TECHNISCHE HOCHSCHULE LÜBECK

Module: Pharmaceutical Law

Level	Master	**Short Name**	PL
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory elective	**ECTS Credit Points**	2,5
Semester of Studies	3	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	75
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	75

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

Exam Type	Project Work	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes	1. Through the Pharmaceutical Law module, the student acquires the fundamental knowledge necessary to independently determine the regulatory qualification of medicinal products—including blood, blood products, and combination products. 2. The student is able to identify the key regulatory requirements relevant in Germany and the EU for the medicinal products in question and, on this basis, to develop and present a regulatory strategy for market authorization, including the applicable authorization procedures. 3. The student is able to compare the European authorization framework for medicinal products with the European framework for the placing on the market of medical devices. 4. The student is able to classify international approval concepts and recommendations (e.g. ICH, WHO) in the pharmaceutical field from a regulatory-scientific perspective and to compare and evaluate national or regional approval requirements with these.
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: Pharmaceutical Law

(of Module: Pharmaceutical Law)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	2,5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	75
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	75
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 framework for medicinal products in the European Union • Definitions in the field of medicinal products • Aspects of demarcation between medicinal products, medical devices, cosmetic products • Key regulations governing medicinal products in Germany and in the EU • International recommendations for marketing authorization of medicinal products (ICH, WHO) • Authorities and committees • Marketing authorization procedures • Marketing authorization documentation • Specific aspects of preparing and submitting marketing authorization applications • Maintenance of marketing authorization
Literature	• European Pharmaceutical Law and related governmental guidance according to EudraLex with regard to pharmaceutical legislation for medicinal products for human use, see: • German Medicinal Products Act (in its current version) • ICH – relevant guidelines at • WHO – relevant guidelines at • Relevant articles and publication from the Regulatory Affairs Professional Society – RAPS

	• Niels Eckstein: Arzneimittel – Entwicklung und Zulassung [Medicinal Products – Development and Marketing Authorization]; for study and practice; 2nd, revised and expanded edition, 2018
Remarks	