TECHNISCHE HOCHSCHULE LÜBECK

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	

TECHNISCHE HOCHSCHULE LÜBECK

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	