TECHNISCHE HOCHSCHULE LÜBECK

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	