TECHNISCHE HOCHSCHULE LÜBECK

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	