapy Medicinal Products (ATMPs) such as Autologous Chondrocyte Transplantation (ACT) and Chimeric Antigen Receptor-(CAR)-T-cells. **Seminar GMP/GLP** • What does quality / quality deficiencies mean in the context of pharmaceutical manufacturing processes? • Consequences of serious quality defects in pharmaceutical manufacturing • Phases of drug development • Quality management and quality assurance • Qualification and validation • Basic contents of pharmaceutical regulations such as AMG, EU GMP guidelines, European Pharmacopoeia (Ph. Eur.), AMWHV, PICs and ICH. • Work instructions, standard operating procedure (SOP), manufacturing instructions, site master file, • Responsibilities of federal and state authorities for pharmaceutical manufacturing • Design of a clean room facility with clean room zones, airlocks and their functions in the manufacturing process • Classification of cleanroom zones (zoning) based on particle counts • Seminar papers on articles from the journal PharmInd and from regulations and codes such as the EC Guide to Good Manufacturing Practice, the AMG, AMWHV, Pharmaceutical Inspection Cooperation Scheme (PIC/S), Pharmacopeia, etc. **Seminar Scientific Presentation Technique** • Relevance as a criterion for success • Introduction to intelligibility research • Outline, simplicity, conciseness and stimulation in a scientific context • Language as a tool: argumentation and defense, best

	practice, examples • Structure of scientific papers: the IMRaD-canon under the microscope • Scientific quality criteria, source research, citing sources, forms for references and bibliographies • Copyright and utilization rights, Open Access and indices • Revision techniques • Student presentations: The students individually give a 10-minute presentation on topics from the seminar in which they apply what they have learned. In a feedback round with the plenary, they have the opportunity to explain and, if necessary, defend their approach. The students' presentations are filmed and handed out to the students afterwards.
Indicative bibliography	**Lecture Introduction to Biotechnology** • Taschenatlas der Biotechnologie und Gentechnik, Rolf D. Schmid, 3. Auflage 2016 • Biotechnologie für Einsteiger, Reinhard Renneberg, 2. Auflage, 2007, ISBN-13: 978-3-8274-1847-0 • Biotechnologie, W. J. Thieman, M. A. Palladino,1. Auflage, 2007, ISBN 9783827372369 **Seminar GMP/GLP** • GLP-Handbuch für Praktiker, G. A. Christ, S. J. Harston, H.-W., Hembeck, K.-A. Opfer, 2. überarbeit. Aufl., ISBN 3-928865-25-0 • EG-Leitfaden der Guten Herstellungs-Praxis für Arzneimittel und Wirkstoffe, Link: Bundesministeriums der Justiz und für Verbraucherschutz (18.07.2016)): Gesetz über den Verkehr mit Arzneimitteln: AMG. Online: https://www.gesetze-im-internet.de/amg_1976/AMG.pdf, zuletzt geprüft am 11.08.2017 • GMP-Berater, Nachschlagewerk für Pharmaindustrie und Lieferanten, Maas & Peither, GMP Verlag. **Seminar Scientific Presentation Technique** • H. Balzert, C. Schäfer, M. Schröder, U. Kern: Wissenschaftliches Arbeiten: Wissenschaft, Quellen, Artefakte, Organisation, Präsentation, 4. Nachdruck, W3L-Verlag, Herdecke/Witten 2010
Teaching and learning methods	• Introduction to Biotechnology (L), 2 WH, 2 CP • GMP/GLP (S), 2 WH, 2 CP • Scientific Presentation Technique(S), 2 WH, 2 CP
Workload	**Lecture Introduction to Biotechnology** Attendance studies: 30 h Individual study time: 30 h

	Seminar GLP/GMP Attendance studies: 30 h Individual study time: 30 h **Seminar Scientific Presentation Technique** Attendance studies: 30 h Individual study time: 30 h **Total** Attendance studies: 90 h Individual study time: 90 h Total: 180 h
Form of examination and assessment	The examination consists of a written exam (60 minutes) on the contents of the courses "Introduction to Biotechnology" and "GMP / GLP", as well as a presentation on the contents of the seminar "Scientific Presentation Technique". Only students who have successfully completed the preliminary examination (seminar paper as wE) for the course "GMP / GLP" are admitted to the written examination "Introduction to Biotechnology & GMP / GLP". Only students who have successfully completed the preliminary examination for the seminar (seminar paper as written paper) are admitted to the examination "Scientific Presentation Technique".
Grading	The module grade corresponds to the result of the two examinations.

Process Engineering Basics	
Code	(not yet provided)
Credit points according to ECTS	7
Attendance time (WH)	6
Course Language	German
Duration	2 semester
Offered	Every semester
Module coordinator	Prof. Dr. Hesse
Lecturers	Dr. Haas, Prof. Dr. Burghardt, Prof. Dr. Annette Schafmeister
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 1st and 2nd semester
Prerequisites	**Fundamentals of Process Engineering 1**

	• none **Fundamentals of Process Engineering 2** • Fundamentals of Process Engineering 1 • Mathematics I from the module Physics **Mathematics II** • Mathematics I from the module Physics
Learning Outcomes	Students who have successfully completed this module, **Fundamentals of Process Engineering 1** • can apply the basic concepts of process engineering and understand and evaluate simple technical processes. • know the fields of work and applications of process engineering. **Fundamentals of Process Engineering 2** • can carry out simple calculations from different areas of process engineering (balancing, flow phenomena, heat and mass transfer processes, mixing processes) and are familiar with the basic use of characteristic numbers. **Mathematics II** • know the basics of higher mathematics that are required for application-related scientific and technical studies and can solve exercise problems.
Content	The following technical content is taught in this module: **Lecture Fundamentals of Process Engineering 1** • Process engineering and bioprocess technology • Basic operations of mechanical, thermal, chemical and bio-process engineering • Thermodynamic fundamentals of solids, liquids and gases (phase states, thermal energy and thermal power, ideal gas law, mass and energy conservation laws, phase equilibria) • Basics, technologies and applications of bioreactors (physical processes during mixing and stirring, designs and components of stirred vessels, calculation of power consumption of stirrers). • Introduction to material science (systematics of materials, steels, non-ferrous metals, ceramic materials, plastics, corrosion) **Lecture Fundamentals of Process Engineering 2** • Flow processes and fluidic basics (property of fluids,

	flow forms, hydraulics) • Basic principles of heat transfer (stationary and transient heat conduction, free and forced convection, thermal radiation, calculation approaches for apparatus and systems) • Basic principles of mass transfer (stationary diffusion in quiescent media with and without chemical reaction, insight into transient diffusion, convective mass transfer) • Mixing and stirring (physical processes during mixing and stirring, influence of the stirrer type on the mixing process, calculation of the power consumption of stirrers) **Lecture Mathematics II** • Differential calculus: differentiability, differentiation rules, chain rule, derivation of the inverse function, curve discussion • Integral calculus: indefinite integral • Real-valued functions of several variables: partial derivatives, gradients, local extrema, integration in several dimensions, polar and spherical coordinates • Properties of functions
Indicative bibliography	**Lecture Fundamentals of Process Engineering** • script **Lecture Mathematics II** • L. Papula, Mathematik für Ingenieure und Naturwissenschaftler, Vieweg + Teubner, 2011--15, Bd. 1-3 • Rießinger, T., Mathematik für Ingenieure, Springer Vieweg, 2013 • Rießinger, T., Übungsaufgaben zur Mathematik für Ingenieure, Springer Vieweg, 2013 • Burg, K.; Haf, H.; Meister, A. & Wille, F., Höhere Mathematik für Ingenieure, Springer Vieweg, 2013, Bd. 1-3
Teaching and learning methods	• Fundamentals of Process Engineering 1 (L+E), 2 WH, 2 CP • Fundamentals of Process Engineering 2 (L+E), 2 WH, 3 CP • Mathematics 2 (L+E), 2 WH, 2 CP
Workload	**Lecture + Exercise Fundamentals of Process Engineering 1** Attendance studies: 30 h Individual study time:45 h **Lecture + Exercise Fundamentals of Process Engineering 2** Attendance studies: 30 h

	Individual study time:45 h **Lecture Mathematics II** Attendance studies: 30 h Individual study time:30 h **Total** Attendance studies: 90 h Individual study time: 120 h Total: 210 h
Form of examination and assessment	The examination is a written examination (90 minutes) for the entire module. There are no preliminary examinations in this module.
Grading	The module grade corresponds to the result of the examination performance.

General, Inorganic and Analytical Chemistry I	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	6
Course Language	German
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Traub
Lecturers	Prof. Dr. Traub
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 1st semester
Prerequisites	**Lecture + Exercise Basic Chemistry** Recommendation: Chemistry lessons at school **Lecture General and Analytical Chemistry I** Recommendation: Contents of the course "Basic Chemistry" **Practical Course Chemical Analytics I** Recommendation: Basic Chemistry, General and Analytical Chemistry I
Learning Outcomes	Students who have successfully completed this module, • have basic knowledge of general, inorganic and

	analytical chemistry. • are able to evaluate raw data of laboratory experiments according to the quality standards of the study program PBT and to create experimental protocols. • are familiar with simple routine work procedures in the chemical-analytical field, especially in dimensional analysis. • have initial experience in carrying out analytical methods according to Ph. Eur. and in analytical chemistry as well as in the area of occupational safety in the laboratory. • have knowledge of the handling of hazardous substances and the rules of conduct in the laboratories of the Faculty of Biotechnology. • have basic knowledge of "chemical calculation". • are proficient in the correct use of volumetric instruments (especially pipettes) and precision balances. • are able to calculate and prepare dilution solutions and dilution series.
Content	The following technical content is taught in this module: **Lecture + Exercise Basic Chemistry** • Introduction to Human Toxicology • Occupational safety and hazardous substances • Operating instructions • Quality assurance when working in laboratory practical's (keeping laboratory journals, general raw data acquisition, calibration, adjustment) • Chemical calculation (e.g. preparation of dimensional solutions, calculation of mixtures, significance of measurands) • Periodic table of the elements • Practical introduction to routine laboratory techniques: Weighing, volume determinations (especially pipetting), filtration, density and melting point determination. **Lecture General and Analytical Chemistry I** • Chemical bonds • Intermolecular interactions • Chemistry of aqueous solutions • Acids/bases, pH value, pKs value, neutralization reactions, acid-base buffer • Water qualities according to Pharm. Eur., substances in water, water analysis, endotoxin determination, analysis of ions, (DOC/TOC), water treatment • Redox reactions/metal corrosion • Coordinative binding

	• Titrations (e.g. according to Ph. Eur.) **Practical Course Chemical Analytics I** • Quantities, content and concentration data (preparation of measured solutions and dilution series) • Acid-base titrations • Acid-base buffer systems • Analytical methods according to the European Pharmacopoeia (ion detection, endotoxin determination by means of LAL, carbohydrates) • Methods of isolation and purification • Refractometry
Indicative bibliography	**Lecture + Exercise Basic Chemistry** • Mortimer, Das Basiswissen der Chemie, Thieme Verlag. • Hübschmann, Einführung in das chemische Rechnen **Lecture General and Analytical Chemistry I** • Mortimer, Das Basiswissen der Chemie, Thieme Verlag • Atkins, Chemie einfach alles, VCH • Ehlers, Analytik I und II, Deutscher Apotheker Verlag • Pharm. Eur. **Practical Course Chemical Analytics I** • Mortimer, Das Basiswissen der Chemie, Thieme Verlag • Ehlers, Analytik I und II, Deutscher Apotheker Verlag • Pharm. Eur.
Teaching and learning methods	• Basic Chemistry (L+PC), 2 WH, 2 CP • General and Analytical Chemistry I (L), 2 WH, 2 CP • Chemical Analysis I (L), 2 WH, 2 CP
Workload	**Lecture + Exercise Basic Chemistry** Attendance studies: 30 h Individual study time: 30 h **Lecture General and Analytical Chemistry I** Attendance studies: 30 h Individual study time: 30 h **Practical Course Chemical Analytics I** Attendance studies: 30 h Individual study time: 30 h **Total** Attendance studies: 90 h Individual study time: 90 h Total: 180 h
Form of examination and assessment	The examination is a written exam (60 minutes) covering the entire module. Only students who have successfully

	completed the preliminary examinations "Basic Chemistry" (written examination) and "Chemical Analysis I" (written paper) are admitted to this written examination.
Grading	The module grade corresponds to the result of the examination performance.

General, Inorganic and Analytical Chemistry II	
Code	(not yet provided)
Credit points according to ECTS	7
Attendance time (WH)	6
Course Language	German
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Traub
Lecturers	Prof. Dr. Traub
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 2nd semester
Prerequisites	**Lecture General and Analytical Chemistry II** Recommendation: Chemistry lectures from the 1st semester **Practical Course Chemical Analytics II** Recommendation: Chemistry lectures and practical course Chemical Analysis I from the 1st semester.
Learning Outcomes	Students who have successfully completed this module, • have theoretical and practical knowledge in the fields of spectroscopy and chromatography. • are able to independently carry out routine chemical-analytical work in the above-mentioned areas, evaluate it and record it correctly. • have knowledge in the fields of analytical and preparative chromatography (with a focus on LC) and spectroscopy. • have practical knowledge in the areas of enrichment/purification of organic substances and in instrumental analysis. • possess the ability to conduct independent literature research in the field of chemical analysis. • are able to correctly record raw data and carry out an evaluation of the measurement results.

Content	The following technical content is taught in this module: **Lecture General and Analytical Chemistry II** • Spectroscopic methods: Basics of spectroscopy (Planck's equation, atomic spectra, molecular spectra); UV/Vis spectroscopy (Lambert- Beer, application examples from the field of chemical/biochemical analysis: Protein determination Abs. 280/205, Biuret, Lowry, BCA, Bradford); Fluorescence spectroscopy/fluorescence detection (Jablonsky, Stokes shift, fluorescence intensity, intrinsic/ extrinsic fluorescence). • Basics of chromatography (separation principles, overview of chromatography methods) • Chromatographic parameters and evaluation of chromatograms (e.g. van Deemter equation, cause of band broadening, NG/BG, calibration functions) • Stationary phases in liquid chromatography: NPC (e.g. polarities, eluotropic series); RP (e.g. polarities, eluotropic series, solid phase extraction); HIC (application in protein enrichment/purification); IC (with examples from the fields of AS and protein analysis, water analysis); SEC (desalting, rebuffering, fractionation of macromolecules, molecular weight determination); AC (ligand-receptor WW., preparation of affinity matrices, monospecific/group-specific ligands, ex. for matrices: protein A/G, lectins, purification of tagged proteins, IMAC); mixed-mode media. • Thin layer chromatography (Rf value, two-dimensional DC, detection methods, derivatization methods) • HPLC (performance, areas of application, detection methods in comparison, HPLC-MS) • Mass spectroscopy • Gas chromatography **Practical Course Chemical Analytics II** • Redox titration, precipitation titration, complexometry • UV/Vis spectroscopy (e.g. detection of active pharmaceutical ingredients; kinetics of enzymatic reactions) • Colorimetric methods for quantitative protein determination • Thin layer chromatography of active pharmaceutical ingredients and amino acids • Ion chromatography and size exclusion chromatography • Derivatization and analytics of natural products • Individual final analysis (incl. independent literature research by the students)
Indicative bibliography	**Lecture General and Analytical Chemistry II**

	• Chromatographie/Spektroskopie, Böcker, Vogel Verlag • Lottspeich, Bioanalytik, Spektrum Verlag • Ehlers, Analytik I und II, Deutscher Apotheker Verlag **Practical Course Chemical Analytics II** • Böcker, Chromatograpie/Spektroskopie, Vogel Verlag • Lottspeich, Bioanalytik, Spektrum Verlag • Ehlers, Analytik I und II, Deutscher Apotheker Verlag • Pharm. Eur.
Teaching and learning methods	• General and Analytical Chemistry II (L), 2 WH, 2 CP • Chemical Analysis II (PC), 4 WH, 5 CP
Workload	**Lecture General and Analytical Chemistry II** Attendance time: 30 h Individual study time: 30 h **Practical Course Chemical Analytics II** Attendance time: 60 h Individual study time: 90 h **Total** Attendance time: 90 h Individual study time: 120 h Total: 210 h
Form of examination and assessment	The examination is a written exam (60 minutes) covering the entire module. Only students who have successfully passed the preliminary examination of the practical course "Chemical Analysis II" (written examination) are admitted to this written examination.
Grading	The module grade corresponds to the result of the examination performance.

Microbiology	
Code	(not yet provided)
Credit points according to ECTS	8
Attendance time (WH)	8
Course Language	German, English
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Gaisser
Lecturers	Prof. Dr. Gaisser

Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 1st semester
Prerequisites	Recommendation: English

Learning Outcomes	Within the framework of the module Microbiology, students acquire extensive knowledge and skills in the field:
	
	• Participants will gain in-depth specific knowledge in the area as well as acquiring hands-on experience in microbiological standard methods and techniques:
	  • Preparation of culture media and cultivation of microorganisms
	  • Microscopy, diagnostic tests
	  • Structure and function of bacterial cells
	  • Insights into bacterial diversity, bacterial genetics, microbial ecology and virology.
	• Essential aspects of the acquired expertise include social competences, also highlighting the importance of teamwork skills. Furthermore, students will gain experience in writing scientific texts by assembling information and results of experiments in form of reports. Further important aspects include self-directed learning skills and self-competence, promoted by independent processing of English-language scripts, experimental instructions and scientific texts. The students acquire extensive knowledge of subject-specific terminology in German and English.
	The broad spectrum of competences acquired is essential for future work in an international, industrial working environment.

Content	Overview of the content of the lecture: **Lecture Microbiology** • Introduction to microbiology, historical milestones, importance of microbiology: pathogens, food industry, ecology, biomining, biotechnology. • Phylogenetic tree/16S rRNA, microbial evolution: Microfossils, stromatolites, prokaryotic/eukaryotic cells • Prokaryotic cells: characteristics, membrane and transport • Structure of peptidoglycan, Gram staining, teichoic acids, archaea, cell wall as target: lysozyme, penicillin • Gram-negative bacteria: outer membrane, structure and importance of lipopolysaccharides, porins, periplasm, capsules and slime, pili and flagella, motility. • Cell inclusions: Gas vesicles, endospores, carboxysomes, magnetosomes, inclusion bodies, storage materials, *Bacillus thuringiensis* protein crystals. • Cell growth: binary fission, divisome, cytoskeleton, cell

	division and peptidoglycan biosynthesis, growth kinetics • Prokaryotic diversity: Proteobacteria: Pseudomonads, acetic acid bacteria, enterobacteria, *proteus*, *helicobacter,* myxobacteria • Prokaryotic diversity: Gram-positive bacteria: *Staphylococcus*, lactic acid bacteria, endospore-forming bacteria, streptomycetes, cyanobacteria, spirochetes • Structure of viruses, replication, CRISPR-Cas, SARS • Bacterial genetics: genome, nucleoid, chromosome, plasmids, cloning, transformation, transduction, conjugation • Bacteria and the environment: habitats, extremophiles, halophiles, biotechnological importance • Fermentation, alcohol, lactate **Practical course microbiology** • Introduction to working in a microbiology laboratory, preparation of culture media, aseptic techniques, autoclave. • Contamination risks, disinfection, sterilization, membrane filter method • Mixed cultures - pure cultures - plating techniques, dilution series • microscopy and cell morphology, colony characteristics • Mode of action of antibiotics, agar diffusion test • Cultivation of anaerobic microorganisms using *Clostridium pasteurianum*, endospores • 16S rRNA gene analysis • staining methods to differentiate bacteria: Gram staining, KOH test; capsule: negative staining with india ink. • Microbial starch degradation • Diagnostic tests, miniaturized commercial test systems: API-20E tests and EnteroPluri test; MALDI-TOF-MS • Growth of a bacterial culture: total cell count, viable cell count, growth curve, and calculation of growth parameters. • Group reports and practice worksheets promote social skills and experience in the analysis of scientific texts, data collection and evaluation.
Indicative bibliography	**Lecture Microbiology** • Lecture scripts • Fuchs, G and Schlegel, HG: General Microbiology, ISBN 3-13-444608-1 (ISBN 978-3-13-444608-1) • Madigan, MT and Martinko, JM: Brock: Biology of Microorganisms, ISBN 978-0321-53615-0

	Practical Course Microbiology • script • Fuchs, G und Schlegel, HG: Allgemeine Mikrobiologie, ISBN 3-13-444608-1 (ISBN 978-3-13-444608-1) • Madigan, MT and Martinko, JM: Brock: Biology of Microorganisms, ISBN 978-0321-53615-0
Teaching and learning methods	• Microbiology (L), 2 WH, 2 CP • Microbiology (PC), 6 WH, 6 CP
Workload	**Lecture Microbiology** Attendance time: 30 h Individual study time: 30 h **Practical course Microbiology** Attendance time: 90 h Individual study time: 90 h **Total** Attendance time: 120 h Individual study time: 120 h Total: 240 h
Form of examination and assessment	Written exam (60 minutes) covering the entire module. Permission to take the exam "Microbiology" granted based on successfully written group report/s (Practice worksheet), accepted by the course supervisors (Prerequisite).
Grading	The module grade corresponds to the result of the examination performance.

Cell and Molecular Biology	
Code	(not yet provided)
Credit points according to ECTS	10
Attendance time (WH)	9
Course Language	German
Duration	2 semesters
Offered	Every semester
Module coordinator	Prof. Dr. Otte
Lecturers	Prof. Dr. Otte, Prof. Dr. Zimmermann, Dr. Manuela Kast, Dr. Elisabeth Isbary
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 1st + 2nd semester
Prerequisites	**Lecture Physiology and Immunology**

	Recommendation: Cell Biology and Molecular Biology **Lecture Molecular Biology** Recommendation: Cell Biology, 1st semester **Practical Course Molecular Biological Analysis** Recommendation: Lecture Molecular Biology
Learning Outcomes	Students who have successfully completed this module, • know the basics of the molecular structure of the cell and genetic processes taking place in the cell, as well as the basics of physiology and pathophysiological processes in humans. • are able to apply the basic methods when working with DNA (security level S1) and are able to evaluate and summarize data in scientific protocols and reports. • know the structure (cell organelles/membrane systems) and the function (protein modifications and sorting, signal transmission and forwarding, transport processes, cell cycle sequence and control) in the eukaryotic cell. • are familiar with the basics of physiology. • have an understanding of the basic pathophysiological processes in humans. • have a basic understanding of the current areas of research in the pharmaceutical industry based on the knowledge acquired. • have knowledge of the genetic processes in the cell (replication, transcription, translation), as well as mutations and the repair of DNA. • have a basic knowledge of the methodical handling of nucleic acids (methods of genetic engineering).
Content	The following technical content is taught in this module: **Lecture Cell Biology** • Introduction: Historical overview of cell biology, book presentation, overview of cell types (pro- and eukaryotes). • Overview of macromolecules, cell organelles, membrane structure and transport systems • Cell compartments and principles of protein sorting: signal sequences, endocytosis, exocytosis, synthesis of proteins of the secretory pathway on ER-bound ribosomes, retention of ER-resident proteins. • Post-translational modifications of secretory proteins in the ER and Golgi, quality control, transport through the Golgi, transport into the lysosomes, continuous and regulated secretion

	• Receptor-mediated endocytosis: protein synthesis at free ribosomes, protein transport into the cell nucleus, mitochondria, peroxisomes • Overview of signaling systems, signal transduction, signaling molecules, receptor molecules • G protein-coupled receptors, second messenger, agonists and antagonists • Receptor tyrosine kinases, Ras-cycle, kinase cascade, signal transduction (gene expression) • Overview cytoskeleton, microfilaments: Actin-myosin movements, intermediate filaments • Microtubules, transport along intracellular tracks, cell-cell connections, extracellular matrix • Cell-cell communication • Cell cycle and cell cycle control: checkpoints and cyclically controlled protein kinases, cancer **Lecture Physiology and Immunology** • Basics of physiology: cells and tissues, rest and action potential, regulatory circuits • Skin / temperature balance • Heart and cardiovascular system • Respiration and transport of respiratory gases in the blood • Blood and blood components • Digestion, liver metabolism • Kidney and homeostasis • Musculature and motor skills • Hormones: local and remote signals, endocrine system • Synaptic transmission and central nervous system • Peripheral nervous system: sympathetic and parasympathetic nervous system • Immunology: basics of immune defense, innate and acquired immunity, complement reactions, T and B cell activation, MHC- I and MHC-II, antibodies, effector function. **Lecture Molecular Biology** • Introduction and History Molecular Biology • Structure of nucleic acids: nucleotides, double helix, DNA rings, cell nucleus, chromatin, nucleosome, chromosomes • Chromatin and chromosomes • Replication: processes at the replication fork in pro- and eukaryotes • Transcription: promoter structure, transcription factors, elongation, termination • Processing of mRNA: splicing, editing, capping, polyadenylation

	• Translation: process and elements of translation • Genetic code, recombination, mutation, repair • Transcription control • Mitosis and meiosis, dominant and recessive heredity • Epigenetics • CRISPR/Cas9 • Non-coding RNAs **Practical Course Molecular Biological Analysis** • Mini preparation of plasmid DNA • Gel electrophoresis for the separation of nucleic acids • Purification of DNA from agarose gels • Concentration determination of nucleic acids by gel electrophoresis and spectrometry • DNA restriction analysis • Southern Blot Transfer • Polymerase chain reaction (PCR) • Labelling of a DNA sample with digoxigenin • Hybridization with labelled DNA primers and detection of specific nucleic acid sequences.
Indicative bibliography	**Lecture Cell Biology** • Molecular Biology of the Cell, Alberts et al. • Molecular Cell Biology, Lodish et al. • Taschenatlas der Biochemie, Koolmann und Röhm **Lecture Physiology and Immunology** • Despopoulos/Silbernagl: Taschenatlas der Physiologie • Schütt/Bröker: Grundwissen Immunologie **Lecture Molecular Biology** • Molekulare Genetik, Alfred Nordheim & Rolf Knippers, Thieme Verlag, Stuttgart • Molecular Biology of the Gene, Watson, Baker, Bell, Gann, Levine, Losick, Addison Wesley Verlag • Der Experimentator: Molekularbiologie/Genomics, Cornel Mülhardt, Spektrum Akademischer Verlag, 5. Auflage, 2006 **Practical Course Molecular Biological Analysis** • Molecular cloning: A Laboratory manual, Maniatis, Sambrook, Rusell, 3rd Volume Edition • Der Experimentator Molekularbiologie/Genomics, C. Mülhardt, Spektrum Akademischer Verlag, 5. Auflage, 2006
Teaching and learning methods	• Cell Biology (L), 2 WH, 2 CP • Physiology and Immunology (L), 2 WH, 2 CP • Molecular biology (L), 2 WH, 2 CP

	• Molecular biological analytics (PC), 3 WH, 4 CP
Workload	**Lecture Cell Biology** Attendance study: 30 h Individual study time: 30 h **Lecture Physiology and Immunology** Attendance study: 30 h Individual study time: 30 h **Lecture Molecular Biology** Attendance study: 30 h Individual study time: 30 h **Practical Course Molecular Biological Analysis** Attendance study: 45 h Individual study time: 75 h **Total** Attendance study: 135 h Individual study time: 165 h Total: 300 h
Form of examination and assessment	Only students who have successfully passed the preliminary examinations of all courses, lecture "Cell Biology" (written examination), lecture "Physiology and Immunology" (oral examination), lecture "Molecular Biology" (written examination), practical course "Molecular Biological Analysis" (written elaboration in the form of protocols for the practical course) in this module are admitted to the examination.
Grading	The module grade corresponds to the result of the examination performance.

Organic Chemistry and Biochemistry	
Code	(not yet provided)
Credit points according to ECTS	5
Attendance time (WH)	4
Course Language	German
Duration	2 semesters
Offered	Every semester
Module coordinator	Prof. Dr. Zimmermann
Lecturers	Prof. Dr. Traub, PD Dr. Joachim Bischof
Classification within the	Pharmaceutical Biotechnology BSc, compulsory

study program	module, 1st + 2nd semester
Prerequisites	**Lecture Organic Chemistry** Recommendation: Basic Chemistry, General and Analytical Chemistry **Lecture Biochemistry of the Metabolism** Recommendation: Organic Chemistry, General and Analytical Chemistry
Learning Outcomes	Students who have successfully completed this module, • know the basics of organic reaction mechanisms and the classification of the most important bioorganic molecules into substance classes. • possess the competence to understand and apply biochemical reactions as a sub-field of organic chemistry. • know the interaction and regulation of metabolic pathways depending on the physiological state of the cell. • have an overview of important organic reaction types. • have knowledge in the field of reaction kinetics and energetics as well as in the field of biopolymers and their basic building blocks. • are able to recognize the most important biochemical groups of substances, understand their reaction pathways and classify them in the context of the metabolism. • understanding the regulation of the metabolism as well as pathological mechanisms.
Content	The following technical content is taught in this module: **Lecture Organic Chemistry** • Energetics and kinetics of organic reactions (enthalpy, reaction energetics in biochemical reactions, entropy, Gibbs free enthalpy, reaction rate, reaction order, activation energy, catalysis in general, enzymatic catalysis) • Molecular structures: Covalent bonds (geometry of molecules and molecular orbitals, single and multiple bonds, resonance structures, aromatics), stereochemistry (constitutional isomers, stereoisomers). • Important basic types of organic reactions: Reaction mechanisms for saturated hydrocarbons (nucleophilic substitution, radical substitution, elimination reactions), reaction mechanisms for unsaturated hydrocarbons (electrophilic addition), reaction mechanisms for carbonyl compounds. • Biopolymers and their basic building blocks: Amino

	acids and proteins, carbohydrates, fatty acids and fats; with cross-references to metabolic reactions. **Lecture Biochemistry of the Metabolism** • Thermodynamic basics, reaction energetics, basic principles of biochemistry • Structure and metabolism of carbohydrates, glycolysis, gluconeogenesis, glycogen, Cori cycle • Citrate cycle, anaplerotic reactions, pentose phosphate pathway, coenzymes, prosthetic groups, and vitamins. • Functions, structure and metabolism of lipids, beta-oxidation, fatty acid synthesis, ketone body metabolism, lipid neogenesis • Oxidative phosphorylation, chemiosmosis, ATP synthesis, redox potential • Photosynthesis, light-dependent and -independent reactions • Metabolism of ketogenic and glucogenic amino acids, urea cycle • Integration of metabolism: digestion, absorption and fluxes of metabolizable substances, regulation of metabolism by hormones, organ specialization in metabolism, pathobiochemistry • Metabolism of tumor cells and cell lines
Indicative bibliography	**Lecture Organic Chemistry** • Hart, Organische Chemie, WILEY-VCH • Mc Murry, Organische Chemie der biologischen Stoffwechselwege; Spektrum Akademischer Verlag **Lecture Biochemistry of the Metabolism** • Lecture slides • Stryer: Biochemie • Löffler, Petrides: Biochemie und Pathobiochemie • Koolman, Röhm: Taschenatlas Biochemie des Menschen
Teaching and learning methods	• Organic Chemistry (L), 2 WH, 3 CP • Biochemistry of the Metabolism (L), 2 WH, 2 CP
Workload	**Lecture Organic Chemistry** Attendance time: 30 h Individual study time: 60 h **Lecture Biochemistry of the Metabolism** Attendance time: 30 h Individual study time:30 h **Total** Attendance time: 60 h Individual study time: 90 h Total: 150 h

Form of examination and assessment	The examination is a written exam (90 minutes) covering the entire module. Only students who have successfully passed the preliminary examination of the lecture "Biochemistry of the Metabolism" (oral examination) are admitted to this written examination.
Grading	The module grade is composed of 50 % of the performance in organic chemistry and 50 % of the performance in biochemistry.

Modules in the 2nd study stage (3rd - 5th semester)

Chemistry of Biomolecules	
Code	(not yet provided)
Credit points according to ECTS	10
Attendance time (weekly hours)	9
Language	German
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Kiefer
Lecturers	Prof. Dr. Kiefer, Prof. Dr. Zimmermann, Prof. Dr. Burghardt
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 3rd semester
Prerequisites	**Lecture + Exercise Biostatistics** Recommendation: Mathematics 1 & 2, Technical Mathematics (module Process Engineering, during the semester), Biochemistry, Genetics **Lecture Biochemical Analytics** Recommendation: Basic knowledge of biology, chemistry and physics **Lecture Protein Biochemistry** Recommendation: Lecture Biochemistry of the Metabolism **Practical Course Analytical Biochemistry and Assay Development** Recommendation: Lecture Biochemistry of the Metabolism
Learning Outcomes	Students who have successfully completed this module, **Lecture + Exercise Biostatistics** • know the basics of statistics as far as they are required for the evaluation of experimental data in the study program. • can carry out experimental evaluations with the help of statistical software and apply the acquired knowledge to experiments in protein biochemistry during the semester. **Lecture Biochemical Analytics** **Lecture Protein Biochemistry**

	Practical Course Analytical Biochemistry and Assay Development • have learned the physical and chemical properties of proteins and gained an overview of their structure and dynamics. They can apply this knowledge in protein purification and analysis. • can attribute the behavior of proteins during processing and storage to their physical-chemical properties and thus optimize processes in such a way that the stability and specific activity of the proteins is maximized. They can select and apply the appropriate biochemical methods for specific questions. • can research questions on specific proteins in internet databases and answer them with the help of online tools • are able to understand the composition of enzymatic and immunochemical assays and interpret their significance. • have theoretical and practical knowledge of qualitative, quantitative and semi-quantitative immunological assays. • master biochemical working techniques and develop assay optimization skills.
Content	The following technical content is taught in this module: **Lecture + Exercise Biostatistics** The course content is divided into the following topics, which are deepened with exercises and examples: • Fundamentals of statistics and probability theory • Evaluation of measurement data using statistical software • Hypothesis tests (e.g. t-test, binomial test) • Equalization (linear and non-linear fits) **Lecture Biochemical Analytics** • General principles of assay development • Analytical methods based on enzymes and enzyme kinetics • Basics of photometric and spectrometric analysis • Antibodies and immunological detection methods • Immobilization procedure • Preparation of the experiments in the practical course biochemistry • Evaluation of the results of the experiments in the practical course biochemistry **Lecture Protein Biochemistry** • Structure and dynamics of proteins • Biosynthesis and degradation • Protein-ligand binding

	• Enzyme kinetics • Protein folding • Regulation of protein activity • Protein databases on the internet • Drug development **Practical Course Analytical Biochemistry and Assay Development** • Enzyme kinetics with different inhibitions • Coupled enzymatic tests for carbohydrate detection • Cytotoxicity assay • Direct ELISA • Competitive ELISA • Sandwich ELISA • SDS-PAGE with glycoprotein detection and Coomassie staining • Western blot
Indicative bibliography	**Lecture + Exercise Biostatistics** • Rudolf, Kuhlisch; Biostatistik, Pearson Studium, 2008 • Ross, S. M.: Statistik für Ingenieure und Naturwissenschaftler, Spektrum sa Verlag, 2006 • D. C. Montgomery & George C. Runger, Applied Statistics and Probability for Engineers, Wiley, 2010 • Box, G. E. P.; Hunter, W. G. & Hunter, J. S. Statistics for Experimenters John Wiley & Sons, 2005 **Lecture Biochemical Analytics** • Wollenberger: Analytische Biochemie: Eine praktische Einführung in das Messen mit Biomolekülen **Lecture Protein Biochemistry** • Lecture presentations • Jeremy M. Berg et al.: Biochemie, 8. Aufl., Springer, 2018, ISBN 9783662546208 (E-Book) • Gregory A Petsko and Dagmar Ringe: Protein Structure and Function, New Science Press, London, 2008 **Practical Course Analytical Biochemistry and Assay Development** • Instructions • Lottspeich, Engels: Bioanalytik
Teaching and learning methods	• Biostatistics (L+E), 2 WH, 3 CP • Biochemical analytics (L), 1 WH, 1 CP • Protein biochemistry (L), 2 WH, 2 CP • Analytical Biochemistry and Assay Development (PC), 4 WH, 4 CP
Workload	**Lecture + Exercise Biostatistics**

	Attendance time: 30 h Individual study time: 40 h **Lecture Biochemical Analytics** Attendance time: 15 h Individual study time: 15 h **Lecture Protein Biochemistry** Attendance time: 30 h Individual study time: 30 h **Practical Course Analytical Biochemistry and Assay Development** Attendance time: 60 h Individual study time: 60 h **Total** Attendance time: 135 h Individual study time: 145 h Total: 280 h
Form of examination and assessment	The examination is a written exam (120 minutes) covering the entire module. Only students who have successfully passed the preliminary examination "Biostatistics" of the practical course "Analytical Biochemistry and Assay Development" (written paper) are admitted to this written examination.
Grading	The module grade corresponds to the result of the examination performance.

Genetic Engineering	
Code	(not yet provided)
Credit points according to ECTS	7
Attendance time (WH)	6
Course Language	German
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Otte
Lecturers	Prof. Dr. Otte
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 3rd semester
Prerequisites	**Practical course Genetic Engineering**

	Recommendation: Lecture Molecular Biology and practical course Molecular Biological Analysis **Seminar Genetic Engineering** Recommendation: Lecture Molecular Biology and practical course Molecular Biological Analysis
Learning Outcomes	Students who have successfully completed this module, • have advanced knowledge in the field of genetic engineering, especially with regard to cloning and gene expression. • know the latest techniques in the field of genetic engineering and genomics. • can apply acquired knowledge to create their own protocols. • have advanced practical and theoretical knowledge in the use of genetic engineering methods, focusing on methods for cloning genes and their expression in different host organisms.
Content	The following technical content is taught in this module: **Practical course Genetic Engineering** • Cloning of a gene and heterologous expression of the cloned gene: • Restriction digestion to isolate insert and vector • Dephosphorylation of a vector • Preparative gel electrophoresis for the isolation of DNA from agarose gels • Purification of DNA from agarose gels • Concentration determination of DNA by spectrometry • Ligation reaction for the production of recombinant vectors • Production of competent bacteria and transformation of recombinant DNA into prokaryotic host organisms • Selection and verification of positive transformants by plasmid preparation and restriction digestion as well as colony PCR • Heterologous protein expression in E. coli • Fluorescence microscopy • RNA preparation from E. coli • cDNA synthesis • quantitative real-time PCR **Seminar Genetic Engineering** • Next generation sequencing techniques • Genome and transcription sequencing • Microarray analyses • Genome modification with CRISPR/Cas9

	• Eukaryotic and prokaryotic expression systems for heterologous protein production • Optimization of expression systems through genetic modulation • Non-coding RNAs as genetic engineering tools • Current technical innovations
Indicative bibliography	**Practical Course Genetic Engineering** • Molecular cloning: A Laboratory manual, Maniatis, Sambrook, Rusell, 3rd Volume Edition • Der Experimentator Molekularbiologie/Genomics, C. Mülhardt, Spektrum Akademischer Verlag, 5. Auflage, 2006 **Seminar Genetic Engineering** • Current scientific articles
Teaching and learning methods	• Genetic engineering (PC), 5 WH, 6 CP • Genetic engineering (L), 1 WH, 1 CP
Workload	**Practical Course Genetic Engineering** Attendance study: 75 h Individual study time: 105 h **Seminar Genetic Engineering** Attendance study: 15 h Individual study time: 15 h **Total** Attendance study: 90 h Individual study time: 120 h Total: 210 h
Form of examination and assessment	The examination is a written exam (60 minutes) covering the entire module. Only students who have successfully completed the preliminary examination of the practical course "Genetic Engineering" (written paper) are admitted to this written examination.
Grading	The module grade corresponds to the result of the examination performance.

Technical Microbiology	
Code	(not yet provided)
Credit points according to ECTS	5
Attendance time (WH)	5
Course Language	German, English
Duration	1 semester

Offered	Every semester
Module coordinator	Prof. Dr. Gaisser
Lecturers	Prof. Dr. Gaisser
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 3rd semester
Prerequisites	**Lecture Microbial Production Processes** Recommendation: Lecture/Practical Course Microbiology (1st semester) **Practical Course Technical Microbiology** Recommendation: Lecture/Practical Course Microbiology (1st semester)

Learning Outcomes	Successful completion of this module will deepen existing knowledge, also enhancing practical skills relating to different aspects of biotechnological production processes:
	
	• Expansion of professional competence:
	  • Students gain insight into practical techniques used to carry out microbial fermentations
	  • Participants are provided with the opportunity to gather hands-on experience using 2 l benchtop fermentors
	  • Students will be familiar with basic concepts of microorganism-based manufacturing processes of important industrial products such as antibiotics (penicillin, erythromycin).
	  • Students gain in-depth knowledge regarding the importance of microorganisms in biotechnological production processes and related working techniques. Examples of traditional and modern microbial production processes are presented.
	  • Successful participants are able to use lab-scale fermentors for microbial cultivations. Furthermore, students will be familiar with the subject-specific terminology in German and English.
	• Deepening of social competence promoted by routine teamwork and writing of group reports
	• Increasing experience in the analysis of scientific texts, data collection and evaluation.
	• Students develop key competences that are essential for successful future work in a professional working environment.

Content	overview of the content of the lecture and competences gained: **Lecture Microbiological Production Processes** • Assembly and components of a bench-top fermentor

	(detailed working procedures in parallel to the practical course) • historical overview: Microorganisms and biotechnology, products, examples of primary and secondary metabolites. • Overview of the production process, microbial producer strains, screening procedures, bioprospecting and biomining • Strain development: traditional methods: mutagenesis and screening, example: penicillin • Strain development: modern methods: transcriptome/ proteome/ metabolome, gene shuffling, CRISPR-Cas • Process development and media development, growth parameters • Batch/Fed-Batch/Continuous process mode, yeast production, Pasteur- and Crabtree effect, quorn, astaxanthin, probiotics • Organic acids: citric acid production, gluconic acid, lactic acid, acetic acid production • Amino acids and vitamins: Glutamate, lysine, aspartame, vitamin B12, vitamin B2, biotin, vitamin C • Polymers: PHB and bioplastic, natto, polyaminoacids, xanthan, dextran • Antimicrobial and chemotherapeutic agents: Salvarsan, sulfanilamide, quinolone, penicillin, streptomycin, antibiotics Overview • Enzymes: alpha-amylases, solid state fermentation, enzymes and detergents, recombinant products: Insulin **Practical Course Technical Microbiology** Work instructions for carrying out microbial fermentations are introduced at the beginning of the lecture "Microbiological Production Processes" before the start of the practical course. During the course students will gain insight into • Components and assembly of the bioreactor, preparation for autoclaving, set-up, use of control unit, calibration of the pH- electrode, DO- electrode (dissolved oxygen) control in zero-solution, media preparation, inoculation and harvesting, sampling. • Pre-culture and fermentation of *E. coli* XL1Blue, dismantling the bioreactor, autoclaving, cleaning the equipment, documentation of the results. • Inoculation, sampling, computer-aided data acquisition, growth curve, harvesting, autoclaving and cleaning of the glass vessel, writing of a report • Fermentation of an *E. coli* strain to express GFP; the strain represents the construct generated by the

	students in the genetic engineering practical course. • The frozen cell sediment is further used as part of the Biotechnological Processing practical course. • Cultivation of the Gram-positive bacterium *Saccharopolyspora erythraea* (Erythromycin producer) • Cultivation of the organism in liquid culture, microscopic analysis of mycelial growth, growth on agar plates: substrate mycelium, aerial mycelium, spores. • Inoculation of production medium (shake flask) • Harvest of supernatant of the production culture • The supernatant is assessed using an agar diffusion test.
Indicative bibliography	**Lecture Microbiological Production Processes** • Lecture notes, working procedures, Biostat Bplus and script provided at the beginning of the practical course • Fermentation Microbiology and Biotechnology, EMT El-Mansi et al., second edition, ISBN-10: 0-8493-5334-3 **Practical Course Technical Microbiology** • Lecture notes, working procedure Biostat Bplus and script provided at the beginning of the practical course • Fermentation Microbiology and Biotechnology, EMT El-Mansi et al., second edition, ISBN-10: 0-8493-5334-3
Teaching and learning methods	• Microbiological Production Processes (L), 2 WH, 2 CP • Technical Microbiology (PC), 3 WH, 3 CP
Workload	**Lecture Microbiological Production Processes** Attendance study: 30 h Individual study time: 30 h **Practical Course Technical Microbiology** Attendance study: 45 h Individual study time: 45 h **Total** Attendance study: 75 h Individual study time: 75 h Total: 150 h
Form of examination and assessment	Written examination (60 minutes) covering the entire module. Permission to take the exam “Technical Microbiology” granted based on the successfully written group report (Prerequisite), accepted by the course supervisors.
Grading	The module grade corresponds to the result of the examination performance.

Process Engineering	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	6
Course Language	German and English
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Schafmeister
Lecturers	Prof. Dr. Schafmeister, Eichel (LB)
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 3rd semester
Prerequisites	**Lecture Technical Mathematics** Recommendation: Mathematics I (module Physics) and Mathematics II (module Fundamentals of Process Engineering), Biostatistics (module Chemistry of Biomolecules). **Lecture Thermal Process Engineering and Lecture Mechanical Process Engineering** Recommendation: Lecture and exercise "Fundamentals of Process Engineering", courses on mathematics, physics, chemistry (general)
Learning Outcomes	Students who have successfully completed this module, **Lecture + Exercise Technical Mathematics** • know the basics of higher mathematics required for application-oriented scientific and technical studies • can solve exercises **Lecture Thermal Process Engineering and Lecture Mechanical Process Engineering** • possess theoretical and practical skills in basic process engineering operations (unit operations) as they are necessary for the design and understanding of industrial production processes in biotechnology. • know the basic operations whose common goal is to separate homogeneous mixtures of substances by "thermal" means, for example by using thermal molecular motion. • can balance material and energy flows. • demonstrate a deeper understanding of phase equilibria, mass and heat balances (conservation laws),

	mass transfer apparatuses and the associated theory of theoretical separation stages. • have comprehensive knowledge of the production, transformation, description, measurement and handling of disperse systems (particle technology) of any kind, for example: suspensions, emulsions, aerosols, bulk materials, etc., as they play a role in manufacturing processes of pharmaceutical products as well.
Content	The following technical content is taught in this module: **Lecture + Exercise Technical Mathematics** • Descriptive statistics: frequency distributions, location and dispersion parameters • Measurement error and error propagation • Linear algebra: systems of linear equations, matrices, determinants • Integration methods: partial integration, substitution rule, etc. • Fourier transform **Lecture Thermal Process Engineering** • Fundamentals for thermal separation processes: selected topics from the process engineering disciplines thermodynamics, physical chemistry, heat and mass transfer • Introduction to the theory of thermal separation processes: General, terms and definitions • Distillation • Rectification • Extraction • Crystallization **Lecture Mechanical Process Engineering** • Labelling of dispersive substance systems • Representation of quantity distributions • Particle measurement technology: deposition, optical and other measurement methods • Adhesive forces in solid systems and agglomeration: binding mechanisms, measurement of adhesive forces, properties of agglomerates • Resistance behavior of particles in flows: Flow resistance of a sphere, equation of motion for particles • Dimensional Analysis and Similarity Laws: Scale Up, Pi Theorem • Flow through packings: Characterization of a packing, void ratio and distribution, packing structures, heaps and influence of capillary force, flow through a packing. • Separation processes: Identification of a separation, separation in flows (counterflow, crossflow)

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Indicative bibliography	**Lecture + Exercise Technical Mathematics** • L. Papula, Mathematik für Ingenieure und Naturwissenschaftler, Vieweg + Teubner, 2011--15, Bd. 1-3 • Rießinger, T., Mathematik für Ingenieure, Springer Vieweg, 2013 • Rießinger, T., Übungsaufgaben zur Mathematik für Ingenieure, Springer Vieweg, 2013 • Burg, K.; Haf, H.; Meister, A. & Wille, F., Höhere Mathematik für Ingenieure, Springer Vieweg, 2013, Bd. 1-3 **Lecture Thermal Process Engineering** • Mersmann, A., Kind, M., Stichlmair, J.: Thermische Trennverfahren, Grundlagen und Methoden, Springer-Verlag Berlin Heidelberg, 2005; • Lohrengel, B.: Einführung in die thermischen Trennverfahren, Trennung von Gas-, Dampf- und Flüssigkeitsgemischen, Oldenbourg Wissenschaftsverlag GmbH, 2007 **Lecture Mechanical Process Engineering** • Schubert, H.: Handbuch der Mechanischen Verfahrenstechnik, WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim, 2003, Band 1 und 2 • Bohnet, M.: Mechanische Verfahrenstechnik, WILEY- VCH Verlag GmbH & Co. KGaA, Weinheim, 2004
Teaching and learning methods	• Technical Mathematics (L + E), 2 WH, 2 CP • Thermal process engineering (L), 2 WH, 3 CP • Mechanical process engineering (L), 2 WH, 3 CP
Workload	**Lecture + Exercise Technical Mathematics** Attendance study: 30 h Individual study time: 60 h **Lecture Thermal Process Engineering** Attendance study: 30 h Individual study time: 60 h **Lecture Mechanical Process Engineering** Attendance study: 30 h Individual study time: 60 h **Total** Attendance study: 90 h Individual study time: 180 h Total: 270 h

Form of examination and assessment	The examination is a written exam (120 minutes) for the entire module. There are no preliminary examinations in this module.
Grading	The module grade corresponds to the result of the examination performance.

Plant and Clean Room Technology	
Code	(not yet provided)
Credit points according to ECTS	7
Attendance time (WH)	7
Course Language	German and English
Duration	2 semesters
Offered	Every semester
Module coordinator	Prof. Dr. Hesse
Lecturers	Dr. Sievers; Dr. Jürgen Haas; Prof. Dr. Hesse; Prof. Dr. Hannemann
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 3rd +4th semester
Prerequisites	**Lecture Measurement and Control Technology** Recommendation: Mathematics, Physics, Chemistry and Fundamentals of Process Engineering **Lecture Plant and Apparatus Engineering** Recommendation: Fundamentals of Process Engineering, Thermal and Mechanical Process Engineering **Lecture Sterile and Clean Room Technology** Recommendation: Seminar GMP/GLP **Excursion Biotechnological Processes** Recommendation: Fundamentals of Pharmaceutical Biotechnology and Process Engineering Fundamentals
Learning Outcomes	Students who have successfully completed this module, • can apply the relevant design criteria in biopharmaceutical manufacturing processes (technologies in measurement and control technology, clean room design, sterile technology and in the planning of biopharmaceutical production facilities). • know the process variables, the laboratory and application-oriented process measurement and control technology as well as the reference to operational

	practice. • know the functional principles and the mode of operation of measuring, actuating and control elements as well as the possible sources of error. • know the planning phases of a pharmaceutical plant from pre-project planning to commissioning and are familiar with the design aspects of fittings as well as the possibilities and limits of different membrane filter tests. • know planning contents, planning tools, required qualification documents, qualification and validation processes as well as risk analyses. • know the basics of sterile and cleanroom technology (terminology, history and structural conditions, cleanroom classes). • know the relationship between particles, germs and cleanroom class, the difference between turbulent mixed flow and low-turbulence displacement flow. • can plan premises for the production of active pharmaceutical ingredients with the aid of the relevant regulations.
Content	The following technical content is taught in this module: **Lecture Measurement and Control Technology** • General introduction to measurement and control technology • Basics of electrical engineering, pneumatics, hydraulics, measurement technology, control technology, terms and regulations. • Process variables and measurement errors • Sensors, transmitters and measuring instruments, design and function, installation guidelines • Graphical representations, logic modules and process control technology • Position and process control, cascade control and drag control, structure and function • P, PI, PID function in controllers, linear and equal-percentage action of controls, leading and lagging controls, unfavorable control behavior and its causes • Design of control valves with exercises • Design of volume flow, temperature and pressure controls • Complete construction of controlled supply circuits (e.g., sterile water supply incl. pump control and taps). • Practical exercises on a functional model with assessment of the characteristic curves **Lecture Plant and Apparatus Engineering** • Plant design in the pharmaceutical industry: documentation and information (databases, flow

	diagrams: Block flow diagram, process flow diagram, P&I flow diagram), equipment, pipe classes, layout planning, pipe routing, support areas for production, feasibility studies, contracts and risks, approval procedures, official requirements, plant planning with phase model, project planning (concept, basic and detail engineering, safety analyses, operating manual), planning tools, qualification documentation, qualification and validation, risk analysis (FMEA). • Technical basics in plant engineering for hygienic and sterile applications: Selection criteria for plant and equipment components (materials, sealing technology), surface finishes and connection types, valve function principles, diaphragm valves for sterile processes, poppet valves for steam, valves in control applications. • Integrity test on membrane filters: physical basics of the test procedures, bubble point test, forward flow test, water intrusion test, integrity test equipment **Lecture Sterile and Clean Room Technology** • Structural requirements for the construction of clean rooms • History and development of hygiene and cleanroom technology • Turbulent mixed flow and low-turbulence displacement flow (laminar flow) • Purity classes according to DIN ISO 14644 or according to the EC Guide to Good Manufacturing Practice • Particle monitoring and classification of cleanrooms • Cleanroom qualification, cleanroom classes and behavior in cleanrooms • Sterile technology and sterilization of equipment • Basics and techniques of heat sterilization • Supply and disposal of ultra-pure media • Particle properties and particle measurement techniques **Excursion Biotechnological Processes** • Structures and premises in pharmaceutical manufacturing plants
Indicative bibliography	**Lecture Measurement and Control Technology** • Reichwein, J., Hochheimer, G., Simic, D.: Messen, Regeln und Steuern, WILEY –VCH Verlag GmbH & Co. KGaA, 2007 • Töster: Steuerungs- und Regeltechnik, Oldenbourg Wissenschaftsverlag GmbH, 2001 • Gränicher, W. H. Heini.: Messung beendet – Was nun?, vdf Hochschulverlag AG ETH Zürich und B G. Teubner, Stuttgart, 1996

	• Philips Lehrbriefe Elektrotechnik, Hüthig-Verlag, 1982 • Kroupa Ralph: Ventiltechnologie im Anlagenbau, WILEY –VCH, 1994 **Lecture Plant and Apparatus Engineering** • G. Bernecker: Planung und Bau verfahrenstechnischer Anlagen: Projektmanagement und Fachplanungsfunktionen, Springer Verlag Berlin, 2001 • R. Herz: Grundlagen der Rohrleitungs- und Apparatetechnik, Vulkan-Verlag Essen, 2009 • L. Gail, H.-P. Hortig (Hrsg.): Reinraumtechnik, Springer-Verlag Berlin, 2001 • Chmiel, H.: Bioprozesstechnik, Spektrum Akademischer Verlag, 2011 • FMEA- Fehlermöglichkeits- und Einflussanalyse, Deutsche Gesellschaft für Qualität, DGQ-Band 13-11, 2008 • Paul Präve: „Standardisierungs- und Ausrüstungs-empfehlungen für Bioreaktoren und periphere Einrichtungen“, Frankfurt am Main, DECHEMA, 1991 **Lecture Sterile and Clean Room Technology** • Reinraumtechnik, Lothar Gail und Hans-Peter Hortig, Springer Verlag, ISBN 3-540-66885-3, 2001 • Bioreaktoren und periphere Einrichtungen, Winfried Storhas, Vieweg Verlag, 1994, ISBN 3-528-06510-9, 2000 • EG-Leitfaden der Guten Herstellungspraxis, 8. Auflage, 2007, Editio Cantor Verlag, ISBN 978-3-87193-359-2, 2007 **Excursion Biotechnological Processes** • None
Teaching and learning methods	• Measurement and control technology (L), 2 WH, 2 CP • Plant and apparatus engineering (L), 2 WH, 3 CP • Sterile and clean room technology (L), 2 WH, 2 CP
Workload	**Lecture Measurement and Control Technology** Attendance study: 30 h Individual study time: 30 h **Lecture Plant and Apparatus Engineering** Attendance study: 30 h Individual study time: 30 h **Lecture Sterile and Clean Room Technology** Attendance study: 30 h Individual study time: 30 h

	Excursion Biotechnological Processes Attendance study: 15 h Individual study time: 15 h **Total** Attendance study: 105 h Individual study time: 105 h Total: 210 h
Form of examination and assessment	The examination performance is assessed in two written examinations. The first exam (60 minutes) covers the contents of the two lectures "Measurement and Control Technology" and "Plant and Apparatus Engineering". The second exam (60 minutes) covers the contents of the lecture "Sterile and Cleanroom Technology". Only students who have successfully completed the preliminary examination "Sterile and Cleanroom Technology" (wE) are admitted to this examination. In order to pass the course "Excursion Biotechnological Processes", students have to prepare written papers on the pharmaceutical companies visited.
Grading	The module grade is calculated from the grades of the written examination for the courses: 1. measurement and control technology and plant and apparatus engineering multiplied by 2/3 added to the grade of the written examination "Sterile and clean room technology" multiplied by 1/3.

Biotechnological Processing	
Code	(not yet provided)
Credit points according to ECTS	12
Attendance time (WH)	12
Course Language	English, German
Duration	2 semesters
Offered	Every semester
Module coordinator	Prof. Dr. Kiefer
Lecturers	Prof. Dr. Kiefer, Prof. Dr. Traub
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 4th + 5th semester
Prerequisites	**Lecture Downstream Processing** Recommendation: Lecture Protein Biochemistry **Practical Course in Downstream Processing** Recommendation: Lecture Downstream Processing

	Practical Course Protein Analytics Recommendation: Lecture protein biochemistry, Seminar Protein Analytics (accompanying practical course) **Seminar Protein Analysis** Recommendation: Lecture Protein Biochemistry
Learning Outcomes	Students who have successfully completed this module, • know the processing of proteins and other biopharmaceutical active substances from different sources, • can describe how their degree of purity is determined, how critical contaminants are detected and removed • can select which methods are suitable for different tasks in each case. • have been given an overview of methods used in the processing of biopharmaceuticals, especially proteins, on a laboratory and industrial scale and can select the appropriate methods themselves in specific cases. • Use chromatography and filtration techniques in the laboratory to purify and analyze recombinant proteins from different sources. • have learned how to use the chromatography system (ÄKTA pure) independently. They can pack columns and check their packing quality. • have learned protein analytical methods theoretically and practically, which can be carried out in biochemical laboratories without expensive technical equipment. • can independently compile original English-language publications from topics of protein analytics and present them in English. Based on these publications, they have obtained an overview of protein analytical techniques.
Content	The following technical content is taught in this module: **Lecture Downstream Processing** • Overview of multi-stage purification processes • Cell harvesting, preparation of a lysate; centrifugation and microfiltration techniques. • Chromatography: IEX, SEC, HIC, RPC, AC • Ultrafiltration, diafiltration, adsorber membranes • Separation of DNA, viruses, endotoxin, host cell proteins (HCPs) and product-related contaminants • Special purification techniques: extraction from aqueous multiphase systems, radial flow chromatography, continuous chromatography, precipitation and crystallization

	• Design and implementation of PAT (Process Analytical Technologies) and QbD (Quality by Design) • Set-up and operation of the ÄKTA-pure chromatography system **Practical Course in Downstream Processing** • Purification of green fluorescent protein (GFP) by Ni-IMAC • Development of a multi-stage chromatographic purification of a given enzyme: cell disruption, extract preparation, ion exchange chromatography, hydrophobic interaction chromatography, affinity chromatography, gel filtration, analysis of protein content, purity and activity. Planning is done by the groups with the help of self-researched literature. • Optimization of the selectivity and resolution of a cation exchange chromatography. Planning and evaluation supported by DoE software "Modde". (joint event with Biostatistics) **Practical Course Protein Analytics** • Purification of lysozyme from chicken egg white by ion exchange chromatography, protein determination by BCA assay, SDS gel electrophoresis, activity determination • Measurement and optimization of protein stability • Removal and detection of critical contaminants (endotoxin, DNA, HCPs) from a protein solution • Measurement of protein-ligand binding, determination of K_D and B_{max} **Seminar Protein Analysis** • Protein identification and quantification • Immunological detection methods • Analysis of post-translational modifications • Measurement of protein activity • Micromethods/Mass spectrometry • Protein structure analysis
Indicative bibliography	**Lecture Downstream Processing** • Lecture presentations • Desai, Mohamed A. [Hrsg.]: Downstream processing of proteins: methods and protocols, Humana Press, 2000; ISBN 0-89603-564-6 • Protein purification manuals from GE Healthcare (available via ILIAS as pdf) • Special issue BioProcess International March 2008 (available via ILIAS as pdf) **Practical Course in Biotechnological Processing**

	• Lecture presentations • Desai, Mohamed A. [Hrsg.]: Downstream processing of proteins: methods and protocols, Humana Press, 2000; ISBN 0-89603-564-6 • Handbücher zur Proteinaufreinigung von GE Healthcare (über ILIAS als pdf verfügbar) **Practical Course Protein Analytics** • Experiment instructions • Literature of the seminar Protein Analysis **Seminar Protein Analysis** • Issued original publications (changing) • Introductions (presentations)
Teaching and learning methods	• Biotechnological processing (L), 3 WH, 3 CP • Biotechnological processing (PC), 5 WH, 5 CP • Protein analytics (PC), 3 WH, 3 CP • Protein analytics (S), 1 WH, 1 CP
Workload	**Lecture Downstream Processing** Attendance time: 45 h Individual study time: 45 h **Practical Course in Biotechnological Processing** Attendance time: 75 h Individual study time: 75 h **Practical Course Protein Analytics** Attendance time: 45 h Individual study time: 45 h **Seminar Protein Analysis** Attendance time: 15 h Individual study time:15 h **Total** Attendance time: 180 h Individual study time:180 h Total: 360 h
Form of examination and assessment	The examination performance is assessed by two written examinations. The first exam "Biotechnological work-up" (90 minutes) covers the material from the practical course and lecture "Downstream/Biotechnological Processing", the second exam covers the material from the practical course and seminar "Protein analytics" (60 minutes). Only students who have successfully completed the preliminary examination "Biotechnological Processing (PC)" and "Protein Analysis (PC)" (one written paper each) are admitted to these written examinations.

Grading	The module grade is calculated from the grades "Protein Analysis" multiplied by 1/3 plus the exam grade "Biotechnological Processing" multiplied by 2/3.

Cell Culture Technology	
Code	(not yet provided)
Credit points according to ECTS	12
Attendance time (WH)	10
Course Language	English
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Hannemann
Lecturers	Prof. Dr. Hannemann, Prof. Dr. Schafmeister
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 4th semester
Prerequisites	**Seminar Cell Culture Technology** Recommendation: Lecture Cell Biology, Practical Course Technical Microbiology **Practical Cell Culture Technique** Recommendation: Lecture Cell Biology, Practical Course Technical Microbiology **Practical Course Bioprocess Engineering** Recommendation: Mathematics, Physics, Fundamentals of Process Engineering I + II, Thermal and Mechanical Process Engineering
Learning Outcomes	Students who have successfully completed this module, • know the principal function of the equipment used in cell biology laboratories (e.g. microscopes, sterile workbenches (laminar flow benches), CO_2-Incubators, etc.). • can carry out sterile processes under a sterile workbench as part of cell culture work. • can name the advantages and disadvantages of the different transfection methods • know the use of retroviral vectors for gene transfer and

	for use as gene therapy medicinal products (ATMP). • know the basic methods for isolating transfected and selected cells (adherent cells and suspension cells). • know the function of the serum frequently used in cell culture (as a media additive) and the basic functions of the growth factors used. • have a good basic theoretical and practical knowledge of standard methods in cell biology laboratories (e.g. trypsinization of adherent cells, cell counting using Neubauer cell counting chamber and automated systems (Cedex), transfection of adherent cells with different transfection reagents, upscaling of suspension cells (hybridoma cells) from T25 flask to shake flask, spinner to 2L benchtop fermenter, analysis of cellular GFP (Green Fluorescent Protein) expression using inverted fluorescence microscope and flow cytometry. • know the differences when working with adherent cells and cells growing in suspension. • know different cell lines (adherent and suspension cell lines). • Perform transfer tasks in the following procedures: - Heat and mass transfer, - Mixing and stirring, - Mechanical separation processes (filtration), - Thermal separation processes (rectification), - Dimension analysis (power input stirrer).
Content	The following technical content is taught in this module: **Seminar Cell Culture Technology** • History of cell culture technology • Theory of sterile working techniques • Sources and types of contamination • Media and media components • Laboratory equipment and sterilization • Cell staining and cell count • Cultivation vessels and conditions • Cell types (adherent cells and suspension cells) • Different transfection and selection methods • Gene transfer using retroviral vectors and quantification of these recombinant viruses **Practical course cell culture technology** • Sterile work under a sterile workbench • Medium approach • Cultivation of cells that grow adherently or in suspension • Expansion of suspension cells from the T-flask, shaking flask, spinner to the 2L benchtop fermenter (including the necessary preparatory work, such as sterilization, setting up and filling the fermenter, taking samples and

	the final cleaning). • Trypan blue staining and cell counting using the Neubauer counting chamber and the automated cell counting device "Cedex" • Calculate and set the required cell density for passaging cells • Different transfection methods • Analysis of fibroblast cells transfected with the GFP (Green Fluorescent Protein) gene by fluorescence microscope and flow cytometer • Analysis of in-process controls to evaluate the fermentation process such as glucose content, pO_2, pH, ammonium, lactate. **Practical Course Bioprocess Engineering** In a series of experiments, the following processes are executed, evaluated and discussed: • Mixing and stirring: Power input of different stirrers in a bioreactor (development of performance characteristics). • Mass transfer: Determination of the oxygen transfer rate and the mass transfer coefficient (k_La value) in a stirred bioreactor. • Mechanical separation processes: Different filtration processes for sterile filters and membranes and their testing with a filter tester, which is often used in pharmaceutical plants. • Thermal separation processes: Design and implementation of a rectification process.
Indicative bibliography	**Seminar + practical course cell culture technology** • Zell- und Gewebekultur: Einführung in die Grundlagen sowie ausgewählte Methoden und Anwendungen, Toni Lindl, 2. Auflage, 2013, ISBN 978-3827411945 • Culture of Animal Cells: A Manual of Basic Technique, R. Ian Freshney, 2. Auflage 2005, ISBN 978-0471453291 **Practical course bioprocess engineering** • Chmiel, H.: Bioprozesstechnik: Einführung in die Bioverfahrenstechnik, Bd. 1; UTB, Stuttgart, 1991 • Zlokarnik, M.: Rührtechnik; Theorie und Praxis, Springer-Verlag Berlin Heidelberg New York 1972 • Lohrengel, B.: Einführung in die thermischen Trennverfahren, 2007 Oldenbourg Wissenschaftsverlag GmbH
Teaching and learning methods	• Cell culture technology (S), 1 WH, 2 CP • Cell culture technology (PC), 5 WH, 6 CP • Bioprocess engineering (PC), 4 WH, 4 CP
Workload	**Seminar Cell Culture Technology**

	Attendance time: 15 h Individual study time: 45 h **Practical Course Cell Culture Technology** Attendance time: 75 h Individual study time: 105 h **Practical Course Bioprocess Engineering** Attendance time: 60 h Individual study time: 60 h **Total** Attendance time: 150 h Individual study time: 210 h Total: 360 h
Form of examination and assessment	The examination is a written exam (90 minutes) covering the entire module. Only students who have successfully completed the preliminary examination from the practical course "Cell Culture Technology" and "Bioprocess Technology" (written work in the form of the practical course protocols) are admitted to this written examination.
Grading	The module grade corresponds to the result of the examination performance.

Bioprocess Development	
Code	(not yet provided)
Credit points according to ECTS	10
Attendance time (WH)	10
Course Language	German
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Hesse
Lecturers	Prof. Dr. Hesse, Prof. Dr. Burghardt
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 5th semester
Prerequisites	**Lecture Process-oriented Mathematics** Recommendation: Mathematics 1 & 2, Technical Mathematics, Biostatistics, Physics, Genetic Engineering, Molecular Biology, Protein Analysis **Lecture Process Development and Process**

	Optimization Recommendation: Bioprocess engineering and cell culture technology module **Practical Course Bioprocess Technology** Recommendation: Seminar GMP/GLP, practical course Cell Culture Technology and practical course Biotechnological Processing
Learning Outcomes	Students who have successfully completed this module, **Lecture and exercise Process-oriented mathematics** • know the basics of higher mathematics required for application-oriented scientific and technical studies and can solve exercise problems • can apply the acquired skills in statistical experimental design **Lecture Process Development and Process Optimization** • can plan and carry out a production process on a small technical scale under GMP-like conditions. For this, the process for the production of a recombinant protein is carried out from the thawing of the production cell line to the step-by-step multiplication of the cells, the production of the protein in a bioreactor, to the purification and analysis of the product. • can prepare the necessary work instructions and protocols according to GMP guidelines, as well as evaluate and assess the individual phases of the manufacturing process. • know the most important cultivation and process control strategies as well as the technical realization of these strategies. • can carry out process balancing independently. • have basic knowledge in the area of process design and process optimization. • are able to carry out process evaluations independently.
Content	The following technical content is taught in this module: **Lecture and Exercise process-oriented Mathematics** The course content is divided into the following topics, which are deepened with exercises and examples: • Statistical Design of Experiments (DOE) and Evaluation of Experiments • Ordinary differential equations: Definition and meaning of differential equations, elementary integrable differential equations, linear differential equations;

	examples for modelling growth processes. • Measurement data evaluation: measurement repetitions **Lecture Process Development and Process Optimization** • Introduction to process development • Cell factories • Growth models and kinetics • Cultivation and process strategies • Balance equations • Process design and process optimization • Media development • Process monitoring and process control • Process evaluation • Process concepts in industrial practice and hybrid processes **Practical Course Bioprocess Technology** • Independent creation of work instructions and protocols according to GMP guidelines • Cultivation and propagation of a cell line under sterile conditions (thawing, passaging, cell counting, cultivation in T-flasks and shake flasks, sterility tests). • Cultivation of the cell line in the bioreactor in fed-batch mode (preparation and execution of the fermentation, sampling, sterile tests, medium tests, harvesting of the culture). • Protein purification (separation of cells by centrifugation/crossflow, capture of the product with protein A, ion exchange chromatography, re-buffering and desalting, sterile filtration). • Product analysis (SDS-PAGE, ELISA, protein determination, NEPHGE, glycan analysis) • Summarizing of the protocols drawn up in accordance with GMP guidelines in a manufacturing protocol • Evaluation of the manufacturing process
Indicative bibliography	**Lecture and Exercise process-oriented Mathematics** • Eriksson et al., Design of Experiments, Umetrics Academy, 2008 • D. C. Montgomery & George C. Runger, Applied Statistics and Probability for Engineers, Wiley, 2010 • Box, G. E. P.; Hunter, W. G. & Hunter, J. S. Statistics for Experimenters, Wiley, 2005 • L. Papula, Mathematik für Ingenieure und Naturwissenschaftler, Vieweg + Teubner, 2011--15, Bd. 1-3 • Rießinger, T., Mathematik für Ingenieure, Springer Vieweg, 2013

	• Rießinger, T., Übungsaufgaben zur Mathematik für Ingenieure, Springer Vieweg, 2013 • Burg, K.; Haf, H.; Meister, A. & Wille, F., Höhere Mathematik für Ingenieure, Springer Vieweg, 2013, Bd. 1-3 **Lecture Process Development and Process Optimization** • Lecture notes Script **Practical Course Bioprocess Technology** • Practical Course script and work instructions
Teaching and learning methods	• Process-oriented mathematics (L+E), 2 WH, 2 CP • Process development and process optimization (L), 2 WH, 2 CP • Bioprocess technology (PC), 6 WH, 6 CP
Workload	**Lecture and Exercise process-oriented Mathematics** Attendance Time: 30 h Individual study time: 30 h **Lecture Process Development and Process Optimization** Attendance Time: 30 h Individual study time: 30 h **Practical Course Bioprocess Technology** Attendance Time: 90 h Individual study time: 90 h **Total** Attendance Time: 150 h Individual study time: 150 h Total: 300 h
Form of examination and assessment	The examination is a written exam (90 minutes) covering the entire module. Only students who have successfully completed the preliminary examination of the practical course "Bioprocess Technology" (written elaboration, protocols) are admitted to this written examination.
Grading	The module grade corresponds to the result of the examination performance.

Fundamentals of Pharmaceutics and Pharmacology	
Code	(not yet provided)
Credit points according to ECTS	8

Attendance time (WH)	6
Course Language	German
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Zimmermann
Lecturers	Prof. Dr. Zimmermann; Dr. Trommeshauser; Dr. Stopfer; Dr. Presser; Prof. Dr. Mavoungou, Rebecca Rittersberger
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 5th semester
Prerequisites	**Lecture Immunopharmacology and Antibody Engineering** Recommendation: Physiology and Immunobiology, Cell and Molecular Biology, Protein Biochemistry **Lecture Fundamentals of Pharmaceutics and Pharmacology** Recommendation: General and microbiology, cell and molecular biology, chemistry of biomolecules **Lecture Pharmaceutical Technology** Recommendation: General and Analytical Chemistry II, Organic Chemistry, Physics I and II
Learning Outcomes	Students who have successfully completed this module, • can evaluate the different physiological processes and their use as drug targets and understand general processes in drug development. • are able to recognize the fundamentals of applied immunology, immunopathology and interactions with biopharmaceuticals and understand their modern applications in the development of antibodies or other biopharmaceuticals. • know current biotechnological tools for rational antibody design. • have the fundamentals of pharmacology, physiology, pharmacodynamics and pharmacokinetics. This includes the basic principles of pharmacokinetics (absorption, biotransformation, distribution and excretion) as well as knowledge of the functions of the most important organs (stomach/intestine, liver, kidney). The students are also familiar with the various physiological processes and their use as drug targets and corresponding treatment options as well as general processes of drug development. • have an overview of the role and importance of drug product development in drug development.

	• know the general processes for the production of various pharmaceutical dosage forms (tablet, capsule, lyophilizates, liquid dosage forms and aerosols), quality requirements, packaging materials and the use of excipients as well as various tests for quality and release
Content	The following technical content is taught in this module: **Lecture Immunopharmacology and Antibody Engineering** • General immunology: innate and adaptive immunity, antigen presentation and recognition, T- and B-cell repertoires, effector functions of antibodies, Fc-FcR interactions, tolerance. • Immunopathology, hypersensitivities, allergy, immunogenicity and autoimmunity • Active and passive immunizations, immunotherapies and oncology/tumor immunology • Therapeutic antibodies, antibody fragments, scaffolds and Fc fusion proteins • Pharmacokinetics of biopharmaceuticals and half-life extension • Fc-Engineering, Glycoengineering und Antibody-Drug-Conjugates • Antibody generation and selection: phage display, synthetic libraries, production in animals and polyclonal human antibody products. • Bi-specific formats, BiTEs and CAR-T cell therapy • Applied and clinical examples of established antibody and analogue therapies but also risks of such therapy. **Lecture Fundamentals of Pharmaceutics and Pharmacology** • Introduction to pharmacology: history of pharmacology and toxicology, definitions, examples of pharmaceuticals from nature, different dosage forms. • Drug development: pharmacological/biochemical studies in research, preclinical and clinical pharmacokinetics, clinical development, approval process • Pharmacodynamics and pharmacokinetics: fundamentals and basic knowledge of pharmacodynamics, fundamentals and basic knowledge of absorption and distribution, biotransformation and excretion, mathematical principles and applications of pharmacokinetics in drug development. • Sympathetic and parasympathetic nervous system: structure and physiology, differentiation of sympathetic/parasympathetic effects, targets for

	pharmaceuticals and corresponding treatment options for special diseases such as rhinitis, allergies, asthma/COPD, hypertension, ADHD • Toxicological effects, drug interactions • Cardiovascular system: physiology and structure, description of heart failure and targets for pharmaceuticals, description of hypertension and targets for pharmaceuticals • Pharmacogenetics in drug research: pharmacogenetics in pharmacodynamics and pharmacokinetics, definition of "Personalized Medicine". • Pathophysiology and treatment options for type I and II diabetes • Introduction to the blood coagulation system and anticoagulant treatment options • Introduction to the functions of the most important organs (stomach/intestine, liver, kidney) and their influence on the biotransformation and excretion of pharmaceuticals • Introduction to the effects of nicotine and the toxic effects of tobacco smoking • Introduction to different mediators such as dopamine, histamine and serotonin and corresponding treatment options for specific diseases such as Parkinson's disease or migraine • Pathophysiology of pain and corresponding treatment options with NSAIDs, glucocorticoids and opioids. • Introduction to oncology and corresponding therapy options **Lecture Pharmaceutical Technology** • Introduction and fundamentals of biopharmacy • Liquid preparations (solutions, emulsions, suspensions, parenteral formulations) • Formulation development for proteins • Sterilization and water qualities • Freeze-drying / lyophilization • Preparations for inhalation • Design of experiments, data evaluation and statistics • Quality requirements: Stability and compatibilities • Packaging (requirements and special features) • Solid preparations I (powder, granules) • Solid preparations II (tablets, capsules, coatings) • Semi-solid preparations (ointments, creams, gels)
Indicative bibliography	**Lecture Immunopharmacology and Antibody Engineering** • Schütt/Bröker: Grundwissen Immunologie • Abbas: Cellular and Molecular Immunology

	• Murphy: Janeway's Immunobiology **Lecture Fundamentals of Pharmaceutics and Pharmacology** • Taschenatlas der Pharmakologie, Heinz Lüllmann, Klaus Mohr, Lutz Hein, ISBN-10: 3-13-707706-0 • Mutschler Arzneimittelwirkungen: Lehrbuch der Pharmakologie und Toxikologie **Lecture Pharmaceutical Technology** • Lehrbuch der Pharmazeutischen Technologie; Kurt H. Bauer, Karl-Heinz Frömming, Claus Führer, ISBN: 978-3804722224, Wissenschaftliche Verlagsgesellschaft; Auflage 8
Teaching and learning methods	• Immunopharmacology and Antibody Engineering (L), 2 WH, 2 CP • Fundamentals of Pharmaceutics and Pharmacology (L), 2 WH, 3 CP • Pharmaceutical Technology (L), 2 WH, 3 CP
Workload	**Lecture Immunopharmacology and Antibody Engineering** Attendance Time: 30 h Individual study time: 50 h **Lecture Fundamentals of Pharmaceutics and Pharmacology** Attendance Time: 30 h Individual study time: 50 h **Lecture Pharmaceutical Technology** Attendance Time: 30 h Individual study time: 50 h **Total** Attendance Time: 90 h Individual study time: 150 h Total: 240 h
Form of examination and assessment	The examination is a written exam (120 minutes) covering the entire module. Only students who have successfully completed the preliminary examination "Immunopharmacology and Antibody Engineering" (oral examination) are admitted to this written examination.
Grading	The module grade is composed of 37.5 % each of the performances of Fundamentals of Pharmaceutics and Pharmacology and pharmaceutical technology and 25 % of the performances of immunopharmacology and antibody engineering.

Selected Topics of Modern Biotechnology	
Code	(not yet provided)
Credit points according to ECTS	5
Attendance time (WH)	3
Course Language	English
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Gaisser
Lecturers	Prof. Dr. Gaisser; multiple consultants
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 4th semester
Prerequisites	**Lecture Biotechnology (lecture series)** Recommendation: Microbiology, Cell and Molecular Biology, Technical Microbiology, Pharmaceutical Biotechnology, Protein Biochemistry, Genetic Engineering **Seminar Selected Topics in Modern Biotechnology** Recommendation: Contents of biotechnologically relevant modules of semesters 1-3
Learning Outcomes	Successful participants will improve their English language skills and further expand their academic knowledge based on contents of recently published papers. • Further improvement of self-directed learning skills and self-competence, promoted by reading recently published articles and preparation of slides required for their respective presentations. • Presentations are given in Englis, students deliver their presentations in front of an audience (course participants). • Participants gain an overview of different aspects of current biotechnological methods and developments in industry and research preparing their presentation and during lectures presented in the accompanying lecture series. The lecture series provides the opportunity to invite researchers working in different industrial areas or laboratory teams presenting overviews over recent developments as experts in their respective fields.
Content	The following technical content is taught in this module:

	Lecture Biotechnology (Lecture Series) The contents change depending on the selected topics and lecturers **Seminar Selected Topics in Modern Biotechnology** • Introduction, Drug Discovery: An Overview • Natural Products, Marine-derived Drugs • Antibiotics • Problems and Pathogens: Coronavirus Outbreak • Problems and Pathogens: Vector-borne Diseases • Biofilm • Microbiota and Disease • Plant-based Production of Pharmaceuticals • Malaria and Artemisinin, Avermectin • Biopharmaceutical Benchmarks
Indicative bibliography	**Lecture Biotechnology (Lecture Series)** • Is specified in the individual courses and changes every semester **Seminar Selected Topics in Modern Biotechnology** • Recent publications
Teaching and learning methods	• Biotechnology (Lecture Series) (L), 1 WH, 2 CP • Selected topics of modern biotechnology (S), 2 WH, 3 CP
Workload	**Lecture Biotechnology (Lecture Series)** Attendance Time: 15 h Individual study time: 45 h **Seminar Selected Topics in Modern Biotechnology** Attendance Time: 30 h Individual study time: 60 h **Total** Attendance Time: 45 h Individual study time: 105 h Total: 150 h
Form of examination and assessment	Written examination (60 minutes) covering the entire module. Permission to take the exam "Selected Topics in Modern Biotechnology" based on a successful written report (Prerequisite), accepted by the course supervisors.
Grading	The module grade corresponds to the result of the examination performance.

Databases, Economics and Soft Skills

Code	(not yet provided)
Credit points according to ECTS	5
Attendance time (WH)	5
Course Language	German
Duration	2 semesters
Offered	Every semester
Module coordinator	Prof. Dr. Hannemann
Lecturers	Prof. Dr. P. Fischer; Dipl.-Ing. Florian Ehrlich; Hädicke, Anika M.Sc./M.A.
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 4th + 5th semester
Prerequisites	**Lecture with exercises Databases and Software for Gene Analysis and Protein Design** Recommendation: Fundamentals of genetics and molecular biology **Lecture Business Administration/Economics** Recommendation: None **Seminar Job Application and Presentation** Recommendation: Modules of the 2nd study stage
Learning Outcomes	Students who have successfully completed this module, • have basic knowledge in the use of scientific databases, online tools and selected cloning software. • are able to "virtually" clone the cDNA (or vectors for the expression) of "therapeutic proteins" (G-CSF, antibodies, etc.) on the computer. • can carry out literature searches in specialized databases (for DNA/protein sequence searches and alignments, vector constructions with special software, sequence optimizations, simple structure predictions and *in silico* analysis of proteins as a prerequisite for the optimized implementation of experiments in the wet lab). • can use some special databases to design antibodies. • acquire basic knowledge of selected business and economic topics in order to grasp and better understand economic interrelationships. • are able to assess the consequences of choosing the legal form of a company • can distinguish between common entrepreneurial financing alternatives • are able to better assess their own profile, better identify their personal qualifications, search for suitable jobs

	more effectively, write a job application in a qualified manner and better prepare for an interview. Students apply the skills they have acquired in exercises.

Content	The following technical content is taught in this module:
	
	Lecture with exercises Databases and Software for Gene Analysis and Protein Design
	• Scientific literature research (e.g. PubMed/MeSH) and text mining (e.g. Quertle), all about the target/protein to be cloned, protein networks (e.g. iHOP) as well as (molecular) medical backgrounds.
	• Cloning techniques and assays *via* full-text searches and biopharmaceutical methods on the WWW
	• Identification and comparison of DNA and protein sequences (e.g. NCBI GQuery, BLAST, Clustal)
	• Construction of expression vectors *in silico* (e.g. Vector NTI)
	• Optimizing protein expression by identifying and correcting problematic DNA sequences & Pharmacogenomics online
	• Virtual protein analytics (structure, function, interaction)
	• Special tools and databases for antibody sequences, immunoglobulin germline genes and L(D)J junction analysis.
	
	Lecture Business Administration/Economics
	• Economic foundations
	  • Economic circular models
	  • Functioning of the market economy system
	
	• Business basics
	  • Organization of a company
	  • Overview of sole proprietorships, partnerships and corporations
	  • Basics of financing and investment
	  • Basics of operational processes from the production of services to the utilization of services
	  • Key business figures
	  • Accounting basics
	
	Seminar Job Application and Presentation
	• Situation analysis before the job search: current market situation for life scientists; creation of an individual competence and interest profile
	• Search for job offers: Identifying and working out requirements; job research and making contact, speculative applications.
	• The (digital) application folder: Formal and content-related things about application documents (cover

	letter, cover sheet, CV, photo, certificates and supporting documents) • The job interview: Questions in the interview process; non-verbal communication, self-presentation and practice. • Applicant selection - what do companies look for?
Indicative bibliography	**Lecture with exercises Databases and software for gene analysis and protein design** • http://www.ncbi.nlm.nih.gov/home/learn.shtml • Online descriptions of the databases and software **Lecture Business Administration/Economics** • Günther Wöhe: Einführung in die Allgemeine Betriebswirtschaftslehre, Vahlen-Verlag, Munich • Brunner/Kehrle: Volkswirtschaftslehre, Vahlen-Verlag, Munich **Seminar Job Application and Presentation** • Püttjer, Schnierda: Bewerbungstraining für Hochschulabsolventen • Püttjer, Schnierda: Perfekte Bewerbungsunterlagen für Hochschulabsolventen • Hesse/Schrader: Bewerbung für Hochschulabsolventen
Teaching and learning methods	• Databases and Software for Gene Analysis and Protein Design (L), 2 WH, 2 CP • Business Administration/Economics (L), 2 WH, 2 CP • Job Application and Presentation (S), 1 WH, 1 CP
Workload	**Lecture with exercises Databases and software for gene analysis and protein design** Attendance time: 30 h Individual study time: 30 h **Lecture Business Administration/Economics** Attendance time: 30 h Individual study time: 30 h **Seminar Job Application and Presentation** Attendance time: 15 h Individual study time: 15 h **Total** Attendance time: 75 h Individual study time: 75 h Total: 150 h
Form of examination and assessment	The examination for this module consists of three parts: a 30-minute written examination for the lecture with exercises "Databases and Software for Gene Analysis and Protein Design", a 60-minute written examination for the lecture

	"Business Administration/Economics" and a written paper in the seminar "Job Application and Presentation". There are no preliminary examinations in this module.
Grading	The module grade corresponds to the result of the examination performance.

Legal Basis	
Code	(not yet provided)
Credit points according to ECTS	4
Attendance time (WH)	3
Course Language	German
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Burghardt
Lecturers	Dr. Hans Michelberger; Dr. Wolfgang Stock
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 5th semester
Prerequisites	none
Learning Outcomes	Students who have successfully completed this module, • know the legal basics of drug law and genetic engineering law. • understand the structure of the legal foundations and have the ability to find the legal foundations relevant to an issue and to recognize their complexity and references. • are able to answer simple questions on pharmaceutical law and genetic engineering law. • have basic knowledge of patent law and German Employee Invention Act, • know the importance of protecting inventions for innovative companies and what measures are required to acquire and maintain this protection.
Content	The following technical content is taught in this module: **Lecture Drug Law/Validation** • History and overview • Definitions/Delimitations (esp. medical devices, food) • Individual regulations • Manufacturing authorization • Responsible person according to Drug Law/Regulations

	• Authorization requirement for medicinal products • Clinical trials/observational studies (GCPVO) • Liability • Validation • Good Manufacturing Practice • AMNOG (German Medicines Market Reorganization Act) - overview, goals and effects **Lecture Genetic Engineering Law** • History • Overview • The Genetic Engineering Act (GenTG) • Individual regulations • Regulations **Lecture Patent Law and Invention Protection** • Classification of patent law and other technical and non-technical property rights in the system of industrial property and intellectual property rights • Patentability requirements: The concept of invention, substantive requirements for protection (novelty, inventive step, industrial applicability), patentability exclusions, formal patentability requirements. • Patent granting procedure and revocation procedure: Structure and components of a patent application, basic elements of the patent granting procedure, revocation of a granted patent, regional and international patent associations and their legal bases, coordination of national, regional and international patent procedures. • Effects of the patent: rights arising from a patent application and a granted patent, limits of the effects, determination of the scope of protection of a patent, territorial and temporal scope, supplementary protection certificates for medicinal products, judicial and extrajudicial enforcement of the rights arising from the patent, patent infringement action • Employee invention law: rights and obligations of employees and employers, reporting a service invention, claiming a service invention, remuneration of employee inventors • Patents in pharmaceutical biotechnology: inventions in the field of biology and biotechnology, special substantive protection requirements ("bio-patent law") and formal requirements, licensing of patent rights and know-how, inventions in the context of cooperation’s
Indicative bibliography	**Lecture Drug Law/Validation** • AMG-Gesetzestext, AMWHV (Arzneimittel- und Wirkstoff-herstellungs-Verordnung) • Hügel / Mecking / Kohm: Pharmazeutische Gesetzes-kunde, DAV Verlag Stuttgart, 35. Aufl. 2013

	• Kügel / Müller | Arzneimittelgesetz: AMG | 2. Auflage 2016, Buch, Kommentar, 978-3-406-67177-7 **Lecture Genetic Engineering Law** • GentG und Verordnungen • Deutsches Gentechnikrecht: Textsammlung mit Einführung, Pharmind Serie Dokumentation, broschiert, Horst Hasskarl, 2007 • Eberbach / Lange / Ronellenfitsch (Hrsg.), Recht der Gentechnik und Biomedizin, EG-Recht, Gesetze, Verordnungen, Formulare, ZKBS-Empfehlungen, Beschlüsse des LAG, Richtlinien, Empfehlungen, Gesetzestext Loseblattwerk mit 109. Aktualisierg 2020, C.F. Müller **Lecture Patent Law and Invention Protection** • Beck-Texte im dtv: Patent- und Musterrecht; 14. Auflage, 2018 • Däbritz/Jesse/Bröcher: Patente; Verlag C.H. Beck, 3. Auflage, 2009 • Gruber: Gewerblicher Rechtsschutz und Urheberrecht; Niederle Media; 9. Auflage 2018
Teaching and learning methods	Drug Law/Validation (L), 1 WH, 2 CP Genetic engineering law (L), 1 WH, 1 CP Patent Law and Invention Protection (L), 1 WH, 1 CP
Workload	**Lecture Drug Law/Validation** Attendance time: 15 h Individual study time: 45 h **Lecture Genetic Engineering Law** Attendance time: 15 h Individual study time: 15 h **Lecture Patent Law and Invention Protection** Attendance time: 15 h Individual study time:15 h **Total** Attendance time: 45 h Individual study time: 75 h Total: 120 h
Form of examination and assessment	The examination is a written exam (90 minutes) covering the entire module. Preliminary examinations are not required in this module.
Grading	The module grade corresponds to the result of the examination performance.

Modules in the 3rd study stage (6th - 7th semester)

Practical Semester	
Code	(not yet provided)
Credit points according to ECTS	30
Attendance time (WH)	Industrial internship with at least 95 attendance days + 4
Course Language	German, English
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr.-Ing. Annette Schafmeister
Lecturers	Different supervisors and reviewers
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 6th semester
Prerequisites	**Seminar Course accompanying the practical semester** Recommendation: Seminar Job Application and Presentation, Job Fairs
Learning Outcomes	Students who have successfully completed this module, **Industrial Internship** • are able to plan and carry out in detail the practical/scientific questions within the framework of their industrial internship, which was carried out in an industrial company or a research institution, by selecting suitable methods and to work independently on the necessary experiments. **Seminar Course accompanying the practical semester** • can publicly present and discuss their report on the industrial internship. In the discussion with the audience, the validity of the results achieved should be defended on the basis of provable data.
Content	The student is to work under operating conditions and under the guidance of a supervisor experienced in the intended professional field on tasks that are characteristic of the intended professional practice and qualification. This means that practical experience is gained in typical fields of work of a biotechnologist.
Indicative bibliography	Depending on the topic of the practical semester thesis
Teaching and learning methods	Industrial internship with at least 95 attendance days (26 CP) Accompanying course (S), 4 WH, 4 CP

Workload	**Industrial Internship** Attendance time: 780 h **Seminar Course accompanying the practical semester** Attendance time: 60 h Individual study time: 60 h **Total** Attendance time: 840 h Individual study time: 60 h Total: 900 h
Form of examination and assessment	There is one examination (wE) in this module. This is the report on the "Industrial Internship".
Grading	The module grade corresponds to the grade of the report for the "Industrial Internship".

Quality Management	
Code	(not yet provided)
Credit points according to ECTS	8
Attendance time (WH)	4
Course Language	German
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Prof. Dr. Mavoungou
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: Recommendation: Seminar GMP/GLP
Learning Outcomes	Students who have successfully completed this module, • are able to create and assess qualification and validation documents. • are able to assess the corresponding documentation. • are familiar with the theoretical background of quality management and can draw the links between quality management and GCP/GMP/GQP/GLP/ GVP. • have an overview of the differences in quality management systems in the USA, the EU and can assess their impact on a production in Germany.

Content	The following technical content is taught in this module: **Lecture Quality Assurance in Pharmaceutical companies** • Qualification, validation, verification • Regulatory Requirements, Regulatory Standards • Legal requirements • Qualification team • Qualification planning and procedure • Maintenance of the qualification status • Old plant qualification • Quality by design, process validation, process evaluation, regulatory requirements, legal requirements, life cycle • Carrying out a validation • Validation scope, validation report • Accompanying validation • Retrospective validation, simultaneous validation • Maintenance of the validated status • Revalidation • Validation of sampling procedures • Change Control / Change Request issues • Six-Sigma and Lean Management • Types of risk analysis & real time monitoring • Computer validation • Planning and needs assessment • Quality Assurance in Pharmaceutical-Biotechnolog. Operations • Supplier qualification (technical agreements in quality assurance), supply chain • Interfaces between "Qualified Person", "CMC- Regulatory Affairs" and drug safety, release procedure **Lecture "International Quality Management":** • Management and quality management • Model ideas on management and quality management • Quality management activity terms • Quality and pharmaceutical law • Total Quality Management System (TQM) • Quality and costs • Standardized quality assessment • The Quality Management Circle • Quality management and quality assurance • Quality assurance in the USA and the EU • Change Management • Life Cycle Management in Quality Management
Indicative bibliography	**Lecture Quality Assurance in Pharmaceutical Companies**

	• Pharmazeutische Produkte und Verfahren, Gerd Kutz und Armin Wolff, Wiley Verlag, 2007 • Die pharmazeutische Industrie. Veröffentlichungen über sämtliche Aspekte der Herstellung und des Vertriebs pharmazeutischer Erzeugnisse. Deutschland: Editio Cantor Verlag, ISSN 0031-711X **Lecture International Quality Management** • Grundlagen und Elemente des Qualitätsmanagements: Systeme-Perspektiven, Walter Geiger, Willi Kotte, 2007, ISBN 3834802735, 9783834802736 • Die pharmazeutische Industrie. Veröffentlichungen über sämtliche Aspekte der Herstellung und des Vertriebs pharmazeutischer Erzeugnisse. Deutschland: Editio Cantor Verlag, ISSN 0031-711X
Teaching and learning methods	Quality assurance in pharm. Cooperation's (L), 2 WH, 4 CP International Quality Management (L), 2 WH, 4 CP
Workload	**Lecture Quality Assurance in Pharmaceutical Companies** Attendance time: 30 h Individual study time: 90 h **Lecture International Quality Management** Attendance time: 30 h Individual study time: 90 h **Total** Attendance time: 60 h Individual study time: 180 h Total: 240 h
Form of examination and assessment	The examination is a written exam (60 minutes) covering the entire module.
Grading	The module grade corresponds to the result of the examination performance.

Elective-01: Pharmacology and Pathophysiology	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4
Course Language	German

Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Prof. Dr. Zimmermann
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: Recommendation: Modules of the 2nd study stage
Learning Outcomes	Students who have successfully completed this elective subject, • gain an insight into current research areas in the field of general pharmacy, biopharmacy and pathobiological principles. • are able to work independently on a complex topic, to develop new findings with the help of primary literature and to present and discuss them in an understandable way.
Content	The following subject content is taught in this elective subject: • Applied examples from pharmacology and pathophysiology are used to explain how therapeutic strategies have been and are being developed. • Publications and patents are reviewed, presented, explained and discussed in presentations.
Indicative bibliography	• Current primary literature on the issued topics • Mutschler Drug Effects: Textbook of Pharmacology and Toxicology
Teaching and learning methods	Pharmacology and Pathophysiology (S), 2 WH, 3 CP
Workload	**Seminar Pharmacology and Pathophysiology** Attendance time: 30 h Individual study time: 30 h
Form of examination and assessment	The examination performance is a written paper.
Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Elective-02: Nanoparticles and Aerosols	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4
Course Language	German
Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Prof. Dr. Schafmeister
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: Recommendation: Fundamentals of Process Engineering, Mechanical Process Engineering
Learning Outcomes	Students who have successfully completed this elective subject, • possess specific additional knowledge in different subject areas. They deepened their skills in the independent preparation of current scientific texts as well as in presentation techniques.
Content	The following subject content is taught in this elective subject: • Excerpts from the individual subject areas, which are elaborated with specialist literature and current publications • Nanoparticles (NP): structure and function, NP in product design, NP in medicine (e.g. inhalants) • Aerosols: physics of gas-borne particles, generation, sampling, identification and measurement techniques
Indicative bibliography	Current scientific texts from the field of particle technology, e.g.: • Journal of Aerosol Science, Particle and Particle System Characterization • Hinds: Aerosol-Technology • Baron Willeke: Aerosol Measurement • Friedlander: Smoke, Dust and Haze
Teaching and learning methods	Nanoparticles and Aerosols (S), 2 WH, 3 CP
Workload	**Seminar Nanoparticles and Aerosols** Attendance time: 30 h Individual study time: 30 h

Form of examination and assessment	The examination performance is a written paper.
Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Elective-03: Process Optimization	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4
Course Language	German
Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Prof. Dr. Hesse
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: Recommendation: Bioprocess Development Module
Learning Outcomes	Students who have successfully completed this elective subject, • are able to assess different aspects of the optimization of bioprocesses for the production of biopharmaceutical active substances.
Content	The following subject content is taught in this elective subject: • Modern approaches and aspects for the optimization of biopharmaceutical manufacturing processes (e.g. optimization of process control strategies, media development, cell line optimization) as well as current trends in the field (e.g. process analytical technology, disposable bioreactors) are developed by the students in the form of seminar presentations.
Indicative bibliography	• Primary literature (will be mentioned in the course) and lecture notes

Teaching and learning methods	Process optimization (S), 2 WH, 3 CP
Workload	**Seminar Process Optimization** Attendance time: 30 h Individual study time: 30 h
Form of examination and assessment	The examination performance is a written paper.
Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Elective 04: Molecular Medicine	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4
Course Language	German, English
Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Prof. Dr. Otte
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: Recommendation: Modules of the 2nd study stage
Learning Outcomes	Students who have successfully completed this elective subject, • have an insight into current research areas in the field of molecular medicine and know their impact on causal research, diagnostics and therapy. • are able to work independently on a current topic and to present new research directions and findings adequately in terms of content and form.
Content	The following subject content is taught in this elective subject: • How molecular biotechnology, based on new

	fundamental knowledge in the life sciences, is helping to identify and diagnose causes of disease through technological innovation and to develop new medicines through drug discovery and production. • Current developments and publications are reviewed, explained and discussed in oral presentations.
Indicative bibliography	• Primary literature (will be named in the course)
Teaching and learning methods	Molecular Medicine (S), 2 WH, 3 CP
Workload	**Seminar Molecular Medicine** Attendance time: 30 h Individual study time: 30 h
Form of examination and assessment	The examination performance is a written paper.
Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Elective-05: Packaging Materials	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4
Course Language	German
Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	N.N.
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: Recommendation: Pharmaceutical technology, pharmaceutical law
Learning Outcomes	Students who have successfully completed this elective subject, • have an overview of packaging management.

	• Understand the regulatory requirements placed on packaging design to achieve patient compliance. • have an overview of packaging innovations and understand the role of packaging innovations in improving the handling of packaging by patients and are able to understand the need for new forms of application. • are able to assess appropriate packaging systems. • have learned the basics of medical devices and are able to understand and assess certification procedures and conformity assessment procedures in the EU.
Content	The following subject content is taught in this elective subject: • Definitions of packaging materials: Packaging, packaging in the sense of DIN 55 405, packaging materials, packaging materials for the market, finished medicinal products (pharmaceutical law). • Packaging as an information carrier: printed packaging • Regulatory requirements, legal requirement: correlation between drug identification and packaging • Packaging and product/medicine safety • Packaging and pharmaceutical quality • Role of functional packaging materials in the therapy of medicinal products in the OTC sector • Basics for the selection of packaging, therapy-appropriate devices, packaging performance (functionality, dosage & design: patient compliance) • Leachable studies and testing of extractables • Components of secondary packaging: Package insert, folding boxes, labels, films, packaging aids • Packaging innovations: latest developments in inhalers, needle-free applications for biotechnological medicines and vaccines using the example of powder injectors, matrix patches, reservoir patches • Introduction to the basics of medical device law • New developments on combined preparations between medicinal products and medical devices
Indicative bibliography	• Primary literature (will be named in the course)
Teaching and learning methods	Packaging materials (S), 2 WH, 3 CP
Workload	**Seminar Packaging** Attendance time: 30 h Individual study time: 30 h
Form of examination and assessment	The examination performance is a written paper.

Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Elective-06: Small Molecule Drugs	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4
Course Language	English
Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Prof. Dr. Gaisser
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: Recommendation: Biotechnology and Microbiology, modules of the 1st and 2nd study stage
Learning Outcomes	Students who have successfully completed this elective subject, • expand their competence in the independent preparation of current publications and acquire an overview of the field of "small molecule d r u g s ". Focus on the field of antibiotic development and the importance of new drugs for the treatment of infectious diseases and cancer. • expand their ability to present lectures in English.
Content	The following subject content is taught in this elective subject: • "Small molecule drugs: an overview • The importance of natural products • Antibiotics and resistance • Microbiological agent discovery • Natural products from sea and ocean • Nonribosomally synthesized peptides • Aromatic aromatic polyketides • Erythromycin

	• Rapamycin and mTOR • Geldanamycin and cancer (HSP90) • Spinosyns
Indicative bibliography	• Relevant current publications on antibiotic development, drugs for the treatment of infectious diseases, cancer, etc. from e.g. Nature, Science, etc. serve as literature.
Teaching and learning methods	Small molecule drugs (S), 2 WH
Workload	**Seminar Small molecule drugs** Attendance time: 30 h Individual study time: 30 h
Form of examination and assessment	The examination performance is a written paper.
Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Elective-07: Harvest Technology	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4
Course Language	German
Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Dr. Haas (LB)
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	
Learning Outcomes	Students who have successfully completed this elective subject, • know the possible process steps between upstream and downstream processing in order to provide cell-free fluid for further purification after cell cultivation (e.g.

	centrifugation, tangential flow filtration, depth filtration). • know the advantages and disadvantages of the individual process steps and can combine them with each other • know the essential scale up strategies of the different steps and are able to perform a scale up • are able to compile, summarize and critically assess the content of various works on a topic on the basis of literature. • expand their ability to present their findings to an audience (in English, if necessary) in a way that is comprehensible in terms of content and form.
Content	The following subject content is taught in this elective subject: • Process steps in the harvesting of cell cultures • Microfiltration • Tangential flow filtration • Cell retention by means of e.g. acoustic methods • Depth filtration • Centrifugation • Single use systems • Economic considerations
Indicative bibliography	
Teaching and learning methods	Harvest Technology (S), 2 WH,
Workload	**Seminar Harvest Technology** Attendance time: 30 h Individual study time: 30 h
Form of examination and assessment	The examination performance is a written paper.
Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Elective-08: The Path to Marketing Approval for New Medicines	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4

Course Language	English
Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Dr. Schindler (LB), Dr. Pisternick-Ruf (LB), Dr. Knieps (LB)
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	
Learning Outcomes	
Content	The following subject content is taught in this elective subject: • Introduction to the most important aspects of drug approval. • Assessment of efficacy and safety in clinical trials for new medicines • Structure of submissions for marketing approval in Europe and the USA • Important clinical documents • Differences in submissions of NCEs (new chemical entities), NBEs (new biological entities), generics and biosimilars • Concept of transparency in clinical research • Gather information on clinical trial results • Obtain clinical documents from public sources • Basics of scientific writing
Indicative bibliography	
Teaching and learning methods	The path to marketing approval for new medicines (S), 2 WH,
Workload	**Seminar The path to marketing approval for new medicines** Attendance time: 30 h Individual study time: 30 h
Form of examination and assessment	The examination performance is a written paper.
Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Elective-10: Pharma Marketing	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4
Course Language	English
Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Dr. Wolf
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: Recommendation: Basics of the Medicines Act, drug development, marketing
Learning Outcomes	Students who have successfully completed this elective subject, • Students gain insight and basic knowledge about the marketing of finished medicinal products
Content	The following subject content is taught in this elective subject: • Definitions of the terms marketing, brand, pharmaceutical marketing • Overview of the pharmaceutical market: size, companies, products, main indications • Trends and current problems in the pharmaceutical market • Medicines Act, Therapeutic Products Advertising Act, Code of the Pharmaceutical Industry (FSA) • Drug pricing, costs & reimbursement • Target group marketing, product-specific marketing, cooperations in the pharmaceutical industry
Indicative bibliography	• Pharmaceutical Marketing, T. Trilling, 2nd edition • Current publications on the topic of pharmaceutical marketing and the pharmaceutical market according to the bibliography or web links. • Medicines Act, Therapeutic Products Advertising Act, Voluntary Self-Monitoring of Medicines • Script "Pharma Marketing", D. Wolf

Teaching and learning methods	Pharma Marketing (S), 2 WH, 3 CP
Workload	**Seminar Pharma Marketing** Attendance time: 30 h Individual study time: 30 h
Form of examination and assessment	The examination performance is a written paper.
Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Elective-11: Biophysics	
Code	(not yet provided)
Credit points according to ECTS	6
Attendance time (WH)	4
Course Language	German
Duration	1 semester
Offered	Depending on the demand and the necessary supply
Module coordinator	Prof. Dr. Mavoungou
Lecturers	Prof. Dr. Burghardt
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: Recommendation: Mathematics, physics, process engineering,
Learning Outcomes	Students who have successfully completed this elective subject, • expand their competence in the independent elaboration of contents in the field of biophysics that are still unknown to them.
Content	The following subject content is taught in this elective subject: • Measurement methods, examples of which are: Mass spectrometer, modern microscopes, protein structure determination by means of X-ray diffraction and NMR

	• Physical properties of proteins, protein folding • Biological membranes: self-organization, phase transformation, cell adhesion • Nerve conduction
Indicative bibliography	• current literature on the given topics will be mentioned during the course
Teaching and learning methods	Biophysics (S), 2 WH, 3 CP
Workload	**Seminar Biophysics** Attendance time: 30 h Individual study time: 30 h
Form of examination and assessment	The examination performance is a written paper.
Grading	The module grade corresponds to the average of the results of the two examinations (wE, written papers) of the two compulsory elective subjects. In order to achieve the required 6 CP, two of the offered compulsory elective subjects (i.e. a total of 4 WH) must be selected and successfully completed in this module. The number and titles of the courses offered may vary from semester to semester.

Bachelor Thesis	
Code	(not yet provided)
Credit points according to ECTS	16
Attendance time (SWS)	Bachelor Thesis (Practical part) +2
Course Language	German, English
Duration	1 semester
Offered	Every semester
Module coordinator	Prof. Dr. Kiefer
Lecturers	vary
Classification within the study program	Pharmaceutical Biotechnology BSc, compulsory module, 7th semester
Prerequisites	• Content: **Seminar Bachelor Thesis Colloquium** Recommendation: Seminar Job Application and Presentation
Learning Outcomes	Students who have successfully completed this module, **Bachelor Thesis (Practical part)** • are able to thoroughly plan and work on scientific

	questions that arise in industrial settings or research institutions including Biberach University by selecting suitable methods and independently carry out the necessary experiments. **Seminar Bachelor Thesis Colloquium** • Can present and discuss their Bachelor thesis in public. In the discussion with the audience, the validity of the results obtained should be defended on the basis of provable data.
Content	Different
Literature recommendation	Depending on the topic of the Bachelor thesis
Teaching and learning methods	Bachelor thesis (PC), x SWS, 12 CP Colloquium for the Bachelor thesis (S), 2 SWS, 4 CP
Workload	**Bachelor thesis (Practical part)** Attendance time 360 h Individual study time: h **Seminar Bachelor Thesis Colloquium** Attendance time 30 h Individual study time: 90 h **Total** Attendance time 390 h Individual study time: 90 h Total: 480 h
Form of examination and assessment	Two examinations take place in this module. The "Bachelor Thesis" requires a written paper, and the "Colloquium on the Bachelor Thesis" requires an oral examination.
Grading	The module grade is calculated from the grades for the colloquium for the Bachelor thesis and the grade of the Bachelor thesis. Whereby the grade of the Bachelor thesis accounts for 75% of the total grade and the colloquium for 25% of the total grade.

Appendix

List of abbreviations

ECTS	European Credit Transfer System
CP	Credit Points
h	Hours
PC	Practical Course
S	Seminar
wE	Written Elaboration
WH	Weekly Hours
E	Exercise / Practice Questions
L	Lecture