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Regulations
of the Department of Applied Natural Sciences
of Technische Hochschule Lübeck
concerning studies and examinations
in the online Master's program in Regulatory Affairs
– Study and Examination Regulations (SPO) 2026
Online Master's Program in Regulatory Affairs –
Dated June 15, 2026

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Pursuant to Section 52 of the Higher Education Act as promulgated on February 5, 2016 (Official Gazette of Schleswig-Holstein, p. 39), most recently amended by Article 1 of the Act of December 11, 2025 (Official Gazette of Schleswig-Holstein 2025/144), the following statutes are enacted following a resolution by the Faculty Council of the Department of Applied Natural Sciences on May 27, 2026, a statement by the Senate on June 10, 2026, and approval by the Executive Board of the Technische Hochschule Lübeck on June 11, 2026:

Part I – General Provisions

§ 1
Scope

These study and examination regulations apply to all students newly enrolled from the 2026/2027 winter semester onwards. They govern the objectives and structure of the degree program as well as the requirements for and conduct of examinations in the online Master’s degree program in Regulatory Affairs. They supplement the University of Applied Sciences’ Examination Procedure Regulations (PVO) with program-specific provisions.

§ 2
Degree Program

The Master’s examination for the online Regulatory Affairs degree program constitutes a further professional qualification, building upon a successfully completed initial professional degree program. The examination is designed to demonstrate a high level of professional and academic proficiency and to determine whether students possess a comprehensive understanding of their field, the ability to apply scientific methods and findings, and the competence to apply fundamental, subject-specific, and interdisciplinary knowledge effectively and purposefully in both theory and practice. The degree program is conducted entirely in English, thereby reflecting the international nature of the Regulatory Affairs field.

§ 3
Degree Awarded

Upon successful completion of the online Master's degree program, the Technische Hochschule Lübeck awards the academic degree "Master of Science" (M.Sc.) as a professional qualification.

Part II – Objectives and Structure of the Degree Program

§ 4
Qualification Objectives, Content, and Professional Fields of Activity

(1) Graduates are familiar with the fundamental technical methods and procedures for the national and international conformity assessment and authorization of medical devices—including in vitro diagnostics—across the entire product life cycle, and are able to apply them competently. They are used to key issues and procedures regarding conformity assessment and authorization and can employ them to solve problems in specific application scenarios. Graduates are able to analyze fundamental problems in the field of medical device conformity assessment and authorization and resolve them in a goal-oriented manner; they can also structure technical content and present it effectively in both written and oral formats. They

possess the capacity for scientific thinking, critical judgment, and responsible action, as well as for communication and cooperation.

(2) Graduates acquire comprehensive knowledge and skills in the field of conformity assessment and the market authorization of medical devices. Key subject areas include analyzing approaches to ensuring the marketability of medical devices and implementing authorization strategies that take into account clinical results as well as quality and risk management requirements. This encompasses participating in the planning of clinical and performance studies, as well as planning and executing international authorization processes—with a focus on all constituent quality and risk management procedures in compliance with applicable legal and regulatory standards. Furthermore, students develop analytical and creative skills that are crucial for professional practice in a highly regulated market.

(3) The professional profile of graduates is highly diverse in terms of product range, company size, and specific fields of activity. The majority of graduates will work in the field of medical device regulatory affairs; key prerequisites for this include the ability to work independently and across disciplines, conceptual thinking skills, creativity, teamwork, and strong communication skills. The degree program fosters these abilities and prepares graduates for the aforementioned tasks. Other potential career paths include founding one's own company or working for regulatory authorities and notified bodies.

(4) Through the acquisition of relevant specialist knowledge and additional professional skills and competencies, graduates are qualified for demanding professional roles in the private sector, public administration, or academia, particularly in the following areas:

1. manufacturers of medical devices (virtually all corporate divisions, but specifically regulatory affairs and QM/QA departments),
2. other economic operators, such as authorized representatives,
3. notified bodies,
4. research institutions,
5. consulting firms,
6. Federal Institute for Drugs and Medical Devices (BfArM),
7. Paul-Ehrlich-Institut (PEI),
8. market surveillance authorities,
9. interest groups/associations.

§ 5
Admission Requirements

The admission requirements for the online Master's degree program in Regulatory Affairs are:

(1) Degree:

1. a first professionally qualifying university degree worth 210 ECTS credits in the fields of engineering or natural sciences (e.g., physics, biology, chemistry), medicine, medical sciences, or law, with an overall grade of at least 2.5, as well as at least one year of professional experience following the first professionally qualifying university degree;
2. or a first professionally qualifying university degree worth 180 ECTS credits in the fields of engineering or natural sciences (e.g., physics, biology, chemistry), medicine, medical sciences, or law, with an overall grade of at least 2.5, as well as at least one year of professional experience following the first professionally qualifying university degree. Admission is subject to the condition that the student completes additional coursework amounting to 30 ECTS credits prior to registering for the final thesis. The responsible program management determines which modules must be completed.

(2) Language:
A good command of English is required to follow courses taught in English. Proof is provided by:

1. evidence of good English proficiency at level B2 of the Common European Framework of Reference for Languages:

1) TOEFL test
2) or a comparable internationally recognized English test demonstrating the required proficiency level
3) or a university certificate attesting to the corresponding proficiency.

2. or evidence based on meeting at least one of the following criteria:
1) English was the official language of school education,
2) a study or work stay of at least six months in an English-speaking country,
3) English was the official language of the degree program qualifying the applicant for the online Master's program in Regulatory Affairs.

In cases of doubt, the Examination Board decides on the verification of language proficiency.

§ 6

Objective of the Study Program, Start of Studies, Standard Period of Study, Scope of Study, Structure and Content

(1) The program aims to provide an education based on scientific principles through practice-oriented teaching, thereby qualifying students for independent professional practice. Through their studies, students are to acquire the ability to think and act on a scientific basis. They must be able to understand, independently apply, and further develop the relevant methods and specialist knowledge concerning all regulatory aspects of medical devices throughout the entire product life cycle.

(2) The study program begins in the winter semester.

(3) The standard period of study is four semesters. The program is structured in such a way that it can generally be completed alongside professional employment.

(4) The scope of the study program is 90 ECTS credits.

(5) The degree program is structured as follows:

	Semester	**ECTS**
Compulsory modules	1 – 3	50
Elective modules	3	5
Practical project	3	5
Thesis	4	27
Final colloquium	4	3
Total:	1-4	90

(&) The degree program comprises the modules listed in Appendix 1, including all examinations and coursework that students must complete to successfully finish the program.

(7) Elective modules totalling 5 ECTS credits must be completed. The selection catalog is set out in Appendix 1.

§ 7

Courses

(1) For online courses, learning content is implemented through digitally supported course formats that serve to convey content as well as to deepen understanding and assess learning progress:

Type of course	Course content
Assessment and practice formats	Creation and annotation of wikis (individual or group work)
Interactive online self-tests	Multiple-choice tests, matching exercises, and fill-in-the-blank tasks with immediate feedback
Multimedia	Video-based learning (short instructional films or interactive quiz lessons); online research assignments; instructor-narrated audio casts/audiobooks as module introductions; chats for synchronous communication during learning cycles involving group work; moderated sessions accompanying the module (e.g., web conferences)
Projects (Pj)	Completion of project tasks
Exercises	Practice questions requiring free-text input
Seminars	Study of selected topics

(2) The subject matter and corresponding type of course, as well as the duration, scope, number, and timing, are specified in Appendix 1 to these Study and Examination Regulations.

(3) In the English-language online Master's degree program in Regulatory Affairs, all compulsory modules are offered in English. Elective modules may also be offered in German in some cases.

(4) Individual modules from the elective catalog (see Appendix 1) may be conducted as in-person classes at the Technische Hochschule Lübeck. Attendance is mandatory for these modules. The modules are marked accordingly in Appendix 1.

Part III – Examination Requirements and Conduct

§ 8
Final Thesis and Final Colloquium

(1) The final thesis is generally completed during the fourth semester of study. It is worth 27 ECTS credits, and the completion period is six months.

(2) The final thesis may be written in German or English.

(3) The final colloquium is conducted as an oral subject examination and is worth 3 ECTS credits. It lasts 60 minutes. The presentation of the thesis should not exceed 20 minutes of this time.

(4) The final colloquium may be taken in German or English.

§ 9
Prerequisites and Admission

(1) Admission to a course assessment is granted to:
1. anyone enrolled in the online Master's degree program in Regulatory Affairs,
2. and who has paid the media access fee.

(2) Admission to an examination is granted to:
1. anyone enrolled in the online Master's degree program in Regulatory Affairs,
2. and who has paid the media access fee.

(3) Decisions regarding admission to course assessments and examinations are made by the examiner or, in cases of doubt, by the Examination Board. Notice of admission shall be given in an appropriate manner.

(4) Admission shall be denied if the admission requirements are not met.

(5) A prerequisite for admission to the final thesis is proof of at least 50 credit points, including proof of completion of all academic requirements for the first and second semesters as specified in the module plan of these study and examination regulations.

(6) A prerequisite for admission to the final colloquium is proof of completion of all academic requirements specified in the module plan of these study and examination regulations and a passing grade on the final thesis.

§ 10
Examination Procedure

The examination procedure is governed by the Examination Procedure Regulations (PVO) of the Technische Hochschule Lübeck.

§ 11
Language of Examination

Examinations are taken in the language in which the corresponding courses are offered.

§ 12
Grading, Weighting, and Calculation of the Overall Grade

(1) If modules consist of several partial module examinations, each individual partial module examination must be graded at least "sufficient" (4.0) for the module to be considered passed.

(2) Final module examinations and partial module examinations are weighted according to the assigned credit points (LP). The credit points relevant for weighting the modules are specified in Appendix 1.

(3) To determine the unified grade, the grades for the final thesis and the colloquium are weighted at a ratio of 75 percent to 25 percent.

(4) The overall grade for the degree is calculated based on the credit points assigned to the module examinations and the unified grade for the final thesis and the final colloquium, weighted according to the assigned credit points.

Part IV – Internships

§ 13
Practical Project

(1) The practical project is an essential component of the online Master's degree program in Regulatory Affairs; it serves to provide a project-based, subject-specific, and practical introduction to the work and tasks encountered in the future professional environment. In doing so, the student applies the skills and competencies acquired during their studies.

(2) The scope of the practical project is 150 hours.

(3) A prerequisite for completing the practical project is proof of having successfully completed all coursework and examinations for the first subject-specific semester.

(4) Further details regarding the subject matter and nature of the practical project are governed by the guidelines for conducting the practical project within the Master's degree program in Regulatory Affairs.

§ 14
Final Provision

These regulations enter into force on September 1, 2026.

Lübeck, June 15, 2026

Prof. Dr. Manfred Rößle
Dean of the Department of Applied Natural Sciences, Technische Hochschule Lübeck

Module No.	Module Name	Course Name	Semester	Achievement		Language	ECTS
				Exam Achievement	Coursework		
Compulsory modules							
1	**Introduction - Systematic Concepts and Legal Aspects**					englisch	**5**
		Introduction - Systematic Concepts and Legal Aspects	1	MP-PF			5
2	**Classification and Essential Requirements**					englisch	**5**
		Classification and Essential Requirements	1	MP-PF			5
3	**Quality Management**					englisch	**5**
		Quality Management	1	MP-PF			5
4	**Medical Technology I - Introduction**					englisch	**5**
		Medical Technology I - Introduction	1	MP-PF			5
5	**CE Marking and Certification**					englisch	**5**
		CE Marking and Certification	2	MP-PF			5
6	**Clinical Evaluation, Clinical Trials and Clinical Data**					englisch	**5**
		Clinical Evaluation, Clinical Trials and Clinical Data	2	MP-PF			5
7	**Statistics and Quality Assurance**					englisch	**5**
		Statistics and Quality Assurance	2	MP-PF			5
8	**Medical Technology II – Safety Concepts**					englisch	**5**
		Medical Technology II – Safety Concepts	2	MP-PF			5
9	**Medical Device Safety and Surveillance**					englisch	**5**
		Medical Device Safety and Surveillance	3	MP-PF			5
10	**International Markets and Approvals**					englisch	**5**
		International Markets and Approvals	3	MP-PF			5
Elective modules							

W1	**Medical Technology Lab****					german/ englisch	**2,5**
		Medical Technology Lab	3		SLb		2,5
W2	**Entrepreneurship**					englisch	**2,5**
		Entrepreneurship	3	MP-PA			2,5
W3	**Project Management**					englisch	**2,5**
		Project Management	3	MP-PA			2,5
W4	**Pharmaceutical Law**		3			englisch	**2,5**
		Pharmaceutical Law	3	MP-PA			2,5
W5	**Basics of Business Administration**					englisch	**2,5**
		Basics of Business Administration	3	MP-K (60 Min.)			2,5
W6	**Basics of Marketing**					englisch	**2,5**
		Basics of Marketing	3	MP-PA			2,5
W7	**Communication and Negotiation Skills**					englisch	**2,5**
		Communication and Negotiation Skills	3	MP-PA			2,5
W8	**Audits – Basics and Practice**					englisch	**2,5**
		Audits – Basics and Practice	3	MP-PF			2,5
W9	**Artificial Intelligence in Applications – Focus Seminar**					german/ englisch	**2,5**
		Artificial Intelligence in Applications – Focus Seminar	3	MP-PF			2,5
W10	**Artificial Intelligence in Applications – Focus Project**					german/ englisch	**2,5**
		Artificial Intelligence in Applications – Focus Project	3	MP-PF			2,5
W11	**Specific Topics related to Regulatory Affairs I**					german/ englisch	**2,5**
		Specific Topics related to Regulatory Affairs I	3	MP-PF			2,5
W12	**Specific Topics Related to Regulatory Affairs II**					german/ englisch	**5**
		Specific Topics Related to Regulatory Affairs II	3	MP-PF			5
W13	**Quality Management Coursework**					englisch	**1**
		Quality Management Coursework	4		SLu		1

Practical Project							
P1	**Practical Project**					englisch	**5**
		Practical Project	3	MP-PA			5
Degree completion							
A1	**Diploma**					german/ englisch	**30**
		Master Thesis	4	6 Monate			27
		Master Colloquium	4	MP-M (60 Min.)			3

CP: Credit points
MP-K: Module examination (written exam)
MP-M: Module examination (oral exam)
MP-PF: Module examination (portfolio)
MP-PA: Module examination (project work)
SLu: Ungraded coursework
SLb: Graded coursework

*** Elective modules totaling 5 ECTS credits must be selected from the defined catalog.**
**** This module takes place in person at the Technische Hochschule Lbeck. On-site attendance is required.**