

Study Plan for the CAS Study Program in Regulatory Affairs



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UNIVERSITÄT
BERN

15 March 2024

The study program in Regulatory Affairs is a continuing education program leading to the award of the Certificate of Advanced Studies in Regulatory Affairs, Universität Bern (CAS RA 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 CAS RA

The participants:

- a are familiar with the regulatory requirements, processes, and terms in all life cycle phases of a therapeutic product in the European market,
- b are familiar with the regulatory environment and European legislation,
- c are able to initiate and accompany the introduction and monitoring of a therapeutic product on the European market.

Scope and Structure
CAS RA

The CAS Regulatory Affairs comprises at least 15 ECTS credits (approx. 375-450 working hours). It is made up of 3 compulsory modules totaling 15 ECTS credits.

The detailed description of the modules can be found in the appendix to the study plan. The Study Commission may extend and adapt the catalogue of modules.

Language

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

2. Performance Assessments

Performance Assessment

Written and/or oral assessment per module in the form of quizzes and/or exercises and/or group works and/or presentations and/or final examinations. A final grade will be given for each of the modules.

The specific form of the module assessments can be found in the module tables in the appendix to the study plan.

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.

³ 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 CAS degree.

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