Study Plan for MAS Study Program in Regulatory Affairs and Quality Management

15 March 2024

The study program in Regulatory Affairs and Quality Management is a continuing education program leading to the award of the Master of Advanced Studies in Regulatory Affairs and Quality Management, Universität Bern (MAS RAQM Unibe).

The legal basis is the Regulations of the Faculty of Medicine for Continuing Education and the “Reglement für die Weiterbildungsstudiengänge in Regulation in Translational Medicine” from 24 April 2024.

1. Objectives, Scope and Structure of the Study Program

Objectives MAS RAQM

The participants:

- *a* pursue the objectives of the CAS in Regulatory Affairs,
- *b* pursue the objectives of the CAS in Quality Management in Translational Medicine,
- *c* pursue the objectives of the CAS in Advanced Regulatory Affairs,
- *d* apply their acquired knowledge in a MAS thesis.

Scope and Structure MAS RAQM

The MAS Regulatory Affairs and Quality Management comprises at least 60 ECTS credits (approx. 1500-1800 working hours) and consists of the following elements:

- *a* the successfully completed CAS Regulatory Affairs (15 ECTS)
- *b* the successfully completed CAS Quality Management (15 ECTS)
- *c* the successfully completed CAS Advanced Regulatory Affairs (15 ECTS)
- *d* a MAS thesis (15 ECTS)

The detailed description of the modules can be found in the appendix to the study plans of the CAS study programs.

Language

The course language in all modules is English. All performance assessments (module assessments, written assignments, presentations) are conducted in English.

2. Performance Assessments

Thesis

MAS Thesis
15 ECTS

In the MAS thesis, participants will describe an in-depth critical evaluation of a regulation and/or its implementation, or they scrutinize and

assess the implementation of a quality management system and develop a strategy to improve or analyse parts of such system, or, provide a description of the application of regulations to a novel medical product or new technology.

Details are provided in the guidelines to the thesis.

Internship

Participants of the MAS program who have no professional experience in a relevant field must complete an internship related to regulatory affairs and/or quality management in translational medicine.

The internship must be approved in written form by the program management before it begins.

The minimum duration of an internship is 8 weeks based on fulltime employment. The minimum degree of employment is 40 percent with a corresponding extension of the internship duration.

For the internship to be recognized, an activity report must be prepared. This report must contain the signature of the HR manager of the employer and/or line manager. If the report is recognized, 5 ECTS are credited for the internship.

Performance Assessment

The module assessments are described in the study plans of the CAS study programs.

Performance assessment is governed by the study regulations. Unsatisfactory performance assessments can be repeated once. The repetition must take place no later than 3 months after the written notification of the participant.

The Study Commission decides based on the assessment of the performance records and the fulfilment of the other performance requirements on the passing of the examination and the award of the MAS title.

Implementing provisions

Further details are regulated in the guidelines of the program.

3. Final Provisions

Entry into force

This study plan enters into force on 1 June 2024.

Decided by the Study Commission:

Bern, 15 March 2024 The Chairman

Prof. Dr. Rudolf Blankart

Approved by the Faculty of Medicine:

Bern, 24 April 2024 The Dean

Prof. Dr. Claudio Bassetti