

## **REGULATORY AFFAIRS FOR BIOPHARMACEUTICALS INCLUDING ATMPs**

(Seminars and Postgraduate Master Course)

### **Examination Regulations**

These Examination Regulations, adopted by EUCRAF – European Centre of Regulatory Affairs Freiburg, Germany, apply to the Postgraduate Master Course “Regulatory Affairs for Biopharmaceuticals including ATMPs”.

#### **§ 1 PRINCIPLES OF ASSESSMENT OF SUCCESSFUL ATTENDANCE OF THE COURSE**

Examinations as outlined in § 7 are conducted in all nine Seminars of the Postgraduate Master Course “Regulatory Affairs for Biopharmaceuticals including ATMPs”. Students also need to prepare for and participate in case studies for all Seminars as outlined in § 7. Every Seminar requires home study of certain topics specified by the course leaders.

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 and present it.

#### **§ 2 AIM OF EXAMINATION**

By passing the examination the students demonstrate that they have gained knowledge and skills relevant for a regulatory affairs professional as specified in § 2 of the Study Regulations.

#### **§ 3 DEGREE**

The entire course programme is equivalent to 60.1 ECTS. Upon successful completion of the course a Master Certificate “Regulatory Affairs for Biopharmaceuticals including ATMPs” is awarded by the European Centre of Regulatory Affairs Freiburg (EUCRAF).

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

#### **§ 4 DURATION OF STUDY**

The course consists of a series of free-standing Seminars according to § 7 of the Study Regulations. Nine Seminars are offered each year with a duration of 2 to 5 days and must be attended by the students of the course. The Saturday of the week of the Seminar is reserved for course students to discuss the content of the Seminar, to prepare themselves and to sit the exam for this Seminar. The programme starts in September and lasts one year, with the opportunity to complete in the following years those parts of the course which have been missed and to submit the required thesis.

#### **§ 5 ADMISSION AND EXAMINATION COMMITTEE**

1. The Admission and Examination Committee appointed as defined by § 12 of the Study Regulations appoints examiners and is responsible for awarding the results as outlined in § 11.
2. 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.

3. The members of the Admission and Examination Committee have the right to be present when examinations are taking place.
4. The Course Secretariat is responsible for conducting all logistical and organisational matters.

#### § 6 EXAMINERS

Lecturers who have taught during the course, or recognised experts working in the field of regulatory affairs, may be appointed as examiners. Reappointment is possible. The names of the examiners are announced well in advance. Students may propose the names of examiners, though this does not substantiate a claim.

#### § 7 TYPE AND EXTENT OF THE ASSESSMENT OF SUCCESSFUL ATTENDANCE OF THE COURSE

1. Each Unit is concluded with an examination (see § 7 of the Study Regulations). Examination is conducted as self examination (multiple choice) or presentation of assessment of a case study. In addition, case study preparation and conduct of the group work followed in the conduct, preparation and approval of a study diary on the home study topics and case study preparation and plenary presentations, will also be examined.
2. The final thesis encompasses 30, and not more than 50 pages.

#### § 8 EXAMINATION ENTRY

1. Registration to enter the first study-related examination represents the commencement of the examination process. Only those candidates may be entered who have been admitted to the Postgraduate Master Course “Regulatory Affairs for Biopharmaceuticals including ATMPs” as defined by § 3 of the Admission Regulations. Those candidates who have successfully completed all Seminars and study-related examinations, and have regularly attended the courses as defined by the Study Regulations, may be admitted for the final thesis.

#### § 9 RECOGNITION OF STUDY PERIODS, STUDY CREDITS AND GRADED EXAMINATIONS

1. Study periods, study credits and graded examinations from other courses of study are acknowledged, provided they are proven to be equivalent. They are equivalent if the study periods, study credits and graded examinations correspond to a large extent in their content, scope and requirements to those of the Postgraduate Master Course “Regulatory Affairs for Biopharmaceuticals including ATMPs”. A schematic comparison is noted, but rather an overall review and assessment.
2. If studies and graded examinations are acknowledged, the grades – as far as the grading systems are comparable – are accepted and incorporated in the calculation of the overall grade. If the grading systems differ, the grade “passed” is accepted. Reference may be made to such recognition in the certificate.

#### § 10 FINAL WRITTEN THESIS

1. The final written thesis is a component of the academic training. With such a written paper, the candidates must demonstrate that they have acquired the expertise and skills relevant for a regulatory affairs professional.
2. The thesis is to be written in English.

3. The topic is assigned on the basis of the candidate's proposal and the agreement of the tutor. The candidate can recommend a tutor with practical experience for the purposes of planning, executing and elaborating the written thesis. Students may make their own suggestions regarding tutors.
4. The topic of the thesis must be designed in such a way that it can be completed within approximately 3 months. If justified, an application for extension of the period by a maximum of three months may be granted. The topic of the thesis may be abandoned only once, and only during the first month of the processing period.
5. The thesis can be written as an individual work, or group topic by two or three students, provided the contribution of each person to be graded can be clearly discerned and assessed.
6. The work must be submitted in duplicate to the Admission and Examination Committee. Submission must be recorded. The paper should be accompanied by a written declaration, stating that the work (or for group topics the respective sections) has been prepared independently and no other resources other than those stated have been used.
7. The work will be assessed by the tutor as the first examiner, and then by a further examiner. § 12 applies, accordingly, to the assessment. Should the assessments of the examiners differ, the arithmetic mean will be taken as the grade. Should one examiner, in contrast to the other, award a grade of "not sufficient", the Examination Committee shall appoint a third examiner. Should the grades for the work differ by more than one whole grade, the Examination Committee may likewise appoint a third examiner. The work is accepted if two examiners achieve a grade of at least "sufficient"; the grade is derived in such cases from the mean of the two best individual scores. The outcome of the assessment should be available within four weeks of submission of the paper, in the form of a written appraisal submitted to the Chairperson of the Admission and Examination Committee.

#### § 11 ASSESSMENT OF ACADEMIC PERFORMANCE

1. The performance of the student is documented by a local and an ECTS grade:

##### LOCAL GRADE:

- 1.0–1.5 = Excellent – outstanding performance with only minor errors
- 1.6-2.5 = Very good – above average standard but with some errors
- 2.6-3.5 = Good – generally good work with a number of notable errors
- 3.6-3.9 = Satisfactory – fair but with significant shortcomings
- 4.0 = Sufficient – passable performance, meeting the minimum criteria
- Above 4.0: Fail (see below)

##### ECTS GRAD:

- A best 10%
- B next 25%
- C next 30%
- D next 25%
- E next 10%
- FX Fail – some more work required before the credit can be awarded
- F Fail – considerable further work is required

2. The final examination has been passed if the exams of the Units and the final written thesis have all been assessed as at least “sufficient”. The overall grade of the final examination is “Fail” if one of the two examinations was assessed as a “Fail”.
3. The results of the study-related exams, assessment of the case studies, assessment of the student diary and the final written thesis are all included in the overall assessment. Of the results from the study-related exams in the Units, the student may select four to be included in the overall assessment.
4. The overall grade of the course degree is calculated as follows: 60% from the grades of the study-related exams weighted by study points, 20% from the performance during the study (case studies student diaries) and 20% from the final written paper and assessments. Overall grades are derived from the arithmetic means of the individual grades. The overall grade is as follows:

FROM AN AVERAGE:

1.0-1.5 = Excellent

1.6-2.5 = Very good

2.6-3.5 = Good

3.6-3.9 = Satisfactory

4.0 = Sufficient

Above 4.0: Fail

5. On conclusion of the examination, the Admission and Examination Committee determines the overall grade and immediately informs the candidates thereof in writing. If the examinations have not been passed, information will be provided on whether and to what extent examinations may be repeated to gain the Master Certificate.
6. If the final examination is not passed, a written attestation of the examinations which have been attained and not yet taken may be issued, upon request.

#### § 12 REPEAT EXAMINATION

1. If a study-related examination is not passed, the student may retake the exam once. If this examination is also not passed, the Admission and Examination Committee shall decide if it may be retaken a second time.
2. A final written thesis may be repeated only once, on a new topic.

#### § 13 DEFAULT, WITHDRAWAL, DECEIT

1. Should a candidate fail to submit a final thesis without cause or fail to take an examination without cause, this will be regarded as a fail.  
The final written thesis is also regarded as “not sufficient” (failed) if it is not submitted on time or an application for extension has not been submitted by the due date.
2. If good reason is claimed for the default or withdrawal, written notification and substantiation must be sent to the Admission and Examination Committee immediately. In the event of sickness, a doctor’s certificate must be presented. If the reasons are accepted, a next examination date will be set. Examinations already graded will be acknowledged.
3. Should a candidate attempt to influence the outcome of a graded examination by deceit or use of inadmissible resources, the respective examination will be graded as “not sufficient” (failed).

4. If such deceit first becomes apparent after the examination process, paragraph (3) shall apply accordingly. Any certificate already issued shall be retracted.
5. Prior to such a decision, the candidate is given the opportunity to comment.

#### § 14 CERTIFICATES

1. Participants having attended individual Seminars of the Postgraduate Master Course “Regulatory Affairs for Biopharmaceuticals including ATMPs” but not taking an examination may be issued confirmation of such. This certificate is issued by EUCRAF.
2. Participants who have attended single Seminars of the Postgraduate Master Course “Regulatory Affairs for Biopharmaceuticals including ATMPs” receive a certificate of attendance.
3. Participants having completed the entire course and final examination receive a certificate Postgraduate Master Course “Regulatory Affairs for Biopharmaceuticals including ATMPs”. The certificate also contains the individual grades of all examinations, the overall grade and the topic of the final thesis. The certificate is issued on the date of the last examination. It bears the seal of the company and signature of the Chairperson of the Admission and Examination Committee.

#### § 15 INSPECTION OF EXAMINATION RECORDS

Upon conclusion or discontinuation of the examination process, the candidate may be granted access to the examination records.

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