Course-specific Examination and Study Regulations for the Master Degree Programme of Pharmaceutical Biotechnology at the Hamburg University of Applied Sciences

Dated 19 July 2023

On 19 July 2023, the Presidium of the Hamburg University of Applied Sciences approved pursuant to Sec. 108(1), sentence 3 of the *Hamburgisches Hochschulgesetz – [Hamburg Higher Education Act]*HmbHG – of 18 July 2001 (*HmbGVBl.* [Hamburg Gazette] p. 171), as last amended on 11 July 2023 (HmbGVBl. p. 243), the Course-specific Examination and Study Regulations for the Master Degree Programme of Pharmaceutical Biotechnology at the Hamburg University of Applied Sciences which was adopted on 30 June 2023 in accordance with Sec. 91 (2) item 1 of the HmbHG by the Faculty Council of the Faculty of Life Sciences, based on the proposal of the Department Council of Biotechnology dated 20 June 2023 in accordance with Sec. 14 (4) item 2 of the Basic Regulations of the Hamburg University of Applied Sciences in conjunction with Sec. 92 (1) sentence 2 item 2 and (5) of the HmbHG, as amended below.

Preamble

The consecutive Master degree programme of Pharmaceutical Biotechnology builds upon a Bachelor's degree programme in biotechnology. The aim of the course of study is to deepen the qualification for engineering and scientific activities in the pharmaceutical industry. Furthermore, the Master's students acquire competences that generally enable them to take part in a subsequent doctoral study programme.

The focus in terms of contents is on pharmaceutical production processes taking into account industrial requirements. In addition, knowledge is imparted on the identification of new pharmaceutical active substances and relevant pharmacological aspects.

Art. 1 General provisions, scope and subject matter

These Course-specific Examination and Study Regulations supplements with its provisions set out below, the "General Examination and Study Regulations for Bachelor and Master Degree Programmes in Engineering, Science, Life Sciences and Computer Science at Hamburg University of Applied Sciences" (GESR-ESLC) as amended.

Art. 2 Academic degree (Art. 3 of the GESR-ESLC)

(1) The University awards students the academic degree of "Master of Science (M.Sc.)" after having completed this programme.

(2) The academic degree is awarded if it can be proven that a total of 300 credit points (credit points, CP, according to ECTS) have been achieved. The 300 CPs are to be acquired in the previous course of study and in this master degree programme.

Art. 3 Duration of studies, credits and structure of studies (Articles 2, 9 of the GESR-ESLC)

(1) The course consists of 90 CP and lasts one and a half years or three semesters. One CP corresponds to an average workload of 30 hours.

(2) The Master Thesis will be written in the third semester and comprises 30 CP.

Art. 4 Contents of the studies (Articles 8, 10 of the GESR-ESLC)

(1) The course consists of ten modules, including the Master Thesis. For more details on the structure and composition of the courses (modules and classes), please refer to the module table attached hereto in the Appendix. The module manual as amended is available on the website of the Hamburg UAS in the "Ordnungen in Studium und Lehre" [Regulations on studies and teaching] section.

(2) For all students, the first year of study includes a course offering comprising 60 CP.

(3) Students can put together a module from the classes offered by other master degree programmes at the Hamburg University of Applied Sciences or other higher education institutions in Germany or abroad, provided that they have a content-related relationship with biotechnology. These classes will be combined in an replacement module. The replacement module must have at least the same number of CP as the module to be replaced; credit can only be given at the level of the CP of the module to be replaced. The "Biopharmaceutical Engineering I and II" modules and the "Master Thesis" module cannot be replaced. The classes grouped in the replacement module shall include at least one examination. The grade awarded to the replacement module will be determined by the weighting of the examination performances achieved in the replacement classes according to the CP or, where not indicated in CP, according to *SWS* [semester periods per week]. This compilation of the classes made by the students themselves requires the consent of the person entrusted with the study subject counselling and the approval of the chair member of the Examination Committee. A change of choice is only possible once and requires the consent of the person entrusted with the study subject counselling. Failure to pass examinations will then be transferred to the new compilation of classes. If all options for repeating examinations according to Art. 23 of the GESR-ESLC for a class of the compiled modules have been exhausted, a change to another module is no longer permitted.

Art. 5 Examination types (Art. 14 of the GESR-ESLC)

(1) If different types of examinations are permitted for a study or examination performance, the teacher shall make a binding provision on the relevant examination type at the latest at the beginning of the class and shall make it known to the students.

(2) If, in accordance with Art. 14 (3) of the GESR-ESLC, an examination performance is achieved in the form of a home project paper, the examiner may stipulate that a supplementary colloquium is to be carried out after the submission of such paper, at the latest one month after the submission date. The total grade of the home project paper will then be calculated to 2/3 from the written work and to 1/3 from the grade of the colloquium.

Art. 6 Language (Art. 10 of the GESR-ESLC)

The teaching and examination language is English.

Art. 7 Master Thesis (Art. 16 of the GESR-ESLC)

(1) General regulations for the Master Thesis are laid down in the GESR-ESLC (Article 16).

(2) The time available for writing the Master Thesis is six months.

(3) In addition, work on the Master Thesis can only be started once modules of the first year of study in the scope of at least 45 CP have been successfully completed. Exceptions to this rule may be approved by the Examination Committee.

Art. 8 Scope and evaluation of the Master examination (Art. 21 of the GESR-ESLC)

(1) For information on the weighting of the module grades, please refer to the table in the Appendix (column No 10 "Share of final grades in %"). The final grade is the result of calculating the weighted average of the module grades according to their weighting.

(2) If a module is composed of several examination results, the module grade will be calculated from the CP-weighted evaluations of the individual examination results.

Art. 9 Entry into force, expiry

(1) These Course-specific Examination and Study Regulations shall enter into force one day after their publication in the university gazette. They apply to all students starting their studies from the 2024 summer semester.

(2) The "Course-specific Examination and Study Regulations for the Master Degree Programme of Pharmaceutical Biotechnology at the Hamburg University of Applied Sciences" of 31 July 2014 (University Gazette No. 97/2014, p. 12) will expire at the end of the 2026/2027 winter semester. At the end of the 2026/2027 winter semester, the Regulations referred to in paragraph 1 shall apply to all students in the Master Degree programme. The students to which the regulations mentioned in sentence 1 still apply, will be transferred to these Regulations. The details shall be laid down in an equivalence directive to be adopted by the Examination Committee. A change from the regulations referred to in paragraph 2, sentence 1 to the Regulations referred to in paragraph 1 or vice versa is not possible before this date (end of the 2026/2027 winter semester).

Hamburg, 19 July 2023
Hamburg University of Applied Sciences

Appendix: Curriculum

1	2	3	4	5	6	7	8	9	10
No.	**Module**	**Semester***	**ECTS credits**	**Class**	**Type of class**	**SWS** [Semester Periods per Week]	**Examination type**	**Examination form**	**Final grade share in %**
1	Biopharmaceutical Engineering I	1, 2	6	Process Development and Automation	Se U	2	PL	H, K, or M	9.28
				Process Analysis and Optimization	Se U	2			
2	Biopharmaceutical Engineering II	1, 2	6	Biopharmaceutical Engineering Practice	Üb	2	SL	LA	0
				Bioprocess Automation Special Course	Pr ak	2			
3	Purification Techniques	1, 2	9	Purification Techniques	Se U	2	PL	H, K, or M	4.66
				Purification Techniques – Special Course	Pr ak	1	SL	LA	
				Good Manufacturing Practice	Se U	2	SL	FS	
4	Pharmaceutical-Technology	1, 2	6	Pharmacology	Se U	2	PL	K, M or PP	9.28
				Drug Development and Formulation	Se U	2			
5	Cell Culture Systems	1, 2	6	Cell Culture Techniques	Se U	2	PL	H, K, or M	4.66
				Cell Culture Techniques Special Course	Pr ak	2	SL	LA	
6	Immunobiotechnology	1, 2	6	Immunology: Basic and Biotechnological Applications	Se U	2	PL	PP	9.28
				Frontiers in Cell and Molecular Biotechnology	Se U	2			
7	Bioanalytics	1, 2	6	Biochemical Analytics	Se U	2	PL	PP	9.28
				Bioassays	Se U	2			

1	2	3	4	5	6	7	8	9	10
No.	**Module**	**Semester***	**ECTS credits**	**Course**	**Course**	**SWS** [Semester Periods per Week]	**Examination type**	**Examination form**	**Final grade share in %**
8	Process Simulation	1, 2	6	Analysis, Modeling, and Simulation of Bioprocesses	SeU	2	PL	H, K, M, Pj, or R	9.28
				Analysis, Modeling, and Simulation of Bioprocesses Practice	Üb	2			
9	Biopharmaceutical Research	1, 2	9	Laboratory Project	P	4	PL	Pj	9.28
				Research Seminar	P	1	SL	R	
10	Master Thesis	3	30	-	-	-	PL	Mas	35.00

SeU: taught seminar, Prak: laboratory internship, S: seminar, Üb: exercise, P: project, SL: study performance (ungraded), PL: examination performance (graded);
K: written examination, M: oral examination, R: presentation, H: home project, PP: portfolio examination, Pj: project close, LA: lab work completion, ÜT: exercise slip, FS: case study, Mas: Master Thesis

* Explanatory notes to the "Semester" column: the classes "1, 2" are offered only once a year (either in the summer or in the winter semester). Students therefore take these classes in their 1st or 2nd semester of studies depending on whether they start their studies in the winter or summer semester.