TECHNISCHE HOCHSCHULE LÜBECK

Module Catalog

Regulatory Affairs, Master

State: 26.06.2026

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TECHNISCHE HOCHSCHULE LÜBECK

Regulatory Affairs, Master

1st Semester of Studies

Module: Classification and Essential Requirements

Level	Master	**Short Name**	CER
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	1	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes

The student possesses an in-depth understanding of the fundamental terms and concepts regarding medical device regulation in the EU and Germany. Furthermore, the student is able to place these regulatory requirements within the context of international recommendations based on the guidelines of the International Medical Device Regulators Forum (IMDRF) and its predecessor organization, the Global Harmonisation Task Force (GHTF). This includes detailed knowledge of

• the legal definition of medical devices, including in vitro diagnostic medical devices (IVDs);

• product qualification, specifically the distinction between medical devices and other product groups such as medicinal products, blood products, food and feed, cosmetic products, and consumer goods;

• the risk-based concept for the classification and categorization of medical devices—including combination products and IVDs—under the previous European Directives (90/385/EEC, 93/42/EEC, 98/79/EC), the EU Regulations on medical devices and IVDs (Regulation (EU) 2017/745 and Regulation (EU) 2017/746), and international recommendations (IMDRF/GHTF);

• classification rules under the European Directives and EU Regulations, as well as international recommendations (IMDRF/GHTF);

• essential requirements for medical devices (Annex I of Directives 90/385/EEC and 93/42/EEC) and IVDs (Annex I of Directive 98/79/EC), including requirements for product labeling and product information;

• general safety and performance requirements (Annex I of Regulation (EU) 2017/745 and Annex I of Regulation (EU) 2017/746), including requirements for product labeling and product information;

	• the so-called “Essential principles for safety and performance” in accordance with IMDRF/GHTF recommendations; • any applicable additional German provisions (MPG, MPDG, and subordinate ordinances); • the procedures required to compile technical documentation for medical devices and IVDs regarding compliance with essential requirements or general safety and performance requirements. Based on the intended purpose of medical devices, the student is able to independently determine the regulatory classification of a product. The student is able to identify all relevant regulatory requirements in Germany and the EU for the medical devices in question—including IVDs, software, and combination products—and, on this basis, develop and present a regulatory strategy for the market entry of a medical device or IVD. This applies to all classes and categories of medical devices and IVDs. Furthermore, the student is able to distinguish in detail between the essential requirements set out in Annex I of the European directives, the requirements regarding the performance and safety of medical devices and IVDs set out in Annex I of the European regulations, and the "Essential principles for safety and performance" (based on IMDRF/GHTF recommendations); to apply these to specific cases; and, on this basis, to determine and evaluate the key contents of the technical documentation. In this context, the student is specifically qualified to describe the risk management process—in accordance with Annex I of the EU regulations on medical devices or in vitro diagnostic medical devices (IVDs) and the EN ISO 14971 standard—as an iterative process, and to evaluate it within the framework of an integrated approach within a medical device manufacturer's quality management system.
Participation Prerequisites	

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	
Remarks	

TECHNISCHE HOCHSCHULE LÜBECK

Module Course: Classification and Essential Requirements

(of Module: Classification and Essential Requirements)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	Basic definitions within the European and national regulatory systems for medical devices and according to IMDRF/GHTF recommendations Product demarcation/qualification Classification concepts and rules General requirements and principles regarding the safety and performance of medical devices, including IVDs Risk management system and process EN ISO 14971 Product labeling and information
Literature	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)

	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices Medical Devices Act in the version of the notification of 7 August 2002 (Federal Law Gazette I, p. 3146), as last amended by Article 223 of the Regulation of 19 June 2020 (Federal Law Gazette I, p. 1328) Medical Devices Law Implementation Act of 28 April 2020 (Federal Law Gazette I, p. 960), as amended from time to time EN ISO 14971 – Medical devices – Application of risk management to medical devices (ISO 14971:2019); All relevant MDCG, MEDDEV, NBOG, IMDRF, and GHTF documents regarding the definition, classification, and general requirements for medical devices (including IVDs) in their currently valid versions Applicable guidance documents from associations such as MedTech Europe, COCIR, BVMed, VDGH, etc.
Remarks	

Module: Introduction – Systematic Concepts and Legal Aspects

Level	Master	**Short Name**	SLA
Responsible Lecturers	Wachenhausen, Heike, Prof. Dr. jur.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	1	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150
The following section is filled only if there is **exactly one** module-concluding exam.			
Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	• Students understand the framework of applicable regulatory requirements and can apply them to their specific issue or case scenario. • Students analyze regulatory terms and provisions and assign them to the appropriate category. • Students apply a nuanced understanding of regulatory areas of responsibility and the associated legal obligations and tasks in order to implement measures correctly and assign responsibilities accurately. • Students are able to discuss and weigh up legal aspects. • Students are able to reliably select applicable requirements for a specific issue and implement them in a structured manner. • Students are able to identify problems within the framework of regulatory requirements and develop potential solutions and alternatives. • When faced with differing perspectives on legal requirements, students work with the relevant stakeholders to develop a strategy for reaching a consensus.		
Participation Prerequisites			
The previous section is filled only if there is **exactly one** module-concluding exam.			
Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)		
Applicability			

Remarks	

Module Course: Introduction – Systematic Concepts and Legal Aspects

(of Module: Introduction – Systematic Concepts and Legal Aspects)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	• Structure of regulatory requirements at European and national levels • Scope of application of regulatory requirements • Definition of medical devices and classification criteria • Competencies and responsibilities • Operation and use • Liability (including compliance, anti-corruption) • Advertising for medical devices
Literature	1. Baumgartner/Harer/Schröttner, Medical Devices and In Vitro Diagnostics, Springer, 2023 2. Gassner, Medizinprodukterecht: MP-VO | IVD-VO | MPDG, Nomos, 2025 3. Vollebregt, The enriched MDR and IVDR, 2nd Edition, 2022 4. European Commission: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en 5. MDCG-Guidance: https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en 6. The 'Blue Guide' on the implementation of EU product rules 2022: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC

	7. Access to European Union Law: https://eur-lex.europa.eu/homepage.html?lang=en 8. Court of Justice of the European Union – Case law data base: https://infocuria.curia.europa.eu/tabs/affair?lang=en
Remarks	

Module: Medical Technology I - Introduction

Level	Master	**Short Name**	MTI
Responsible Lecturers	Müller, Stefan, Prof. Dr.-Ing.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	1	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	• Students can explain the key measurement principles used in medical devices and the associated sensors.• Students are familiar with the fundamental physiological and anatomical concepts and can explain the functions of the organs of the cardiovascular system.• Students can design simple circuits for measuring biosignals (particularly ECGs) based on operational amplifiers.• Students can analyze the functions of key medical devices.• Students are able to assess technical risks that may arise from the malfunction of medical devices.		
Participation Prerequisites			

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	
Remarks	

Module Course: Medical Technology I - Introduction

(of Module: Medical Technology I - Introduction)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	• Introduction (Technical Fundamentals) • Electrical Activity of Excitable Cells • The Cardiovascular System • The Electrocardiogram (ECG) • Pulmonary Function Diagnostics • Invasive Blood Pressure Measurement • Infusion and perfusion systems • Hemodialysis • Electrotherapy for cardiac arrhythmias
Literature	1. Thomas Harriehausen, Dieter Schwarzenau; Moeller: Fundamentals of Electrical Engineering; Springer Vieweg; ISBN 978-3834817853 2. Ulrich Tietze, Christoph Schenk, Eberhard Gamm; Semiconductor Circuit Design; Springer; ISBN 978-3642310256; Rainer Parthier; Measurement Technology; Springer Vieweg; ISBN 978-3658049591 3. Ute Morgenstern, Marc Kraft; Biomedical Engineering – Fascination, Introduction, Overview; De Gruyter; ISBN 978-3-11-025198-2 4. John G. Webster; Medical Instrumentation – Application and Design; John Wiley & Sons; ISBN 9780471676003 5. Jürgen Werner; Cooperative and Autonomous Systems in Medical Technology; Oldenbourg; ISBN 3-486-27559-3
Remarks	

Module: Quality Management

Level	Master	**Short Name**	QM
Responsible Lecturers	Wang, Wen-Huan, Prof. Dr.-Ing.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	1	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	1. Students can explain the benefits of quality management for companies. 2. They can apply quality management terminology. 3. When faced with quality-related tasks, they can assess the suitability of specific quality techniques for solving the problem at hand. 4. They can explain the requirements for quality management systems. 5. They can independently analyze quality-related tasks using quality techniques.		
Participation Prerequisites			

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	The following modules listed below build upon the QM1 module: • MRA Module: Quality Management II – Statistics and Quality Assurance • MRA Module: CE Marking and Certification • MRA Module: International Markets and Regulatory Approval • MRA Module: Auditing – Fundamentals and Practice
Remarks	

Module Course: Quality Management

(of Module: Quality Management)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	1 Managing Quality 2 Requirements and Customer Satisfaction 3 Process Management 4 Problem Solving and Quality Techniques 5 Seven Basic Quality Tools 6 Seven Management Tools 7 Quality Management Systems and Standards
Literature	Online Course Script DIN EN ISO 9000 – Quality management systems – Fundamentals and vocabulary. Berlin: Beuth DIN EN ISO 9001 – Quality management systems – Requirements. Berlin: Beuth DIN EN ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes With regard to standards, the current version always applies.
Remarks	

TECHNISCHE HOCHSCHULE LÜBECK

Regulatory Affairs, Master

2nd Semester of Studies

Module: CE Marking and Certification

Level	Master	**Short Name**	CEM
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.; Urban, Max, Prof. Dr		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	2	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	SuSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes	1. Graduates of this module are capable of independently—or under the coordination of a scientific team—developing and implementing a regulatory strategy for the selection and execution of appropriate conformity assessment procedures for medical devices, including IVDs. 2. In doing so, graduates of this module distinguish between the tasks and responsibilities of all involved parties—both on the part of the manufacturer and on the part of third parties, such as Notified Bodies and, where applicable, regulatory authorities or expert groups to be involved (e.g., consultation procedures, "scrutiny" procedures pursuant to EU regulations on medical devices or IVDs, etc.). 3. Graduates identify, distinguish, and evaluate all statutory and normative requirements regarding quality and risk management systems within the context of medical device manufacturing (including IVDs). Students possess the competence to independently implement these requirements as part of the establishment, maintenance, and continuous improvement of the management system, specifically as an integrated management system. 4. Students possess a comprehensive overview of the workflow involved in certification and accreditation procedures and are capable of distinguishing between the specific objectives of these procedures. 5. In addition to aspects of conformity assessment focused purely on medical device law, students gain an overview of other legal provisions applicable to the medical device sector—such as those pertaining to artificial intelligence, the benefit assessment (health technology assessment/HTA) of medical devices, and German and European patent law.

Participation Prerequisites	
The previous section is filled only if there is **exactly one** module-concluding exam.	
Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	
Remarks	

Module Course: CE Marking and Certification

(of Module: CE Marking and Certification)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	Conformity Assessment Procedures for Medical Devices of All Risk Classes, Including in Vitro Diagnostic Medical Devices Consultation Procedures EU Reference Laboratories Common Specifications Modular System for Conducting Conformity Assessment Procedures Quality and Risk Management Systems Integrated Management Systems German and European Patent Law Health Technology Assessment: Reimbursement of health products in Germany and in the European Union Further regulations that can be applicable to (IVD) medical devices, such as, for example, requirements related to artificial intelligence in healthcare
Literature	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices Medical Devices Act, as promulgated on 7 August 2002 (BGBl. I p. 3146), last amended by Article 223 of the Ordinance of 19 June 2020 (BGBl. I p. 1328) Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) Medical Devices Law Implementation Act of 28 April 2020 (BGBl. I p. 960), last amended by Article 2 of the Act of 12 May 2021 (BGBl. I p. 1087) DIN EN ISO 14971 – Medical devices – Application of risk management to medical devices (ISO 14971:2019); German version EN ISO 14971:2019 DIN EN ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016); German version EN ISO 13485:2016, Corrigendum to DIN EN ISO 13485:2016-08; German version EN ISO 13485:2016/AC:2016 DIN EN ISO/IEC 17000 – Conformity assessment – Vocabulary and general principles (ISO/IEC 17000:2020); Trilingual version EN ISO/IEC 17000:2020 DIN EN ISO/IEC 17021-1 – Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements (ISO/IEC 17021-1:2015); German and English version EN ISO/IEC 17021-1:2015 DIN EN ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017); German and English versions of EN ISO/IEC 17025:2017 DIN EN ISO/IEC 17011 – Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011:2017); German and English versions of EN ISO/IEC 17011:2017 All relevant MDCG, MEDDEV, NBOG, EMA, Team-NB, IMDRF, and GHTF documents relating to conformity assessment procedures and the essential requirements for medical devices (including IVDs), in their currently valid versions Applicable guidance documents from associations such as MedTech Europe, COCIR, BVMed, VDGH, and others
Remarks	

Module: Clinical Evaluation, Clinical Trials and Clinical Data

Level	Master	**Short Name**	CE
Responsible Lecturers	Tolkmitt, Florian, Dipl.-Ing., Wachenhausen, Heike, Prof. Dr., Spitzenberger, Folker, Prof. Dr.; Vonthein, Reinhard, Priv.-Doz. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	2	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	SuSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150
The following section is filled only if there is **exactly one** module-concluding exam.			
Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	1. Graduates of this module are capable of presenting, distinguishing, and critically evaluating the requirements for the clinical evaluation of medical devices—or, respectively, the performance evaluation of in vitro diagnostic medical devices (IVDs)—within the context of European and national legislation (MDR, IVDR, MPDG, and, where applicable, subordinate regulations) and international recommendations (IMDRF, GHTF, WHO), both prior to and following market launch. 2. Graduates are able to identify and apply the regulatory requirements for the planning and conduct of clinical investigations involving medical devices, in accordance with European and national guidelines. 3. In doing so, graduates of this module distinguish between the duties and responsibilities of all involved parties—including both the manufacturer and third parties such as Notified Bodies, as well as relevant authorities or expert groups—particularly with regard to the approval of clinical investigations, the authorization by ethics committees, and similar processes. 4. Graduates identify, distinguish, and evaluate all normative requirements pertaining to the clinical evaluation and performance evaluation of medical devices and IVDs, respectively—both prior to and following market launch—referencing relevant standards (e.g., ISO 14155, EN 13612, ISO 18969, ISO 20916). 5. Students possess the competence to independently implement these requirements within the scope of establishing, maintaining, and continuously improving a Quality Management (QM) system, as well as integrating a Post-Market Surveillance system—including Post-Market		

	Clinical Follow-Up (PMCF) and/or Post-Market Performance Follow-Up (PMPF). 6. Students are familiar with the specific requirements for the performance evaluation of IVDs—specifically regarding analytical and clinical performance evaluation, as well as the evaluation of the scientific validity of IVDs in accordance with the current international state of the art—and are able to distinguish between these requirements and apply them by way of example.
Participation Prerequisites	

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	
Remarks	

Module Course: Clinical Evaluation, Clinical Trials and Clinical Data

(of Module: Clinical Evaluation, Clinical Trials and Clinical Data)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	• Concepts for clinical evaluation and clinical investigation in accordance with European MDR requirements • Performance evaluation and performance studies for in vitro diagnostic devices in accordance with European IVDR requirements • Concepts of Post-market Clinical Follow-Up (PMCF) • Concepts of Post-market Performance Follow-Up (PMPF) • Clinical investigations in accordance with ISO 14155 and the state of the art • Performance studies for IVDs in accordance with ISO 20916, EN 13612 and the state of the art • Recommendations from IMDRF, GHTF and WHO in the context of clinical (performance) evaluation and clinical investigations (performance studies) of medical devices/(IVD medical devices)
Literature	• Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC • Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

	• Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) • Council Directive 93/42/EEC of 14 June 1993 concerning medical devices • Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices • Medical Devices Act, as promulgated on 7 August 2002 (Federal Law Gazette I, p. 3146), last amended by Article 223 of the Ordinance of 19 June 2020 (Federal Law Gazette I, p. 1328) • Medical Devices Law Implementation Act of 28 April 2020 (Federal Law Gazette I, p. 960), last amended by Article 2 of the Act of 12 May 2021 (Federal Law Gazette I, p. 1087) • DIN EN ISO 14155 – Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155:2020); German version EN ISO 14155:2020 • DIN EN 13612 – Performance evaluation of in vitro diagnostic medical devices • DIN EN ISO 20916 – In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice • ISO/DIS 18969 – Clinical evaluation of medical devices • DIN EN ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017); German and English versions EN ISO/IEC 17025:2017 • All relevant MDCG, MEDDEV, NBOG, Team-NB, EMA, IMDRF, and GHTF documents relating to the clinical evaluation/ performance evaluation of medical devices or IVDs, and relating to clinical investigations/performance studies of medical devices or IVDs, in their respective current versions • Applicable guidelines from associations such as Medtech Europe, COCIR, BVMed, VDGH, and others
Remarks	

Module: Medical Technology II – Safety Concepts

Level	Master	**Short Name**	MT II
Responsible Lecturers	Müller, Stefan, Prof. Dr.-Ing		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	2	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	SuSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes	• Students are familiar with the key safety concepts employed in medical technology and can explain the underlying principles. • Students are able to functionally analyze major generic medical devices (specifically infusion pumps and ECGs), identify hazards, assess risks, and design safety measures (using a risk-based approach). • Students are familiar with the essential principles and methods of biological safety and can plan and evaluate a biological safety assessment. • Students are familiar with the safety principles for electromedical devices and can apply these principles to generic product groups. • Students are familiar with the methodology for weighing the risks—including residual risks—of a medical device against its benefits • Students understand safety issues of software in medical devices on a prominent medical device example (Therac-25) • Students understand how software for medical devices must be developed, tested, and maintained to ensure patient safety according to IEC 62304 standard
Participation Prerequisites	

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	

Remarks	

Module Course: Medical Technology II – Safety Concepts

(of Module: Medical Technology II – Safety Concepts)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	• Introduction (Fundamentals, Definitions, Safety, Balancing Safety and Effectiveness/Benefit) • Risk-Based Approach – Concepts for Risk Management • Regulatory Framework and Standards (Technical Standards) for Safety: Process Standards, General Product Standards, and Standards for Specific Products • Physical and Mechanical Safety • Electrical Safety • Biological Safety • Functional Safety • Application Safety – Usability • Software development and Lifecycle process management to ensure safe software
Literature	1. Wintermantel E, Ha S-W: Medical Technology – Life Science Engineering. 5th Edition, Springer Heidelberg, Berlin (2009); ISBN: 978-3-540-93935-1 (e-ISBN: 978-3-540-93936-8) 2. Rüdiger Kramme (Ed.): Medical Technology. 3rd Edition; Springer Medizin Verlag Heidelberg (2007); ISBN-13: 978-3-540-34102-4 3. Alexander K, et al.: Good Design Practice for Medical Devices and Equipment – A Framework. University of Cambridge Engineering Design Centre (2001); ISBN: 1-902546–08-3 4. Havel, P.: How to Design Safe Medical Products. Machine Design (2014): 62–69; ISSN: 0024-9114, www.machinedesign.com/medical/how-design-safe-medical-products

	5. IEC 62304
Remarks	

Module: Statistics and Quality Assurance

Level	Master	**Short Name**	SQ
Responsible Lecturers	Wang, Wen-Huan, Prof. Dr.-Ing.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	2	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	SuSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	1. Students can explain the utility of statistics in everyday life and in quality assurance. 2. They can apply statistical concepts. 3. For quality-related tasks (e.g., reducing production defect rates, increasing product lifespan), they can assess the suitability of statistical methods for solving the problem. 4. They can explain the underlying mechanisms of statistical methods. 5. They can independently analyze quality-related tasks using statistical methods. 6. They can develop solution approaches for quality-related tasks using statistical methods.		
Participation Prerequisites			

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	
Remarks	

Module Course: Statistics and Quality Assurance

(of Module: Statistics and Quality Assurance)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	1 Statistics – Why and How? 2 Basic Concepts of Statistics and Data Collection 3 One-Dimensional Frequency Distributions 4 Measures of Location 5 Measures of Dispersion 6 Measures of Concentration 7 Ratios 8 Two-Dimensional Frequency Distributions and Measures 9 Regression Analysis 10 Time Series Analysis
Literature	Online Script
Remarks	

TECHNISCHE HOCHSCHULE LÜBECK

Regulatory Affairs, Master

3rd Semester of Studies

Module: International Markets and Approvals

Level	Master	**Short Name**	IMMA
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	3	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes	1. Students are able to identify the market authorization requirements and procedures for medical devices—including in vitro diagnostics and combination products—in international markets and to evaluate the roles of the various stakeholders, particularly manufacturers and the authorities responsible for product authorization. 2. Students are able to develop and implement appropriate strategies and solutions for the market authorization of medical devices (including in vitro diagnostics and combination products) in international markets, such as the USA, Canada, the United Kingdom (UK), China, and Brazil. 3. Students are able to critically evaluate international authorization concepts and procedures by comparing them with the key concepts and guidelines of the International Medical Device Regulators Forum (IMDRF) and the Global Harmonisation Task Force (GHTF). 4. Students independently address trade- and location-specific issues regarding the authorization of medical devices in resource-limited settings. 5. Students critically compare the national/European system for the conformity assessment of medical devices with key international authorization concepts and procedures and independently evaluate these systems.
Participation Prerequisites	

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)

Applicability	
Remarks	

Module Course: International Markets and Approvals

(of Module: International Markets and Approvals)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	Regulatory approval of medical devices, including IVDs, in accordance with requirements including those of the USA, UK, Canada, China, and Brazil WHO Prequalification Program International and supra-regional consensus concepts and procedures: IMDRF, GHTF, GHWP Mutual Recognition Agreements (MRAs) International standardization
Literature	Theisz, Val: Medical Device Regulatory Practices: An International Perspective; Pan Stanford Publishing, 2015 Wong, Jack and Tong, Raymond K. Y.: Handbook of Medical Device Regulatory Affairs in Asia; Pan Stanford Publishing, 2015 Blue Guide Laws, regulations, guidelines, and procedures of the respective national authorities or international organizations, as found on the corresponding websites: www.who.int www.wto.org www.imdrf.org

	www.ahwp.info www.fda.gov www.tga.gov.au www.hc-sc.gc.ca www.pmda.go.jp www.mhra.gov.uk www.hsa.gov.sg www.gmdnagency.com www.sfda.gov.sa www.fda.gov.tw/EN www.iso.org www.raps.org
Remarks	

Module: Medical Device Safety and Surveillance

Level	Master	**Short Name**	MDSS
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	3	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes

1. Graduates of the module identify the concept of post-market surveillance/market surveillance—which complements pre-market conformity assessment procedures for medical devices—as it applies to the post-market phase of the products.

2. Graduates are capable of independently establishing and maintaining a post-market surveillance system for medical devices. They recognize and assess the roles of the various stakeholders within the medical device safety and surveillance system.

3. Provided the statutory requirements of Article 15 of the MDR or IVDR are met, graduates are also specifically qualified to work as a "Person Responsible for Regulatory Compliance" (PRRC) in the medical device industry, thereby competently fulfilling a central role within this system.

4. Graduates of the module distinguish between and evaluate the tasks and responsibilities of the various authorities within the safety and surveillance system at both national and European levels. They are capable of independently and competently discussing emerging issues in their future field of activity with representatives of the authorities and of developing regulatory solutions in collaboration with authorities or Notified Bodies.

5. Graduates are able to assess the national and European information systems for medical device safety and surveillance and to reflect on the perspectives of the various stakeholders within the surveillance and vigilance system. They develop appropriate regulatory strategies and communicate them competently to all stakeholders.

6. Graduates are capable of coordinating and overseeing change management for medical devices—including in vitro diagnostic (IVD) medical devices—in a manner that ensures regulatory compliance.

	7. Graduates have an overview of the functions and capabilities of the European Database on Medical Devices (Eudamed) and are able to distinguish between the individual Eudamed modules and utilize them in test versions, where available.
Participation Prerequisites	

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	
Remarks	

Module Course: Medical Device Safety and Surveillance

(of Module: Medical Device Safety and Surveillance)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	Change management for medical devices under MDR/IVDR and existing guidelines European post-market surveillance system European vigilance system Eudamed and German medical device information and database system UDI system European nomenclature for medical devices National and European information system for medical device safety and surveillance
Literature	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices Medical Devices Act in the version of the notification of 7 August 2002 (Federal Law Gazette I, p. 3146), as last amended by Article 223 of the Regulation of 19 June 2020 (Federal Law Gazette I, p. 1328) Medical Devices Law Implementation Act of 28 April 2020 (Federal Law Gazette I, p. 960), as last amended by Article 2 of the Act of 12 May 2021 (Federal Law Gazette I, p. 1087) Ordinance on the Operation of Medical Devices, in the version currently in force Ordinance on the adaptation of the Medical device legislation aligning with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (Medical Devices EU Adaptation Ordinance – MPEUAnpV) of 11 February 2021, as amended ISO/TR 20416:2020 – Medical devices – Post-market surveillance for manufacturers All relevant MDCG, MEDDEV, NBOG, EMA, IMDRF, and GHTF documents relating to medical device safety and surveillance in the post-market phase Applicable guidelines from associations such as MedTech Europe, COCIR, BVMed, VDGH, etc.
Remarks	

Module: Practical Project

Level	Master	**Short Name**	PP
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	3	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	(Flexible)	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Project Work	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes	The practical project enables students to apply the specialized knowledge acquired during their studies in a real-world setting relevant to their future careers. Students learn to implement regulatory requirements within practical workflows—for instance, by coordinating and managing European or international authorization procedures. The project combines practical work in the field of Regulatory Affairs with a scientific question related to regulatory matters. Ultimately, students enhance their ability to think and act in a regulatory context; the practical work may be carried out either within companies or within regulatory authorities (including the functions of Notified Bodies).
Participation Prerequisites	Proof of all coursework and examination results from the first semester.

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	
Remarks	

Module Course: Practical Project

(of Module: Practical Project)

Course Type	Project Work	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	During the practical project, students have the opportunity to apply the knowledge they have acquired in the field of Regulatory Affairs to practical, concrete projects.
Literature	The literature used for the practical project depends on the project's specific topic. In principle, the projects are based on elements of European Regulation (EU) 2017/745, Regulation (EU) 2017/746, IMDRF/GHTF recommendations, further national, regional or international regulations and guidelines.
Remarks	

Module: Audits – Basics and Practice

Level	Master	**Short Name**	ABP
Responsible Lecturers	Wang, Wen-Huan, Prof. Dr.-Ing.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory elective	**ECTS Credit Points**	2,5
Semester of Studies	3	**Semester Hours per Week**	2
Length (semesters)	1	**Workload (hours)**	75
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	75
The following section is filled only if there is **exactly one** module-concluding exam.			
Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	1. Students can explain the advantages and disadvantages of audits. 2. They can apply terminology related to audits. 3. They can plan and prepare value-adding internal ISO 9001 audits. 4. They have gained initial experience in conducting value-adding internal system audits.		
Participation Prerequisites	Quality Management Module – Fundamentals		
The previous section is filled only if there is **exactly one** module-concluding exam.			
Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)		
Applicability			
Remarks			

Module Course: Audits – Basics and Practice

(of Module: Audits – Basics and Practice)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	yes	**ECTS Credit Points**	2,5
Participation Limit	12	**Semester Hours per Week**	2
Group Size	4	**Workload (hours)**	75
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	75
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	Fundamentals: 1. The QM audit within the management context 2. Audit planning and preparation 3. Conducting audits 4. Audit reporting and follow-up 5. Communication aspects of auditing 6. Certification 7. Interpretation of ISO 19011 for auditors 8. Potential audit evidence for ISO 9001 requirements Practical component: Practical tasks involving audit planning and preparation are addressed, and a remote audit is conducted in the form of a role-play exercise.
Literature	Online Course Notes - DIN EN ISO 9000 – Quality management systems – Fundamentals and vocabulary. Berlin: Beuth - DIN EN ISO 9001 – Quality management systems – Requirements. Berlin: Beuth

	- DIN EN ISO 19011 – Guidelines for auditing management systems. Berlin: Beuth With regard to standards, the current version always applies.
Remarks	Attendance at the web conferences is mandatory. The groups present the results of the practical assignments and receive feedback. A webcam is required for the remote audit. The "Audit Preparation" practical assignment constitutes the graded portfolio assessment.

Module: Basics of Business Administration

Level	Master	**Short Name**	BBA
Responsible Lecturers	Opresnik, Marc, Prof. Dr. Dipl.-Kfm.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory elective	**ECTS Credit Points**	2,5
Semester of Studies	3	**Semester Hours per Week**	2
Length (semesters)	1	**Workload (hours)**	75
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	75

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Written Exam	**Exam Language**	English
Exam Length (minutes)	60	**Exam Grading System**	One-third Grades

Learning Outcomes	In this module, students acquire fundamental knowledge of general business administration in the areas listed under "Course Content." They learn and practice the ability to handle business-related tasks and complex issues, and to solve, analyze, and discuss them in a nuanced manner. Students are able to: • explain key business administration concepts and apply them to practical and theoretical problems, • describe business functions as well as their content and tasks, • discuss and describe fundamental, overarching issues in business administration and within specific functional areas, • research concepts and methods in the literature in a targeted manner, • apply basic problem-solving methods—specifically, by adapting the general problem-solving process to specific problems, • analyze and independently solve basic (simple) problems in business administration and within functional areas, • recognize and articulate fundamental interrelationships within business administration.
Participation Prerequisites	

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods

	✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	Due to its orientation, the module can be used in all degree programs(see remarks).
Remarks	Knowledge of business administration is essential for all students who intend to assume leadership responsibilities in their future careers or as entrepreneurs.

Module Course: Basics of Business Administration

(of Module: Basics of Business Administration)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	2,5
Participation Limit		**Semester Hours per Week**	2
Group Size		**Workload (hours)**	75
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	75
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	Students gain an overview of business processes and issues. In addition to presenting and explaining fundamental business concepts and interrelationships, the course adopts a decision- and management-oriented perspective on business administration. Particular emphasis is placed on identifying and describing fundamental strategic and operational planning and decision-making problems, as well as outlining key elements of market-oriented corporate management and marketing. 1 Classification and development of business administration • 1.1 Business administration as a discipline • 1.2 Development of the field 2 Objectives, key performance indicators, and types of business entities • 2.1 The objective-setting process • 2.2 Corporate objectives • 2.3 The economic principle 3 Personnel and organization • 3.1 Fundamental objectives and tasks • 3.2 Classical organizational structures 4 Finance and accounting • 4.1 Overview

	• 4.2 Finance 5 Operational value creation process 3 09.08.2021 • 5.1 Overview of the operational value creation process • 5.2 Production management and manufacturing • 5.3 Sales policy instruments and the marketing mix
Literature	• Opresnik, M. / Rennhak, C.: Fundamentals of General Business Administration, 2nd ed., Wiesbaden, 2014 • Schierenbeck, H. / Wöhle, C. B.: Principles of Business Administration, 17th ed., Munich, 2008 • Wöhe, G.: Introduction to General Business Administration, 25th ed., Munich, 2013
Remarks	

Module: Basics of Marketing

Level	Master	**Short Name**	BM
Responsible Lecturers	Opresnik, Marc, Prof. Dr. Dipl.-Kfm.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory elective	**ECTS Credit Points**	2,5
Semester of Studies	3	**Semester Hours per Week**	2
Length (semesters)	1	**Workload (hours)**	75
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	75

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Project Work	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	In this course, students are introduced to key practical tools, approaches, and methods in the field of marketing. Through case studies, they have the opportunity to apply marketing and sales-related tools, concepts, and strategies to a concrete case example.		
Participation Prerequisites			

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	Due to its orientation, the module can be used in all degree programs(see remarks).
Remarks	Knowledge of marketing is essential for all students who intend to assume leadership responsibilities in their future careers or as entrepreneurs.

Module Course: Basics of Marketing

(of Module: Basics of Marketing)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	2,5
Participation Limit		**Semester Hours per Week**	2
Group Size		**Workload (hours)**	75
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	75
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	1 Fundamentals of Marketing 2 Analysis and Understanding of the Market Situation I 3 Analysis and Understanding of the Market Situation II 4 Fundamentals and Methods of Market Research 5 Formulation of Marketing Strategies 6 Product Policy 7 Pricing Policy 8 Distribution Policy 9 Communication Policy
Literature	• Opresnik, M. / Hollensen, S.: Marketing: Fundamentals and Practice: A Management-Oriented Approach, 2018 • Kotler, P., Keller, K., Opresnik, M.: Marketing Management, 15th ed., Pearson, Munich, 2017
Remarks	Marketing knowledge is essential for all students who wish to assume leadership responsibilities in their future careers or as entrepreneurs.

Module: Communication and Negotiation Skills

Level	Master	**Short Name**	CNS
Responsible Lecturers	Opresnik, Marc, Prof. Dr. Dipl.-Kfm.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory elective	**ECTS Credit Points**	2,5
Semester of Studies	3	**Semester Hours per Week**	2
Length (semesters)	1	**Workload (hours)**	75
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	75
The following section is filled only if there is **exactly one** module-concluding exam.			
Exam Type	Study Work	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	Students are familiar with fundamental communication and negotiation techniques and can successfully apply them in typical leadership conversations and in a negotiation of their own. They also learn to assess and manage the impact they have on others through their demeanor, language, and behavior during conversations.		
Participation Prerequisites			
The previous section is filled only if there is **exactly one** module-concluding exam.			
Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)		
Applicability	Due to its orientation, the module can be used in all degree programs(see remarks).		
Remarks			

Module Course: Communication and Negotiation Skills

(of Module: Communication and Negotiation Skills)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	2,5
Participation Limit		**Semester Hours per Week**	2
Group Size		**Workload (hours)**	75
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	75
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	1. Fundamentals of Communication 1.1 The importance of communication as a factor for success 1.2 Watzlawick's axioms of communication 1.3 The iceberg model of communication 1.4 Schulz von Thun's communication square 1.5 Self-esteem 1.6 Transactional analysis 1.7 Fundamentals of motivation 1.8 Feedback and its importance 1.9 The fundamentals of successful communication 2. Fundamentals of Negotiation 2.1 Preparation 2.2 Self-motivation 2.3 The greeting 2.4 Needs analysis 2.5 The presentation

	2.6 Handling objections 2.7 Closing 2.8 Follow-up
Literature	• Lürssen / Opresnik: The Hidden Rules of Career Success: How to Leverage Workplace Unwritten Laws for Your Success, 3rd ed., 2010 • Opresnik: The Secrets of Successful Negotiation: Negotiate Better – In Every Respect, 3rd ed., 2017 • Opresnik: Persuade! Successful Communication, Presentation, and Negotiation: Inspire People and Achieve More, 3rd ed., 2018 • Seifert: Visualizing – Presenting – Facilitating, 23rd ed., 2009
Remarks	

Module: Medical Technology Lab

Level	Master	**Short Name**	MTL
Responsible Lecturers	Müller, Stefan, Prof. Dr.-Ing.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory elective	**ECTS Credit Points**	2,5
Semester of Studies	3	**Semester Hours per Week**	2
Length (semesters)	1	**Workload (hours)**	75
Frequency	WiSe	**Presence Hours**	10
Teaching Language	English	**Self-Study Hours**	65
The following section is filled only if there is **exactly one** module-concluding exam.			
Exam Type	Project Work	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	The laboratory course deepens the theoretical knowledge gained in the Medical Technology I lecture through hands-on experience with selected equipment. Students gain insight into various standard procedures in medical technology. As a result, they are able to evaluate the functionality of new procedures.		
Participation Prerequisites			
The previous section is filled only if there is **exactly one** module-concluding exam.			
Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)		
Applicability			
Remarks			

Module Course: Medical Technology Lab

(of Module: Medical Technology Lab)

Course Type	Practical Training	**Form of Learning**	Presence
Mandatory Attendance	no	**ECTS Credit Points**	2,5
Participation Limit		**Semester Hours per Week**	2
Group Size		**Workload (hours)**	75
Teaching Language	English	**Presence Hours**	10
Study Achievements ("Studienleistung", SL)	Practical Training	**Self-Study Hours**	65
SL Length (minutes)		**SL Grading System**	One-third Grades

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	• Introduction (fundamentals, definitions, safety, balance between safety and efficacy/benefit) • Risk-based approach – risk management concepts • Regulatory framework and standards (technical standards) regarding safety: process standards, general product standards, and standards for specific products • Physical and mechanical safety • Electrical safety • Invasive blood pressure measurement • Biological safety • Functional safety • Safety in use – usability
Literature	1. Wintermantel E, Ha S-W: Medizintechnik – Life Science Engineering. 5th edition, Springer Heidelberg, Berlin (2009);ISBN: 978-3-540-93935-1 (e-ISBN: 978-3-540-93936-8) 2. Rüdiger Kramme (Ed.): Medizintechnik. 3rd edition; Springer Medizin Verlag Heidelberg (2007); ISBN-13 978-3-540-34102-4

	3. Alexander K, et al.: Good Design Practice for Medical Devices and Equipment – A Framework. University of Cambridge Engineering Design Centre (2001) ISBN 1-902546–08-3 4. Havel, P.: How to Design Safe Medical Products. Machine Design (2014) 62-69; ISSN: 0024-9114
Remarks	

Module: Pharmaceutical Law

Level	Master	**Short Name**	PL
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory elective	**ECTS Credit Points**	2,5
Semester of Studies	3	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	75
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	75

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Project Work	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes	1. Through the Pharmaceutical Law module, the student acquires the fundamental knowledge necessary to independently determine the regulatory qualification of medicinal products—including blood, blood products, and combination products. 2. The student is able to identify the key regulatory requirements relevant in Germany and the EU for the medicinal products in question and, on this basis, to develop and present a regulatory strategy for market authorization, including the applicable authorization procedures. 3. The student is able to compare the European authorization framework for medicinal products with the European framework for the placing on the market of medical devices. 4. The student is able to classify international approval concepts and recommendations (e.g. ICH, WHO) in the pharmaceutical field from a regulatory-scientific perspective and to compare and evaluate national or regional approval requirements with these.
Participation Prerequisites	

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	
Remarks	

Module Course: Pharmaceutical Law

(of Module: Pharmaceutical Law)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	2,5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	75
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	75
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	• Regulatory framework for medicinal products in the European Union • Definitions in the field of medicinal products • Aspects of demarcation between medicinal products, medical devices, cosmetic products • Key regulations governing medicinal products in Germany and in the EU • International recommendations for marketing authorization of medicinal products (ICH, WHO) • Authorities and committees • Marketing authorization procedures • Marketing authorization documentation • Specific aspects of preparing and submitting marketing authorization applications • Maintenance of marketing authorization
Literature	• European Pharmaceutical Law and related governmental guidance according to EudraLex with regard to pharmaceutical legislation for medicinal products for human use, see: • German Medicinal Products Act (in its current version) • ICH – relevant guidelines at • WHO – relevant guidelines at • Relevant articles and publication from the Regulatory Affairs Professional Society – RAPS

	• Niels Eckstein: Arzneimittel – Entwicklung und Zulassung [Medicinal Products – Development and Marketing Authorization]; for study and practice; 2nd, revised and expanded edition, 2018
Remarks	

Module: Project Management

Level	Master	**Short Name**	PM
Responsible Lecturers	Opresnik, Marc, Prof. Dr. Dipl.-Kfm.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory elective	**ECTS Credit Points**	2,5
Semester of Studies	3	**Semester Hours per Week**	2
Length (semesters)	1	**Workload (hours)**	75
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	75

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Study Work	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes	Students are introduced to the methods of modern project management and enabled to apply them when planning their own project.
Participation Prerequisites	

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	Due to its orientation, the module can be used in all degree programs(see remarks).
Remarks	Project management skills are essential for all students who intend to assume leadership responsibilities in their future careers or as entrepreneurs.

Module Course: Project Management

(of Module: Project Management)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	2,5
Participation Limit		**Semester Hours per Week**	2
Group Size		**Workload (hours)**	75
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	75
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	• Introduction to project management • Project organization • Project phases: development phase, planning, execution benchmarking, closure • Communication Leadership styles
Literature	• Lürssen / Opresnik: The Hidden Rules of Career Success: How to Leverage Workplace Unwritten Laws for Your Success, 4th ed., Frankfurt/ New York, 2014 • Opresnik: Project Management: A Systematic Path to Success – A Practical Guide with Numerous Tools, Checklists, and Templates, Lübeck, 2017 • Patzak / Rattay: Project Management, 5th ed., 2008
Remarks	

Module: Specific Topics related to Regulatory Affairs I

Level	Master	**Short Name**	STRA
Responsible Lecturers	n.d.		
Department, Facility	(Unspecified)		
Course of Studies	(Unspecified)		
Compulsory/elective	Elective	**ECTS Credit Points**	2,5
Semester of Studies	3	**Semester Hours per Week**	2
Length (semesters)	1	**Workload (hours)**	75
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	75
The following section is filled only if there is **exactly one** module-concluding exam.			
Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	Various		
Participation Prerequisites			
The previous section is filled only if there is **exactly one** module-concluding exam.			
Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)		
Applicability			
Remarks			

Module Course: Specific Topics related to Regulatory Affairs I

(of Module: Specific Topics related to Regulatory Affairs I)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	2,5
Participation Limit		**Semester Hours per Week**	2
Group Size		**Workload (hours)**	75
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	75
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	Various
Literature	Various
Remarks	

Module: Specific Topics Related to Regulatory Affairs II

Level	Master	**Short Name**	STRAII
Responsible Lecturers	n.d.		
Department, Facility	(Unspecified)		
Course of Studies	(Unspecified)		
Compulsory/elective	Elective	**ECTS Credit Points**	5
Semester of Studies	3	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150
The following section is filled only if there is **exactly one** module-concluding exam.			
Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	Various		
Participation Prerequisites			
The previous section is filled only if there is **exactly one** module-concluding exam.			
Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)		
Applicability			
Remarks			

Module Course: Specific Topics Related to Regulatory Affairs II

(of Module: Specific Topics Related to Regulatory Affairs II)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	Various
Literature	Various
Remarks	

TECHNISCHE HOCHSCHULE LÜBECK

Regulatory Affairs, Master

4th Semester of Studies

Module: Abschluss (Final Degree)

Level	Master	**Short Name**	AB
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	30
Semester of Studies	4	**Semester Hours per Week**	
Length (semesters)	1	**Workload (hours)**	900
Frequency	(Flexible)	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	900
The following section is filled only if there is **exactly one** module-concluding exam.			
Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			
The previous section is filled only if there is **exactly one** module-concluding exam.			
Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)		
Applicability			
Remarks			

Module Course: Master Thesis

(of Module: Abschluss (Final Degree))

Course Type	Project Work	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	27
Participation Limit		**Semester Hours per Week**	0
Group Size		**Workload (hours)**	810
Teaching Language	German/English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	810
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type	Thesis	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades
Learning Outcomes	In their final thesis, students demonstrate the ability—acquired during their studies—to think and act on a scientific basis within the field of Regulatory Affairs. They are familiar with the relevant regulations, methods, and strategies concerning regulatory aspects of medical devices; they independently apply these to regulatory-scientific issues and are capable of further developing them.		
Participation Prerequisites	Admission to the Master's thesis requires proof of completion of all coursework and examinations prescribed for the period up to the end of the second semester under the standard curriculum of the applicable study and examination regulations. However, up to two course requirements or examinations from the second semester may be completed subsequently.		

The previous section is filled only if there is a course-specific exam.

Contents	Written thesis on 6 months scientific work
Literature	• Statutory and normative regulations at national, European, and international levels, depending on the subject area of the master's thesis • National, European, and international guidelines regarding medical devices, including in vitro diagnostic medical devices • Course materials from the degree program
Remarks	

Module Course: Master Colloquium

(of Module: Abschluss (Final Degree))

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	yes	**ECTS Credit Points**	3
Participation Limit		**Semester Hours per Week**	0
Group Size		**Workload (hours)**	90
Teaching Language	German/English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	90
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type	Oral Exam	**Exam Language**	German/English
Exam Length (minutes)	60	**Exam Grading System**	One-third Grades

Learning Outcomes	In the final colloquium, students demonstrate their ability to present the content of their thesis in a timely manner and in accordance with academic principles, as well as to respond appropriately to unexpected—and potentially critical—questions. Furthermore, students demonstrate their ability to place the topic of the master's thesis within the broader context of the knowledge acquired during the degree program.
Participation Prerequisites	Admission to the oral final examination (colloquium) is conditional upon proof of completion of all academic requirements specified in the standard curriculum of the study and examination regulations, as well as a passing grade on the Master's thesis.

The previous section is filled only if there is a course-specific exam.

Contents	Presentation of the thesis results and discussion
Literature	• Lecture notes from university studies • Statutory and normative regulations at national, European, and international levels, depending on the master's thesis topic
Remarks	