Module Regulatory Affairs

Module Name: Regulatoy Affairs

Module Number		Level Master	Short Name RA
Responsible Lecturers	Prof. Folker Spitzenberger		
Department, Facility	THL, Applied Natural Sciences		
Course of Studies	Biomedical Engineering, Master		
Compulsory/elective	Compulsory	ECTS Credit Points	2
Semester of Studies	2	Semester Hours per Week	2
Length (semesters)	1	Workload (hours)	50
Frequency	SuSe	Presence Hours	10
Teaching Language	English	Self-Study Hours	40
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	Biomedical Engineering		
Remarks	None		

Module Regulatory Affairs

Module Course Regulatory Affairs

Course 1 Regulatory Affairs

Course Number		Short Name	RA
Course Type	Lecture	Form of Learning	Online
Mandatory Attendance	☐	ECTS Credit Points	2
Participation Limit	None	Semester Hours per Week	2
Group Size (practical training, exercises, …)	n. a.	Workload (hours)	50
Teaching Language	English	Presence Hours	10
Study Achievements („Studienleistung“, SL)	n. a.	Self-Study Hours	40
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