Legally not binding informal translation of the Master of Pharma
Business Administration Program Regulations

Regulations of the Faculties of Economics and Business Administration and
Biochemistry, Chemistry and Pharmacy of Goethe University, Frankfurt am
Main for the Masters Course "Master of Pharma Business Administration"
which confers the qualification "Master of Business Administration (MBA)"
dated June 20, 2016, in the version of March 2, 2017

Approved by the Presidium of the University at the meeting of March 14, 2017

Based on sections 20 and 44(1)(1) of the Hesse Higher Education Act (Hochschulgesetz) in the version dated December 14, 2009, last amended on November 30, 2015, the Faculty Councils of the Faculties of Economics and Business Administration and Biochemistry, Chemistry and Pharmacy at Goethe University, Frankfurt am Main on June 15, 2016 and June 20, 2016 approved the following regulation for the Masters Course "Pharma Business Administration." The Executive Council provisionally approved this regulation pursuant to section 37(5) of the Hesse Higher Education Act on March 14, 2017. It is hereby published.
Table of contents:

Part I: General
Article 1 Scope of the Regulation (FR: article 1)
Article 2 Purpose of the Master's examination (FR: article 2)
Article 3 Academic degree (FR: article 3)
Article 4 Normal course length (FR: article 4)

Part II: course objectives; course implementation; commencement of studies and course admission requirements
Article 5 Course objectives (FR: article 6)
Article 6 Course implementation
Article 7 Commencement of studies (FR: article 7)
Article 8 Admission onto the Masters Course and to the Master's examination; admissions panel (FR: article 9)

Part III: Course structure and organization
Article 9 Course composition; modularization (FR: Article 11)
Article 10 Module descriptions/Module Handbook (FR: article 14)
Article 11 Scope of the course and of the modules; credit points (CP) (FR: article 15)
Article 12 Teaching and learning formats; access to modules (FR: article 16)
Article 13 Course records (evidence of performance and participation) (FR: article 17)
Article 14 Course schedule; information (FR: article 18)
Article 15 Course guidance; orientation event (FR: article 19)
Article 16 Academic administration and those responsible for delivering modules (FR: article 20)

Part IV: Examination organization
Article 17 Examination Board; Examinations Office (FR: article 21)
Article 18 Responsibilities of the Examination Board (FR: article 22)
Article 19 Examiners; observers (FR: article 23)

Part V: Examination requirements and procedures
Article 20 Time of the examination and registration process (FR: article 25)
Article 21 Absence and withdrawal from module examinations (FR: article 26)
Article 22 Completion of course work and examinations in case of illness and disability; special
circumstances (FR: article 27)

Article 23 Binding course guidance; time limits for the sitting of examinations (FR: article 28)

Article 24 Cheating and breach of regulation (FR: article 29)

Article 25 Faults in the examination process (FR: article 30)

Article 26 Recognition and accreditation of performance (FR: article 31)

Article 27 Accreditation of skills acquired outside higher education (FR: article 32)

**Part VI: Implementation of module examinations**

Article 28 Module examinations (FR: article 33)

Article 29 Oral examinations (FR: article 34)

Article 30 Tests and other written supervised examinations (FR article 35)

Article 31 Term papers and other written papers (FR: article 36)

Article 32 Project work (FR: article 38)

Article 33 Master’s thesis (FR: articles 40, 41)

**Part VII: Assessment of course work and examinations; creation of grades and overall grade; failure to pass the examination overall**

Article 34 Assessment/grading of course work and examinations; creation of grades and of the overall grade (FR: article 42)

Article 35 Pass and failure to pass examinations; notification of grades (FR: article 43)

Article 36 Compiling the examination result (data transcript) (FR: article 44)

**Part VIII: Change of mandatory and electives modules; major fields of study; retaking examinations; loss of the right to take an examination and final failure to pass**

Article 37 Change of elective modules (FR: article 45)

Article 38 Retaking examinations (FR: article 46)

Article 39 Loss of the right to take an examination and final failure to pass (FR: article 47)

**Part IX: Examination certificate; degree certificate and Diploma Supplement**

Article 40 Examination certificate (FR: article 48)

Article 41 Master's degree certificate (FR: article 49)

Article 42 Diploma Supplement (FR: article 50)

**Part X: Invalidity of the Master's examination; examination documents; appeals and objections, examination fees**

Article 43 Invalidity of examinations (FR: article 51)
Article 44 Access to examination documents; retention periods (FR: article 52)

Article 45 Appeals and objections (FR: article 53)

Article 46 Course fees

**Part XI: Final provisions**

Article 47 Entry into effect (FR: article 56)

**Appendix 1: Regulation for special access requirements/ aptitude assessment procedures for Master’s courses**

**Appendix 2: Sample course schedule**

**Appendix 3: Module descriptions**

Appendix 4: Sample Module Handbook

Appendix 5: Sample Transcript of Records
**List of abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP</td>
<td>Credit points</td>
</tr>
<tr>
<td>ECTS</td>
<td>European Credit Transfer System</td>
</tr>
<tr>
<td>GVBl.</td>
<td>Gazette of Statutes and Ordinances for the State of Hesse</td>
</tr>
<tr>
<td>HImmaVO</td>
<td>Hesse Matriculation Regulation of February 24, 2010 (GVBl. I, p. 94), last amended on April 23, 2013 (GVBl. I, p. 192)</td>
</tr>
<tr>
<td>MT</td>
<td>Mandatory &quot;Master's Thesis&quot; module</td>
</tr>
<tr>
<td>MBA</td>
<td>Master of Business Administration</td>
</tr>
<tr>
<td>PF</td>
<td>Mandatory module</td>
</tr>
<tr>
<td>FR</td>
<td>Framework Regulation for Tiered and Modularized Courses of Study at Goethe University, Frankfurt am Main dated April 30, 2014</td>
</tr>
<tr>
<td>SH/W</td>
<td>Semester hours per week</td>
</tr>
<tr>
<td>WP</td>
<td>Elective module</td>
</tr>
</tbody>
</table>
Part I: General

Article 1 Scope of the Regulation (FR: article 1)
This regulation contains the course-specific regulations for the extra-occupational Masters Course of Pharma Business Administration (further referred to as the "Masters Course" or "course"). It applies in conjunction with the Framework Regulation for Tiered and Modularized Courses of Study at Goethe University, Frankfurt am Main dated 30 April 2014, UniReport Statutes and Regulations dated July 11, 2014 as amended from time to time, further referred to as "Framework Regulation" (FR).

Article 2 Purpose of the Master’s examination (FR: article 2)
(1) The Masters Course ends with the provision of a further professional degree qualification. The Master's examination serves to ascertain whether those studying have achieved the objective of the Masters Course. The examinations are cumulative, meaning that the totals from the module examinations within the Master of Pharma Business Administration course, including the Master's thesis, combine to form the Master’s examination.
(2) The cumulative Master's examination should establish whether students have acquired the basic knowledge in the examination areas and have an overview of the nexuses of the subject, and whether they have the ability to apply research methods and knowledge independently and are ready for the transition to professional practice.

Article 3 Academic degree (FR: article 3)
Once the course has been successfully completed and the examination passed, the Faculties of Economics and Business Administration and Biochemistry, Chemistry and Pharmacy award the academic degree of "Master of Business Administration", abbreviated as MBA.

Article 4 Normal course length (FR: article 4)
(1) The normal course length for the Masters Course of Pharma Business Administration is four semesters.
(2) Pursuant to article 11, 90 credit points ("CP") need to be acquired within the Masters Course of Pharma Business Administration. Taking into account the first degree conferring a professional qualification and any other recognized qualifications, 300 CP are needed in order to achieve the Master's level.
(3) On the basis of this regulation, the Faculties of Economics and Business Administration and Biochemistry, Chemistry and Pharmacy, which are involved in the degree program, offer a range of courses and shall ensure appropriate examination dates are set so that the course can be completed within the normal course length.

Part II: Course objectives; course implementation; commencement of studies and course admission requirements

Article 5 Course objectives (FR: article 6)
(1) The Masters Course of Pharma Business Administration tends to be geared towards practice.
(2) Successful completion of the course gives students analytical skills as well as the practical knowledge for a demanding career in leadership positions of the pharmaceuticals industry. It primarily enables junior employees to acquire cross-disciplinary skills in the area of management or on pharmaceutical subjects of particular practical relevance, and qualifies them for entrepreneurial activity in line with academic standards. On completion of the course, students are in a position to define and interpret the special features and terminology
of their area of study. By giving in-depth knowledge in the specialist areas of the course, the basis is laid for the development and application of independent, cross-disciplinary methodological skills. Through this, the students also acquire, in particular, the ability to apply their knowledge and understanding in the multi-disciplinary aspects of their subject, specifically management and pharmacy. To that end, the course combines academic and business practice through the inclusion of qualified lecturers from enterprises, by setting tasks within the course that are based on commercial practice and through institutional cooperation between the university and business in the conception and running of this course.

Article 6 Course implementation

The Masters Course is run by Goethe Business School not-for-profit limited company on behalf of the Faculties of Economics and Business Administration and Biochemistry, Chemistry and Pharmacy (hereinafter "Goethe Business School") in accordance with this regulation. This task includes, in particular:

a) the organization and running of lectures in line with this regulation,
b) the organization and running of examinations,
c) the organization and implementation of cooperations with other institutions required to run the program,
d) further development of the program in line with progress in academic knowledge and market requirements and
e) economic management of the program.

Article 7 Commencement of studies (FR: article 7)

The course can only be taken up starting in the winter semester.

Article 8 Admission onto the Masters Course and the Master's examination; admissions panel (FR: article 9)

(1) The general condition for admission onto the Masters Course is

a) evidence of completion of a bachelor's degree in the faculty of biochemistry, chemistry and pharmacy, of medicine or law or economics or an equivalent field, each with a normal course length of at least six semesters or
b) evidence of completion of at least an equivalent degree from a German university or German university of applied sciences in a related field or
c) evidence of completion of at least an equivalent foreign degree in the same or a related field with a normal course length of at least six semesters.
(2) In addition,

a) evidence must be provided of at least two years' professional experience in the pharmaceutical industry or in a related field; the Examination Board decides on justified exceptions,

b) evidence must be provided of payment of the fee set by the Executive Committee under section 16(3) HHG.

(3) The particular admission requirements are governed by Appendix 1.

(4) A further admission requirement is to provide evidence of English-language skills normally of the language level C 1, but at least B 2 of the “Common European Framework of Reference for Languages” dated September 2000. Evidence of language skills may be provided, for example, through TOEFL or IELTS.

(5) Applicants are admitted onto the Masters Course by an admissions panel put in place by the Examination Board. The admissions panel shall, as a minimum, be composed of:

   a) two professors authorized to examine on a Masters Course
   b) one Goethe Business School employee responsible for admissions
   c) in an advisory capacity, one student member enrolled on the Masters Course.

(6) The admissions panel determines the number of course participants. It decides whether to accept applicants based on the written application documents submitted. Applicants have no legal right to be accepted. For applicants with fewer than 210 CP from their first professional degree, the admissions panel will assess, on a case-by-case basis, whether the qualifications defined in the admissions requirements can be demonstrated by taking into account knowledge and skills acquired outside higher education, e.g. through the two years of qualified work under article 8(2)a). It is possible to recognize up to 30 CP in this way.

(7) Upon admission to the Course, the participants are simultaneously admitted to the Master’s examination.

**Part III: Course structure and organization**

**Article 9 Course composition; modularization (FR: article 11)**

(1) The Masters Course of Pharma Business Administration is a single-subject course.

(2) The Masters Course of Pharma Business Administration has a modular course structure. One module is a teaching and learning unit that is complete time-wise and in terms of its content. It includes a set of lectures, project work and self-study periods that are interrelated in terms of content, and is dedicated to a pre-defined learning objective. Modules last for one to two semesters.

(3) The Masters Course of Pharma Business Administration is divided into a foundation courses phase, a concentration courses phase, a specialization phase and a completion phase.

(4) Modules may be core modules, which are obligatory and include the Master’s thesis, or electives, which need to be selected from a pre-set catalogue of modules.
(5) The following course structure for the Master of Pharma Business Administration course is derived from the allocation of modules to different stages of the course, to what degree modules are mandatory and the student workload calculated in CP under article 13:

<table>
<thead>
<tr>
<th>Foundation Courses</th>
<th>Mandatory Module (PF)/ Elective (WP)</th>
<th>Credit points (CP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managerial Accounting &amp; Controlling</td>
<td>PF</td>
<td>6</td>
</tr>
<tr>
<td>Organizational Behavior</td>
<td>PF</td>
<td>6</td>
</tr>
<tr>
<td>Corporate Finance</td>
<td>PF</td>
<td>6</td>
</tr>
<tr>
<td>Strategic Management &amp; Corporate Development</td>
<td>PF</td>
<td>6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concentration Courses</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation Management &amp; Pricing</td>
<td>PF</td>
<td>5</td>
</tr>
<tr>
<td>High Performance Teams</td>
<td>PF</td>
<td>5</td>
</tr>
<tr>
<td>Foundations of Patent &amp; Pharmaceutical Law</td>
<td>PF</td>
<td>5</td>
</tr>
<tr>
<td>Pharmaceutical Value Chain</td>
<td>PF</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specialization Phase</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>WP 1</td>
<td>WP</td>
<td>5</td>
</tr>
<tr>
<td>WP 2</td>
<td>WP</td>
<td>5</td>
</tr>
<tr>
<td>WP 3</td>
<td>WP</td>
<td>5</td>
</tr>
<tr>
<td>WP 4</td>
<td>WP</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Completion Phase</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Scientific Methods for Research &amp; Writing&quot; seminar</td>
<td>PF</td>
<td>6</td>
</tr>
<tr>
<td>Master's thesis</td>
<td>PF</td>
<td>20</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>90</strong></td>
</tr>
</tbody>
</table>

(6) Where there is a lack of capacity the choice of options may be restricted by a decision of the Faculty Council. Goethe Business School shall immediately notify the students of the restriction. Article 14(2) applies. Additional options may also be allowed by a decision of the Faculty Council without an amendment of this regulation, provided these match the options governed by this regulation in terms of their scope and requirements. Article 10(4) applies mutatis mutandis. Article 14(2) shall be complied with.

(7) The classes within the modules are divided into mandatory and optional lectures/seminars in terms of how obligatory they are. Compulsory classes are clearly indicated in the module description by the content and format of the class. Optional classes are classes that students need to select from a certain specialist area or in relation to a certain subject area.

(8) Where individual classes are offered in German, this is regulated in the Module Handbook.

(9) Where a module's classes build on each other, the students must take them in the sequence indicated in the module description.

(10) Depending on the number of spaces available, students have the option of sitting an examination or assessment within the Masters Course of Pharma Business Administration other than the modules prescribed in this regulation (additional modules). The result of such examination is not included in the overall grade for the Master's examination.
Article 10 Module descriptions/Module Handbook (FR: article 14)

(1) For every mandatory module and option Appendix 3 contains a module description in line with article 14(2) FR. The module descriptions are an integral part of this regulation.

(2) The module descriptions are supplemented by a regularly updated Module Handbook. This contains the additional information required under paragraph 3 and is used in particular to provide information to students.

(3) The following are included in the Module Handbook as minimum requirements pursuant to article 14(5) FR:
   - where relevant an indication that this is an import module
   - the frequency with which the modules are offered (e.g. annually or every semester)
   - student workload broken down into attendance or contact time and self-study in hours and credit points (CP).
   - length of the modules
   - recommended requirements
   - teaching/examination language
   - classes with teaching and learning formats as well as semester hours per week and credit points
   - person responsible for delivering the module
   - where relevant, timeframe of the modules

(4) Amendments in the Module Handbook that do not relate to the content of the module descriptions under article 14(2) FR are possible by decision of the Faculty Council in good time prior to commencement of the semester teaching period and up to that time should be advertised during the information events held once a semester via Goethe University's central e-learning platform OLAT. They are not permitted to lead to substantive changes to the curriculum.

Article 11 Scope of the course and of the module; credit points (CP) (FR: article 15)

(1) Each module is allocated credit points (CP) in the module description based on the European Credit Transfer Systems (ECTS) taking into account the decisions and recommendations of the Conference of the Ministers of Education and Cultural Affairs from the different German Länder and of the German Rectors' Conference. The CP facilitate the transfer of credits to other courses at Goethe University or other universities, and vice versa, as the case may be.

(2) CP are a quantitative measurement of the workload that averagely able students need to accept in order to successfully complete the corresponding module for the face-to-face course, participation in practical training outside the university or in excursions, preparatory and follow-up work on the syllabus and the preparation and composition of their own input and examination performance. One CP equates to a workload of 30 hours. A normal course-related workload for a masters course involves no more than 1,380 working hours per course year. The average workload per semester comes to 22.5 CP.

(3) The Masters degree in Business Administration requires 300 CP including the preceding course ending in the
first completion of a degree conferring a professional qualification.

(4) CP are only awarded for a module that has been successfully completed in full.

(5) A credit point account for each student is set up with the Examinations Office. Within the parameters of what is organizationally possible, students may access the current status of their accounts at any time.

(6) The workload is assessed as part of the evaluation under section 12(1) and (2) HHG and for the reaccreditation of the course and is adjusted to the workload identified as a result of the evaluation.

**Article 12 Teaching and learning formats; access to modules (FR: article 16)**

(1) Classes within the Masters Course of Pharma Business Administration normally take place in the following formats:

a) Lectures: interrelated presentation and sharing of basic and specialist knowledge and methodology through a talk or, where relevant, in connection with demonstrations or experiments. Teaching staff develop and share the course content with the involvement of the students;

b) Exercises: working through and in-depth treatment of the syllabus as well as training in specialist methodology and teaching of special skills by working through and discussing sample tasks;

c) Introductory seminars/seminars: development of academic knowledge or processing of current problems using academic methods through input, learning and practice exercises normally prepared by the students or the improvement of presentation and discussion techniques;

d) Project: development of concepts and the implementation of solutions to more complex, practice-based tasks; the teaching of social skills through largely independent processing of the task but under professional guidance and using appropriate work methodology;

e) Excursions: prepared events outside the university;

f) Self-study: independent working through the course content, preparation for and follow-up work after lectures and exercises, preparation for assessments.

(2) Where, according to the module description, access to classes within a module depends on successful completion of other modules or attendance of course guidance, or should participation in a single class be conditional (according to the module description) upon evidence of participation in, or work done for, a different class, the Examinations Office of Goethe Business School will verify the student's right to participate.

(3) The module description may envisage that participation in the module or in specific classes within the module is conditional upon binding registration. Whether a binding registration needs to occur and what the procedure is is advertised in good time during the information events occurring once a semester and via Goethe University's central e-learning platform OLAT.

**Article 13 Course records (Evidence of performance and participation) (FR: article 17)**

(1) During the course, course records (evidence of performance and participation) are envisaged as evidence of proper course work (pre-examination work) or, together with the CP for the module examination passed, as a precondition to the award of the CP to be earned for the module. The following provisions apply:

(2) To the extent the obligation to regularly attend classes is regulated in the module description, this is documented
through records of participation or through attendance lists. The class director shall decide on the format of the documentation. Evidence of regular participation does not count as course work within the meaning of paragraph 5.

(3) Regular participation at a class is satisfied if the student was present at all individual classes scheduled by the class director in the course of the semester. It should also be confirmed if the student missed up to three classes out of a total of 15 or 20% of the class time in the case of fewer classes. Where the permitted time of absence is exceeded for reasons beyond the student’s control, such as e.g. illness, the need to look after a child living in the same household or care for a close relative (children, parents, grandparents, spouse, partner in a non-marital partnership) or work as an appointed or elected representative within the academic or student administration, the person responsible for delivering the module shall decide whether and in what way equivalent output is necessary and reasonable. The provisions in article 22 governing the making up of any disadvantage need to be complied with.

(4) Contrary to paragraph 3, the module description may also specify that, in order for a record of participation to be issued, the student has not just regularly participated within the meaning of paragraph 3 but has also actively participated in the class. However, it may also simply assume active participation. Active participation includes, depending on what is determined by the class director, the completion of smaller papers such as reports, short oral presentations and co-authored work. These tasks are neither graded nor assessed as having been passed/not passed.

(5) Any performance record required under the module description for a class will document the successful performance of course work. Course work is successful if it is graded by the teacher as “passed” in accordance with the module description or, where article 34(3) applies, is positively assessed using a grade. In case of co-authored work it must be possible to clearly separate out and assess the performance of individuals. Marks for course work are not included in the grade for the module. Where the teacher so stipulates, regular participation in the class within the meaning of paragraph 3 is also required for a record of performance.

(6) Course work may, in particular, be

- written papers or term papers
- presentations (with or without a written draft)
- expert talks
- work reports, logs
- the completion of exercises
- tests
- literature surveys or documentation
- excursions

The teacher advises the students at the beginning of the class of the format and time limit in which the course work is to be done. The criteria for awarding the record of performance may not be amended during the current semester to the detriment of the students. The teacher may allow the students an opportunity to improve a piece of written work by setting them an additional deadline.

(7) Written papers not done under supervision are to be prepared by the student according to the rules of good academic practice. When submitting the paper the students have to affirm in writing that they have prepared it themselves and that they have listed all sources and aids used by them in the paper. It further needs to be stated that the paper has not previously (even in the form of extracts) been used as non-graded or graded work in a different
course. Article 24(1) applies accordingly. In order to be able to verify compliance with the rules of good academic practice, teachers are entitled to require the students to submit written work not done under supervision also in an appropriate electronic format. The Examination Board shall decide more specific requirements in this regard.

(8) Course work passed cannot be repeated. Course work not passed can be repeated an unlimited number of times.

**Article 14 Course schedule; information (FR: article 18)**

(1) The course schedule attached as Appendix 2 provides students with tips for how to structure their studies in a focused manner. It takes account of the connections in content between modules and the organizational requirements of the course.

(2) Goethe Business School will, via Goethe University's central e-learning platform OLAT, set up a directory for the Masters Course of Pharma Business Administration containing general information and regulations relating to the course as these are updated from time to time. This is also where the Module Handbook and course schedule are published.

(3) Goethe Business School will draw up for the Masters Course of Pharma Business Administration an annotated list of classes with a description of the course content and organization based on the module descriptions and on the course schedule. This should be updated every semester and made available to the students during the information events held once a semester or no later than in the last week of lectures in the previous semester, via Goethe University's central e-learning platform OLAT.

**Article 15 Course guidance; orientation event (FR: article 19)**

(1) The students have the option of seeking course guidance for the Masters Course of Pharma Business Administration at Goethe Business School throughout the duration of their studies. Course guidance is provided by the person delegated to do so there. Within the framework of course guidance, students receive support, in particular with issues of how to structure their studies, study techniques and the choice of classes. Course guidance should be drawn upon in particular:

- at the beginning of the first semester;
- upon failure to pass examinations and failed attempts to obtain the required record of performance;
- in case of difficulties with individual classes;
- on a change of course or university.

(2) In addition to the course guidance, students also have recourse to Central Student Advisory Services at Goethe University. As the source of general course advice it instructs on course options, course content, structure and requirements and advises in case of personal difficulties that are course-related.

(3) Prior to the beginning of the lecture period in any semester in which students are able to start their course, there is an orientation event organized by Goethe Business School to which freshers are invited using publicly-displayed notices or otherwise. Within this students are informed about the structure and overall composition of the course and about any special features that are semester-specific. The students are given an opportunity to clarify issues relating in particular to course organization.
(1) At the suggestion of the respective Faculty Councils, the Deans of Studies at the Faculties of Economics and Business Administration and Biochemistry, Chemistry and Pharmacy each delegate the task of academic leadership of the Masters Course of Pharma Business Administration to a member of the group of professors authorized to examine on the Masters Course for a term of at least two years. The academic directors are advisory members of the Academic Commission and have, in particular, the following tasks:

- coordination of the teaching and examinations offered as part of the course, working together with those responsible for module delivery, where relevant also from other faculties;
- compiling and updating lists of examiners;
- course evaluation and implementation, where relevant, of any resulting quality assurance measures developed in cooperation with the Academic Commission (cf. in this regard article 6 Evaluation Rules for Teaching and Studies);
- where relevant, the appointment of the person responsible for module delivery (paragraph 2 remains unaffected).

(2) For every module the course's academic director will appoint someone responsible for module delivery from the group of teachers of the module. For interdisciplinary modules the person responsible for module delivery is appointed in collaboration with the other faculty's Dean of Studies. The person responsible for module delivery is a professor or tenured academic staff member. He or she is responsible for the coordination of all content relating to the module and the organizational tasks allocated to him or her by this regulation, particularly for collaboration on the organization of the module examination. The person responsible for module delivery is represented by the academic director of the course. Where no professor or tenured academic staff member is available, the academic director shall take on the role of the person responsible for delivery of the module.

**Part IV: Examination organization**

**Article 17 Examination Board; Examinations Office (FR: article 21)**

(1) The Faculty Councils participating in the Master of Pharma Business Administration degree program shall set up a joint Examination Board for the Master’s degree program.

(2) The Examination Board has at least seven members including two members of the group of professors from the Faculty of Economics and Business Administration and two members of the group of professors from the Faculty of Biochemistry, Chemistry and Pharmacy, one Goethe Business School employee responsible for admissions and two students enrolled in the Masters course.

(3) At the suggestion of the relevant groups, the members of the Examination Board, along with a deputy, are elected by the Faculty Councils of the Faculties of Economics and Business Administration and Biochemistry, Chemistry and Pharmacy that are participating in the respective course. Students are appointed for one year. Other members are appointed for two. Reelection is permitted.

(4) In case of circumstances relating to a member of the Examination Board, that person's membership is suspended in relation to these circumstances and their duties are carried out by the deputy. This does not apply in case of purely organizational matters.

(5) The Examination Board elects a chair from among the professors that belong to it. The deputy chair is elected from among the professors belonging to the Examination Board or their deputies. The chair directs the business of the Examination Board. He or she invites members to meetings of the Examination Board and chairs all sessions.
and decision-making. As a rule, the Examination Board should meet at least once every semester. A meeting should be convened if at least two members of the Examination Board so request.

(6) The Examination Board does not sit in public. It is quorate if at least half the members, including the chair or the deputy chair, are present and the majority of professors' votes is ensured. Agreement by the majority of those present is required for decisions to be passed. Where votes are tied the chair has the deciding vote. Decisions of the Examination Board should be minuted. Otherwise, procedure is determined by the internal regulations of the bodies of Goethe University.

(7) The Examination Board is able to transfer individual tasks to its chair for implementation and decision-making by him/her alone. The members of the Examination Board and the examinee affected have a right of appeal against the latter's decisions. The chair of the Examination Board may delegate implementation of tasks to the Examinations Office of Goethe Business School (“Examinations Office”). This is the office of the Examination Board. It runs ongoing business as instructed by the Examination Board and its chair.

(8) The members of the Examination Board and their deputies are bound by a duty of confidentiality. Unless they are public servants they are to have a duty of non-disclosure imposed on them by the chair; they confirm this obligation by their signature which is kept on file.

(9) The members of the Examination Board are entitled to listen in on oral examinations.

(10) The Examination Board may publish directives, the setting of dates and other decisions in compliance with the provisions of data protection law with legally binding effect by displaying notices at the Examinations Office or through other suitable measures under section 41 Hesse Administrative Procedures Act.

(11) Negative decisions by the Examination Board or the chair of the Examination Board should be notified to the student without delay, giving reasons for the same and with information on legal remedies attached to them. The student is given opportunity to comment prior to the decision.

**Article 18 Responsibilities of the Examination Board (FR: article 22)**

(1) The Examination Board and the Examinations Office responsible for the Masters Course of Pharma Business Administration are responsible for the organization and the proper conduct of the examinations as part of the Masters Course of Pharma Business Administration. The Examination Board shall take care that the provisions of this regulation are complied with and decide in case of doubt on questions of interpretation of this regulation. It decides on all examination matters that are not transferred by regulation or statute to a different body or to the chair of the Examination Board.

(2) As a rule, the Examination Board is responsible for the following tasks:

- decision on satisfaction of the requirements for access to the Master’s course;
- setting the examination dates, periods and examination registration and withdrawal periods and publishing the same;
- (where relevant) appointment of examiners;
- decisions on admission for examination;
- decisions on the transfer of credits pursuant to articles 26 and 27;
- the calculation and notification of examination grades and of the overall grade for the Master's degree;
- decisions in relation to the Master’s thesis;
- pass or non-pass decisions;
- decisions on making up a disadvantage and on the extension of the time allowed for examinations or the completion of course work;
- decisions on breaches of examination regulations;
- decisions on the invalidity of the Master's degree;
- decisions on appeals and objections by students to decisions made in examination procedures should these be sustained;
- regular compilation of reports within the Academic Commission on the development of the examination and course times including the time allowed for completion of the Master's thesis, as well as on student demand for different options;
- publication of the allocation of subject grades and overall grades;
- suggestions for the reform of this regulation.

(3) For the purposes of verifying compliance with good academic practice the Examination Board is entitled also to use appropriate electronic devices to check academic papers for cheating and attempted cheating. To this end it may request examination papers to be made available to it within a reasonable time in electronic format. Where the author does not comply with this request the paper may be assessed as having been failed.

**Article 19 Examiners; observers (FR: article 23)**

(1) Members of the group of professors and academic staff engaged to teach are authorized to conduct university examinations, as are lecturers and teaching staff engaged for specific purposes (section 18(2) HHG). University lecturers (Privatdozentinnen and Privatdozenten), extracurricular professors and honorary professors who teach any of the examination subjects may also, with their consent, be appointed as examiners by the Examination Board, as may professors who have been released from their duties or who have retired. In specific cases the Examination Board may appoint someone from outside Goethe University but who is an authorized examiner under sentence 1 as the provider of a second opinion for the Master's thesis. Examination work may only be assessed by people holding at least the qualification being assessed by the examination or an equivalent.

(2) As a rule, the examination belonging to a module is conducted by those teaching the module with no separate appointment being made by the Examination Board. Should there be compelling reasons why a teacher is not able to conduct examinations, the Examination Board may appoint a different examiner.

(3) Written examination work that can no longer be retaken should be assessed by two examiners. This does not affect article 33(17). Oral examinations should be conducted by multiple examiners or by one examiner in the presence of an observer.

(4) Only members of Goethe University who have passed a Master's degree or comparable examination may be appointed as observers for oral examinations. The observer is appointed by the chair of the Examination Board. He or she may delegate the appointment to the examiner.

(5) Examiners and observers are bound to respect official secrecy.
Part V: Examination requirements and procedures

Article 20 Time of the examination and registration process (FR: article 25)

(1) Module examinations are taken at the time of and in the context of the corresponding modules. Module examinations for mandatory modules and options that start once a year should, as a rule, be offered at least twice a year.

(2) The final oral examinations for the module test papers should be completed within the examination periods set by the Examination Board. The examination periods are, as a rule, the first two and last two weeks of the lecture-free period of the Masters Course.

(3) The exact examination dates for the module examinations are set by the Examination Board in agreement with the examiners. The Examinations Office shall notify the students of the time and place of the examinations and the names of the examiners involved as early as possible within an examination schedule, but no later than four weeks prior to the examination dates, by putting this on public display or by other suitable means. Where there are compelling reasons to deviate from the examination schedule, the date may be changed only with the approval of the chair of the Examination Board. Dates of final oral examinations for modules or for examinations held at the same time as individual classes will be set by the examiner, where relevant following consultation with the students.

(4) Students may only take a module examination where they have matriculated at Goethe University. Furthermore, they need to have provided the required performance and participation records for the module in accordance with the module description. Where admission to a module examination or partial module examination depends on course work having been completed and where this has not yet been fully done, admission to a module examination or part of a module examination is possible only on a provisional basis. The module is not passed until all course work and module examinations have been passed. The Examination Board decides on any exceptions. Students who have been granted leave of absence are not permitted to take any examinations or earn any records of performance. However, during the leave of absence they are permitted to re-sit examinations not passed. Students are also entitled to carry out non-graded and graded work during a leave of absence if the leave of absence occurred on the basis of maternity rights or due to the taking of parental leave or due to the provision of care, based on a medical certificate, to a relative who is in need of care or due to fulfilment of an official duty pursuant to article 12 a of Germany's Basic Law or due to their work as an appointed or elected representative within the academic administration.

(5) Students may withdraw their examination registration up until one week before the examination date without providing reasons. In case of a later withdrawal article 21(1) applies.

(6) In exceptional cases, particularly in cases where students change their place of study, their subject area or resume their studies, the Examination Board may, upon request, waive the matriculation obligation in relation to individual module examinations.

Article 21 Absence and withdrawal from module examinations (FR: article 26)

(1) A module examination taken is deemed a “fail” (5.0) pursuant to article 34(3) if, for no good reason, the student misses an examination date that is binding on him/her or leaves the examination before completing it. The same applies if he or she failed to do a written piece of work for the module examination within the time period allowed or gave in a blank page as his/her module examination work in a supervised written paper or was silent in an oral examination.

(2) The alleged reason for missing or abandoning the examination must be plausibly indicated in writing to the chair of the Examination Board as soon as the reason becomes known. Any incapacity to take an examination occurring
while the examination is being taken needs to be put forward to the examiner or the examination proctor. This is without prejudice to the obligation to promptly indicate and give a plausible account of the reasons to the Examination Board. In case of illness a doctor's certificate and certificate of incapacity for an examination must be provided promptly by the GP/consultant and in any case within three working days. The doctor's certificate/certificate of incapacity must make clear the type of examination (written examination, oral examination, extended examinations or other examination formats) affected by the medical incapacity on the date of the examination. The chair of the Examination Board shall decide on the incapacity to take an examination, on the basis of the formula attached in Appendix 11 of the Framework Regulation. Where there are grounds for doubt a certificate should additionally be requested from a medical officer.

(3) The illness of a child whom the student has to look after and who has not yet turned 14 or of a close relative in need of care (children, parents, grandparents, spouse or life partner) is treated the same as that student's own illness. The application of maternity rights is also deemed to be cause.

(4) The chair of the Examination Board shall decide on the acceptance of the grounds for missing or withdrawing from an examination. Where the grounds are recognized, a new date is set without delay.

(5) In the case of a recognized withdrawal or missing of an examination, the examination results for those parts of the module already taken remain in place.

**Article 22 Completion of course work and examinations in case of illness and disability; special circumstances (FR: article 27)**

(1) In classes and examinations, account needs to be taken of the nature and severity of students’ disabilities or chronic illnesses or of the strain of pregnancy or childcare or of looking after close relatives in need of care.

(2) Students should promptly provide the chair of the Examination Board with evidence of the nature and severity of the strain by presenting appropriate documents, including a doctor's certificate in case of illness. In cases of doubt, a medical officer's certificate may also be requested.

(3) Where students are able to make a credible case for being unable, due to a disability, chronic illness, their care for a close relative in need of care, pregnancy or the fact that they are bringing up a child who has not yet turned 14, to complete their examination or course work in the given format either wholly or in part, then such disadvantage must be made up for through appropriate measures such as, for example, extending the time allowed or reconfiguring the examination process. It should be made possible for students to utilize their statutory maternity rights and take periods of parental leave upon providing appropriate evidence.

(4) Decisions on making up for disadvantages in the taking of examinations shall be made by the chair of the Examination Board and, in case of course work, by the chair of the Examination Board in consultation with the person responsible for the class.

**Article 23 Binding course guidance; time limits for the sitting of examinations (FR: article 28)**

(1) Where the course of their studies has been delayed by more than two semesters compared with the course schedule, students are obliged to participate in a binding consultation. Following the binding consultation the Examination Board shall impose a requirement on the person affected to complete the module examinations that, when the requirement is imposed, remain outstanding compared with the course schedule within a time limit to be set by the Examination Board (at least two semesters). Failure to meet this requirement results in the loss of entitlement to take examinations on the Masters Course of Pharma Business Administration. Students should be
made aware of this when the requirement is imposed. Where the person affected under paragraph 3 is able promptly to put forward a credible case for being prevented (for cause) from meeting the requirement, the Examination Board shall extend the time limit for compliance with the requirement by at least one further semester. In case of an initial non-appearance at the consultation the student will shortly thereafter be invited to a further consultation. Where the student again fails to attend the consultation, sentences 2 to 5 shall apply without there being a further invitation to a consultation.

(2) The Master's examination needs to be successfully completed by the end of the sixth semester. Students who, at the end of their sixth semester, have not passed the Master's examination will be encouraged by the Examinations Office to seek course guidance. Where the completion period under sentence 1 is exceeded without any of the requirements existing for an extension under paragraph 3, this shall lead to the loss of entitlement to be examined in the Masters Course of Pharma Business Administration.

(3) The period set for the
- fulfilment of the requirement
- for the successful completion of the Master's examination

under paragraph 1 should be extended at the student's request if the delay is the responsibility of Goethe Business School or the student was not in a position to meet the time limit due to extreme circumstances. When complying with time limits, extensions and interruptions in the period of study are ignored to the extent they were caused

1. by an approved leave-of-absence semester;
2. by the student's work as an appointed or elected representative within the academic or student administration;
3. by illness, disability or chronic illness or for any other reason beyond the student's control;
4. by maternal rights or parental leave;
5. by the need to look after a child until they turn 14 or to care for a close relative (children, parents, grandparents, spouse or life partner) falling within a care level under article 15(1) of Book 11 of the German Social Security Code;
6. due to membership of an A, B, C or D/C squad within a German sports association

In case of number 4, the utilization of the time limits under section 3(2) and section 6(1) of the German Maternity Protection Act (Mutterschutzgesetz or "MuSchG") and the provisions regarding paternal leave in sections 15 and 16 of the Parental Allowances and Parental Leave Act (Bundeseltern geld- und Elternzeitgesetz or "BEEG") should be taken into account accordingly. An organized course of one to two semesters abroad is also not taken into account. The application should be made when the student recognizes that a time extension will be necessary. The application should essentially be made before the time limit expires. The obligation to produce evidence is a matter for the student; this should be submitted with the application. In case of illness a medical officer's certificate should be submitted. The fourth sentence of article 21(2) applies accordingly. In cases of doubt a medical officer's certificate may be requested. The Examination Board shall decide on the application for an extension of the time limit.

Article 24 Cheating and breach of regulation (FR: article 29)

(1) Should the student attempt to influence the result of his or her examination or course work by cheating or by
using aids that are not permitted, the examination or course work is deemed graded as a "fail" (5.0). An attempt to cheat also exists, in particular, where the student brings aids that are not permitted into the examination room or gives a false explanation under articles 13(7), 28(7), 31(5), 33(16) or if he/she has submitted the same piece of work (or parts of the same) as graded or non-graded (course) work more than once.

(2) A student who actively aids an attempt to cheat may be excluded by the relevant examiner or by the proctor from continuing the relevant examination, in which case the relevant examination or course work is deemed graded as a "fail" (5.0).

(3) In cases of particularly serious cheating, particularly where there is repeated cheating or cheating involving the attachment of a written statement by the student that he/she prepared the work independently and with no unpermitted aids, the Examination Board may decide to exclude the option of the examination being retaken and of further course work being done, so that the right to take an examination in the Masters Course of Pharma Business Administration expires. The severity of the cheating should be judged based on the lengths the student went to cheat, such as organized cooperation or the use of technical aids (such as radios and mobile telephones) and the impact on the equality of opportunity caused by the cheating.

(4) A student who disrupts the proper course of an examination may be excluded by the relevant examiner or by the proctor, normally following a warning, from continuing the relevant examination, in which case the relevant examination work is graded as a "fail" (5.0). The first sentence of paragraph 3 applies mutatis mutandis.

(5) Where the culpable behavior of a student has led to illegitimate participation in an examination, the Examination Board may decide not to pass the relevant examination performance ("fail" (5.0)).

(6) The student may, within a period of four weeks, request that decisions under paragraphs 1 to 5 are reviewed.

(7) Negative decisions by the Examination Board should be notified to the student without delay, giving reasons for the same and with information on legal remedies attached to them.

(8) For term papers, written dissertations and the Master's thesis, the subject-specific citation rules set for the preparation of academic papers apply. Where these are not complied with there should be a review of whether there has been an attempt to cheat.

(9) In order to be able to review the suspicion of academic misconduct, the Examination Board may decide that written examination and/or course work not completed under supervision must also be submitted in electronic format.

Article 25 Faults in the examination process (FR: article 30)

(1) Should it transpire that there were faults in the oral or written examination process which have affected the examination result, the Examination Board should, at the request of a student or on its own authority, order the examination to be retaken by a particular student. The defects need to be complained of, in case of a written examination, to the proctor during the examination situation, and, in case of oral examinations, after the examination, to the chair of the Examination Board or to the examiner. Where the student believes the corrective measures taken by the proctor in case of a written examination to be inadequate, he/she must bring the complaint to the chair of the Examination Board immediately after the examination.

(2) Orders under paragraph 1 can no longer be made six months after completion of the examination.

Article 26 Recognition and accreditation of performance (FR: article 31)
(1) Periods of study, course work and examinations passed are credited without an equivalence assessment if they were done at a university in Germany within the same course, the course is accredited and no significant differences exist in the modules regarding the qualifications targets achieved. Where the Examination Board is unable to provide evidence of a significant difference, the periods of study, course work and examinations passed should be credited.

(2) Periods of study, course work and examinations passed in relation to other courses are credited unless significant differences exist in terms of the skills acquired. When crediting these there is no need to carry out a schematic comparison. Rather, this should be looked at and assessed overall from the content, scope and demands of the course work and examinations passed, particularly taking into account the qualifications targets achieved. The Examination Board bears the burden of proving any lack of equivalence. The second sentence of paragraph 1 applies accordingly.

(3) Paragraph 2 applies accordingly for the crediting of periods of study, course work and examinations passed in nationally recognized, distance-learning courses, at other education institutions, particularly at state-run or nationally recognized vocational academies, for multimedia-supported course work and examinations completed, as well as for students on the basis of article 54(5) HHG course work and examinations completed.

(4) Paragraph 2 similarly applies to the crediting of work done at foreign universities. When transferring credits the equivalence agreements approved by the Conference of the Ministers of Education and Cultural Affairs and the German Rectors' Conference along with arrangements within the framework of university partnership agreements should be observed. Where no equivalence agreements exist, the Examination Board shall decide. In case of doubt as to equivalence, the Central Office for Foreign Education should be consulted.

(5) Final papers (e.g. Master's theses, diploma theses, state examination theses) which students have already successfully completed outside the current Masters Course of Pharma Business Administration at Goethe University are not credited. Furthermore, it is not possible for the same piece of work within the same Masters Course of Pharma Business Administration to be credited more than once.

(6) Course work and examinations passed in relation to a Bachelors course cannot normally be credited for the purposes of the Masters Course.

(7) Where examinations are credited, the grades (where the grading systems are comparable) should be adopted and included in the calculation of the overall grade. In case of grading systems that are not comparable, the description "passed" is used. Credited achievements are normally marked in the degree certificate to indicate the university where they were acquired.

(8) The applicant presents the Examination Board with all the documents required for crediting or recognition, on which the assessment, the CP and the timings of all examinations are based which he/she has taken to date as part of a different course or at different universities. It must be clear from the documents which examinations and course work were not passed or were retaken. The Examination Board may request the presentation of further documents such as the legally binding module descriptions of the module to be recognized.

(9) Fails in other courses or in courses at other universities are counted to the extent they were counted when they arose.

(10) The crediting and recognition of examinations passed more than five years ago may be refused in individual cases. The decision may be connected to the imposition of requirements. Where the requirements of paragraphs 1 to 4 in conjunction with paragraph 8 exist, there is a legal right to have credits taken into account. This is without prejudice to the first sentence and paragraphs 5 and 9.
(11) Decisions of general application on issues of the counting of credits are made by the Examination Board; in individual cases crediting is done by its chair, where required with the involvement of a subject examiner. Taking the credits into account he or she stipulates a semester.

(12) Where course work and examinations passed are taken into account which do not carry CP, the corresponding equivalents should be calculated and recorded in the “study account” accordingly.

(13) Where credits are transferred, this may be linked with requirements in relation to course work to be repeated or examinations to be retaken. Requirements and any time limits for fulfilment of requirements must be notified in writing to the applicant. The notification must be accompanied by advice on the legal remedies available.

**Article 27 Accreditation of skills acquired outside higher education (FR: article 32)**

For knowledge and skills acquired before the beginning of the course or during the course but outside a university and which are equivalent to course modules in their level and learning outcome, the CP for the corresponding modules may be added upon request. The credits are added by the Examination Board on a case-by-case basis at the suggestion of the person responsible for module delivery. This is conditional on written evidence (e.g. reports, certificates) on the scope, content and the work completed. Overall, not more than 50% of the CP required in the course may be replaced through the transfer of credits. CP are added without a grade. This is shown accordingly in the report.

**Part VI: Implementation of module examinations**

**Article 28 Module examinations (FR: article 33)**

(1) Module examinations are done alongside the course. They mark completion of the relevant module. They are examinations which can be repeated a limited number of times and which are assessed with a grade.

(2) Modules generally end with a single module examination which can also be held concurrently with one of the classes for the module (class-based module examination). The module examination may be made up of a number of elements.

(3) The student shall provide evidence through the module examination that he/she has mastered the content and methods of the module in the main respects and is able to apply the knowledge and skills acquired. The subject matter of module examinations is essentially the content of the classes for the relevant module specified in the module descriptions. In case of class-based module examinations, the overriding qualifications objectives for the module are examined at the same time.

(4) The relevant format for the module examination or partial module examination is derived from the module description. Written examinations occur in the form of:

- written tests;
- term papers;
- written papers (e.g. essays, written dissertations);
- thesis papers;
- project work;

Oral examinations occur in the form of:
other forms of examination are:
- speeches as part of a seminar;
- dissertations;
- presentations.

(5) The format and length of module examinations and, where relevant, the elements of the same are regulated in the module descriptions. Where the module description envisages multiple options where examination formats are concerned, the format for the relevant examination will be specified by the examiner and notified to the students at the beginning of the classes for that module, but no later than when the date of the examination is announced.

(6) The language of the examination is English. Individual written or oral examinations may be taken in a foreign language where there is mutual agreement among all examination participants. The module description provides more detail.

(7) Written papers prepared not under supervision (for example, term papers) are to be prepared by the student according to the rules of good academic practice. When submitting the paper the students have to affirm in writing that they have prepared this themselves and that they have listed all sources and aids used by them in the paper. It further needs to be stated that the paper has not previously (even in the form of extracts) been used as non-graded or graded work in a different course.

(8) Participants in module examinations have to prove their identity through presentation of an official photo ID.

(9) The examiner decides whether and which aids may be used in a module examination. The aids allowed must be publicized in good time before the examination.

**Article 29 Oral examinations (FR: article 34)**

(1) Oral examinations are conducted as an individual examination by the examiner in the presence of an observer. Group examinations of up to five students are permitted.

(2) Oral examinations should last between a minimum of 15 minutes and a maximum of 60 minutes per student being examined. The length of the relevant module examination is derived from the module description.

(3) The main topics and results of the oral examination should be recorded by the observer in a report. The examiners' report should be signed by the examiner and the observer. Before the grade is decided on, the observer should be consulted in the absence of the examinee and of the public. The report should be sent to the Examinations Office without delay.

(4) The result of the oral examination should be notified to the student immediately after the oral examination and, in the absence of a pass or upon a request voiced immediately, should be explained in more detail; the reasons provided should be recorded in the report.

(5) Oral examinations are open to members of the university where these are students who are to take the same examination. The student being examined may object to the public being admitted. The giving of advice and notification of the examination result to the student being examined is not open to the public. Public admission may
also be restricted on grounds of capacity. For the purpose of verifying the grounds referred to in the first sentence, the chair of the Examination Board may request corresponding evidence.

**Article 30 Tests and other written supervised examinations (FR article 35)**

(1) Tests include the answering of an assignment or of multiple assignments or questions. In a test or other supervised written paper the student should provide evidence that he/she is able to solve the assignments independently within a time limit and under supervision with limited aids and, on the basis of the necessary basic knowledge or by applying current methods in the subject area, is able to recognize a problem and find ways to a solution.

(2) For tests where more than 25% of the total marks available are to be achieved through multiple-choice questions, the following provisions should be complied with when compiling the selection of questions and assessing the tests:

- The examination questions must permit reliable examination results. The examination questions must be understandable free of ambiguity, clearly answerable and must be such that they clearly establish the student's level of understanding and knowledge to be assessed. In particular, there should be no reasonable solution possible other than the solution that is presented in the assessment as the correct one. The Examination Board must take reasonable measures to ensure this;

- Where the assignments prove to be unsuitable in this regard, they must be removed from the assessment. Where answers do not match the given sample solution but are nevertheless reasonable they are accepted in the student's favor. It is not permissible to deduct points for wrong answers.

- The questions and list of answers must be compiled by at least two authorized examiners and at least one of them is required to belong to the group of professors;

- The pass conditions and the test's marking scheme must be notified to the students no later than when the assignment is set.

A test that contains more than 25% multiple-choice questions is passed if the student has accurately answered at least 50% (pass mark) of the questions asked or if the number of questions accurately answered by the student is not more than 22% below the average result of all examination participants taking the examination for the first time.

(3) Where a student arrives late for the test he/she cannot make up the time missed. The examination room may only be left with permission from the proctor.

(4) The proctor of a test must prepare a short report about each test. This must contain all incidents relevant to the establishment of the examination results, particularly incidents under articles 21 and 24.

(5) The time allowed for tests and for other supervised written papers should be based on the scope of the module being assessed or, in case of partial module examinations, on the scope of the part of the module being assessed. For tests as an individual examination this is at least 60 minutes and no more than 240 minutes. The specific length is specified in the relevant module descriptions.

(6) The tests and other supervised written papers are generally assessed by one examiner. In case of a failure where they are retaken for the last time, they should be assessed by a second examiner. Reasons for the grade awarded should be given in writing. Where there is a disparity in the grades, the grade for the test or other supervised written paper is calculated from the average of the two grades. The marking process for tests should not take more than two weeks.

(7) Multimedia-supported tests ("e-tests") are permitted where they are appropriate to meet the examination
objective. They may only be completed using DP systems approved for this purpose administered by the university or by the Examinations Office by agreement with the university computer center. The electronic data must be guaranteed to remain clearly identifiable in the process. The data must be unique and must be capable of being permanently attributed to the student. The examination is to be held in the presence of a subject specialist who compiles a report on the same. A record must be prepared of how the examination went, which must give at least the names of the person compiling the report and of the students, the beginning and end of the examination and any particular incidents. Access to the multimedia-supported examination and to the examination results is governed by article 44. The assignment, including any sample solution, the marking scheme, the individual examination results and the record must be archived in accordance with the statutory requirements.

Article 31 Term papers and other written papers (FR: article 36)

(1) The student should show with a written term paper that he/she is equipped to process the problem from a subject area on his/her own in accordance with scientific methods. It must be a component of a module.

(2) A term paper may be permitted as co-authored work if the individual contributions to be assessed are recognizable based on objective criteria.

(3) The student may be given the opportunity to suggest a topic. The topic is given out by the examiner who documents the time allowed for completion of the term paper.

(4) Term papers should have a completion time of at least two and no more than four weeks (on an extra-occupational basis, i.e. a workload of 2 to 4 CP). The time allowed for completion of the particular term paper is specified in the module description. The time limits for submission of the term papers shall be set and documented by the examiners.

(5) The term paper must be submitted to the examiner within the set completion time in a single copy with an article 28(7) declaration attached; where sent by post the relevant date is that of the postmark. Submission of the term paper is to be recorded on file by the examiner.

(6) The term paper should be assessed by the examiner within two weeks of submission; reasons for the grade awarded should be given in writing. Article 30(6) otherwise applies mutatis mutandis.

(7) A student whose term paper has been graded as a “fail” (5.0) may apply to the examiner to be allowed to make subsequent improvements to the term paper. This does not apply where the “fail” grade (5.0) is a result of article 21 or article 24. The examiner shall set a time limit for the subsequent improvement of the term paper. In terms of the decision on the improved term paper, the only decision to be made is whether the term paper should be given a grade of 4.0 or worse. Where the time limit for submission of the improved term paper is not met, the term paper is given a final “fail” grade (5.0).

(8) For the other written papers, paragraphs 1 to 6 apply accordingly.

Article 32 Project work (FR: article 38)

(1) Project work should demonstrate the ability to develop, argue and present concepts. Here, the students should demonstrate that they are able to define goals within a larger task and work out problem-solving approaches and concepts.

(2) The length of the project work is regulated in the module description.

(3) In case of project work done in the form of team work, the contribution of the individual students must be clearly
recognizable and meet the requirements of paragraph 1.

**Article 33 Master's thesis (FR: articles 40, 41)**

(1) The Master's thesis is a mandatory component of the Masters Course. It forms a stand-alone module in the completion phase of the course.

(2) The Master's thesis should show that the student is in a position to explore a topic comprehensively and in depth within a set time limit in line with the objectives under articles 2 and 5. The topic must be such that it is capable of being explored within the time limit envisaged.

(3) The scope of work on the Master's thesis amounts to 20 CP. The time allowed for completion is 20 weeks.

(4) In order to be able to apply for admission of the Master's thesis, all modules in the foundation, concentration and specialization phase need to have been completed. The module description governs the particulars.

(5) The Master's thesis is supervised by someone from the group of authorized examiners under article 19. The latter has a duty to guide the student in the preparation of the Master's thesis and regularly check on the progress of the work. The supervisor must ensure that, where relevant, the equipment required to carry out the Master's thesis is available. The supervisor is generally the provider of the first opinion on the Master's thesis.

(6) With the permission of the chair of the Examination Board, the Master's thesis may also be completed outside Goethe University. In that case, the topic must be set with a member of the group of professors at the Faculties of Economics and Business Administration and Biochemistry, Chemistry and Pharmacy.

(7) The topic of the Master's thesis should be agreed with the supervisor and notified to the chair of the Examination Board when the Master's thesis is registered. Should the student not find a supervisor, the chair of the Examination Board shall ensure, at the student's request, that the latter is given a topic and the required supervision for the Master's thesis in good time as far as possible.

(8) The chair of the Examination Board shall decide on the admission of the Master's thesis.

(9) The topic is issued by the chair of the Examination Board. The topic and the time it was issued must be kept on file at the Examinations Office. The Master's thesis may not be worked on before the issue of the topic recorded on file.

(10) The Master's thesis may also be allowed in the form of co-authored work if the contribution of the individual student to be examined is clearly distinguishable and assessable based on references to articles, page numbers and other objective criteria facilitating a clear demarcation, and the requirements of paragraph 2 are met.

(11) The Master's thesis must be written in English. With the permission of the chair of the Examination Board, it may be prepared in a different language. Preparation of the Master's thesis in another language must be applied for no later than when the Master's thesis is registered with the Examination Board. Agreement to the preparation of the thesis in the other language chosen is given at the same time as the topics are issued provided the written agreement of the supervisor is available when the Master's thesis is registered and it is possible to appoint someone with adequate language skills in the language chosen to provide a second opinion. Where the Master's thesis is, with the permission of the chair of the Examination Board, prepared in another language, a summary in German must be attached.

(12) The topic set can only be rejected once and only within the first third of the time allowed for completion of the Master's thesis. The new topic set must differ in its content from the topic that was rejected.

If, as a result of withdrawal under the third sentence of article 13, a new topic is issued for the Master's thesis, that
topic cannot be rejected.

(13) Where the submission date cannot be complied with for reasons beyond the student's control (e.g. illness of the student or of a child in his/her care), then the chair of the Examination Board shall extend the time allowed if the student applies for this before the submission date. An extension of the time allowed may be granted of no more than 50%. Where the obstacle persists for longer, the student may withdraw from the examination.

(14) The Master's thesis must be handed in to the Examinations Office within the time limit. The time of receipt must be recorded on file. Where sent by post, the relevant date is that of the postmark. Where the Master's thesis is not delivered on time it is assessed as a "fail" (5.0).

(15) The Master's thesis must be submitted in two written (bound) copies and in an appropriate electronic counterpart. Where the Master's thesis is not delivered in the prescribed format within the time limit for submission it is assessed as a "fail" (5.0).

(16) The Master's thesis is to be composed in line with the rules of good academic practice. In particular, all passages, pictures and illustrations that are literally or effectively taken from publications or other third-party texts should be marked as such. Attached to the Master's thesis there should be a statement by the student that he/she has written the thesis (in the case of co-authored work he/she has written a section of the paper marked to that effect) on his/her own and without using sources or aids other than those cited. Furthermore, it should be stated that the Master's thesis has not, even in extracts, be used for other graded or non-graded work.

(17) The Examination Board forwards the Master's thesis to the supervisor as the provider of the first opinion, for assessment under article 34(3). At the same time, it shall appoint a further examiner from the circle of authorized examiners under article 19 for the purpose of a second assessment, and shall also forward the thesis to him/her for assessment. At least one of the examiners must belong to the group of professors at the Faculties of Economics and Business Administration and Biochemistry, Chemistry and Pharmacy. The provider of the second opinion may, when he/she agrees with the assessment of the provider of the first opinion, limit him/herself to co-signing the latter's opinion. The assessment should be made by the examiners without delay; it should be available no later than four weeks after thesis submission. Where the two examiners differ in their assessment of the Master's thesis the grade for the Master's thesis is determined in line with article 34(5).

Part VII: Assessment of course work and examinations; creation of grades and overall grade; failure to pass the examination overall

Article 34 Assessment/grading of course work and examinations; creation of grades and of the overall grade (FR: article 42)

(1) Course work is assessed by the relevant teacher as "passed" or "not passed".

(2) Examinations are generally graded and, in exceptional cases as indicated in the module description, assessed as having been "passed" or "not passed". The grading or assessment of examinations is done by the corresponding examiners. This should always be based on the individual performance of the student.

(3) The following marks are to be used to grade individual examinations or elements of the same:

<table>
<thead>
<tr>
<th></th>
<th>very good</th>
<th>an excellent performance;</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>good</td>
<td>a performance that is significantly above the average requirements;</td>
</tr>
</tbody>
</table>
In order to differentiate the assessment of examination performance, grades may be increased or reduced by 0.3 to intermediate values; the following grades are permitted: 1.0; 1.3; 1.7; 2.0; 2.3; 2.7; 3.0; 3.3; 3.7; 4.0 and 5.0.

(4) Where the module examination is made up of different elements the grade for the module is calculated based on the arithmetical mean of the grades for the individual elements unless otherwise regulated in the module description. In doing this, only the first decimal place after the decimal point is taken into account. If the module description permits latitude with respect to the weighting of individual elements, the student is informed of the specific weighting at the start of the lectures for the module, but no later than the announcement of the examination date.

(5) Where the module examination is graded differently by two or more examiners, the module grade is calculated from the arithmetical mean of the grades from the examiners' assessments. When formulating the module grade, only the first decimal place after the decimal point is taken into account.

(6) An overall grade is created for the Master's examination which takes into account the results of all module examinations for the entire course.

(7) Where more CP are earned in an option area than anticipated, the modules completed first will be used to generate the overall grade. Where multiple modules are completed in the same semester those with the better grades count.

(8) The overall grade for a Master's examination passed is generated from the following illustration, with only the first decimal place after the decimal point being taken into account; all further digits are deleted without being rounded up or down:

- 1.0 to 1.5 inclusive: very good
- 1.6 to 2.5 inclusive: good
- 2.6 to 3.5 inclusive: satisfactory
- 3.6 to 4.0 inclusive: sufficient
- above 4.0: fail

(9) Where an English-language translation of the grades is prepared, the grades for performance in the individual examinations and the overall grade are illustrated according to the following scale:

- 1.0 to 1.5 inclusive: very good
- 1.6 to 2.5 inclusive: good
- 2.6 to 3.5 inclusive: satisfactory
- 3.6 to 4.0 inclusive: sufficient
- above 4.0: fail
(10) In case of an overall grade of 1.0 or less the overall assessment is "passed with distinction". The English-language translation of "passed with distinction" is "excellent".

(11) For the sake of making the overall grade transparent, an ECTS grading scale is included in the Diploma Supplement pursuant to article 42.

Article 35 Pass and failure to pass examinations; notification of grades
(FR: article 43)

(1) A module examination consisting of a single examination taken is passed if it is assessed with a grade of "sufficient" (4.0) or better.

(2) A module examination consisting of multiple elements is only passed if the average grade calculated from all the elements produces an overall assessment of at least "sufficient" (4.0). The Master's examination is passed if all modules prescribed in this regulation have been successfully completed, meaning that the required course records are available and the prescribed module examinations including the Master's thesis have been graded at least "sufficient" (4.0).

(3) The results of all examinations must be notified without delay. The Examination Board decides on whether grades are made available on an anonymized basis to members of the university by being publicly displayed and/or via the computerized examination administration system, in which case the interests of those affected meriting protection should be protected. Where a module examination has ultimately been assessed as a "fail" or where the Master's thesis has been assessed as worse than "sufficient" (4.0), the student receives from the chair of the Examination Board a written decision attaching advice on legal remedies available and which should include advice on whether and, where relevant, to what extent and how soon the module examination or Master's thesis, as the case may be, can be retaken or resubmitted.

Article 36 Compiling the examination result (data transcript) (FR: article 44)

Upon request students are issued with a certificate of examinations passed, in the form of a data transcript (sample Appendix 5) in German and in English, containing at least the module title, the date of the individual examinations and the grades.

Part VIII: Change of mandatory and electives; major fields of study; retaking examinations; loss of the right to take an examination and final failure to pass

Article 37 Change of electives (FR: article 45)

Where an option is failed for the final time, this may be replaced with a new option.

Article 38 Retaking examinations (FR: article 46)

(1) Examinations or elements passed cannot be retaken.

(2) All options examinations not passed must be retaken. Where a module examination consists of multiple elements only the element not passed needs to be retaken where the module examination is not passed.

(3) Module examinations not passed may be retaken no more than twice.

(4) A Master's thesis not passed may be repeated once. A different topic is allocated. The topic of the Master's thesis
may only be rejected in the context of a re-examination if the student has not taken advantage of this possibility when preparing the original Master's thesis. Repeated rejection of the topic is not permitted. A Master's thesis may be repeated as soon as the grade is notified.

(5) Where module seminars are repeated there is no right to repeat a particular seminar or to a particular examiner.

(6) Failures of the same or a comparable module examination from a different course at Goethe University or at a different German university should be counted within the permitted number of retakes. The Examination Board may, in particular cases, particularly in case of a change of course, refrain from counting these.

(7) The Examination Board may set an oral examination in place of a written examination not passed, with the exception of the Master's thesis. There is no legal right to repeat the module examination with a specific examiner or to repeat the format of the module examination that was not passed.

(8) The first retake of a mandatory module should be taken at the end of the relevant semester but in any case no later than the beginning of the following semester. The second should be taken as of the next examination date possible following the unsuccessful retake. Students who have attended an examination are, where they fail to pass the examination, deemed registered for the next date. The Examination Board sets the exact dates for the retaking of examinations and shall advertise them in good time. Where the time limit for retaking an examination is not met, the right to take the examination expires unless the omission was beyond the student's control. Interim de-registration does not extend the time limit for retakes.

(9) For options examinations not passed, a retake no later than the end of the semester immediately following the examination is offered.

(10) Retakes should generally be held in line with the regulation according to which the original examination was taken.

Article 39 Loss of the right to take an examination and final failure to pass (FR: article 47)

(1) The Master's examination is finally not passed and the right to take an examination is finally lost if

1. a module examination has not been passed following the exhaustion of all retake attempts,
2. a time limit for the completion of certain steps under article 23 has been exceeded,
3. a time limit for the retaking of a module examination under article 38 has been exceeded,
4. there is a serious case of cheating or a serious breach of a regulation under article 24.

(2) A decision attaching advice on legal remedies available is issued in regard to the final failure to pass the Master's examination and the associated loss of the right to take the examination.

(3) Where the student has, for the last time, failed to pass the Master's examination and has thereby finally lost the right to take an examination, he/she should be removed from the matriculation register. Against presentation of the certificate of de-registration, the student may, upon request, receive a certificate from the Examinations Office listing the module examinations passed, his/her grades and the credit points earned and from which it is clear that the Master's examination was ultimately unsuccessful.

Part IX: Examination certificate; degree certificate and Diploma Supplement
Article 40 Examination certificate (FR: article 48)

1. In relation to the Master's examination passed, a certificate should, wherever possible, be issued in German—with a translation in English if requested by the student—in line with the requirements of the sample from the Framework Regulation within four weeks of receipt of the assessment of examination performance. The certificate shall indicate the module with the module grades (at the same time, those modules not included in the overall grade for the Master's examination will be marked), the topic and grade of the Master's thesis, the normal course length and the overall grade. Also included in the certificate is the result of examinations in additional modules.

2. The certificate should be signed by the academic director and affixed with the seal of Goethe University. The certificate shall bear the date when the last examination was assessed.

Article 41 Master's degree certificate (FR: article 49)

1. At the same time as the Master's examination certificate the student receives a Master's degree certificate with the date of the examination certificate in line with the requirements of the sample from the Framework Regulation. This confirms the award of the degree. Upon request the degree certificate can also be issued in English.

2. The degree certificate should be signed by the Dean of Studies of the Faculties of Economics and Business Administration and Biochemistry, Chemistry and Pharmacy and by the chair of the Examination Board and affixed with the seal of Goethe University.

3. The academic degree may not be cited until after the degree certificate is awarded.

Article 42 Diploma Supplement (FR: article 50)

1. Along with the degree certificate and the examination certificate, a Diploma Supplement is issued in line with international requirements; this must use the text agreed between the German Rectors' Conference and the Conference of the Ministers of Education and Cultural Affairs as amended from time to time (sample Appendix 10 FR).

2. The Diploma Supplement contains an ECTS grading scale. The overall grades awarded in the relevant course within a comparison cohort should be recorded and their numerical and percentage distribution across the grades pursuant to article 34(8) identified and set out in a table as follows:

<table>
<thead>
<tr>
<th>Overall grades</th>
<th>Total number within the reference group</th>
<th>Percentage of graduates within the reference group</th>
</tr>
</thead>
<tbody>
<tr>
<td>up to 1.5 (very good)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>between 1.6 and 2.5 (good)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>between 2.6 and 3.5 (satisfactory)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>between 3.6 and 4.0 (sufficient)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The reference group is derived from the number of graduates from the relevant course within a period of three academic years. The calculation is only made if the reference group consists of at least 50 graduates. Where fewer than 50 students within the comparison cohort have completed the course, then, by decision of the Examination Board, further year groups may be included in the calculation.
Part X: Invalidity of the Master’s examination; examination documents; appeals and objections, examination fees

Article 43 Invalidity of examinations (FR: article 51)

(1) Where the student has cheated in a piece of course work or an examination and this fact does not become known until after the examination results are handed out, the Examination Board may, as appropriate, retrospectively amend the grades for those pieces of course work or examinations in which the student cheated and declare the examination or piece of course work not passed, either completely or in part. The examiners should be consulted in advance. The student shall be given opportunity to express him/herself prior to a decision.

(2) Where the conditions for admission to an examination were not fulfilled without the student intending to mislead anyone on this, and if this fact only becomes known after the examination results are handed out, then this shortcoming is made good through the passing of the examination. Where the student deliberately illegitimately obtained admission to the examination, then the Examination Board shall decide on the legal consequences, taking into account the Administrative Procedure Act for the State of Hesse, as amended from time to time. The third sentence of paragraph 1 applies accordingly.

(3) The incorrect examination certificate shall be confiscated and, where relevant, a new one shall be distributed. The Diploma Supplement and, where relevant, the corresponding course record shall be confiscated along with the incorrect report and, where relevant, reissued. The Master's degree certificate should also be confiscated with these documents if the examination was declared "failed" as a result of the cheating behavior. A decision under paragraph 1 and the second sentence of paragraph 2 is excluded after a period of five years from the date of the examination certificate.

Article 44 Access to examination documents; retention periods (FR: article 52)

(1) Upon request the student is allowed access to his/her written examination papers, the opinions on them and to the examiners’ reports at the time the examination results are published.

(2) The examination records are to be kept by the Examination Offices. The retention periods for examination documents are determined under article 20 of the Hesse Matriculation Regulation (“HImmaVO”) as amended from time to time. The written examination papers are, with the exception of the Master's theses, returned to the student or discarded one year after their assessment is published. Upon expiry of five years from completion of the entire examination process the Master's theses are discarded.

Article 45 Appeals and Objections (FR: article 53)

(1) It is possible to appeal decisions by the chair of the Examination Board. The appeal should be submitted to the chair of the Examination Board within one month of notification of the decision. The Examination Board shall decide the appeal. If it does not allow the appeal, the chair of the Examination Board shall issue a rejection with reasons, to which advice on the legal remedies available should be attached.

(2) Where advice is given on the legal remedies available, the person affected may file a written objection against the negative decisions of the Examination Board and against examiners' assessments with the chair of the Examination Board (Examinations Office) within one month of these being notified. Where the Examination Board, where relevant following advice from the examiners involved, does not allow the objection, the president shall issue a decision on the objection. The decision on the objection must provide reasons and be accompanied by advice on
the legal remedies available.

**Article 46 Course fees**

(1) Fees are set under section 16(3) HHG and charged by Goethe Business School for application for and participation in the course and for the processing of examinations.

(2) All fees under the fee regulation applicable to the course governed by this examination regulation shall be paid directly to Goethe Business School.

(3) Prompt payment of the fees is a condition of participation in the course, the conduct and assessment of examinations, the handing out of the examination certificate and of the Master's degree certificate under this examination regulation.

**Part XI: Final provisions**

**Article 47 Entry into effect (FR: article 56)**

(1) This regulation shall take effect on the day after its publication in the UniReport/Satzungen und Ordnungen (UniReport Statutes and Regulations) of Goethe University, Frankfurt am Main.

(2) This regulation applies to all students who, from the winter semester 2016/2017, have taken up a place on the Masters Course of Pharma Business Administration.

Frankfurt am Main, March 17, 2017

**Professor Raimond Maurer**

Dean of the Faculty of Economics and Business Administration

Frankfurt am Main, March 15, 2017

**Prof. Dr. Michael Karas**

Dean of the Faculty of Biochemistry/Chemistry/Pharmacy
Appendix 1: Regulation for special access requirements/aptitude assessment procedures

(1) Aside from the first degree conferring a professional qualification, admission is conditional on further qualitative requirements evidencing particular aptitude for the Masters Course.

(2) The following should be enclosed with the application as originals or certified copies:

- a letter of recommendation from the employer,
- evidence of at least two years' postgraduate professional experience in the pharmaceuticals industry (e.g. employment reference letter, a job description certified by the employer); the Examination Board decides on justified exceptions,
- a motivation letter (in English).

(3) The Examination Board for the Masters Course verifies the existence of the conditions precedent under paragraphs 1 and 2 and implements the further procedure. In order to carry out this task it may appoint one or more admissions panels. An admissions panel shall be made up of at least two professors on the Masters Course who are authorized examiners, one Goethe Business School employee responsible for admissions and, in an advisory capacity, one student member enrolled on the Masters Course. The professorial majority must be guaranteed. Where the Examination Board appoints several admissions panels for the same Masters Course, then at the beginning of the selection process, a joint agreement of the assessment criteria takes place, normally chaired by the chair of the Examination Board. The Examination Board or admissions panel may also draw on support from other staff.

(4) The overall assessment is made up of the following part-assessments:

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion or average grade of the qualifying course:</td>
<td>51%</td>
</tr>
<tr>
<td>Evidence normally of at least two years' postgraduate professional experience in the pharmaceutical industry</td>
<td>19%</td>
</tr>
<tr>
<td>Letter of recommendation</td>
<td>15%</td>
</tr>
<tr>
<td>Motivation letter</td>
<td>15%</td>
</tr>
</tbody>
</table>

(5) For the final grade or for the average grade a maximum of 5 points are available under the following table:

<table>
<thead>
<tr>
<th>Grade Range</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 to 1.5</td>
<td>5 points</td>
</tr>
<tr>
<td>1.6 to 1.9</td>
<td>4 points</td>
</tr>
<tr>
<td>2.0 to 2.2</td>
<td>3 points</td>
</tr>
<tr>
<td>2.3 to 2.5</td>
<td>2 points</td>
</tr>
<tr>
<td>2.6 to 4.0</td>
<td>1 point</td>
</tr>
</tbody>
</table>

(6) Between one and five points are given for the recommendation and motivation letters, with one point being given for the worst assessment and five points for the best assessment. The recommendation and motivation letters are assessed from the point of view of the student applicant's aptitude for the course. This involves assessing to what degree the application is, in the opinion of the referee or in his/her own opinion, able to meet the challenges of the program and how sensible participation in the program is. The recommendation letter should follow the sample published on the webpages of Goethe Business School or at any rate contain the information.
requested therein. Where multiple recommendation letters are available, the one with the best assessment is taken.

(7) Between one and five points are given for the evidence normally of at least two years' postgraduate professional experience in the pharmaceutical industry, with one point being given for the worst assessment and five points for the best assessment. The evidence is assessed from the point of view of the suitability of the student applicant’s postgraduate work experience for the course with regard to the basic knowledge available for successful graduation from the course.

(8) An overall assessment under paragraph 4 of at least 3 points is required for admission.
# Appendix 2: Sample course schedule

<table>
<thead>
<tr>
<th>Semester</th>
<th>Name of the class</th>
<th>Class Format</th>
<th>Length (SH/W)</th>
<th>Length (CP)</th>
<th>Acronym</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Foundation Courses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Managerial Accounting &amp; Controlling</td>
<td>L, E</td>
<td>2</td>
<td>6</td>
<td>MACC</td>
</tr>
<tr>
<td>1.</td>
<td>Organizational Behavior</td>
<td>L, E</td>
<td>2</td>
<td>6</td>
<td>ORBE</td>
</tr>
<tr>
<td>1.</td>
<td>Corporate Finance</td>
<td>L, E</td>
<td>2</td>
<td>6</td>
<td>COFI</td>
</tr>
<tr>
<td>1.</td>
<td>Strategic Management &amp; Organizational Change</td>
<td>L, E</td>
<td>2</td>
<td>6</td>
<td>SMOC</td>
</tr>
<tr>
<td></td>
<td><strong>Total CP</strong></td>
<td></td>
<td>8</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Concentration Courses</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Innovation Management &amp; Pricing</td>
<td>L, E</td>
<td>2</td>
<td>5</td>
<td>INMP</td>
</tr>
<tr>
<td>2.</td>
<td>High Performance Teams</td>
<td>L, E</td>
<td>2</td>
<td>5</td>
<td>HPTE</td>
</tr>
<tr>
<td>2.</td>
<td>Pharmaceutical Value Chain</td>
<td>L, E</td>
<td>2</td>
<td>5</td>
<td>PHVC</td>
</tr>
<tr>
<td></td>
<td><strong>Total SH/W or CP</strong></td>
<td></td>
<td>8</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Specialization Phase</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Elective 1</td>
<td>L, E</td>
<td>2</td>
<td>5</td>
<td>WP1</td>
</tr>
<tr>
<td>3.</td>
<td>Elective 2</td>
<td>L, E</td>
<td>2</td>
<td>5</td>
<td>WP2</td>
</tr>
<tr>
<td>3.</td>
<td>Elective 3</td>
<td>L, E</td>
<td>2</td>
<td>5</td>
<td>WP3</td>
</tr>
<tr>
<td>3.</td>
<td>Elective 4</td>
<td>L, E</td>
<td>2</td>
<td>5</td>
<td>WP4</td>
</tr>
<tr>
<td>3.</td>
<td><strong>Total SH/W or CP</strong></td>
<td></td>
<td>8</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Completion Phase</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>&quot;Scientific Methods for Research &amp; Writing&quot; seminar (Part 1)</td>
<td>S</td>
<td>1</td>
<td>4</td>
<td>SMRW</td>
</tr>
<tr>
<td>4.</td>
<td>&quot;Scientific Methods for Research &amp; Writing&quot; seminar (Part 2)</td>
<td>S</td>
<td>1</td>
<td>2</td>
<td>SMRW</td>
</tr>
<tr>
<td>4.</td>
<td>Master's thesis</td>
<td>-</td>
<td>-</td>
<td>20</td>
<td>MT</td>
</tr>
<tr>
<td></td>
<td><strong>Total SH/W or CP</strong></td>
<td></td>
<td>2</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Total for seminars 1.-4</strong></td>
<td></td>
<td></td>
<td>90</td>
<td></td>
</tr>
</tbody>
</table>

1. Abbreviations used: S = seminar; E = exercise; L = lecture.
## Appendix 3: Module descriptions

**Module name:** Managerial Accounting & Controlling (MACC)

**Type of module:** mandatory, foundation-course module (6 CP)

<table>
<thead>
<tr>
<th>1. Content:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Discussion of various costing and calculation concepts</td>
</tr>
<tr>
<td>• Application of information within various monitoring tools, including budgeting, break-even analysis, transfer prices</td>
</tr>
<tr>
<td>• Identification of relevant information and its efficient use for the purpose of decision-making</td>
</tr>
<tr>
<td>• Identification of information that influences decisions in the context of performance measurements and Key Performance indicators as well as its use in the guidance of employees, e.g. within the framework of profit centers</td>
</tr>
<tr>
<td>• The module is taught with the inclusion of all relevant aspects of the course content from an ethical perspective and with special emphasis on considering the application of ethically justifiable courses of action in the respective practical implementation of what has been learned.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Learning outcomes/skills objectives:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The students</td>
</tr>
<tr>
<td>• learn to distinguish between various causes of management control problems and to implement appropriate control mechanisms for solving these problems.</td>
</tr>
<tr>
<td>• learn to develop and critically assess management control systems.</td>
</tr>
<tr>
<td>• learn to identify profit centers as the central organizational unit for the use of accounting control mechanisms.</td>
</tr>
<tr>
<td>• learn to implement financial control systems (e.g. budgeting, transfer prices).</td>
</tr>
<tr>
<td>• learn to choose the correct financial ratios (e.g. ROCE, EVA) either on an isolated basis or in combination with other, non-financial indicators (e.g. balanced scorecard).</td>
</tr>
<tr>
<td>• learn to analyze the advantages and disadvantages of separate and integrated management control systems with respect to various control purposes.</td>
</tr>
<tr>
<td>• learn to address new challenges for controlling and management control systems.</td>
</tr>
<tr>
<td>• within the framework of the exercise gain skills in developing concepts for solving practical exercises</td>
</tr>
<tr>
<td>• learn to consider the aspects of ethical tenability in adequate form when implementing the course content.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Preconditions to participation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation in the module has no further preconditions beyond the general requirements of this examination regulation.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Permitted teaching and learning formats:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecture and exercise.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Course records:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A precondition to admission to the module examination may be the production of ungraded participation and/or records of achievement (short written drafts or brief presentations or work on practice exercises). Where the module examination is in two parts, no ungraded records of achievement need to be produced.</td>
</tr>
</tbody>
</table>
6. **Module examination:**
   The format of the examination on completion of the module is set by the class director at the beginning of the series of classes.

   | Examination on completion of the module, consisting of: | Test (90 minutes) or term paper (10-15 pages) or test (60 minutes) and term paper (max. 5 pages). |

7. **Module grade:**
   Where the module examination consists of a test and a term paper, the grade for the module is normally derived 50% from the test and 50% from the term paper.
**Module name:** Organizational Behavior (ORBE)

**Type of module:** mandatory module, foundation course (6 CP)

1. **Content:**
   
   The class is made up of multiple parts: the employee as the foundation of economic organizations, behavior within organizations, particularly in the pharmaceutical industry and the importance of motivation. Proceeding from the employee as the foundation of organizations, the individual differences between employees are looked at depending on the work context and work motivation. From this, requirements are worked out for appropriate employee motivation and job design in the specific organizational context. At the individual level, this concerns the question of how managers make optimal decisions when these are fraught with risk and are based on incomplete information. At the group level, this is about employee leadership, the successful management of teams and the role of social norms and “peer effects” in the workplace. Finally, at the level of the organization, subjects such as “change” and “culture” are discussed. The module is taught with the inclusion of all relevant aspects of the course content from an ethical perspective and with special emphasis on considering the application of ethically justifiable courses of action in the respective practical implementation of what has been learned.

2. **Learning outcomes / skills objectives:**
   
   The “Organizational Behavior” module is a component of the fundamentals which, in this class, summarizes the most important principles in the area of organization and human resources. The objective is:
   
   - to highlight the key elements of the motivation problem and its solution;
   - to impart to participants the most important management concepts and their connection with organizational behavior.

   Furthermore, participants should:
   
   - develop the ability to apply management concepts in different organizational contexts;
   - learn to analyze decision-making problems in companies and work relationships;
   - learn to structure typical management issues and to develop potential strategies to resolve these issues;

   A framework is jointly developed that should assist the students to uncover typical traps and to develop strategies for better decision-making, thereby taking the aspects of ethical tenability into account.

3. **Preconditions to participation:**
   
   Participation in the module has no further preconditions beyond the general requirements of this examination regulation.

4. **Permitted teaching and learning formats:**
   
   Lecture and exercise.

5. **Course records:**
   
   A precondition to admission to the module examination may be the production of ungraded records of achievement (short written drafts or brief presentations or work on practice exercises) and/or the production of evidence of participation in the exercise. Where the module examination is in two parts, no ungraded records of achievement need to be produced.

6. **Module examination:**
   
   The format of the examination on completion of the module is set by the class director at the beginning of the series of classes.

   Examination on completion of the module, consisting of:
   - Test (90 minutes) or term paper (10-15 pages) or test (60 minutes) and term paper (max. 5 pages).

7. **Module grade:**
   
   Where the module examination consists of a test and a term paper, the grade for the module is normally derived 50% from the test and 50% from the term paper.
<table>
<thead>
<tr>
<th>Module name: Corporate Finance (COFI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of module: mandatory, foundation-course module (6 CP)</td>
</tr>
<tr>
<td>1. Content:</td>
</tr>
<tr>
<td>This module discusses institutional and methodological aspects required for an understanding of advanced ways of looking at problems in the area of Corporate Finance. The participants are familiarized with the basic concepts for the evaluation of investments and financing of pharmaceutical companies. Students are given a basic understanding of interest, risk, diversification, market equilibrium price and capital structure considerations according to modern financial theory. These are, in particular</td>
</tr>
<tr>
<td>- financial instruments: debt, equity, convertible debt, leasing;</td>
</tr>
<tr>
<td>- financial strategies: leverage, payout policy;</td>
</tr>
<tr>
<td>- NPV (net present value), including the value of tax shields;</td>
</tr>
<tr>
<td>- valuation under uncertainty (WACC, CAPM), real options.</td>
</tr>
<tr>
<td>The module takes all ethically relevant aspects of the teaching content into account, with a special emphasis on consideration of the practical application of what has been learned in accordance with ethically tenable courses of action.</td>
</tr>
<tr>
<td>2. Learning outcomes/skills objectives:</td>
</tr>
<tr>
<td>The students</td>
</tr>
<tr>
<td>- get an overview of modern financial market theory;</td>
</tr>
<tr>
<td>- are equipped with the most important conceptual tools in the area of finance required for an understanding of corporate finance and assessment issues;</td>
</tr>
<tr>
<td>- gain skills in the course of this exercise in the development of approaches to problem-solving for practice exercises;</td>
</tr>
<tr>
<td>- learn to take into account aspects of ethical tenability in the application of the teaching content in an adequate manner.</td>
</tr>
<tr>
<td>3. Preconditions to participation:</td>
</tr>
<tr>
<td>Participation in the module has no further preconditions beyond the general requirements of this examination regulation.</td>
</tr>
<tr>
<td>4. Permitted teaching and learning formats:</td>
</tr>
<tr>
<td>Lecture and exercise.</td>
</tr>
<tr>
<td>5. Course records:</td>
</tr>
<tr>
<td>A precondition to admission to the module examination may be the production of ungraded records of achievement (short written drafts or brief presentations or work on practice exercises) and/or the production of evidence of participation in the exercise. Where the module examination is in two parts, no ungraded records of achievement need to be produced.</td>
</tr>
<tr>
<td>6. Module examination:</td>
</tr>
<tr>
<td>The format of the examination on completion of the module is set by the class director at the beginning of the series of classes.</td>
</tr>
<tr>
<td>Examination on completion of the module, consisting of:</td>
</tr>
<tr>
<td>Test (90 minutes) or term paper (10-15 pages) or test (60 minutes) and term paper (max. 5 pages).</td>
</tr>
<tr>
<td>7. Module grade:</td>
</tr>
<tr>
<td>Where the module examination consists of a test and a term paper, the grade for the module is normally derived 50% from the test and 50% from the term paper.</td>
</tr>
</tbody>
</table>
Module name: Strategic Management & Corporate Development (STCD)

Type of module: mandatory, foundation-course module (6 CP)

1. Content:

This module introduces concepts for strategic analysis and strategy development. Proceeding from the basic concept of strategy and from the definition and role of corporate strategy, different strategic analysis tools are considered. This involves looking at the following subject areas, among others:

- company objectives and vision
- industry analysis
- analyses of skills and resources
- diversification and vertical integration
- cost leadership
- internal vs. external growth through strategic alliances, joint ventures and mergers & acquisitions
- roles and tasks of corporate head offices
- implementation of corporate strategies with consideration of the pharmaceutical value chain
- consideration of ethical and corporate social responsibility (CSR) aspects in the formulation and implementation of corporate strategies

2. Learning outcomes/skills objectives:

The module creates a shared foundation for all Master’s students, which summarizes in this class the most important principles in the area of strategy. The students should:

- be familiarized with basic methods, models and results of strategy research;
- understand the basic principles and tools of strategic management;
- obtain more in-depth knowledge in the area of strategy formulation and application in the light of responsible and ethically-oriented corporate management;
- be equipped to develop strategy for a company;
- learn to consider the aspects of ethical tenability in adequate form when implementing the course content.

3. Preconditions to participation:

Participation in the module has no further preconditions beyond the general requirements of this examination regulation.

4. Permitted teaching and learning formats:

Lecture and exercise.

5. Course records:

A precondition to admission to the module examination may be the production of ungraded records of achievement (short written drafts or brief presentations or work on practice exercises) and/or the production of evidence of participation in the exercise. Where the module examination is in two parts, no ungraded records of achievement need to be produced.

6. Module examination:

The format of the examination on completion of the module is set by the class director at the beginning of the series of classes. Examination on completion of the module, consisting of:

- Test (90 minutes) or term paper (10-15 pages) or test (60 minutes) and term paper (max. 5 pages).

7. Module grade:

Where the module examination consists of a test and a term paper, the grade for the module is normally derived 50% from the test and 50% from the term paper.
### Module name: Innovation Management & Pricing (INMP)
**Type of Module:** Compulsory, concentration-phase module (5 CP)

1. **Content:**
   - The module teaches comprehension of strategic innovation management from a theoretically based perspective and gives the participants skills for successfully structuring and leading (innovation) projects in an innovative pharmaceutical company. The content covers the following subject areas, among others:
     - Importance of “disruptive innovations”
     - Innovation/technology development models
     - Financing and evaluation of innovations
   - In addition to the management of innovations, the existing approaches for pricing innovative pharmaceutical products are also examined. The question of pricing following the expiration of the patent protection period is also of special interest here.
   - The module is taught with the inclusion of all relevant aspects of the course content from an ethical perspective and with special emphasis on considering the application of ethically justifiable courses of action in the respective practical implementation of what has been learned.

2. **Learning outcomes/skills objectives:**
   - The students
     - learn to distinguish between various types of innovation;
     - learn the basic methods and models in the area of innovation management;
     - acquire knowledge about different innovation and technology development models;
     - learn how prices are established for innovations in the pharmaceutical context;
     - learn to take into account aspects of ethical tenability in the application of the teaching content in adequate form

3. **Preconditions to participation:**
   - Participation in the module is conditional upon successful participation in at least three of the four recommended modules from the first semester.

4. **Permitted teaching and learning formats:**
   - Lecture and exercise.

5. **Course records:**
   - A precondition to admission to the module examination may be the production of ungraded participation and/or records of achievement (short written drafts or brief presentations or work on practice exercises). Where the module examination is in two parts, no ungraded records of achievement need to be produced.

6. **Module examination:**
   - The format of the examination on completion of the module is set by the class director at the beginning of the series of classes.
   - Examination on completion of the module, consisting of:
     - Test (90 minutes) or term paper (10-15 pages) or test (60 minutes) and term paper (max. 5 pages).

7. **Module grade:**
   - Where the module examination consists of a test and a term paper, the grade for the module is normally derived 50% from the test and 50% from the term paper.
### Module name: High Performance Teams (HPTE)

**Type of module:** mandatory, concentration-phase module (5 CP)

<table>
<thead>
<tr>
<th>1. Content:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The course “High Performance Teams” is devoted to successfully working with and leading research and development teams in the pharmaceutical context.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Learning outcomes/skills objectives:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The students</td>
</tr>
<tr>
<td>• acquire broadened knowledge about the leadership of R&amp;D teams in the pharmaceutical context;</td>
</tr>
<tr>
<td>• learn how decision processes, motivation and communication take place in teams and how to influence them</td>
</tr>
<tr>
<td>• learn to apply different leadership styles in different leadership situations;</td>
</tr>
<tr>
<td>• learn what amounts to good leadership and a good leader;</td>
</tr>
<tr>
<td>• are expected to learn to adequately consider the aspects of ethical tenability in the application of the teaching content.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Preconditions to participation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation in the module is conditional upon successful participation in at least three of the four modules recommended from the first semester.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Permitted teaching and learning formats:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lecture and exercise.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Course records:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A precondition to admission to the module examination may be the production of ungraded participation and/or records of achievement (short written drafts or brief presentations or work on practice exercises). Where the module examination is in two parts, no ungraded records of achievement need to be produced.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Module examination:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The format of the examination on completion of the module is set by the class director at the beginning of the series of classes.</td>
</tr>
<tr>
<td>Examination on completion of the module, consisting of: Test (90 minutes) or term paper (10-15 pages) or test (60 minutes) and term paper (max. 5 pages).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Module grade:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Where the module examination consists of a test and a term paper, the grade for the module is normally derived 50% from the test and 50% from the term paper.</td>
</tr>
</tbody>
</table>
Module name: Foundations of Patent & Pharmaceutical Law (FPPL)
Type of module: mandatory, concentration-phase module (5 CP)

1. Content:

   This module is divided into two parts:

   Part 1
   Introduction to the principles of intellectual property and especially of patent law. The focus is on the different industrial property rights, their interaction, the use of patents to protect R&D expenditures, patenting requirements, the patenting process (national/international), the effects of patents, possible property right strategies, supplemental protection options besides patent protection and the defense of proprietary rights against third-party attacks.
   Introduction to the exploitation of patents, particularly through licenses, limits under civil, antitrust and patent law and structuring options for contracts.
   Introduction to internal patent management, including the basics of employee invention law.
   Students acquire basic legal and practical knowledge in order to be able to negotiate on an equal footing with patent and legal departments and make decisions on proprietary rights.

   Part 2
   Introduction to national and European pharmaceutical law. The focus is on the legal parameters for the safe commerce of human pharmaceuticals and the parameters for commercial provisioning of the population with medications.
   Acquaintance with the purposes of the Medicinal Products Act, the legal requirements for drugs and their manufacture or importation, authorization and the protection of humans in clinical trials. Becoming acquainted with the regulations for the placement of pharmaceuticals on the market, quality assurance and control and the general pharmacovigilance duties and basics of the graduated plan procedure.
   Becoming acquainted with the relevant pharmaceutical regulations in Book V of the German Social Security Code. The focus is on control mechanisms that regulate price and quantity. The goal is to be able to take the parameters of social law into consideration when making strategic decisions.
   The module is taught with the inclusion of all relevant aspects of the course content from an ethical perspective and with special emphasis on considering the application of ethically justifiable courses of action in the respective practical implementation of what has been learned.

2. Learning outcomes/skills objectives:
Part 1
The students learn

- to become acquainted with the various proprietary rights (patents, utility models, designs, trademarks, copyrights) and options for combining proprietary rights in order to obtain comprehensive protection
- the requirements for patentability, particularly novelty, inventive step, industrial applicability of inventions and the exceptions to patentability
- the main features of the registration and award process in Germany, Europe and under the patent cooperation treaty (PCT), including the main features of the unitary patent that is presently under discussion
- how to build and maintain a strategic portfolio
- how to extend the patent protection period through supplementary protection certificates (SPC) and through document protection
- how to read a patent and ascertain the scope of protection
- what possibilities exist in case of patent infringements, especially what legal position a patent conveys, who can enforce it, how and when it can be meaningfully enforced, in which countries and in what manner (litigation strategies)
- how to defend a proprietary right against objections that it is void
- how to deal with contrary third-party proprietary rights (freedom-to-operate, patent monitoring, defense strategies)
- how to exploit patents, including licensing strategies, main features of license formation and antitrust limitations of contract formation
- main features of employee invention law
- the importance of secret knowledge (know-how) in supplement or as an alternative to patents, the requirements for protection and dealing with them

Part 2
The students

- study the key national and European statutes, ordinances and administrative regulations
and learn about their purpose and scope
- acquaint themselves with legislative processes and competing legislation
- learn about the jurisdiction of federal and state public authorities
- recognize that the complex regulatory web in the Medicinal Products Act and Book V of the German Social Security Code is also the result of numerous amendments, become acquainted with the most important amendments and thereby develop a better understanding for current discussions
- obtain an overview of the diverse preventive and reactive safeguards of the Medicinal Products Act and become familiar with the essential definitions
- learn to distinguish pharmaceuticals from other products in order to be able to exploit advantages and disadvantages of the product positioning
- can assess the authorization requirement of products
- know the three hurdles that must be overcome for commercially bringing pharmaceuticals to market
- know the legal provisions for central, decentralized and national authorizations, for authorization of a generic drug, specifics for the distribution or authorization of parallel import drugs, standard authorization and the distinction from registration proceedings
- know the regulations for quality assurance and control of pharmaceuticals
- know the safety precautions in the clinical trial and the ethical aspects which are to be taken into consideration in the course of clinical research
- know the responsibilities of the qualified person, the graduated plan officer and the information officer
- know the organization of the pharmacovigilance system, documentation duties and reporting duties of the authorization holders and are familiar with the graduated plan procedure
- know the requirement for the manufacture and import of pharmaceuticals and familiarize themselves with the different distribution options
- be familiar with the dirigiste and competitive tools for the quantity and price control of pharmaceuticals (aut idem rule, drug guidelines, negative lists, exclusion of over-the-counter drugs, Exclusion of lifestyle drugs, reference prices, imported pharmaceuticals regulation, early benefit assessment, benefits and cost-benefit assessment, price reduction and moratorium, discounts, discount agreements, out-of-pocket payment), be able to critically monitor the further development of instruments and in this way prepare strategic corporate decisions
- be familiar with ethical talking points that make an advance in the context of legal questions on cost reimbursement

3. Preconditions to participation:

Participation in the module is conditional upon successful participation in at least three of the four modules recommended from the first semester.

4. Permitted teaching and learning formats:

   Lecture and exercise

5. Course records:
A precondition to admission to the module examination may be the production of ungraded participation and/or records of achievement (short written drafts or brief presentations or work on practice exercises). Where the module examination is in two parts, no ungraded records of achievement need to be produced.

6. Module examination:
The format of the examination on completion of the module is set by the class director at the beginning of the series of classes.

<table>
<thead>
<tr>
<th>Examination on completion of the module, consisting of:</th>
<th>Test (90 minutes) or term paper (10-15 pages) or test (60 minutes) and term paper (max. 5 pages).</th>
</tr>
</thead>
</table>

7. Module grade:
Where the module examination consists of a test and a term paper, the grade for the module is normally derived 50% from the test and 50% from the term paper.
**Module name:** Pharmaceutical Value Chain (PHVC)
**Type of module:** mandatory, concentration-phase module (5 CP)

1. **Content:**

The pharmaceutical value chain depicts the development and life cycle of a medicinal product and thereby structures a complex and highly regulated process which is comparable for all drugs. Beginning with basic research, a new active ingredient candidate is developed through the preclinical phase, through clinical phases I–III and up through marketing approval. Following formal medicinal product authorization, prescription drugs in Germany are subjected to the early benefit assessment. Then the pharmaceutical company and the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) negotiate a reimbursement amount on the basis of, among other things the additional benefit identified by the Federal Joint Committee. In addition, even after the authorization, medicinal products are subject to continuing surveillance with respect to their benefit-risk ratio. Similarly, after the authorization, so-called phase IV clinical studies are conducted in order to gain further insights into the medicinal product. The commercialization of medicinal products takes place through marketing and sales. In the process, various distribution strategies and channels are utilized with consideration given to the product life cycle and the respective market environment.

Knowledge of the pharmaceutical value chain is essential for the ability to understand the complex interplay and flow of the various processes in the area of research and development, production and quality control over the medicinal product authorization and safety up through market access and reimbursement. Ethical aspects are also considered in the course of the module.

2. **Learning outcomes / skills objectives:**

The students
- learn how new therapeutic approaches are identified and assessed
- obtain an overview of tools in the basic research on the search for, identification and optimization of active ingredients
- learn to identify initial indications of the effectiveness of preclinical models
- obtain an overview of the milestones in the clinical development, including dose finding, proof of concept, phase III studies and termination criteria for the clinical development
- obtain an overview of the scale-up from the pilot scale to production
- become acquainted with the European authorization procedures (central procedure, decentralized procedure, procedure of mutual recognition and national procedures)
- gain insight into the life cycle management of authorizations and the processing of amendments
- become familiar with basic fundamentals of a quality management system
- learn to recognize and determine the added benefit of market access and its monetary valuation
- obtain an overview of drug safety, post-marketing surveillance, reporting of adverse events after authorization
- obtain an overview of the refinancing of research costs: patent protection period, document protection and generic competition
- obtain an overview of joint-venture concepts for the early development phase
- become informed concerning the basics of advertising and marketing of medicinal products
- learn to consider the aspects of ethical tenability in adequate form when implementing the course content

3. **Preconditions to participation:**

Participation in the module is conditional upon successful participation in at least three of the four recommended modules from the first semester.

4. **Permitted teaching and learning formats:**

Lecture and exercise.

5. **Course records:**

A precondition to admission to the module examination may be the production of ungraded participation and/or records of achievement (short written drafts or brief presentations or work on practice exercises). Where the module examination is in two parts, no ungraded records of achievement need to be produced.

6. **Module examination:**

The format of the examination on completion of the module is set by the class director at the beginning of the series of classes.

Examination on completion of the module, consisting of:
- Test (90 minutes) or term paper (10-15 pages) or test (60 minutes) and term paper (max. 5 pages).

7. **Module grade:**

Where the module examination consists of a test and a term paper, the grade for the module is normally derived 50% from the test and 50% from the term paper.
<table>
<thead>
<tr>
<th>Module name: Elective module 1-4 (WP1 – WP4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of module: Elective module Specialization Phase (5 CP)</td>
</tr>
<tr>
<td>1. Content:</td>
</tr>
<tr>
<td>As part of their specialization, students need to complete a total of four electives such as, e.g.</td>
</tr>
<tr>
<td>• Research, Development &amp; Galenics</td>
</tr>
<tr>
<td>• Pharmaceutical Production</td>
</tr>
<tr>
<td>• Quality Control &amp; Assurance</td>
</tr>
<tr>
<td>• Regulatory Affairs</td>
</tr>
<tr>
<td>• Pharmacovigilance</td>
</tr>
<tr>
<td>• Market Access &amp; Health Economics</td>
</tr>
<tr>
<td>• Intrapreneurship &amp; Business Planning</td>
</tr>
<tr>
<td>The number of electives offered and type of option topics may change. The Module Handbook regulates this in greater detail. The modules are taught by the lecturers with the inclusion of all ethically relevant aspects of the teaching content and with a special emphasis on consideration of the practical application of what has been learned in accordance with ethically tenable courses of action.</td>
</tr>
<tr>
<td>2. Learning outcomes/skills objectives:</td>
</tr>
<tr>
<td>The students</td>
</tr>
<tr>
<td>• gain content-related and methodological skills from the major field of study – finances;</td>
</tr>
<tr>
<td>• acquire detailed knowledge and learn methods in relation to selected areas that permit a focus on their content;</td>
</tr>
<tr>
<td>• get insight into specific areas of application;</td>
</tr>
<tr>
<td>• obtain practical skills relevant to the labor market;</td>
</tr>
<tr>
<td>• gain skills in developing concepts for solving practical exercises within the framework of this training.</td>
</tr>
<tr>
<td>• learn to adequately consider the aspects of ethical tenability in the application of the teaching content</td>
</tr>
<tr>
<td>3. Preconditions to participation:</td>
</tr>
<tr>
<td>Participation in the module is conditional upon successful participation in at least three of the four recommended modules from the first semester and at least three of the four recommended modules from the second semester.</td>
</tr>
<tr>
<td>4. Permitted teaching and learning formats:</td>
</tr>
<tr>
<td>Lecture and exercise.</td>
</tr>
<tr>
<td>5. Course records:</td>
</tr>
<tr>
<td>A precondition to admission to the module examination may be the production of ungraded records of achievement (short written drafts or brief presentations or work on practice exercises) and/or the production of evidence of participation in the exercise. Where the module examination is in two parts, no ungraded records of achievement need to be produced.</td>
</tr>
<tr>
<td>6. Module examination:</td>
</tr>
<tr>
<td>The format of the examination on completion of the module is set by the class director at the beginning of the series of classes.</td>
</tr>
<tr>
<td>Examination on completion of the module, consisting of: Test (90 minutes) or term paper (10-15 pages) or test (60 minutes) and term paper (max. 5 pages).</td>
</tr>
<tr>
<td>7. Module grade:</td>
</tr>
<tr>
<td>Where the module examination consists of a test and a term paper, the grade for the module is normally derived 50% from the test and 50% from the term paper.</td>
</tr>
</tbody>
</table>
### Module name: Seminar Scientific Methods for Research & Writing (SMRW)

**Type of module:** Compulsory, completion-phase module (6 CP)

<table>
<thead>
<tr>
<th>1. Content:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The seminar offers students an introduction into academic work (literature search, use of literature in their own papers, etc.) in the interdisciplinary management and pharmaceutical-specific context. Current research topics in the area of management in the pharmaceutical industry are discussed and developed within the seminar. The development and positioning of research papers is at the heart of the seminar. There is discussion, in particular, of the appropriate design of study for empirical work. The seminar is therefore an ideal preparation for Master’s theses. Following the introduction to academic work (Part 1), the students then present the results of their research work (Part 2).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Learning outcomes/skills objectives:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The core objectives of the seminar lie in the following areas:</td>
</tr>
<tr>
<td>• Students learn how to research a topic with the inclusion of management and of pharmaceutical-specific content.</td>
</tr>
<tr>
<td>• Students understand how scientific papers are structured in the interdisciplinary context.</td>
</tr>
<tr>
<td>• Students understand how Master's theses should be structured in the context of the inclusion of practice-based aspects of management and the pharmaceuticals industry.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Preconditions to participation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation in the module is conditional upon successfully passing module examinations in the recommended mandatory modules for the first two semesters. In especially justified exceptional cases, a deviating arrangement can be applied for with the Examination Board at the request of the student.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Permitted teaching and learning formats:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seminar</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Course records:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular participation (evidence of participation) is a precondition to admission to the module examination.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Module examination:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examination on completion of the module, consisting of: a presentation (about 20 minutes)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Module grade:</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% Presentation</td>
</tr>
</tbody>
</table>
### Module name: Master's thesis

### Type of module: Compulsory, completion-phase module (20 CP)

| 1. Content: |  
| --- | --- |
| Topics from the Management and Pharmacy focus – normally arising from an overarching practice-related question. |

| 2. Learning outcomes/skills objectives: |  
| --- | --- |
| The students  
• gain content-related and methodological skills in relation to their research work;  
• are able to tackle topics set on the basis of the sound knowledge they have gained from research;  
• are capable of developing and formulating solutions through research.  
The Master's thesis largely takes the format of a research essay that can be submitted to a relevant academic journal |

| 3. Preconditions to participation: |  
| --- | --- |
| Participation in the module is conditional upon successfully passing module examinations of the recommended mandatory and electives in the first three semesters Upon the request of the student, in specially justified exceptional cases, a deviating arrangement can be made by the examination board. |

| 4. Permitted teaching and learning formats: |  
| --- | --- |
| Individual or group counseling in which the students are assisted with the planning and implementation of the Master’s thesis. |

| 5. Course records: | **none** |

| 6. Module examination: |  
| --- | --- |
| Examination on completion of the module, consisting of:  
| Master's thesis (20 weeks) |

| 7. Module grade: | **100% Master's thesis** |
### Appendix 4: Sample Module Handbook

<table>
<thead>
<tr>
<th>[Number / short description] [Module name]</th>
<th>Compulsory module/ elective module</th>
<th>[…] CP (total) = […] hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning outcomes / skills objectives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preconditions to participation for module or for individual classes of the module</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommended requirements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Classification of the module (degree program / faculty)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applicability of the module for other degree programs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency of the offering</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of the module</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person responsible for delivering the module</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Course records / possibly as pre-examination work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evidence of participation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Records of achievement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teaching / learning formats</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teaching / examination language</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Examination on completion of the module (Form, length, how grade for the module derived)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 5: Sample Transcript of Records

Transcript of Records

Examination Office of the abc faculty

October 1, 2013

Vorname und Name / first name and surname
Geburtsdatum und -ort / date of birth and place of birth
Matrikelnummer / matriculation number
Studiengang / degree program
Abschlussgrad / degree awarded
gemäß der Ordnung vom / in compliance with the examination regulations dated
Fachsemester / semester

Modul
module
Seminar
seminar
Modulprüfung
module examination

Ergebnis der Masterprüfung: bestanden
Result of the Master Examination: pass

Gesamtnote: gut (2,0) Gesamt-CP: 120
Grade (overall): good (2.0) CP (overall): 120

Frankfurt am Main, on …

_______________________________
abc, Chair of the Examination Board
Legal information


It is published by the President of Goethe University, Frankfurt am Main.