

**Module: Introduction – Systematic Concepts and Legal Aspects**

|                              |                                     |                                |     |
|------------------------------|-------------------------------------|--------------------------------|-----|
| <b>Level</b>                 | Master                              | <b>Short Name</b>              | SLA |
| <b>Responsible Lecturers</b> | Wachenhausen, Heike, Prof. Dr. jur. |                                |     |
| <b>Department, Facility</b>  | Applied Natural Sciences            |                                |     |
| <b>Course of Studies</b>     | Regulatory Affairs, Master          |                                |     |
| <b>Compulsory/elective</b>   | Compulsory                          | <b>ECTS Credit Points</b>      | 5   |
| <b>Semester of Studies</b>   | 1                                   | <b>Semester Hours per Week</b> | 4   |
| <b>Length (semesters)</b>    | 1                                   | <b>Workload (hours)</b>        | 150 |
| <b>Frequency</b>             | WiSe                                | <b>Presence Hours</b>          |     |
| <b>Teaching Language</b>     | English                             | <b>Self-Study Hours</b>        | 150 |

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

|                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                            |                  |
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| <b>Exam Type</b>                   | Portfolio Exam                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Exam Language</b>       | English          |
| <b>Exam Length (minutes)</b>       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Exam Grading System</b> | One-third Grades |
| <b>Learning Outcomes</b>           | <ul style="list-style-type: none"> <li>• Students understand the framework of applicable regulatory requirements and can apply them to their specific issue or case scenario.</li> <li>• Students analyze regulatory terms and provisions and assign them to the appropriate category.</li> <li>• Students apply a nuanced understanding of regulatory areas of responsibility and the associated legal obligations and tasks in order to implement measures correctly and assign responsibilities accurately.</li> <li>• Students are able to discuss and weigh up legal aspects.</li> <li>• Students are able to reliably select applicable requirements for a specific issue and implement them in a structured manner.</li> <li>• Students are able to identify problems within the framework of regulatory requirements and develop potential solutions and alternatives.</li> <li>• When faced with differing perspectives on legal requirements, students work with the relevant stakeholders to develop a strategy for reaching a consensus.</li> </ul> |                            |                  |
| <b>Participation Prerequisites</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                            |                  |

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

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|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Consideration of Gender and Diversity Issues</b> | <ul style="list-style-type: none"> <li>✓ Use of gender-neutral language (THL standard)</li> <li>✓ Target group specific adjustment of didactic methods</li> <li>✓ Making subject diversity visible (female researchers, cultures etc.)</li> </ul> |
| <b>Applicability</b>                                |                                                                                                                                                                                                                                                   |

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| Remarks |  |
|---------|--|

## Module Course: Introduction – Systematic Concepts and Legal Aspects

(of Module: Introduction – Systematic Concepts and Legal Aspects)

|                                                       |               |                                |                  |
|-------------------------------------------------------|---------------|--------------------------------|------------------|
| <b>Course Type</b>                                    | Online Course | <b>Form of Learning</b>        | Online supported |
| <b>Mandatory Attendance</b>                           | no            | <b>ECTS Credit Points</b>      | 5                |
| <b>Participation Limit</b>                            |               | <b>Semester Hours per Week</b> | 4                |
| <b>Group Size</b>                                     |               | <b>Workload (hours)</b>        | 150              |
| <b>Teaching Language</b>                              | English       | <b>Presence Hours</b>          | 0                |
| <b>Study Achievements<br/>("Studienleistung", SL)</b> |               | <b>Self-Study Hours</b>        | 150              |
| <b>SL Length (minutes)</b>                            |               | <b>SL Grading System</b>       |                  |

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

|                                    |                |                            |                  |
|------------------------------------|----------------|----------------------------|------------------|
| <b>Exam Type</b>                   | Portfolio Exam | <b>Exam Language</b>       | English          |
| <b>Exam Length (minutes)</b>       |                | <b>Exam Grading System</b> | One-third Grades |
| <b>Learning Outcomes</b>           |                |                            |                  |
| <b>Participation Prerequisites</b> |                |                            |                  |

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

|                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Contents</b>   | <ul style="list-style-type: none"> <li>• Structure of regulatory requirements at European and national levels</li> <li>• Scope of application of regulatory requirements</li> <li>• Definition of medical devices and classification criteria</li> <li>• Competencies and responsibilities</li> <li>• Operation and use</li> <li>• Liability (including compliance, anti-corruption)</li> <li>• Advertising for medical devices</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Literature</b> | <ol style="list-style-type: none"> <li>1. Baumgartner/Harer/Schröttner, Medical Devices and In Vitro Diagnostics, Springer, 2023</li> <li>2. Gassner, Medizinprodukterecht: MP-VO   IVD-VO   MPDG, Nomos, 2025</li> <li>3. Vollebregt, The enriched MDR and IVDR, 2nd Edition, 2022</li> <li>4. European Commission: <a href="https://health.ec.europa.eu/medical-devices-sector/new-regulations_en">https://health.ec.europa.eu/medical-devices-sector/new-regulations_en</a></li> <li>5. MDCG-Guidance: <a href="https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en">https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en</a></li> <li>6. The 'Blue Guide' on the implementation of EU product rules 2022: <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC</a></li> </ol> |

7. Access to European Union Law: <https://eur-lex.europa.eu/homepage.html?lang=en>
8. Court of Justice of the European Union – Case law data base: <https://infocuria.curia.europa.eu/tabs/affair?lang=en>

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| <b>Remarks</b> |  |
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