

REGULATORY AFFAIRS FOR BIOPHARMACEUTICALS INCLUDING ATMPs

(Seminars and Postgraduate Master Course)

Study Regulations

These Study Regulations, adopted by the Scientific Course Committee of the European Centre of Regulatory Affairs Freiburg (EUCRAF), Germany, as outlined in § 10, apply to the Postgraduate Master Course “Regulatory Affairs for Biopharmaceuticals including ATMPs”.

§ 1 SCOPE

These study regulations stipulate the objectives, content and structure of the Postgraduate Master Course “Regulatory Affairs for Biopharmaceuticals including ATMPs”.

§ 2 OBJECTIVES OF STUDY

1. The subject area Regulatory Affairs ensures that the proof of the quality, safety and efficacy of the medicinal product is demonstrated to be in line with legal requirements for the purposes of marketing safe and efficacious medicinal products solely in the interests of public health. The postgraduate course specializes in regulatory affairs for biopharmaceuticals including ATMPs. European and international particulars are covered.
2. The objective of the practice-oriented, postgraduate course is to acquire or further develop the expertise and experience required for a Regulatory Affairs professional for biopharmaceutical products. This also allows preparation for management positions in this area at companies, authorities and associations.
3. By participating in the course, while also using new media, collaborating in practice-relevant case studies and by developing relevant topics, the students will gain expertise and skills enabling themselves to fulfill the role of a Regulatory Affairs professional.

§ 3 COURSE STRUCTURE

The course consists of a series of free-standing Seminars according to § 7. Nine Seminars are offered each year and the lectures must be attended by the students of the course. The on-site lectures are mainly given in Freiburg/Germany. Other locations might be arranged and will be announced in due course prior to the date of the relevant Seminar. The course regularly starts in September and lasts one year, with the opportunity to complete in the following year those parts of the course which have been missed, to take the outstanding examinations and to submit the required thesis. In addition, the option is offered to start the course with any Seminar.

Exams are conducted as outlined in the Examination Regulations. The exam is scheduled for the last day of the Seminar. Every Seminar requires home study of certain topics specified by the course leaders. The case studies are discussed and evaluated via webinars.

Home study and case study preparation need to be documented in an individual course diary.

To successfully complete the course with the award of the Master Certificate, students must also submit a thesis.

Students wishing to attend only single Seminar for specified training in particular topics will be awarded a Certificate for attendance of these specific Seminars.

§ 4 ADMISSION REGULATIONS

The Admission and Examination Committee shall decide on the suitability and admissibility of prospective students. The details are specified in the Entry Requirements.

§ 5 STUDY CREDITS

Study periods, study credits and graded examinations from comparable courses of study will be recognised as defined by § 9 of the Examination Regulations by the Admission and Examination Committee, provided they are equivalent.

§ 6 COMMENCEMENT AND DURATION OF STUDY

The study regularly commences in September or can be started with any Seminar of the course year. The course of study is offered in nine Seminars of variable duration each. The study can be extended to two years. The specific days of the single Seminars are published on the website of EUCRAF, www.EUCRAF.eu.

§ 7 CONTENT AND SCOPE OF STUDY

The entire course programme is equivalent to 60.1 credit points (CP): 45.1 credit points for the obligatory Seminars, 15 credit points for the final thesis including its presentation. One credit point is equivalent to 25 hours of "Student Investment Time". Credit points are awarded in line with ECTS (1 ECTS point corresponds to about 25 hours of work). The scope and topic of the Seminars are described in the list appended to these Study Regulations. Updates may be made to both the scope and the content. Appendix 1 specifies the topics within the individual Seminars, describing their scope and the specific teaching concept for each course.

§ 8 COURSES AND STUDY RELATED EXAMINATIONS

1. The course is conducted as lectures and seminars pertaining to the case studies. Other means of instruction, such as exercises, study projects, colloquia, tutorials or field trips, may be employed.
2. The course language is English.
3. During the period of the course, examinations will be held on each Seminar. A final thesis must also be prepared.
4. The nature, scope and requirements of the respective examinations will be announced at the start of each course.

§ 9 STUDY COORDINATION

Study coordination is the responsibility of the Study Director according to § 11, in collaboration with the Course Secretariat. Study advisory services to students are provided by the Course Secretariat of the EUCRAF. The Course Secretariat is responsible for conducting all logistical and organisational matters.

§ 10 SCIENTIFIC COURSE COMMITTEE

EUCRAF establishes a Scientific Course Committee which is responsible to adopt the scope and content of the programme. It constantly evaluates the programme in its relevance for potential future developments and changes. This committee furthermore

- appoints the members of the Admission and Examination Committee
- appoints the Study Director
- adopts the Study Regulations, the Guideline on the entry requirements and Examination Regulations of the course.

The Scientific Course Committee is composed of up to 20 members including representatives of European Regulatory Authorities, of the European Directorate for the Quality of Medicines and Health Care (EDQM), of pharmaceutical companies, of the University Strasbourg, of the Albert-Ludwigs University Freiburg, the founding members of EUCRAF and the Study Director. The members of the Scientific Course Committee are involved in the faculty as lecturers.

§ 11 STUDY DIRECTOR

1. The Scientific Course Committee appoints a Study Director for the course for a period of five years, which is renewable. The Study Director is responsible for the
 - preparation of the educational programme
 - evaluation of the need to update it
 - content of the course website and brochure.
2. The Study Director coordinates the work of the Scientific Course Committee and of the Admission and Examination Committee.
3. The Study Director is the main point of contact for students attending the course or for potential candidates.

§ 12 ADMISSION AND EXAMINATION COMMITTEE

1. An Admission and Examination Committee, consisting of up to five members, shall be appointed to select admissible candidates as well as to organise and implement the tasks as required by the Examination Regulations.
2. One member of the Scientific Course Committee, the Study Director, and three experts who are internationally acknowledged in the special subject of biopharmaceutical regulatory affairs, shall make up the Admission and Examination Committee.
3. The members of the Admission and Examination Committee are appointed for a period of five years. They may be reappointed. The Committee shall appoint one of its members as Chairperson. Any member may request the Chairperson to convene a Committee meeting.
4. The Admission and Examination Committee is responsible, in particular, for:
 - Selection of students for the course
 - Appointment of examiners
5. The Admission and Examination Committee shall ensure that the Examination Regulations are fulfilled. It will report regularly on examination dates, study times and the actual running times of the final written paper, provide suggestions for revision of the Examination Regulations and disclose the allocation of individual and overall grades.
6. The Chairperson of the Admission and Examination Committee may make a decision alone in the case of urgent matters which are the responsibility of the Admission and Examination

Committee; he must inform the Admission and Examination Committee thereof without delay.

7. The members of the Admission and Examination Committee have the right to be present when examinations are taking place.
8. The members of the Admission and Examination Committee are sworn to confidentiality.

Version: June 2010

Annex to the Study Regulations

List of Seminars of the course with credits and ECTS assignment

	Semester	Credits
Credit Points:		60
European pharmaceutical regulatory environment	1	3
Regulatory procedures in the EU, USA, Japan and others regions	1	3
Mode of action and side effects of biopharmaceuticals and particulars of their development	1	3
Particulars of authorization of biopharmaceuticals including biosimilairs and advanced therapies	1	6
Specific considerations for the development and authorization of medicinal products for children	2	3
Pharmacovigilance- Post authorization surveillance standards to meet regulatory requirements for product safety	2	3
The essential characteristics of quality systems	2	3
Regulatory strategy and health technology assessment to bridge drug discovery and regulatory affairs efficiently	2	3
Essential skills of and tools for the regulatory affairs professional : communication and interaction, project management and media tools	2	3
Thesis	1 / 2	30