

Guideline for the implementation of the practical project in the Master's degree program in Regulatory Affairs

1 In the standard curriculum, the practical project is scheduled for the third semester. The practical project must have a duration of 150 hours, i.e. approximately 4 full-time working weeks.

2 During the internship, students are given the opportunity to apply the knowledge they have acquired in the field of regulatory affairs in practice in specific projects.

3 Students must submit a completed form and a brief project description - including an outline of the technical content and timeline - to the chair of the study program committee before the start of the practical project. A supervisor will be appointed at the TH Lübeck to evaluate the practical project. After written confirmation by the chairperson of the degree course committee and the Dean's Office has checked the necessary preliminary work - successful completion of all examinations from the first semester - the project can begin.

4 The practical project can be carried out in laboratories and facilities of Lübeck University of Applied Sciences as well as in external institutions (e.g. universities, companies, authorities, etc.) in Germany or abroad. As a rule, however, the work is carried out in the institutions where the student is employed. A supervisor is appointed there whose impressions can be taken into account in the final assessment of the practical project.

5 The practical project should provide students with sound skills in dealing with regulatory requirements as well as special skills, such as the coordination and management of international approval processes. Comprehensive knowledge of the legal and normative framework conditions to which companies that place medical devices on the market are bound should be applied in practice. The practical project must have a recognizable connection to the course content. The practical project must be self-contained and its content must be distinct from the Master's thesis. Project content can be freely chosen by the students, taking into account the requirements set out here.

6. Evidence of the practical project must be provided in the form of an appropriately sized project report, which must be submitted to the chair of the degree program committee within four weeks of completion of the project. This can be done in paper form or electronically. The written project report is assessed as an examination by the supervisor at TH Lübeck.