Module Name: **Clinical Application and Regulatory Affairs**					
Module Number		**Level**	Master	**Short Name**	
Module Responsibility	Assoc. Prof. Dr Till Leissner SDU, Mads Clausen Institute				
Lecturers	Assoc. Prof. Dr Till Leissner (Clinical Application) Prof. Dr. sc. hum. Folker Spitzenberger, THL, Centre for Regulatory Affairs in Biomedical Sciences, (Regulatory Affairs)				

Module Number		**Level**	Master	**Short Name**	
Course of Studies	Medical Microtechnology, 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**	48		
Teaching Language	English	**Self-Study Hours**	192		
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	None				
Remarks	None				

Course 1: Clinical Application			
Course Number		**Short Name**	
Course Type	Lecture and project work	**Form of Learning**	Presence
Lecturer	Leissner		
Mandatory Attendance	☒	**ECTS Credit Points**	3

Participation Limit	None	**Semester Hours per Week**	2
Group Size (practical training, exercises, …)	n. a.	**Workload (hours)**	90
Teaching Language	English	**Presence Hours**	24
Study Achievements („Studienleistung“, SL)	Project work	**Self-Study Hours**	66
SL Length (minutes)	n. a.	**SL Grading System**	7-point grading scale
Exam Type	Oral exam	**Exam Language**	English
Exam Length (minutes)	20	**Exam Grading System**	7-point grading scale
Learning Outcomes	Knowledge • The students understand the basic principles of imaging techniques and image analysis methods relevant for clinical applications. • The students have knowledge about the regulatory guidelines for medical devices. Skills • The students are able to write a project formulation. • The students are able to develop a work plan to solve the given problem. • The students are able to choose relevant experimental techniques. • The students are able to plan, to setup an experiment. • The students can conduct experimental work and data analysis. • The students are able to document their work. • The students are able to present the results to a clinical/industrial partner. • The students are able to conduct project work in teams. • The students are able to reflect on regulatory limitations in project development. Competences • The students are able to work in teams. • The students are able to communicate with a client / external partner. • The students are able to present their project work and the results.		
Participation Prerequisites	None		

Contents	• Clinical sample preparation methods • Basic principles of image analysis, computational imaging and artificial intelligence for image analysis. • Lab-based imaging of biological samples with optical and non-optical methods. • Clinical imaging of biological samples		
Literature	Will be provided during the lectures.		
Remarks	None		
Course 2: Regulatory Affairs			
Course Number		**Short Name**	
Course Type	Lecture	**Form of Learning**	Online
Lecturer	Spitzenberger		
Mandatory Attendance	☒	**ECTS Credit Points**	2
Participation Limit	None	**Semester Hours per Week**	2
Group Size (practical training, exercises, …)	n. a.	**Workload (hours)**	60
Teaching Language	English	**Presence Hours**	24
Study Achievements („Studienleistung“, SL)	None	**Self-Study Hours**	66
SL Length (minutes)	n. a.	**SL Grading System**	n. a.
Exam Type	Written exam	**Exam Language**	English
Exam Length (minutes)	90	**Exam Grading System**	One-third grades
Learning Outcomes	• Knowledge: The relevant legal requirements concerning admission and certification of medical devices in the US and EU, amongst other countries, in addition to the basics in risk management • Skills: Application of risk management to the production process of a medical device according to standards. Concepts of CE-identification (certification). • Abilities: Application and implementation of the regular requirements during the processing of medical products (product safety). Dealing with risks in the market (declarations and regulatory actions risks).		
Participation Prerequisites	Basic knowledge in medical technology, application of medical products and quality management.		

Contents	• Requirements and procedures concerning CE-marking and quality management system certification according to the EU-Legislation based on New Approach 100a-directives. • Relevant directives addressing Medical Devices and comparison with US approval schemes. • Third party inspection/surveillance in EU and corresponding requirements in the USA and other markets. • Essential Requirements for safety and effectiveness, classification and conformity assessment procedures for medical devices. • Clinical evaluation and investigation • Application of risk management requirements and procedures to medical devices. • Implementing adverse event reporting, recalls and corrective/preventive actions in post market surveillance systems in the EU and in the USA. • Technical files and the role and use of Harmonized European standards for the certification and CE-marking. Requirements regarding Instructions for use and marking on the device.
Literature	Hand-out, RL 93/42/EG, 21 CFR 803, 806 und 820
Remarks	None