Degree Program Documentation Bachelor's Program Pharmaceutical Bioprocess Engineering

Part A
TUM School of Life Sciences
Technical University of Munich

General Information:

- Administrative responsibility: TUM School of Life Sciences
- Name of degree Program: Pharmaceutical Bioprocess Engineering
- Degree: Bachelor of Science (B.Sc.)
- Standard duration of study and credits:
  8 semester of enrollment and 180 credit points (CP)
- Form of study: full time
- Admission: unrestricted admission
- Start: Winter semester (WiSe) 2008/2009
- Language: German
- Main Location: Freising
- Academic administrator (program design):
  Prof. Dr.-Ing. Heiko Briesen
- Contact for further questions (regarding this document):
  Team Quality Management
  qm.co@ls.tum.de
- Status as of: 30.08.2023

Table of Contents

1 Degree Program Objectives

1.1 Purpose

For several decades, findings from biology and biochemistry have been increasingly utilized for industrial production processes. The possible applications are almost unlimited due to the diversity of nature's synthesizing power. Utilizing this potential provides processes that use different organisms with low energy input and are more cost-effective, product-friendly and environmentally friendly than comparable chemical processes. Biopharmaceutical products such as hormones, enzymes, vaccines and antibodies are a particularly prominent field in this respect. Due to their complexity, such products often cannot be chemically synthesized in the traditional way, but must be produced using biotechnology. Biotechnology is therefore a key technology of the 21st century with great growth potential and increasing economic importance. Accordingly, the demand for qualified specialists who not only understand the biological background of the processes, but also have excellent knowledge of the industrial implementation of biotechnological processes, is also increasing.

The aim of the Pharmaceutical Bioprocess Engineering degree program is to train interdisciplinary engineers for biopharmaceutical production. Graduates are tasked with the development and quality-assured operation of biotechnological production processes. They can pick up on new developments and turn them into innovations. Responsible handling of the possibilities and limitations of modern biotechnological processes is also part of the profile.

1.2 Strategic Significance

For years, the TUM School of Life Sciences (LS) has been training process engineers who can design and conceptualize biopharmaceutical production processes. The use of fermentative/biotechnological processes is a connecting element to other related Bachelor's degree programs at LS (Food Technology, Brewing and Beverage Technology). However, the focus of those related Bachelor's degree programs is on the food and beverage industry.

The Bachelor's degree program in Pharmaceutical Bioprocess Engineering is followed consecutively by the Master's degree program in Pharmaceutical Bioprocess Engineering at the Technical University of Munich (TUM), which is also based at the LS. The Bachelor's program lays the foundations for acquiring in-depth process engineering and methodological skills. Students also have the opportunity to specialize in a specific area of pharmaceutical bioprocess engineering and gain their first guided experience in scientific work as part of their Bachelor's thesis. With responsibility, talent and scientific and technological excellence, TUM strives to play a leading role in the sustainable transformation of society and innovative value creation in order to enable prosperity in harmony with nature and the environment.

The consecutive degree program in Pharmaceutical Bioprocess Engineering uses the School's structures and competencies in the fields of engineering and biotechnology and supplements them with a biopharmaceutical focus. The thematic networking of the individual related degree programs mentioned above also enables students to gain an insight into different sectors of the biotechnology industry and thus acquire interdisciplinary skills.

With the **TUM Sustainable Futures Strategy 2030,** TUM aims to become a shaper of sustainable development - scientifically, economically, ecologically and socially. The Pharmaceutical Bioprocess Engineering degree program is committed to TUM's mission statement and makes a significant contribution to the implementation of its sustainability strategy in teaching. The program focuses on aspects of social transformation for sustainable and climate-resilient development. To this end, it deals with issues such as the production of high-quality pharmaceutical products and thus makes a contribution to sustainable health. Product manufacturing in an industrial environment is based on the sustainable, climate-friendly utilization of resources, including closed raw material cycles. Through a basic economic education and the possibility of using a TUM Food & Agro Centre for Innovation and Technology (FACIT) tailored to the needs of the relevant areas of application, we lay the foundation for independent, sustainable entrepreneurial action by graduates.

The integration of the study program bundle into the wider LS environment offers a particular advantage for the training of pharmaceutical bioprocess technicians. The Weihenstephan campus has interdisciplinary knowledge of life sciences, especially microbiology, biochemistry and molecular biotechnology. Due to this bundling of competences required for pharmaceutical bioprocess engineering, qualified graduates can be trained here. Synergies also result from the existing knowledge in the field of molecular biotechnology and the cooperation with the School of Engineering and Design.

2 Qualification Profile

Students on the Bachelor's degree program in Pharmaceutical Bioprocess Engineering receive a broad basic education in the natural sciences and mathematics. Microbiological aspects also play a central role here. In various parts parallel to this or building on it, they also acquire a broad technical profile in the field of engineering (together with the related Bachelor's degree programs of the LS) and finally - especially for them - skills in the field of biopharmaceutical technology. After completing the Bachelor's degree program, students are able to combine the specialist knowledge they have acquired from all areas and apply it in a problem-solving manner. The competences that graduates can demonstrate after successfully completing the Bachelor's degree program are listed below.

The content of the following qualification profile corresponds to the requirements of the Qualifications Framework for German Higher Education Qualifications (Hochschulqualifikationsrahmen - HQR) and the requirements contained therein (i) knowledge and understanding, (ii) use, application and generation of knowledge, (iii) communication and cooperation and (iv) scientific self-conception/professionalism. The formal aspects according to the HQF (admission requirements, duration, degree options) are detailed in chapters 3 and 6 as well as in the corresponding subject examination and study regulations.

Knowledge and Understanding

- Graduates know and understand the mathematical/scientific concepts underlying the solution of biotechnological problems (e.g. statistical methods of data evaluation, microbiological principles).

- Graduates know and understand the engineering fundamentals in the fields of mechanics, fluid mechanics and thermodynamics (e.g. strength calculations, pipe flows and energy balancing).
- Graduates know and understand the technologies used in biopharmaceutical production (e.g. freeze-drying).
- Graduates have a broad knowledge of biopharmaceutical processes, products and dosage forms (e.g. fermentation, antibiotics, injections).
- Graduates know and understand the legal and hygienic framework conditions for the production of biotechnological, pharmaceutical products.

Use, Application and Generation of Knowledge

- Graduates are able to apply the mathematical, scientific and engineering fundamentals they have learnt to a wide range of industrial problems.
- Graduates are able to apply common biotechnological methods to produce medicinal substances with the help of microorganisms in accordance with the legal framework and hygiene requirements.
- Graduates are able to assess the starting products and end products of biotechnological processes from a microbiological, chemical-technical and structural point of view.
- Graduates are able to work safely in the laboratory in accordance with analysis regulations.
- Graduates are able to analyze, monitor and design individual biotechnological processes in order to generate and/or ensure the desired properties of pharmaceutical products.
- Graduates are able to carry out experimental work in accordance with the state of the art under supervision and to reflect on, structure and document the results obtained.
- Graduates are able to analyze the economic efficiency of various process alternatives and plan production capacities.

Communication and Cooperation

- Graduates are familiar with the typical working methods of the specialized field and the relevant technical vocabulary.
- Graduates are proficient in interdisciplinary communication and are able to work constructively and solution-orientated in a team.
- Graduates are able to prepare, present and communicate research results in a way that is appropriate for the target group.

Scientific Self-Conception and Professionalism

- Graduates are qualified to work in the biopharmaceutical industry as well as to continue their scientific education in the form of a subsequent Master's program.
- Graduates are able to select and apply suitable statistical methods for analyzing and critically evaluating complex data and processes.
- Graduates are able to work on problems from industrial practice using basic scientific methods.
- Graduates are able to critically reflect on their actions in their professional environment, especially with regard to society's increasing expectations regarding the responsible use of pharmaceutical bioprocess engineering.

3 Target Groups

3.1 Target Audience

The Bachelor's degree program in Pharmaceutical Bioprocess Engineering is aimed at first-year students with a keen interest in scientific and engineering issues and who enjoy solving interdisciplinary problems. A keen interest in biology, chemistry, math and physics as well as the ability to think in an interdisciplinary way are therefore advantageous. In addition, you should have a keen interest in all stages of the pharmaceutical value chain - from the molecule to the marketable drug.

Future pharmaceutical bioprocess technicians should be willing to work in an interdisciplinary team in order to be able to work innovatively in a constantly changing industry and contribute responsibly to solving problems for society as a whole.

3.2 Prerequisites

3.2.1 Basic Requirements

For the Bachelor's degree program in Pharmaceutical Bioprocess Engineering, the general admission requirements for studying at a university must be fulfilled in accordance with the Ordinance on Qualifications for Studies at Universities of the Free State of Bavaria and State-recognized non-state universities (Qualification Ordinance-QualV) (BayRS 2210-1-1-3-K/WK) in the currently valid version. Otherwise, admission to the degree program is not restricted.

Applicants should fulfil the following requirements:

- Ability to work in a scientific or basic research and method-orientated manner
- Recognizable interest and corresponding background knowledge for questions in the field of biotechnology, related fields (e.g. food or biotechnology) as well as other fields (e.g. engineering, natural sciences, etc.)
- Ability to solve complex problems
- Interest in solving application problems

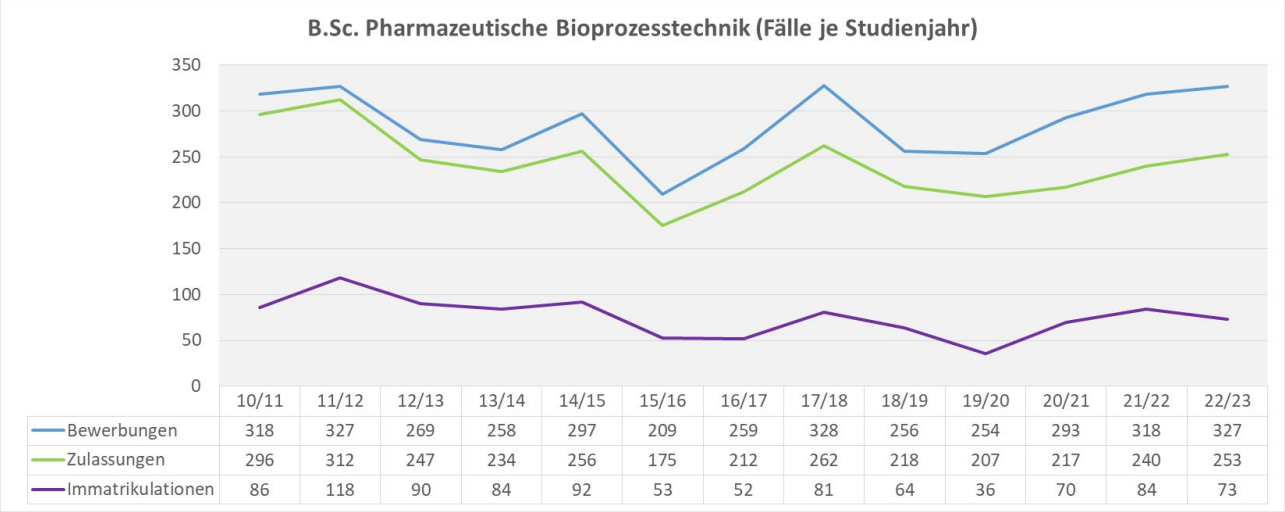
3.2.2 Language Skills

As the lectures are held almost exclusively in German, prospective students who have sufficient knowledge of German are addressed. Foreign students must submit a language certificate recognized by TUM (C2 (Goethe), DSH-2, B2 (DSD II), 4 (TestDaF), telc Deutsch C1 Hochschule) together with all other documents by the application deadline.

Applicants are expected to have the ability to think in an abstract, logical and system-orientated way. A good command of English is also very helpful, as specialized literature is often only available in English. Students with deficits in this area can improve their English language skills as part of the elective program.

3.3 Target Numbers

For the Bachelor's degree program in Pharmaceutical Bioprocess Engineering, the aim is to enroll 70-90 students. A basic and orientation examination in the first year of study helps students to determine their own suitability for the chosen degree program after a short time.



	10/11	11/12	12/13	13/14	14/15	15/16	16/17	17/18	18/19	19/20	20/21	21/22	22/23
Bewerbungen	318	327	269	258	297	209	259	328	256	254	293	318	327
Zulassungen	296	312	247	234	256	175	212	262	218	207	217	240	253
Immatrikulationen	86	118	90	84	92	53	52	81	64	36	70	84	73

Figure 1: Applications, admissions and enrollments in the B.Sc. in Pharmaceutical Bioprocess Engineering plus B.Sc. in Bioprocess Engineering (source: TUM indicator system)

Figure 1 shows the number of first-year students on the Bachelor's degree programs in Pharmaceutical Bioprocess Engineering and its direct predecessor, Bioprocess Engineering, in recent years. In recent years, the number of first-year students has ranged between approx. 40 and 120, which largely corresponds to the target corridor. At the beginning of the reporting period, the double Abitur year was reflected in particularly high numbers of applicants. The "Weihenstephan" and "Technical University of Munich" brands contribute to the high demand for the degree program.

Table 1: Key figures B.Sc. Pharmaceutical Bioprocess Engineering and B.Sc. Bioprocess Engineering (Source: TUM key figure system)

	Winter semester 2019/20	Winter semester 2020/21	Winter semester 2021/2022	Winter semester 2022/23
Applications (cases)				
Pharmaceutical Bioprocess Engineering, B.Sc.	251	293	318	327
Bioprocess Engineering, B.Sc.	3			
Admissions (cases)				
Pharmaceutical Bioprocess Engineering, B.Sc.	207	217	240	253
Bioprocess Engineering, B.Sc.	0			
Admissions rate (cases) in %				
Pharmaceutical Bioprocess Engineering, B.Sc.	82,5	74,1	75,5	77,4
Bioprocess Engineering, B.Sc.				
Rejections (cases)				
Pharmaceutical Bioprocess Engineering, B.Sc.	8	25	40	74
Bioprocess Engineering, B.Sc.				
Enrollments from applications (cases)				
Pharmaceutical Bioprocess Engineering, B.Sc.	36	70	84	73
Bioprocess Engineering, B.Sc.	0			
Proportion of enrollments to admissions (cases) in %				
Pharmaceutical Bioprocess Engineering, B.Sc.	17,4	32,3	35,0	28,9
Bioprocess Engineering, B.Sc.				
Students (cases)				
Pharmaceutical Bioprocess Engineering, B.Sc.	36	97	149	175
Bioprocess Engineering, B.Sc.	81	66	39	25
Total	**117**	**163**	188	200

Table 2: Students in the Bachelor's degree programs Pharmaceutical Bioprocess Engineering plus Bioprocess Engineering by gender and origin for the winter semester 2022/2023 (Source: TUM key figure system)

Total students	thereof male	Female	German	Foreigners	Educational nationals	Educational foreigners
200	90	110	138	62	17	45

Table 2 shows the origin and gender of students in the winter semester 2022/2023. The Pharmaceutical Bioprocess Engineering degree program is slightly more popular with female students. However, the proportion of female students is still around 45%, which corresponds to a practically balanced gender ratio. The historically higher proportion of (male) students in the STEM subjects

appears to have obviously and fortunately been overcome. The degree program also has a pleasing internationalization rate of over 20% foreign students.

4 Demand Analysis

The number of employees in the biotechnology sector continues to rise. Between 2016 and 2019, the number of employees in Germany increased by 15% to over 37,000. There are currently around 680 purely biotech companies in Germany[1] . More than half of these companies work in the medical and pharmaceutical sector.

More than 850,000 people are currently employed in the biotechnology sector worldwide, which will have generated a turnover of around US$ 298 billion in 2020[2] . Expertise in biotechnological production is in high demand both in the immediate vicinity of TUM (Munich and Regensburg bioclusters) and worldwide (large-scale biotechnological industry).

With a Bachelor's degree that qualifies them for a career, graduates mainly find employment in the field of production. However, the majority of graduates decide to continue their education with the consecutive Master's degree program on offer.

Graduates of the Pharmaceutical Bioprocess Engineering program can be deployed in a variety of ways thanks to their wide-ranging training. The core tasks of graduates lie in the planning, monitoring, control and evaluation of fermentative processes and the assurance of product quality. Due to the increasing proportion of biotechnologically produced medicinal products, engineering skills are increasingly required for the partial design of bioprocess plants and components and are in demand in pharmaceutical plant engineering, as the classically trained plant engineers are usually unable to adequately deal with these problems.

Another growing field of employment in the pharmaceutical environment is correct documentation in plant qualification and validation, which students are sensitized to during their training.

Future employers for pharmaceutical bioprocess technicians can therefore be plant manufacturers for the biotechnological and pharmaceutical industry as well as manufacturers of drugs, cosmetics, food supplements, pharmaceuticals or other biotechnologically manufactured products. Companies both in Germany and abroad can be considered.

After completing the Master's degree program in Pharmaceutical Bioprocess Engineering or a subsequent doctorate, fields of work in research and development in industrial laboratories, at universities and public research institutions also open up.

[1] Biotechnology Industry Organisation Germany e.V. 2020, Statista
[2] IBISWorld

5 Competition Analysis

5.1 External Competition Analysis

Only the Technical University of Munich currently offers a Bachelor's degree program with the title "Pharmaceutical Bioprocess Engineering" in Germany.

Similar degree programs with an engineering focus are offered by the following universities:

- B.Sc. Bioengineering - TU Dortmund University
- B.Sc. Bioprocess Engineering - Hamburg University of Technology
- B.Sc. Bio- and Chemical Engineering - Technical University of Kaiserslautern
- B.Sc. Chemical and Bioengineering - Friedrich-Alexander-Universität Erlangen-Nürnberg
- B.Sc. Life Science Engineering - Friedrich-Alexander-Universität Erlangen-Nürnberg
- B.Sc. Biosystems Engineering - Otto von Guericke University Magdeburg
- B.Sc. Bio-, Chemical and Pharmaceutical Engineering - TU Braunschweig

All of these degree programs impart engineering knowledge and skills in addition to scientific fundamentals. However, the Bachelor's degree programs in Bioengineering (TU Dortmund University), Bioprocess Engineering (Hamburg University of Technology), Biochemical and Chemical Engineering (Kaiserslautern University of Technology) and Chemical and Bioengineering (Friedrich-Alexander University Erlangen-Nuremberg) lack a direct link between the course content and the pharmaceutical industry, which is one of the main features of the Pharmaceutical Bioprocess Engineering degree program. The B.Sc. Life Science Engineering (University of Erlangen-Nuremberg) and B.Sc. Biosystems Engineering (University of Magdeburg) offer opportunities to specialize in this area. The biggest competitor in a national comparison is the TU Braunschweig with its undergraduate degree course in Bio, Chemical and Pharmaceutical Engineering, as it has clearly identified pharmaceutical engineering as a specialization and made it compulsory in the curriculum. Due to the geographical distance, however, there is no direct competition, but rather coexistence.

Similar degree programs with a stronger focus on the natural sciences:

- B.Sc. Molecular Biotechnology - Bielefeld University
- B.Sc. Biotechnology - TU Braunschweig

While the Bachelor's degree program in Molecular Biotechnology at Bielefeld University, which focuses on bioprocess technology, molecular biology and (bio)informatics, largely lacks the teaching of engineering skills, the B.Sc. in Biotechnology at the TU Braunschweig includes process engineering as part of the curriculum. In Braunschweig, students specialize in cell biology, molecular biology and bioprocess engineering. However, both degree programs also lack a specialization in the pharmaceutical industry.

Even in the international environment, the majority of degree programs are either clearly focused on pharmacy (and therefore only marginally consider the technical part) or broadly focused on biotech-

nology (without a specific focus on pharmaceuticals). In many universities, biotechnological competences are also anchored as a rather marginal part of chemical engineering training. Basic biotechnology bachelor's degree programs with a clear pharmaceutical focus can only be found in (Northern) Ireland (Munster Technological University, Queen's University Belfast). There is practically no direct competition due to the different national and regional target groups.

5.2 Internal Competition Analysis

Within the Technical University of Munich, the Bachelor's degree program in Pharmaceutical Bioprocess Engineering is complemented by the related Bachelor's degree programs in Brewing and Beverage Technology and Food Technology mentioned above. All three form a joint Professional Profile Life Science Engineering program. Large parts of the scientific and engineering fundamentals are covered in the Pharmaceutical Bioprocess Engineering degree program together with the Brewing and Beverage Technology and Food Technology degree programs, particularly in the early phases of the degree program. Despite the relationship and the structural and content-related similarities in the first semesters, a specialization in the chosen subject area emerges in the course of the degree program. The biopharmaceutical course content taught in the Bachelor's degree program in Pharmaceutical Bioprocess Engineering is only found in this program and thus enables a clear professional distinction. The degree programs are therefore not in competition with each other, but also offer students the opportunity to change their specialization by switching between the degree programs relatively easily.

At the Technical University of Munich, only the Pharmaceutical Bioprocess Engineering degree program teaches equal parts natural sciences and engineering paired with a pharmaceutical-oriented specialization. The gradual development of pharmaceutical bioprocess engineering skills from the first semester of the degree program enables students to obtain a sufficient professional qualification with their Bachelor's degree.

6 Program Structure

The interdisciplinary, German-language Bachelor's degree program in Pharmaceutical Bioprocess Engineering is a full-time course with a total of 180 ECTS credits. The standard period of study is six semesters. The Bachelor's program consists of a foundation and orientation examination in the first year of study, followed by the Bachelor's examination in the second and third year of study. The compulsory modules guarantee a consistently good basic education. The focus in the first year of study is on the natural sciences, which are essential for a successful Bachelor's degree. In the following years of study, the basis for the pharmaceutical-bioprocess technology and engineering training is laid. The Bachelor's degree qualifies graduates for jobs in production and lays the foundation for the scientifically oriented Master's degree program. Figure 2 shows an exemplary course of study.

Figure 2: Exemplary curriculum of the Bachelor's degree program in Pharmaceutical Bioprocess Engineering for the subject examination and study regulations 20221.

Semester	Modules								Credits/ Exams
1.	LS30040 Introduction to Bioprocess Engineering (GOP) K 5 CP	MA9615 Calculus (GOP) (5 CP)	PH9035 Physik für Life-Science-Ingenieure 1 (GOP) K + LL (SL) 7 CP	LS30037 Cell Biology K 5 CP	WZ5322 General and Inorganic Experimental Chemistry with Lab (GOP) K (4 CP)	LS30041 Seminar on Good Scientific Practice LP 4 CP			6 30
2.	LS30038 Economics for Life Science Engineering K 5 CP		PH9036 Physics for Life Science Engineers 2 K 5 CP	WZ5426 Organic and Biological Chemistry (3 CP)		WZ5442 Applied Mechanics (2 CP)	WZ5047 Energetic Use of Biomass K 5 CP	WZ5005 Materials Engineering K 5 CP	6 30
3.	LS30045 Bioprocess Engineering K 5 CP	WZ5299 Statistics K 5 CP	LS30001 Introduction to Microbiology (2 CP)				WZ5196 Intellectual Property Law K 5 CP		6 29
4. Mobility Window	LS30032 Pharmaceutical Technology K 5 CP			LS30047 Biochemistry 2 and Metabolism K + LL (SL) (6 CP) 9 CP		WZ5013 Fluid Mechanics K (6 CP) 8 CP	LS30048 B.Sc. Lemi BrauBPT -Industrial Internship K 5 CP	WZ5010 Analytics of Biomolecules K 5 CP	7 31
5.	LS30030 Drug Production K + LL (SL) 5 CP	LS30039 Packaging Technology K 5 CP		WZ5414 Molecular Biotechnology K 5 CP		LS30036 Thermo-dynamics K 5 CP	LS30027 Energy monitoring K 5 CP	WZ5063 Basics in Programming ÜL (SL) 6 CP	7 31
6.	LS30044 Bachelor´s Thesis W 12 CP	CLA30258 Jazzproject ÜL 3 CP	CLA21023 Passing Exams in Relaxed Mode B 2 CP			LS30035 Hygienic Processing K 6 CP		WZ5435 Ing.wissen-Machine and Plant Engineering K 6 CP	5 29

Key

Dark Blue = Mandatory Bachelor's Thesis
Light Blue = Elective Modules
Grey = Mandatory Modules
Green = Basic and Orientation Exams (GOP)
Orange = General Education Subject

PR = Practical course; CP = Credit Points; SL = coursework;
K = written exam ; M = oral exam; LL = lab work;
ÜL = exercise work; W = scientific research paper
LP = learning portfolio; B = report

6.1 Scientific Basics

In order to be able to understand the engineering and advanced pharmaceutical bioprocess engineering modules in the further course of study, a subject-specific introduction and mathematical/scientific basics (modules marked in green in Figure 2) are taught in the first two semesters of the degree program. The success of this basic training is assessed in the first year of study as part of the basic and orientation examination (GOP). The basic and orientation examination is used for this degree program instead of an admission restriction. All examinations within this GOP must be taken at the scheduled time and may only be repeated once. Students should use the GOP to show whether they are suitable for the Pharmaceutical Bioprocess Engineering degree program.

The **Physics 1+2** and **Advanced Mathematics/Statistics** modules lay the foundations for the engineering modules that follow later. The focus in physics is on basic mechanics, electrical engineering, thermodynamics and optics and is therefore the starting point for mechanical and thermodynamic considerations. Advanced mathematics provides the mathematical tools for engineering and thermodynamics.

In the Inorganic Chemistry module, students are taught the chemical fundamentals of reaction kinetics and atomic models, which are essential for **organic and biological chemistry** and **biochemistry. The Organic and Biological Chemistry** module covers the correct nomenclature as well as formation and reaction pathways. The hydrocarbon compounds dealt with there are involved in all cell biological and physiological processes in biology. Furthermore, students learn the detailed structure of such molecules involved in metabolism and the metabolic mechanisms.

The scientific foundations are rounded off by the **cell biology** module. Students are shown the cellular structure of single and multi-cell organisms and their function. This knowledge is then taken up again in general **microbiology** and **molecular microbiology.** Here, the classification of microorganisms and their biotechnological usability and pathogenicity are discussed at a glance. Knowledge of the properties of microorganisms is very important for their subsequent biotechnological utilization. In addition to the production-positive and therefore useful microorganisms, harmful microorganisms are also discussed, which must be prevented during production with suitable hygiene measures.

6.2 Engineering Sciences

The engineering sciences are one of the focal points of the Bachelor's degree program in Pharmaceutical Bioprocess Engineering. The starting point for all engineering and process technology considerations is **technical mechanics**. This module is at the beginning of the Bachelor's examination. Here, the mechanical approaches from physics are taken up and deepened by means of static and kinetic problems. It thus forms the basis for further engineering modules such as **fluid mechanics** or in-depth electives.

When designing systems for the biotechnological, chemical and pharmaceutical industries, one of the main professional fields of graduates, the consideration of fluid dynamic systems is indispensable. The calculation and design of such systems are learnt in the **fluid mechanics** module. **Thermodynamics** provides a basis for understanding the design of auxiliary material flows (steam, energy), in which students learn, for example, how to calculate thermodynamic cycle and ideal gas processes.

Hygienic working is essential to ensure product quality and shelf life. Undesirable microorganisms can only be kept away from the product if work is carried out cleanly. In the pharmaceutical industry, these potential germs must not be allowed to accumulate in the plant, as they could be transferred to the product during the manufacturing process. On the one hand, it is therefore important to design the systems in such a way that there are as few dead spaces as possible for germs to accumulate. On the other hand, training in the correct cleaning and sterilization of the system is necessary. This topic is covered in the **Hygienic Processing** module.

Students can achieve a further engineering profile by choosing engineering elective modules from the so-called profile area.

6.3 Pharmaceutical Bioprocess Engineering

In addition to the basic scientific training, subject-specific teaching is anchored right from the start. As early as the first semester, students are given an initial overview of key products and processes in bioprocess engineering, from cultivation techniques in fermenters to product purification, in the **Introduction to Bioprocess Engineering** module. The module thus creates a sense of identity for the students and allows them to self-reflect on their own study choices.

In the **bioprocess engineering** module, the topics covered are explored in greater depth, with a particular focus on industry-typical processes. In particular, process design is discussed, from the selection of a suitable production organism to strategies and concepts for process control. Occupational fields in bioprocess engineering are diverse and interdisciplinary. In the future, the manufacture of many old and new products based on biotechnological processes will become more attractive. Practical content and a focus on transferable concepts for process development are intended to prepare students for this future professional practice.

In the **Pharmaceutical Technology** module, students learn how to produce dosage forms from either chemically or biotechnologically produced drugs. They are given a broad overview of all common dosage forms and routes of administration, both those currently used for biopharmaceuticals and those still used exclusively for chemical drugs. The basic manufacturing operations, common manufacturing equipment and the requirements of the European Pharmacopoeia for dosage forms are covered. In addition, the influence of the dosage form on the efficacy of the drug and the interaction of the dosage form with the site of application in the human body are discussed in the area of biopharmacy.

In the **drug production** module, knowledge of pharmaceutical technology is deepened and put into practice. On the one hand, the students produce dosage forms themselves in a practical course. On the other hand, they work on all important aspects of quality management in the pharmaceutical industry, which are legally required for safe, effective and high-quality medicines, in a seminar.

Packaging is also becoming increasingly important for reasons of sustainability. The **packaging technology** module therefore not only lays the foundations for describing mass transfer processes in packaging, but also teaches the basic requirements for packaging in terms of drug safety and shelf life on the one hand and processability on the other. Last but not least, the module shows how modern packaging concepts fulfil these requirements.

6.4 Overarching Content

The general principles of scientific work are taught in the module **Seminar on Good Scientific Practice.** Both techniques for acquiring information (literature research, literature management) and project management tools such as time management are practiced. Students are encouraged to learn and plan independently right from the start of their studies. Later on, necessary skills such as word processing systems, mathematical software packages and presentation techniques are used, and academic texts are analyzed, written and mutually assessed. In this way, students acquire the skills they need to prepare experimental reports, discuss researched information and present their own scientific work.

For the professional practice of many graduates, knowledge of business contexts is of essential importance in today's corporate world and is therefore of the highest practical relevance. The **Economics** module teaches students basic economic and business contexts so that they understand companies as the subject of business administration. In addition, the use of internal and external accounting is explained, with the help of which they can master current challenges for companies in an economic context.

The **general education** module offers a wide range of further education, interdisciplinary, personality-building and horizon-broadening courses, from which students can choose the content that is most compatible with their personal and professional goals, based on their individual interests. To this end, students can choose from various areas, such as courses offered by the Carl von Linde Academy or the Language Centre.

6.5 Elective Modules

Students can use the electives to sharpen their own degree profile. A total of 45 credits can be earned within the framework of specialized electives. Of these 45 credits, 35 must be selected from **profile electives,** which are specified in a catalogue. Up to 10 credits from **industrial internships** can also be included here. As part of the **free elective modules** totaling a maximum of 10 credits, modules can be taken flexibly, provided they serve to develop the student's profile. A further 5 credits must be taken as part of the **General Studies** module.

6.6 Bachelor's Thesis

In the third year of study in particular, the previously acquired skills in the subject areas of natural sciences, engineering and pharmaceutical bioprocess technology are combined. The application-oriented, but at the same time scientifically based degree program concludes with the **Bachelor's thesis**, in which students work on a subject-related topic under the guidance of a scientific supervisor. After structuring and preparing the results in writing, a presentation is given.

6.7 Mobility Window

A stay abroad is best realized in the fourth semester (summer semester). When designing the curriculum, care was taken to ensure that the compulsory modules **Biochemistry 2 and Energy Metabolism** as well as **Pharmaceutical Technology** can alternatively be completed in the 6th semester. The practical course of the 2-semester module **Microbiology** can also be moved to the 6th

semester. The compulsory module **Fluid Mechanics is** a standard module that can also be completed at other European universities. In addition, the 13 ECTS to be completed from elective modules can be taken at the host university and subsequently recognized (on application). It is expressly pointed out that 11 CP elective modules from the 6th semester must already be completed during the stay abroad (4th semester) in order to achieve the required 29 CP in the 4th semester and 31 CP in the 6th semester. The Student Advisory Service at the Campus Office is available for individual planning of the stay abroad.

7 Organization and Coordination

The Bachelor degree program Pharmaceutical Bioprocess Engineering is offered by the TUM School of Life Sciences.

Administrative aspects of study organization are partly the responsibility of the central departments of the TUM Center for Study and Teaching (TUM CST) and partly of the TUM School of Life Sciences (see overview below):

- Student Advising: Student Advising and Information Services (TUM CST) (via Hotline/Service Desk) studium@tum.de +49 (0)89 289 22245
- Departmental Student Advising: Team Student Advising brew-food-bpt.co@ls.tum.de Campus Office Weihenstephan
- Academic Programs Office (within department/school), Infopoint, etc: Contact form Campus Office Weihenstephan
- Study Abroad Advising/ Internationalization: TUM-wide: TUM Global & Alumni Office internationalcenter@tum.de Departmental: Student Counselling Team Contact form Campus Office Weihenstephan
- Gender Equality Officer: Prof Aphrodite Kapurniotu akapurniotu@mytum.de
- Advising – Barrier-Free Education: TUM-wide: Service Office for disabled and chronically chronically ill students and prospective students (TUM CST) handicap@zv.tum.de +49 (0)89 289 22737
- Admissions and enrollment: TUM-wide: Admissions and Enrollment (TUM CST) studium@tum.de +49 (0)89 289 22245 Application, enrollment, student card, leave of absence, re-registration, de-registration
- Aptitude Assessment: TUM-wide: Admissions and enrollment (TUM CST) Departmental: Student Advisory Service Team Dr Sabine Köhler, Tel: +49 (0)8161 71 3336 Contact form Campus Office Weihenstephan
- Semester Fees and Scholarships: TUM-wide: Fees and Scholarships (TUM CST) beitragsmanagement@zv.tum.de

- Examination Office: TUM-wide: Central Examination Office (TUM CST)
  Departmental: Team Examination
  examination.co@ls.tum.de
  Campus Office Weihenstephan
- Examination Board: Prof. Dr.-Ing. Heiko Briesen (Chairman)
  Ivan Babić (acting secretary)
- Quality Management Studies and Teaching: TUM-wide: Studies and Teaching -
  Quality Management (TUM CST)
  www.lehren.tum.de/startseite/team-hrsl/
  Departmental: Quality Management Team
  qm.co@ls.tum.de Campus Office Weihenstephan

8 Enhancement Measures

There were practically no changes to the current statutes, which came into force in the winter semester 2022/2023. As part of the reaccreditation of the consecutive Master's degree program carried out at this time, various changes were made to the statutes in order to harmonize the consecutive course. These amendments to the statutes are now due for reaccreditation.

In general, the conversion of the degree programs of the entire degree program bundle was characterized by enabling students to individualize their own skills profile to a greater extent. The wide range of methodological and technical skills typical of the degree program continues to serve as the basis for profiling. In addition to the mathematical and scientific competences and the specialist bioprocess engineering training, the traditionally important basic engineering orientation is retained. A standardized economic education is also guaranteed.

On the other hand, the previously customary control of the acquisition of competences in the elective area has been largely dispensed with. Whereas previously certain credits always had to be selected from competence-specific catalogues, now only one elective area with profile subjects defined by the examination board is specified. For example, an industrial internship is no longer compulsory, but can of course still be included in the degree program as part of the acquisition of skills. The new structure is intended to meet the demand for graduates with a generalist education through the broad-based compulsory courses, but at the same time also to meet the increasingly differentiated professional fields for which students can prepare themselves by specifically choosing their own profile. A small proportion of credits can even be chosen completely freely from the TUM's range of courses, as long as it clearly contributes to sharpening the profile of the respective student. Of course, students still have the option of diversifying their elective subjects in order to achieve the broadest possible generalist range of competences.

As early as the 2019/2020 winter semester, the decision was made to move automation engineering and process engineering (module from thermal process engineering and process engineering of

disperse systems) to the Master's program. The flexibility this created in the Bachelor's degree program was not filled with compulsory courses, but also allows the above-mentioned greater elective options and the improved integration of a mobility window into the degree program.

A compulsory seminar module on good scientific practice has been integrated into the interdisciplinary program, in which students are introduced to scientific work in a coordinated manner right at the beginning of their studies. The integration of a compulsory general education subject has been retained.

All changes were discussed in detail in the internal and external quality circles and received broad support from all stakeholders.