

Rhenish
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Official Notices

Content:

Examination regulations for the postgraduate Master's course
"Drug Regulatory Affairs"
of the Faculty of Mathematics and Natural Sciences
of the Rhenish Friedrich-Wilhelm University of
Bonn

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Examination regulations
for the postgraduate Master's Course
“Drug Regulatory Affairs”
of the Faculty of Mathematics and Natural Sciences
of the Rhenish Friedrich-Wilhelm University of Bonn,
dated 15 September 2009

In accordance with §§ 2, 4 and 64 section 1 of the Universities Act of the Federal state of North-Rhine Westphalia (*Hochschulgesetz - HG*) in the version of the Higher Education Autonomy Act (*Hochschulfreiheitsgesetz - HfG*) of 31 October 2006 (gazette of laws and ordinances, GV. NRW p. 474), last modified by Article 2 of the Teacher Training Reform Act of 12 May 2009 (GV. NRW p. 308), the Faculty of Mathematics and Natural Sciences at the Rhenish Friedrich-Wilhelm University of Bonn has enacted the following examination regulations:

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Appendix 1: Module plan**Appendix 2: Aptitude Test**

§ 1 Aim of the course and purpose of the examination

- (1) The postgraduate Master's course "Drug Regulatory Affairs" is offered by the Faculty of Mathematics and Natural Sciences at the Rhenish Friedrich-Wilhelm University of Bonn. Its structure is targeted towards practical applications.
- (2) The Master's examination constitutes an additional professional qualification which concludes an application-focused, more extensive academic course of training in the field of the pharmaceutical sciences.
- (3) The aim is for the participants to learn to deal with complex problems and to solve them by using scientific methods which may even exceed the current frontiers of knowledge.
- (4) The course is an interdisciplinary course covering the areas pharmaceutical sciences, medical sciences and law. The aim of the course is to convey knowledge about chemical, pharmaceutical, pharmacological, toxicological and clinical content of marketing authorisation documentation and its evaluation, and, in addition, about information science, drug development, drug safety, quality control and management, pharmaceutical legislation in Europe and in important areas outside Europe as well as marketing authorisation strategies. This is done by means of a focused practice-oriented postgraduate course.
- (5) For the appropriate structure of the course a curriculum is compiled which can be modified if required in order to take individual circumstances into consideration.
- (6) Candidates from any country may apply for admission to the Master's course. The teaching and examination languages are German and English.

§ 2 Academic degree

Upon passing the Master's Examination, the Faculty of Mathematics and Natural Sciences of the Rhenish Friedrich-Wilhelm University of Bonn will award the academic degree of 'Master of Drug Regulatory Affairs' (M.D.R.A.).

§ 3 Criteria for admission

- (1) Anyone who satisfies one of the following admission criteria set out in points 1 to 6 may be admitted upon application:
 1. a degree in the State Examination (*Staatsexamen*) courses in Pharmaceutics, Medicine or Veterinary Medicine,
 2. a degree in Chemistry (Diploma), Biology (Diploma), as a state-registered food chemist or another Diploma degree in the field of Natural Sciences,
 3. a first degree obtained in the EU lasting at least six semesters (Bachelor) in Pharmaceutics and another science subject, in particular, Biology, Chemistry or Food Chemistry,
 4. a first degree obtained at a university outside the EU after evaluation of the scope of the course has been made,

5. a first degree at a university of applied sciences (*Fachhochschule*) or a comparable higher education institution within or outside the EU, obtained in a course in a field related to points 1 or 2 above with the grade 2.0 or above after evaluating the scope of the course or
6. a degree accepted as equivalent by the examining board

In addition:

7. sufficient knowledge of German and English in accordance with the requirements set out in Appendix 2 of these regulations,
8. in the case of a higher education degree in accordance with points 1 and 2 or ten semesters of study at least one year of professional experience, after a maximum of six semesters of study or a degree listed under point 4, three years of professional experience at the beginning of the course,
9. has passed the Aptitude Test according to the regulations in Appendix 2 of these regulations.

(2) Admission is at the discretion of the board of examiners within the limits of the places available on the course. If the number of applications satisfying the criteria according to section 1 exceeds the number of available places on the course, the board of examiners will decide on the basis of the application documents and the results of the aptitude test procedure (Appendix 2).

(3) Admission as special auditor takes place on payment of the required tuition fees.

(4) Applicants who satisfy one of the requirements according to section 1 points 1 - 6 and the requirement listed under point 7 yet only wish to participate in one part of the modules can be admitted to this postgraduate course as individual-module applicants after assessment of the places available has been made. They are not required to complete course work, take part in the written or oral examination or write a Master's thesis. They will receive a certificate confirming their participation.

(5) The application for admission to the Master's course or postgraduate study must be submitted to the German Society for Regulatory Affairs (*Deutsche Gesellschaft für Regulatory Affairs*, DGRA) and addressed to the board of examiners, which decides on admissions.

(6) Admission to the Master's course must be declined if

- a) none of the requirements listed under section 1 points 1 to 6 are fulfilled or
- b) proof of language skills was not submitted or
- c) the Aptitude Test to determine the suitability for this particular course was not passed or
- d) application documents are incomplete or
- e) the final attempt at a relevant examination was failed or
- f) despite the basic admission criteria being satisfied, the number of available places is exhausted.

(7) The applicant must be informed in writing about the decision on the application for admission to the Master's course or to postgraduate study. The letter must contain information on the applicant's statutory rights.

§ 4 Duration and scope of the Master's course

- (1) The standard period of study including the placement and the Master's examination is four semesters (120 credit points).
- (2) The course comprises 60 CPs of modules from the compulsory section and an additional 30 CPs for a 6-month placement. The Master's thesis counts as 30 CPs.
- (3) The theory section of the course will be taught in 12 modules (Appendix 1). Teaching is spread over two semesters.
- (4) Every module is concluded with an assessed module examination, which can also consist of several assessment areas and is evaluated by credit points according to the ECTS (European Credit Transfer and Accumulation System). One of the assessment areas is usually assessed course work. One ECTS credit point corresponds to a calculated work load of 30 hours.
- (5) During the course, a placement with a total duration of six months of full-time work must be completed in the area of 'Drug Regulatory Affairs' or a related area.
- (6) The course content is selected and restricted in such a way that the course can be completed within the standard period of study. With the permission of the board of examiners, participation in the modules can be extended over a period of up to three years, with the total duration of the course lasting up to four years.
- (7) Teaching is in German or English.

§ 5 Status and tuition fees

- (1) For the participation in the Master's course, tuition fees must be paid as laid down by the University of Bonn regulations governing the tuition fees and other fees (status: special auditor). The participants in the postgraduate course according to § 62 section 3 clause 2 HG pay a special auditor fee for the individual modules chosen.
- (2) The amount of fees is calculated on the basis of the sum of the projected costs divided by the projected numbers of participants. It amounts to at least €100.00 per semester.

§ 6 Access to individual classes

If, due to the nature or purpose of the course or for any other reasons related to research or teaching, the number of participants in an individual class needs to be restricted and the number of applications exceeds this capacity, the dean of the Faculty of Mathematics and Natural Sciences, on application by the lecturer concerned, will determine the question of participation on the basis of § 59 HG.

§ 7 Examinations Office of the Faculty

- (1) For the organisation of examinations and the tasks assigned by these examination regulations the Faculty of Mathematics and Natural Sciences will establish an Examinations Office. This is headed by the dean. The Examinations Office is an official body as outlined by administrative procedural law and the code of administrative practice. The dean delegates certain tasks set out in these examination regulations to the board of examiners of the course. This board is active in exercising these functions as a body of the Examinations Office.
- (2) The Examinations Office ensures that the conditions of these examination regulations will be fulfilled and sees to the proper conduct of examinations. It is responsible in particular for the decisions on objections to the decisions made in the examination process.
- (3) Directives, the setting of deadlines and other announcements by the Examinations Office which not simply affect individual persons will be made public by notices or in electronic form while respecting data protection. These notices will be legally binding. Any other additional notices are permitted, but not legally binding.

§ 8 Board of examiners

- (1) The board of examiners consists of one chairperson, a deputy chairperson and four other members. The members of the board of examiners are nominated by the dean of the Faculty of Mathematics and Natural Sciences. The chairperson and the deputy chairperson and two other members are from the teaching staff. At least two members should be from the Faculty of Mathematics and Natural Sciences, an additional member can be from the Faculty of Law and Political Science. The fourth member can be a person who has been a contract lecturer for the course for at least two years. The fifth member belongs to the group of assistant academic staff (*wissenschaftliche Mitarbeiter*) and the sixth is a person from the group of those who are admitted to the Master's course in 'Drug Regulatory Affairs'.
- (2) Those qualified for appointment are: those professors and other academic staff who are teaching in the current academic year or taught in the academic year preceding the election in the Drug Regulatory Affairs course or the subject of Pharmaceutics. This regulation does not apply to delegates from the Faculty of Law and Political Science. From the group of participants, those who are admitted to the Master's course as special auditors are eligible for appointment. For the group of academic staff a representative is appointed. For the other groups one representative per member is appointed. The term of office of the members from the group of academic staff is three years, the term of office of the member from the group of participants is one year. Reappointment is permitted.
- (3) The board of examiners has a quorum if at least half of its members, including the chairperson or deputy chairperson, is present. The board of examiners can grant the chairperson the decision-making power in normal cases. The board of examiners makes its decisions by simple majority. In the event of a tie, the chairperson's vote is decisive. The member from the group of participants does not contribute to the assessment and accreditation of periods of study, of coursework or examinations, to decisions made on examination questions or the appointment of examiners. The members of the board of

examiners have the right to be present during examinations.

(4) The meetings of the board of examiners are not public. The members of the board of examiners, their deputies, the examiners and those responsible for the minutes are sworn to secrecy. If they are not public sector employees they must be sworn to secrecy by the chairperson. The results of the deliberations of the meeting of the board of examiners are recorded in the minutes.

(5) The board of examiners will report regularly to the Faculty Council at least once a year about developments in the duration of exams and periods of study including the duration of Master's projects and discloses the distribution of module grades and overall grades. It advises on reform of the examination regulations and the curriculum.

(6) The decision of chairperson of the board of examiners is binding unless some other field of responsibility is involved in these regulations.

§ 9 Examiners

(1) The Examinations Office appoints the examiners for the individual examinations as suggested by the board of examiners. Academic staff at the University of Bonn and people with practical experience in their profession and experience with training are eligible to examine as far as this is necessary or appropriate in order to achieve the purpose of the examination. Examination results may only be assessed by persons who possess at least the qualification which is being tested by the examination or a comparable qualification or relevant professional experience.

(2) Module examinations are carried out by the member of the teaching staff responsible for the module in each case. If a member of the teaching staff is not able to hold examinations at the appropriate time due to sickness or other important reasons, the examination board will ensure that another examiner will be designated for holding the examination.

(3) The examiners are not bound by official directives in their function as examiners.

(4) The candidate may propose an examiner for the Master's thesis or the oral examination. Where possible, this proposal should be taken into consideration. However, this does not constitute the basis for a legal entitlement.

(5) The chairperson of the board of examiners ensures that the candidate will receive the names of the examiners in good time, at least two weeks before the examination in question is due to take place.

§ 10 Recognition of course and examination achievements

(1) Achievements obtained in the same course at another higher education institution in the Federal Republic of Germany will be officially recognised without being tested for equivalence.

(2) Achievements obtained in other courses or at other higher education institutions in the Federal Republic of Germany will be officially recognised where their equivalence is ascertained. Achievements obtained at higher education institutions outside Germany will be recognised on application where equivalence is ascertained. In this process, the agreements of equivalence as approved by the Conference of the Ministers of Education and Cultural Affairs (*Kultus-ministerkonferenz*) and the German Rectors' Conference (*Hochschulrektorenkonferenz*) and arrangements made as part of partnerships between universities are to be taken into consideration. Equivalence is to be ascertained if achievements are comparable overall in content, scope and standards to those required for this course. This comparison should not be done mechanically, consisting instead of an overall review and assessment. For achievements obtained in further training or a postgraduate course, the above regulations are valid as appropriate.

(3) Upon application other skills and qualifications may be recognised for this course on the basis of the documents submitted.

(4) The responsibility for recognition according to sections 1 to 3 lies with the board of examiners. Before ascertaining equivalence, the representatives of the relevant subjects are to be consulted. Furthermore, if there are doubts about the equivalence of achievements obtained abroad, the Central Office for Foreign Education Systems may be consulted.

(5) If achievements obtained are recognised, the marks are to be carried over and, weighted with the corresponding credit points, are to be included in the overall mark, provided the grading system is comparable. In the case of grading systems which are not comparable, the endorsement 'passed' will be recorded. The recognition will be set out in the transcript. Achievements that were obtained in courses without a credit point system will be converted to credit points by the Examinations Office where the examination in question corresponds to module examinations as laid down in these examination regulations. In this case, the standards approved by the Conference of the Ministers of Education and Cultural Affairs for comparison with the ECTS are to be used as a basis. Achievements obtained in parts of a module can generally not be recognised. However, in individual cases the board of examiners may permit exceptions where this is requested and cogent reasons given.

(6) If the requirements of sections 1 to 2 are satisfied there is a legal entitlement to recognition. The participants must provide all the documents required for recognition and must give any relevant information. The board of examiners may ask them for a statement that all the achievements to be recognised have been disclosed. Recognition may be withheld until the applicant complies with his or her duty to cooperate.

§ 11 Scope of the Master's examination

(1) The Master's examination consists of

- the module examinations held continuously throughout the course, which are based on the course content of the modules set out in Appendix 1 (Module Plan),
- the placement and
- the Master's thesis.

All examinations and course work are to be completed within the standard period of study defined in § 4 section 1.

(2) All examinations will be held during the course. There is a module examination for every module, even if it consists of several different classes. Students will be given credit points on passing the examination. If a module consists of several classes, the credit points will be awarded after the last sub-module examination is passed.

(3) Written examinations and course work are to be completed in the language in which the question or the topic is phrased. As a general rule, the Master's thesis is to be written in English. Work may even be submitted in English if the task is set in German. Oral examinations may be held in English on application by the candidate.

§ 12 Registration and admission, deadlines

(1) Only those persons may be admitted to module examinations

- a) who are registered at the University of Bonn as special auditors for the Master's course "Drug Regulatory Affairs"
- b) who satisfy the special admissions criteria laid down for the module, also with regard to the restrictions on the number of participants.

(2) The application for admission to the Master's examination must be made in writing to the Examinations Office together with the registration for the first module examination. The following must be included in the application:

- a) evidence that the admissions criteria listed in section 1 are met;
- b) a declaration whether the candidate has not passed an examination, including a final attempt of an examination, or the Master's examination in this course, a comparable or related course or is simultaneously being examined in such a course;
- c) a curriculum vitae in tabular form with a photograph of the candidate.

(3) When registering for the Master's thesis, the candidate must submit evidence that he or she has passed the modules required according to the course plan and name the member of staff with whom an arrangement for the supervision of the Master's thesis has been made (§ 18 section 2).

(4) If the candidate cannot submit part of the evidence in the required manner, the evidence may be provided in another way.

- (5) The board of examiners decides on admission to the examination.
- (6) Admission to the examination can only be rejected if
- a) the requirements listed under section 1 are not met,
 - b) the documents required in section 2 are incomplete and/or have not been submitted despite requests to do this,
 - c) the special auditor has not passed a final attempt at an examination or the Master's examination in this course or in a related or comparable course or
 - d) the special auditor is currently undertaking another examination in this or a related or comparable course.

§ 13 Procedure and repetition of (sub-)module examinations

- (1) Module or sub-module examinations refer to the contents of the modules listed in Appendix 1. A module examination is only passed finally if all sub-examinations have been passed. Only on passing the module or sub-module examination will the corresponding credit points be awarded.
- (2) In the (sub-)module examinations, the theoretical knowledge gained and the ability to understand extensive relationships is examined within the context of each module. The module examinations or sub-module examinations take the form of written examinations, oral examinations, pieces of written work or as a practical task. The admissions criteria and the subdivision into sub-examinations are set out in the module plan. The specific nature of the examination will be set at the beginning of the module by the examiner and be announced in good time.
- (3) Every (sub-)module examination that has not been passed or is not regarded as passed can be repeated twice. Unsuccessful attempts in the same or a related or comparable module or course at other higher education institutions will be taken into account. Where necessary the board of examiners will determine which modules or courses are to be regarded as equivalent.
- (4) For all (sub-)module examinations of a semester which are to be taken as a written exam, an examination date will be set, with an examination period being set for oral examinations. In general, the examination date will be set shortly before or at the beginning of the new semester. For each repeat examination the board of examiners sets the examination date. According to § 17 section 2 page 1, the board of examiners can set a minimum time interval until the repeat examination, which must not be less than six weeks.
- (5) If a candidate does not turn up for a repeat examination without a valid excuse, the examination will be graded as 'nicht ausreichend' (inadequate - 5.0).
- (6) If the mark 'nicht ausreichend' is received three times for a compulsory module, the candidate loses the right to be examined and forfeits his or her eligibility as special auditor.
- (7) A (sub-)module examination with a mark of 'ausreichend' ('adequate' - 4.0) and above

cannot be repeated.

(8) If the candidate can, by providing suitable evidence, plausibly demonstrate to the board of examiners that due to a disability which is permanent or lasts more than six months or due to chronic disease, he or she is unable to take the examination in whole or in part in the required manner, the board of examiners will permit proof of equivalent standards of study and/or examination performance to be submitted in a suitable manner, where necessary by also extending the preparation time available.

§ 14 Course work

(1) For each of the modules 1 to 12 a piece of course work has to be written as a module or sub-module examination. The deadline for the course work will be set by the board of examiners.

(2) In course works the candidate is required to show that he or she is independently capable of dealing with, in written form, a topic of limited scope or the questions set using the methods that are standard in this field, and in a manner consistent with the demands of an academic subject in a subject area of the module.

(3) Each piece of course work comprises a minimum of four and a maximum of 20 A4-size pages. It must be assessed by two examiners appointed in accordance with § 9 section 1, with § 13 section 3 being valid accordingly.

(4) In exceptional cases, with agreement of the board of examiners, the course work may be replaced by solving a practical task.

§ 15 Placements

(1) The six-month placement in accordance with § 4 section 5 must be carried out in the field of 'Drug Regulatory Affairs' in one of the following institutions:

- a) Pharmaceutical industry
- b) Contract Research Organisation (CRO)
- c) Licensing authority
- d) Government department
- e) Regulatory authority
- f) Consultancy firm
- g) Institution of the armed forces

(2) The placement may be split and completed at different locations. At least three months should be spent in a facility corresponding to a) or b). The board of examiners may permit exceptions to clause 1 on application and where a valid reason is given.

(3) During the full-time placement the knowledge acquired during the course should be expanded and given practical application. The university will provide a performance-based requirement profile for the placement. The placement student will submit a report on the work done at the end of the placement, which is to be signed by the supervisor. It will also list the

phases of the placement and the weekly hours of work. The board of examiners will decide whether the placement will be recognised as suitable.

(4) Before the beginning of the placement an application for approval of the work intended must be submitted to the board of examiners. Only those periods will be recognised as forming part of this practical training which have taken place after participation in all the modules and on completion of the associated course work. Full-time work in the area of 'Drug Regulatory Affairs' in the institutions listed in section 1 can also be accepted as a placement.

(5) On application the board of examiners may also accept periods of professional experience in a related field lasting at least three years before taking up the course. A report on this work and certification according to section 3 clause 3 must be submitted.

§ 16 Written examinations

(1) In the written examinations the participants are expected to show that they are able to recognise and solve problems from the subject area covered by the module in a limited amount of time and with limited aids. The aids permitted will be made known in good time. The questions for the examinations will be set by the teaching staff participating in the modules.

(2) The examinations on the modules of one semester may be held at the same time. The questions are to be set in such a manner that solving them requires a minimum of 20 and a maximum of 40 minutes per module.

(3) The examinations will be assessed by two examiners.

(4) The mark of each examination for a module is calculated from the arithmetical mean of all the individual marks.

(5) The examination is passed if the total mark is at least 'ausreichend' ('adequate' - 4.0).

(6) On application the candidate is to be given access to his or her examinations after they have been marked. The application must be submitted three months at the latest after publication of the examination results. The board of examiners will inform the candidate in good time about the period when access is permitted.

§ 17 Oral examinations

(1) In oral examinations the candidate is expected to show that he or she has a broad grasp of knowledge in the subject examined, can recognise correlations in this field, can categorise specific aspects within these correlations and is capable of finding solutions to problems.

(2) Oral examinations will either be taken in front of several examiners or in front of one examiner with an observer who is knowledgeable in the field; the examination can be held individually or in a group. The candidates have the right to make suggestions as to the appointment of the examiners. If several examiners are involved, they should have taught

different modules or different fields of the subject. If several candidates are examined simultaneously, these groups should not be larger than three people. The examination will take at least 10 and a maximum of 20 minutes per candidate and module. Before finalising the mark the examiner must consult the other examiners or the observer while excluding the candidates. With group examinations it must be ensured that all candidates within the group are allocated the same examination time.

(3) The examination is passed if at least the mark 'ausreichend' ('adequate' - 4.0) was given.

(4) The main content and the results of the individual exams are to be recorded in the minutes. The candidate is to be informed about the result after the oral examination.

(5) Candidates who wish to take the same oral examination at a later date can, if space in the exam room allows this, be permitted as listeners provided none of the candidates objects. This permission does not extend to the consultation between examiners and announcement of the examination results.

§ 18 Master's thesis

(1) The Master's thesis is a written piece of work which completes the student's academic training. Its aim is to show that the candidate is able to deal independently with a problem from the area of Drug Regulatory Affairs within a given period using scientific methods and present it in a coherent manner. The text of the thesis should not be less than 30 pages and should not exceed 60.

(2) The topic of the thesis is set by the board of examiners in agreement with the candidate and a supervisor who is a member of the teaching staff on the course.

(3) After a period of a maximum of four months, two bound copies of the Master's thesis are to be submitted to the board of examiners. The period can be extended by the board of examiners by four weeks on application by the candidate, who must give cogent reasons for this extension. The application must be submitted ten calendar days before the end of the deadline. The topic may be returned once within six weeks after it has been given to the candidate. The Master's thesis is regarded as not handed out if returned. Theses which are not handed in in due time are to be assessed as 'inadequate ('nicht ausreichend')'. The date and time when the topic was given and the thesis submitted must be officially recorded.

(4) In general, the Master's thesis is to be written in English. The board of examiners decides on any exceptions.

(5) When submitting the Master's thesis, candidates must declare in writing that they have completed the work themselves and used no other sources and aids than those stated and have made clear which parts are quotations.

(6) The Master's thesis must be assessed by a supervisor and another examiner to be assigned by the board of examiners. The mark must be substantiated in writing. The candidate may propose an examiner. The mark of the written thesis is composed of the arithmetic mean of the individual marks, where the difference is not more than 1.5. If the

difference is greater, a third examiner will be appointed by the board of examiners. In this case the mark will be composed of the arithmetic mean of the two better marks. However, the Master's thesis can only be assessed as 'ausreichend' (adequate, i.e. 4.0) or better if at least two marks are 'ausreichend' or better.

(7) If the thesis is a 'fail' (*nicht bestanden*) or is effectively a 'fail', the candidate can repeat it once. The topic of the second Master's thesis must be distinctly different from that chosen for the first thesis. However, it is only possible to return the topic in the sense of section clause 4 if this option was not exercised when working on the first Master's thesis. If even the second Master's thesis is evaluated as 'nicht ausreichend' (fail) the Master's thesis is irrevocably deemed to be a fail.

§ 19 Assessment of the examination results, composition of marks and successful completion of the Master's examination

(1) The marks for the individual sections of examinations are set by the examiner responsible. If several examiners are involved in an exam, the mark is composed of the arithmetic mean of the individual marks. For the assessment the following marks are to be given:

1	sehr gut (very good)	exceptional performance
2	gut (good)	a performance which is considerably above average requirements
3	befriedigend (satisfactory)	a performance which corresponds to the average requirements
4	ausreichend (adequate)	a performance which, in spite of its shortcomings, still meets the requirements
5	nicht ausreichend (inadequate)	a performance which due to considerable shortcomings no longer meets the requirements

For a more differentiated assessment, individual grades can be raised or lowered to intermediate values by 0.3. The marks 0.7 and 4.3 as well as 4.7 and 5.3 are not permitted. An examination passed with a mark of at least 'ausreichend' (4.0) cannot be repeated.

(2) The examination in a module is a pass if the module mark is at least 'ausreichend' (4.0). If the module mark consists of several parts, it is composed of the weighted arithmetic mean of the marks of the individual grades.

The grade to be given in the transcript is:

with an average up to and including 1.5	sehr gut (very good)
with an average of 1.6 up to and including 2.5	gut (good)
with an average of 2.6 up to and including 3.5	befriedigend (satisfactory)
with an average of 3.6 up to and including 4.0	ausreichend (adequate)
with an average of 4.1 and more	nicht ausreichend (inadequate)

(3) The candidate should be notified of the assessment of the written examination in six weeks at the latest, the assessment of the Master's thesis 8 weeks at the latest after it has been submitted.

(4) The Master's examination is passed if all module examinations as well as the Master's thesis were passed with at least 'ausreichend' (4.0), the placement was completed and 120 credit points were earned.

(5) The total mark will be composed as follows: 50 % will be the average of the individual modules weighted by the credit points of the individual modules (arithmetic mean) and 50 % will be the mark of the Master's thesis.

(6) When calculating the marks of the modules and the total mark, only the first digit after the decimal point will be taken into consideration. All other digits after the decimal point will be truncated without rounding.

(7) The Master's examination is irrevocably a fail if

- the candidate has attempted a module examination three times without success or
- the candidate has not completed the placement successfully or
- the Master's thesis, even after a repeat attempt, has been assessed as 'nicht ausreichend'.

§ 20 Precautionary regulations, non-attendance, withdrawal, cheating, infringement of regulations

(1) An examination is assessed with the mark 'nicht ausreichend' (inadequate - 5.0) if the candidate misses an examination without valid reason, or after beginning the examination withdraws from the examination without good reason or does not submit the Master's thesis within the deadline. The same holds good if a piece of course work or a written examination is not carried out within the time allocated. In exceptional cases, where the candidate gives substantive reasons, a request for extension of the time allotted may be submitted and accepted. The candidate can withdraw one week from the corresponding module examination at the latest and must do so in writing and without needing to state a reason. This right may only be exercised once per candidate and module examination or sub-module examination.

(2) Reasons for withdrawal or failure to attend must be submitted to the board of examiners in writing without delay and must be plausible. If the candidate is ill, a doctor's note may be required which contains information on the findings which the board of examiners needs in order to determine the inability to take an examination. The chairperson may in individual cases demand the presentation of a note by a doctor officially appointed by the board of examiners. If the board of examiners accepts these reasons, the examination attempt is declared to be invalid.

(3) If an attempt is made to manipulate the result of the examination by cheating or using inadmissible aids, the corresponding examination is assessed as 'nicht ausreichend' ('inadequate' - 5.0). This will be established by the examiner or invigilator, recorded and

forwarded to the board of examiners. Any candidate who disturbs the proper course of the examination can be banned from continuing the examination by the examiner or invigilator responsible after a warning has been given. In this case the examination will be declared to be a 'fail' and will be assessed as 'nicht ausreichend' ('inadequate' - 5.0). The reasons for the exclusion are to be recorded.

(4) Candidates may demand within a period of two weeks that the decisions are reviewed by the Examinations Office in accordance with section 3 clauses 1 and 2.

(5) On application by the candidate, maternity leave as set out by the Maternity Protection Act (*Mutterschutzgesetz, MuSchG*) must be taken into consideration where applicable. The application must be accompanied by the required evidence. Periods of maternity leave act as suspending the deadlines laid down by these examination regulations. The duration of maternity leave is not included in the deadline.

(6) Likewise the periods of parental leave set out in the relevant legislation on parental allowance and parental leave (*Gesetzes zum Elterngeld und zur Elternzeit, BEEG*) must be taken into consideration. Candidates must inform the Examinations Office in writing at least four weeks before they wish to take parental leave, enclosing the evidence required, for which period(s) they wish to take parental leave. The Examinations Office must check whether the legal requirements are satisfied which would lead to an employee being entitled to parental leave according to the law on parental allowance and parental leave (BEEG) and informs the candidate without delay about the results and the resultant revised examination deadlines. The deadlines involved in a Master's thesis cannot be interrupted by parental leave. The topic given counts as not set. After parental leave has expired the candidate will be given a new topic.

(7) In the event of multiple or grave attempts at cheating admission of the candidate as special auditor may be revoked. The decision about this will be made by the dean on advice from the board of examiners.

(8) Anyone who intentionally violates a rule in these examination regulations on cheating with regard to examinations is committing an offence. This offence may be penalised with a fine of up to 50,000 euros. The administrative authority responsible for the prosecution and punishment of an offence according to clause 1 is the Head of Administration (*Kanzler*) of the University of Bonn.

§ 21 Transcript

(1) On application, the candidate will be issued with a temporary transcript immediately after all final marks are available. Then, where possible within four weeks, a transcript will be issued in German. If requested by the candidate, an English version of the transcript can be issued. The contents of the transcript are

- all modules for which credit points have been gained,
- the semester in which these credit points were gained,
- the marks of the individual examination units,
- the topic and mark of the Master's thesis, and
- the overall mark of the Master's examination.

After completing each year, an overview of the ECTS level achieved will be issued.

(2) The transcript bears the date the last examination was passed. It is accompanied by the seal of the Examinations Office and is signed by the dean and the chair of the board of examiners.

(3) If the Master's examination is not (or not deemed to be) passed at the final attempt, the Examinations Office will issue the candidate with written notification of this together with information on the candidate's statutory rights .

(4) If a special auditor leaves university without a degree, he or she will be issued, upon request, with a transcript listing the examinations and course work passed. This transcript is limited to the parts of the course successfully completed. Moreover, on application by the special auditor, confirmation can be issued listing which examinations were not passed or are still missing in order to pass the Master's examination.

§ 22 Diploma Supplement

The Master's transcript is provided with a diploma supplement. The diploma supplement provides information in English, in a standardised form, on course content, schedule of studies, the academic and professional qualifications obtained with the degree and the higher education institution awarding it.

§ 23 Master's certificate

At the same time as the transcript of the Master's thesis, the candidate will be provided with a Master's certificate in German marked with the date of the transcript, confirming the award of the academic degree 'Master of Drug Regulatory Affairs' (M.D.R.A.). The certificate will be signed by the dean of the Faculty of Mathematics and Natural Sciences and be marked with the seal of the faculty. On application by the candidate, an English version of the Master's certificate can also be issued.

§ 24 Access to examination files

- (1) Within of three months of issuing the transcript, candidates will be given access, upon written request, to their examination files by the board of examiners.
- (2) The board of examiners will decide on the place and time of access. It is not permitted to make copies of or remove parts of the examination file.

§ 25 Invalidity of the Master's examination, revocation of the Master's title

- (1) If a candidate has cheated in an examination and this fraudulent behaviour only becomes known after issuing the transcript, the Examinations Office can a posteriori adjust the marks accordingly for those examinations in which the candidate cheated as well as the overall mark and declare the examination, in whole or in part, to be 'not passed'.
- (2) If the criteria for admission to an examination were not satisfied without the candidate intending to cheat, and this fact only becomes known after the candidate has been given the examination certificate, this shortcoming is remedied by passing the examination. If a candidate has intentionally obtained access to an examination unjustly, the Examinations Office will decide on the legal consequences in accordance with the Administrative Procedures Act of the state of North-Rhine Westphalia.
- (3) The person affected must be given a chance to account for their actions before a decision is made.
- (4) The fraudulent transcript must be impounded and where applicable a new transcript issued. The Master's certificate must also be confiscated together with the fraudulent transcript if one of the examinations is declared to be 'not passed' due to cheating. A decision in accordance with section 1 and section 2 clause 2 is no longer permissible after a period of five years has elapsed subsequent to issuing the transcript .
- (5) If the Master's examination is assessed overall as 'not passed', the Master's degree is to be revoked and the Master's transcript and Master's certificate must be impounded.

§ 26 Transitional arrangements

Special auditors who are attending the 'Master of Drug Regulatory Affairs' course on the basis of the examination regulations of 17 January 2001 (see Official Notices of the University of Bonn, 31st Year No. 9 of 2 March 2001) and have not completed the written thesis may, by submitting a written request which cannot be rescinded, change to the Master's course as set out in these examination regulations. The results obtained to date will be credited according to § 10; further information will be provided by the Examinations Office.

§ 27 Validity and publication

These examination regulations will come into effect on the day after publication in the Official Notices of the Rhenish Friedrich-Wilhelm University of Bonn (Announcements). They apply to the first degree course beginning after these regulations come into force.

U.-G. Meißner
The Dean
of the Faculty of Mathematics and Natural Sciences
of the Rhenish Friedrich-Wilhelm University
Professor Ulf-G. Meißner

Issued on the basis of the decision of the Faculty Council of the Faculty of Mathematics and Natural Sciences of 8 July 2009 and the decision of the Rectorate of 26 August 2009.

Bonn, 15 September 2009

Ch. K. Kuhl
For the Rector
of the Rhenish Friedrich-Wilhelm University of Bonn
Professor Christiane K. Kuhl
Deputy Rector

Appendix 1: Module Plan for the Master's course "Drug Regulatory Affairs"

I. Modules

No.	Module	Examination requirements	Method of examination	Credit points
1	Definition and description of the functions of Drug Regulatory Affairs, Good Regulatory Practices	Regular and active participation, group work	Course work	5
2	Pharmaceutical law Drug law in Germany, the EU and other countries, and related laws	Regular and active participation, group work	Course work and written or oral examination	6
3	International marketing authorisation procedures Principles and procedures of the marketing authorisation for medicinal products, diagnostics and medical devices in the EU, USA, Japan and worldwide	Regular and active participation, group work	Course work and written or oral examination	7
4	Marketing authorisation procedures for special groups of pharmaceuticals and national marketing authorisation procedures Varying standards in registration procedures for single agent and combination preparations, drugs for special therapeutic applications and veterinary drugs; aspects of distribution in Germany and post-authorisation procedures	Regular and active participation, group work	Course work	5
5	Maintenance of marketing authorisations / pharmacovigilance Application-associated monitoring, marketing, variations, renewals	Regular and active participation, group work	Course work and written or oral examination	6
6	Information management, eCTD From literary research via processing of documents and data to assessment of information and electronic submission	Regular and active participation, group work	Course work or practical task	3
	Total 1st semester			32
7	Quality management / medical devices Good practice rules, international standards, quality management and control; medical devices legislation	Regular and active participation, group work	Course work	5
8	Chemical-pharmaceutical documentation Documentation from synthesis via analytics, pharmacopoeia monographs to form of administration and production	Regular and active participation, group work	Course work and written or oral examination	6
9	Pharmacological-toxicological documentation Documentation of pharmacology, toxicology, genotoxicity and ecotoxicology	Regular and active participation, group work	Course work and written or oral examination	6
10	Clinical documentation Documentation of clinical investigations on humans, clinical trials, case studies and reports on drug use	Regular and active participation, group work	Course work and written or oral examination	6
11	Pharmacoeconomics / Health policy Cost-benefit ratio, pricing policy, methods of cost savings	Regular and active participation, group work	Course work	3
12	Decision analytics Marketing authorisation strategies, regulatory aspects, marketing strategies	Regular and active participation, group work	Course work	2
	Total 2nd semester			28
	Total			60

II. Placement **30 CP**

III. Master's thesis **30 CP**

Appendix 2

Test to ascertain the special aptitude for the course in accordance with § 3 of the examination regulations for the postgraduate Master's course in Drug Regulatory Affairs

I. General principles

- (1) The admission to the Master's course in Drug Regulatory Affairs requires evidence of particular suitability for this course in addition to evidence of the admissions criteria listed in § 3 section 1.
- (2) Proof of particular suitability for this course will, according to these regulations, be determined in a special procedure (Aptitude Test).
- (3) The aim of the procedure is to determine whether a candidate has special skills relevant to the course that give reason to expect that the course will be completed successfully.
- (4) The §§ 7 (Examinations Office of the Faculty), 8 (Board of examiners), 9 (Examiners), 10 (Recognition of course work and examination performance), 24 (Access to examination files) and 25 (Invalidity of the Master's examination, revocation of Master's title) are applicable as appropriate.

II. Eligibility for application and application procedure, admission to the Aptitude Test

- (1) Candidates who satisfy the admissions criteria listed under § 3 section 1 or are expected to satisfy these according to section 6 p. 2 may participate in the Aptitude Test..
- (2) The application for admission to the Aptitude Test is to be submitted using the pre-printed forms made available by the board of examiners. Admissions take place in the winter semester. The deadline for applying for the winter semester is 15 June of that year in each case. The receipt stamp of the office of the board of examiners is decisive in determining compliance with the application deadline. The application deadline and the issue of confirmation notices in accordance with section VII will be coordinated with the application deadline.
- (3) The following documents must be appended to the application as photocopies:
 10. evidence of formal qualifications according to § 3 section 1 points 1 to 6,
 11. evidence of language skills according to § 3 section 1 point 7,
 12. the certificate according to § 3 section 1 point 8,
 13. a completed form for application for a place at university,
 14. a CV detailing the applicant's previous educational career.
- (4) A requirement according to § 3 section 1 point 7 is knowledge of German and English. Knowledge of the German language is attested if the person is a native speaker of German or has completed secondary education at a German school (including schools abroad) or a first

degree in a German-speaking higher education course has been obtained which is deemed to serve as a professional qualification. In other cases this must be provided by submitting proof that a German test has been passed according to the DSH (*Deutsche Sprachprüfung für den Hochschulzugang*) or comparable evidence. Evidence of competence in English is regarded as present if English is the applicant's native language or secondary education has been completed at an English-speaking school (including schools abroad) or the candidate possesses a first degree from an English-speaking higher education course. In other cases proof must be supplied by presenting evidence of successful completion of an English test such as TOEFL 550 or computer TOEFL 213, IELTS 6.0 (International English Language Testing System) or equivalent evidence or at least 7 years of successfully completed English courses at a secondary school before the applicant obtained their higher education entrance qualification or by providing evidence of regular use of English in everyday professional life.

(5) The examination board decides on the application for admission to the Aptitude Test.

(6) Admission will be denied if the application is incomplete. If the documents listed in section 3a are not yet available at the time of application, a note to this effect from the relevant university will suffice. Formal proof must be submitted by the applicant immediately after it has been received.

III. Aptitude Test procedure and examiners

(1) The board of examiners for the Master's course is responsible for organising the Aptitude Test. The board of examiners confers and makes its decisions in a meeting which is not open to the public. Decisions will be made by simple majority. In the event of a tie the chair has the deciding vote.

(2) The board of examiners will appoint the examiners for the Aptitude Test. The relevant paragraph is § 9 of the Master's examination regulations.

IV. Aptitude Test

(1) The aptitude specific to this course is deemed to be proven if the applicant

- g) is licensed as a pharmacist or
- h) is licensed as a doctor or
- i) is licensed as a veterinarian or
- j) has passed a state examination as a food chemist or
- k) an examination as a Diploma Chemist or
- l) an examination as a Diploma Biologist or
- m) another Diploma examination in the natural sciences or
- d) has passed a Master's examination in a natural sciences subject

or

- h) has passed a Master's examination in a medical or veterinary subject and
- i) in all the cases above has been assessed in the final examination with a mark of at least 3.0

or

- has obtained a PhD in a course in the natural sciences or
 - a medical course or
 - a veterinary course or
- j) has been awarded a first degree deemed to be a professional qualification according to § 3 section 1 points 3 to 6 and can show at least three years of related professional experience before beginning the course.

(2) With all other candidates it will be first determined on the basis of their application documents whether the required educational training for the subject Drug Regulatory Affairs has been achieved. The standard for ascertaining the level of training is a level of knowledge which combines a solid knowledge of the basics in the scientific subjects of biology, chemistry and pharmaceuticals at a level which can be attained in higher education courses in the natural sciences or medical sciences.

(3) The suitability for this particular course is likewise deemed to be proven if the board of examiners has established that the level of training attained is equivalent to that of candidates as set out in section 1. For the other candidates participation in the Aptitude Test is obligatory.

(4) The Aptitude Test involves an oral or written examination in order to ascertain the aptitude of the candidate with regard to basic scientific and pharmaceutical knowledge as defined in section 2. The duration of oral examinations is at least 20 minutes and a maximum of 30 minutes. The duration of written examinations is between 120 and 150 minutes. The examination is passed if at least 50% of the questions were completed successfully. The examination will take place in German and English. Candidates satisfying the admissions criteria for the Aptitude Test according to II will be notified in writing about the date and location of the examination, and the examination procedures.

(5) If the candidate satisfies the board of examiners by suitable evidence that, due to an impairment lasting more than one semester or permanent or chronic disease, they are unable to take the Aptitude Test, in whole or in part, the board of examiners will permit them to perform a comparable test in a form suitable to the candidate's needs.

V. Absence and cheating

(1) If a candidate fails to attend an examination without good reason, the special course-related aptitude counts as unproven.

(2) If an applicant was unable to take the test due to sickness, a doctor's note is to be presented containing information on the sickness which the board of examiners needs so as to establish that the candidate cannot be tested. If the board of examiners accepts the reasons, it may be possible, within the means available, for the chairperson to set a date for a repeat examination.

(3) If an applicant attempts to manipulate the result of an examination fraudulently or by using aids which are not permitted, the examination will be assessed as '0' (zero) points overall. Upon discovery by an invigilator according to clause 1, the candidate may request the decision to be reviewed by the Examinations Office.

(4) If an applicant has cheated in the Aptitude Test and this fact only becomes known after notification according to VII section 1 has been made, the board of examiners can withdraw the recognition of the applicant's suitability and will inform the Student Secretariat (*Studentensekretariat*) about this. This recognition may be revoked at any time up to the completion of the Master's course.

(5) Incriminating decisions of the board of examiners must be communicated to the applicant immediately in writing according to sections 1 to 3. Those affected must be given an opportunity to comment on the matter before a decision is made.

VI. Assessment of performance in the Aptitude Test

(1) Performance in the oral examination will be assessed on points. The candidate has passed the Aptitude Test if at least 50 per cent of the maximum number of points has been achieved.

(2) The oral examination is either held in front of several examiners or in front of one examiner with an observer familiar with the subject. It can take place individually or in a group. With group examinations it must be ensured that all candidates within the same group receive the same examination time. In the case of an examination involving one examiner, before setting the mark the examiner must consult the observer in the absence of the applicant.

VII. Notification of Test results and repetition of the Aptitude Test

(1) The applicant must be informed in writing about the result of the Aptitude Test. Notification of failure in the Test must be accompanied by information about the candidate's statutory rights; it should contain the reasons for the assessment.

(2) Applicants who have not passed the Aptitude Test can take the Test at the earliest when the next course begins. For this a new application is required. A second repetition of the Test is not possible.

VIII. Applicants from other universities

In the case of applicants who change university while being matriculated in a Drug Regulatory Affairs course or a comparable course at another higher education institution, the board of examiners will evaluate the candidate's qualifications, including any aptitude test already taken. If the board of examiners ascertains that the courses and aptitude test are comparable, the applicant may be exempted from taking the Aptitude Test at the University of Bonn.