

Module: Abschluss (Final Degree)

Level	Master	Short Name	AB
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	ECTS Credit Points	30
Semester of Studies	4	Semester Hours per Week	
Length (semesters)	1	Workload (hours)	900
Frequency	(Flexible)	Presence Hours	
Teaching Language	English	Self-Study Hours	900

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type		Exam Language	
Exam Length (minutes)		Exam Grading System	
Learning Outcomes			
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: Master Thesis

(of Module: Abschluss (Final Degree))

Course Type	Project Work	Form of Learning	Online supported
Mandatory Attendance	no	ECTS Credit Points	27
Participation Limit		Semester Hours per Week	0
Group Size		Workload (hours)	810
Teaching Language	German/English	Presence Hours	0
Study Achievements ("Studienleistung", SL)		Self-Study Hours	810
SL Length (minutes)		SL Grading System	

The following section is filled only if there is a course-specific exam.

Exam Type	Thesis	Exam Language	English
Exam Length (minutes)		Exam Grading System	One-third Grades
Learning Outcomes	In their final thesis, students demonstrate the ability—acquired during their studies—to think and act on a scientific basis within the field of Regulatory Affairs. They are familiar with the relevant regulations, methods, and strategies concerning regulatory aspects of medical devices; they independently apply these to regulatory-scientific issues and are capable of further developing them.		
Participation Prerequisites	Admission to the Master's thesis requires proof of completion of all coursework and examinations prescribed for the period up to the end of the second semester under the standard curriculum of the applicable study and examination regulations. However, up to two course requirements or examinations from the second semester may be completed subsequently.		

The previous section is filled only if there is a course-specific exam.

Contents	Written thesis on 6 months scientific work
Literature	• Statutory and normative regulations at national, European, and international levels, depending on the subject area of the master's thesis • National, European, and international guidelines regarding medical devices, including in vitro diagnostic medical devices • Course materials from the degree program
Remarks	

Module Course: Master Colloquium

(of Module: Abschluss (Final Degree))

Course Type	Online Course	Form of Learning	Online supported
Mandatory Attendance	yes	ECTS Credit Points	3
Participation Limit		Semester Hours per Week	0
Group Size		Workload (hours)	90
Teaching Language	German/English	Presence Hours	0
Study Achievements ("Studienleistung", SL)		Self-Study Hours	90
SL Length (minutes)		SL Grading System	

The following section is filled only if there is a course-specific exam.

Exam Type	Oral Exam	Exam Language	German/English
Exam Length (minutes)	60	Exam Grading System	One-third Grades
Learning Outcomes	In the final colloquium, students demonstrate their ability to present the content of their thesis in a timely manner and in accordance with academic principles, as well as to respond appropriately to unexpected—and potentially critical—questions. Furthermore, students demonstrate their ability to place the topic of the master's thesis within the broader context of the knowledge acquired during the degree program.		
Participation Prerequisites	Admission to the oral final examination (colloquium) is conditional upon proof of completion of all academic requirements specified in the standard curriculum of the study and examination regulations, as well as a passing grade on the Master's thesis.		

The previous section is filled only if there is a course-specific exam.

Contents	Presentation of the thesis results and discussion
Literature	• Lecture notes from university studies • Statutory and normative regulations at national, European, and international levels, depending on the master's thesis topic
Remarks	