

**Module: Practical Project**

|                              |                                  |                                |     |
|------------------------------|----------------------------------|--------------------------------|-----|
| <b>Level</b>                 | Master                           | <b>Short Name</b>              | PP  |
| <b>Responsible Lecturers</b> | Spitzenberger, Folker, Prof. Dr. |                                |     |
| <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>   | 3                                | <b>Semester Hours per Week</b> | 4   |
| <b>Length (semesters)</b>    | 1                                | <b>Workload (hours)</b>        | 150 |
| <b>Frequency</b>             | (Flexible)                       | <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.

|                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                            |                  |
|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------|
| <b>Exam Type</b>                   | Project Work                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Exam Language</b>       | English          |
| <b>Exam Length (minutes)</b>       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Exam Grading System</b> | One-third Grades |
| <b>Learning Outcomes</b>           | <p>The practical project enables students to apply the specialized knowledge acquired during their studies in a real-world setting relevant to their future careers. Students learn to implement regulatory requirements within practical workflows—for instance, by coordinating and managing European or international authorization procedures.</p> <p>The project combines practical work in the field of Regulatory Affairs with a scientific question related to regulatory matters.</p> <p>Ultimately, students enhance their ability to think and act in a regulatory context; the practical work may be carried out either within companies or within regulatory authorities (including the functions of Notified Bodies).</p> |                            |                  |
| <b>Participation Prerequisites</b> | Proof of all coursework and examination results from the first semester.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                            |                  |

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

|                                                     |                                                                                                                                                                                                                                                   |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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>                                |                                                                                                                                                                                                                                                   |
| <b>Remarks</b>                                      |                                                                                                                                                                                                                                                   |

## Module Course: Practical Project

(of Module: Practical Project)

|                                                       |              |                                |                  |
|-------------------------------------------------------|--------------|--------------------------------|------------------|
| <b>Course Type</b>                                    | Project Work | <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>                   |  | <b>Exam Language</b>       |  |
| <b>Exam Length (minutes)</b>       |  | <b>Exam Grading System</b> |  |
| <b>Learning Outcomes</b>           |  |                            |  |
| <b>Participation Prerequisites</b> |  |                            |  |

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

|                   |                                                                                                                                                                                                                                                                                                             |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Contents</b>   | During the practical project, students have the opportunity to apply the knowledge they have acquired in the field of Regulatory Affairs to practical, concrete projects.                                                                                                                                   |
| <b>Literature</b> | The literature used for the practical project depends on the project's specific topic. In principle, the projects are based on elements of European Regulation (EU) 2017/745, Regulation (EU) 2017/746, IMDRF/GHTF recommendations, further national, regional or international regulations and guidelines. |
| <b>Remarks</b>    |                                                                                                                                                                                                                                                                                                             |