

(as of 22 September 2014)

The German version of this document is the only *legally binding version*. This English translation is for your convenience only.

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I. General

§1 Objective of the Master's Examination

- (1) The development of medicines is an integrative process in which the disciplines involved need to interlink and transfer their toxicological findings. This is a prerequisite for understanding the processes in this highly specialised professional area. In the Advanced Safety Sciences for Medicines programme you acquire the required competences in the field of drug safety as well as drug research and development - alongside your work.
- (2) In the master's examination you demonstrate that you have acquired basic and advanced interdisciplinary knowledge in drug safety. With this knowledge you will be able to competently judge toxicological findings from other disciplines in the development process and ensure compliance with regulatory provisions.

§ 2 Academic Degree

Once you have passed the Master's examination, the University of Konstanz awards you the academic degree "Master of Science" (MSc.) in "Advanced Safety Sciences for Medicines".

§ 3 Structure of the Master's Programme

- (1) The Master's programme "Advanced Safety Sciences for Medicines" is a continuing education study programme as defined by § 31 para. 3 *Landeshochschulgesetz LHG* (state law on education). The partner universities organised in the SafeSciMET consortium offer the courses listed in the appendix. In these courses you acquire the required knowledge in drug safety, pharmaceuticals, toxicology as well as non-clinical and clinical studies. You take the examinations leading towards your master's degree as an external student at the University of Konstanz.
- (2) The master's programme consists of subject areas with a coordinated thematic and chronological structure, called modules hereafter:
 1. Drug Discovery and Development
 2. Pharmaceutical Aspects of Drug Safety
 3. Adverse Drug Reactions / Predictive Toxicology / 3 Rs
 4. Non-clinical Assessment
 5. Clinical Assessment
- (3) The master's examination consists of course examinations in the modules according to para. 2 § 15 a and the appendix of this examination regulations, as well as a written master's thesis.
- (4) You can acquire a total of 60 ECTS credits in the master's programme. You can acquire 45 ECTS credits by successfully participating in the mandatory courses

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and the compulsory elective courses according to para. 2 and 3 and § 15 a. You will acquire 15 ECTS credits for completing the final module, including the written master's thesis (§ 15 b).

- (5) One ECTS credit corresponds to a work load of approximately 25 - -30 hours.
- (6) The curriculum of the master's programme is scheduled for four semesters. However, as this is a continuing education programme, you can also take more time to complete the courses.

§ 4 Examinations, Exam Administration and Deadlines

- (1) You complete each module with a course examination according to § 3 para. 2. The master's examination consists of the course examinations in the modules mentioned in § 3 para. 2 as well as the master's thesis in the final module according to § 17.
- (2) If the reasons for not completing an examination are beyond your control, the Examination Board (*StPA*) grants an extension of the examination deadline upon written request and accompanied by the corresponding documentation.
- (3) A data processing system may be used for administrative aspects of exam organisation. In such cases, you are required to check this system, at regular intervals and on specific occasions as needed, for information on the examinations. If you fail to inform yourself and miss an examination, you will have to bear the consequences.

§ 5 Examination Board (*StPA*)

- (1) The Examination Board (*StPA*) organises the examinations and tasks indicated in these examination regulations. The Examination Board consists of professors who work for one of the SafeSciMet consortium partners and teach in one of the modules of the master's programme. The *StPA* is responsible for organising the examinations. The *StPA* appoints one of its members as chairperson. The manager of the Akademie für Wissenschaftliche Weiterbildung at the University of Konstanz as well as a student member of the Department of Biology are also members of the Examination Board and have an advisory vote. The Student Council Biology nominates the student member, the Department Council Biology appoints this student for one year.
- (2) The *StPA* makes its decisions in examination procedures according to the examination regulations. It ensures that the examination provisions are observed and suggests changes to the examination regulations. It can revocably assign certain tasks to the chairperson.

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- (3) The members of the *StPA* are legally bound to maintain confidentiality. Those who are not in civil service shall be sworn by the board chair to maintain confidentiality.
- (4) The *StPA* meetings may also be held via electronic media in a video conference.

§ 6 Examiners and Assessors

- (1) The *StPA* appoints the examiners for the examinations and the master's thesis. The *StPA* can task the chairperson with these appointments.
- (2) Course examinations are usually conducted by the respective course leaders.
- (3) As a rule, exams which are not part of the coursework in conjunction with particular modules can only be conducted by professors and lecturers who have been employed as teachers by the *Akademie für Wissenschaftliche Weiterbildung* in accordance with the cooperation agreement with the University of Konstanz. In such cases, at least one member of the Department of Biology entitled to hold examinations represents the University of Konstanz.

§ 7 Credit for Previous Studies, Coursework and Examination Results

- (1) Prior learning experiences, periods of study, coursework and examination results in the same study programme or other programmes at a state/state-approved institution of higher education/*Berufsakademie* in Germany or abroad are recognised on request provided that the skills thus acquired do not differ significantly from those of the study programmes or degrees for which they serve as a substitute. The competencies are considered similar if contents, learning objectives and examinations largely correspond to the study programme at the University of Konstanz mentioned above. When applying for credit for studies, coursework and examination results achieved outside of Germany, the recommendations of the Standing Conference of the Ministers of Education and Cultural Affairs (Central Office for Foreign Education) and the equivalency agreements of the Federal Republic of Germany, and agreements within the context of university partnerships, must be observed. The Examination Board (*StPA*) decides about exceptions (on request). If applicable, you will be awarded the ECTS credits as listed in the attachment for your corresponding achievements.
- (2) If the prerequisites (see para. 1 and 2) are met, you are legally entitled to recognition of credits. You must submit the required documents when applying for credit.
- (3) If course work and exam results are recognised, the grades earned - insofar as the marking systems are comparable - shall be transferred and shall be included in the calculations made when determining the overall grade. If the grading systems are not comparable, the grade "passed" (4.0) shall be applied. A recognition

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will be stated in your examination certificate.

- (4) The Examination Board (*StPA*) or an appointed representative decides on whether to recognise your achievements.

§ 7a Credit for Extra-Curricular Achievements

- (1) Non-university or non-college achievements can be assessed as course work and examination results if the following apply:
- the knowledge or skills thus acquired are equivalent to the course work and examination results they are to replace, and
 - the institution at which the knowledge or skills were acquired has implemented a quality assurance system, and
 - the prerequisites for acceptance at a college or university are met at the time credit is granted for such achievements.
- (2) When assessing equivalency of knowledge or skills, an overall view must be taken and an overall appraisal made. Equivalency is given if there is no significant difference between the knowledge or skills imparted in the "European Master in Business" programme and those for which credit is sought. No significant difference exists if the skills achieved outside of any institution of higher education largely correspond to the content, educational objective and requirements in the study programme of the University of Konstanz.
- (3) If the equivalence of the non-higher education achievements cannot be determined, a placement test may be administered.
- (4) The maximum total number of ECTS credits that can be granted for non-higher education achievements is 15.
- (5) The Examination Board decides on whether to recognise the achievements and on the necessity and form of placement tests.
- (6) The regulations regarding recognition are not applicable until after the criteria for recognition within the scope of accreditation have been verified.

§ 8 Absence, Withdrawal, Health Impairments, Parental Leave, Fraud, Breach of Regulations

- (1) An examination shall be given the grade "fail" (5.0), if you do not attend the examination without adequate justification or if you withdraw without adequate justification after the examination has already started. The same applies if you do not complete a written examination within the set time limit.
- (2) The explanation for withdrawing or missing the examination must be submitted to the *StPA*, and successfully defended, without delay. In the case of illness you

have to submit a medical certificate. If the reasons are accepted, you have to take the test at the next examination date. In this case, examination results acquired up to that point shall be credited to you (if they can be separated from the part of the examination you still have to complete).

- (3) If you satisfactorily show, by presenting a medical certificate, that you cannot complete examinations entirely or partially due to prolonged or permanent health problems, the chair of the Examination Board *StPA* permits the completion of the examination within an extended period of time or in another, equivalent form. The same applies to coursework.
- (4) On request, the right to parental leave as defined by the applicable federal law in Germany (MSchG) shall be recognised. The required documentation must be submitted with the request. Parental leave interrupts all other periods defined in these examination regulations; in other words, the duration of parental leave is not counted as elapsed time within these periods.
- (5) Similarly, parental leave as defined in the law on the parental leave allowance and parental leave ("*Bundeselterngehalt- und Elternzeitgesetz*," or *BEEG*) shall be recognised on request. You must inform the Examination Board of the period(s) of parental leave to be taken no later than four weeks before the first day of planned parental leave. This must be done in writing and include the necessary documentation. The Examination Board will assess whether the legal prerequisites are met under which employees have the right to parental leave in accordance with the *BEEG* (German law on parental leave and parental allowance), and shall inform you of their decision and, if applicable, of the new schedule for examination dates, without delay. The period allowed for completion of the written master's thesis cannot be interrupted by parental leave. The topic assigned for the thesis shall be revoked. After the parental leave period has ended, you will be assigned a new topic.
- (6) If you have other familial obligations, you can also apply to the Examination Board for an extension of the deadlines set down in these examination regulations. Paragraph 5, sentences 4 to 6 apply accordingly.
- (7) If the candidate attempts to influence the result of an exam through fraud, plagiarism, or the use of aids that are not permitted, the exam shall be marked "fail" (5.0). The relevant examiner or supervisor can exclude a candidate who has violated the examination regulations from continuing the examination. In this case the examination is failed.
- (8) For repeat offences or otherwise serious cases, the *StPA* may decide to deny the candidate permission to take any further exams.
- (9) Incriminating decisions by the *StPA* shall be stated in writing and sent without delay to the candidate, along with information on the options available for legal

recourse. Before the *StPA* decides, the candidate will be given the opportunity to comment the case.

§ 9 Course and Examination Languages

- (1) Courses are in English.
- (2) Coursework and examinations are in English.

§ 10 Assessment of Master's Examination; Determination of Grades

- (1) Grades for the individual examinations are determined by the examiner. Examinations are marked using the following scale of the ECTS system:

If you reach

- 100% to 85% = A (*hervorragend / excellent*)
- <85% to 79% = B (*sehr gut / very good*)
- <79% to 75% = C (*gut / good*)
- <75% to 65% = D (*befriedigend / satisfactory*)
- <65% to 50% = E (*ausreichend / sufficient*)
- <50% = F (*nicht ausreichend / fail*)

The percentage values of the individual exam parts will be used to further calculate your grades for module parts, modules and the overall grade.

- (2) If an examination is evaluated by more than one examiner, the grade shall be calculated by the arithmetic mean of the grades given by each of the examiners according to para. 1. The grades for individual exams shall be calculated to only one decimal place. Additional decimal places shall be discarded without rounding. This also applies to the determination of the module grades and overall grade.
- (3) The final grade for a course examination in one part of the module results from the grade for the written examination and the assessment of your case study. These two grades equally count towards the grade for that part of the module. You have to pass each individual exam component. You need at least 50% of the possible overall points ("sufficient", E) to pass the written exam as well as the case study.
- (4) The overall grade of the master's examination is comprised of:
 - 50 % the arithmetic mean of the grades of all module parts
 - 50 % the grade of the final module, including the master's thesis
- (5) The "Modified Bavarian Formula" is used to convert grades into the German grading system. The Modified Bavarian Formula is as follows:

$$x = 1 + 3 \frac{N_{max} - N_d}{N_{max} - N_{min}}$$

where x is the German overall grade that is to be calculated. (N_{max}) is the highest grade that can be reached in the foreign system (100%, excellent), (N_{min}) is the lowest passing grade that can be reached in the foreign system (50%, sufficient), and (N_d) is your actual grade that is to be converted. The result is rounded to the next German grade. If your result is in between two German grades, the grade shall be rounded to your advantage.

The overall grades are as follows:

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| an average up to 1.5 | = very good |
| an average above 1.5 up to 2.5 | = good |
| an average above 2.5 up to 3.5 | = satisfactory |
| an average above 3.5 up to 4.0 | = sufficient |
| an average above 4.0 | = fail |

- (6) For all grade calculations the minimum number of ECTS credits is used as a basis (see attachment) and not the actually completed number of points of a course or module.

§ 11 Examination Certificate and Degree Certificate

- (1) If you have passed the master's examination, you will receive a certificate. This certificate contains the module grades, the grade and topic of your master's thesis as well as the overall grade according to § 10 (1), including any decimal places according to § 10 (5).
- (2) If you have achieved an overall grade between 1.0 and 1.2, you pass "with distinction".
- (3) Together with the examination certificate you will receive a degree certificate, certifying that you have earned an academic master's degree (Master of Science). In the degree certificate your subject is stated as "Advanced Safety Sciences for Medicines".
- (4) The chairperson of the *StPA* signs the examination certificate and degree certificate and stamps the documents with the seal of the University of Konstanz. The date on these documents shall be the date on which the last examination was completed.
- (5) You will receive a German and an English version of the certificates.
- (6) On request you will receive a Diploma Supplement.

II. Course Examinations

§ 12 Types of Course Examinations

- (1) You have to take examinations for each chosen course in the modules 1-5 (see § 3 para 2). The course examination consists of a written exam following the course as well as a written home assignment case study per course.
- (2) The written exam consists of multiple choice questions as well as an essay.
- (3) You will complete the individual case study at home, in writing and by using specialist literature.

§ 13 Conducting and Repeating Coursework Examinations

- (1) The written exam takes place on the last day of the attendance week at the respective venue of the course. The exam duration is two hours.
- (2) You have to complete the case study within six weeks after the end of the course.
- (3) You can re-sit course examinations only once. Exam re-sits have to take place within six weeks after failing the course exam or in the context of the next course (agreed upon with the examiners). You can re-sit each individual exam part separately.
- (4) If the result of the re-sit is "fail" again, the *StPA* may permit the student to re-sit the exam a second time, if this is deemed justifiable in view of the student's overall performance. Further repetitions of the corresponding exam part are not permitted.

III. External Students' Examination

§ 14 External Students' Examination

- (1) You take the master's examination in the continuing education master's programme "Advanced Safety Sciences for Medicines" as external student.
- (2) You can only be admitted to the external students' examination if you
 - a. have a bachelor's degree (standard period of study four years), or a degree in a three-year (or more) state exam programme or bachelor's programme combined with a degree in a one-year (or more) master's programme or equivalent degree,
 - b. can document a minimum of one year relevant professional practice,
 - c. can document that you are sufficiently prepared for the exam according to paragraph (4),
 - d. can document, on demand, English skills (written and oral) equivalent to IELTS 7.0,
 - e. are not enrolled at a university in Germany or abroad,
 - f. your permanent residence, your habitual residence or your place of work is in Baden-Württemberg or another German state or the Bologna area, in which applicants from Baden-Württemberg can also take external students' examinations and
 - g. have not lost the right to examination in the continuing education master's programme "Advanced Safety Sciences for Medicines".

Under exceptional circumstances applicants may be admitted who do not fulfil the requirement stated in letter f).

- (3) For admission to the external student's examination you have to apply in writing to the Examination Board, no later than the day the topic of the master's thesis is issued. The application must include:
 - a. documentation of the entry requirements listed in para. 2 a) to f) and
 - b. a declaration whether you currently are in the examination process or have failed a master's examination or examination as external student in a continuing education master's programme "Advanced Safety Sciences for Medicines" .
- (4) You are sufficiently prepared for the exam acc. to para 2 c) if you can document your participation in
 - a. ten compulsory courses, see attachment
 - b. as well as additional compulsory elective courses, see attachment,worth a total of 45 ECTS credits

IV. Master's Examination

§ 15 Type and Scope of the Master's Examination

The master's examination consist of:

- a. course examinations in the modules listed in § 3 para 2 and 3 to the extent defined in § 14 para. 4 and § 12 para. 1 as well as in the attachment
and
- b. a written master's thesis acc. to § 17.

§ 16 Admission to the Master's Examination

- (1) You can apply for admission to the master's thesis after you have passed the third course exam in a module. You have to apply to the *StPA* no later than one year after the last passed exam component of a module. The one-year deadline starts the day your attendance certificate is issued.
- (2) Your application may include a suggestion of a topic for the master's thesis and an examiner (supervisor). There is no right guaranteeing that your suggestion has to be considered.
- (3) You can only be admitted to the Master's thesis if you
 - a. have not lost the permission to sit exams in this master's programme,
 - b. and have completed the required course examinations worth 45 ECTS credits in the modules listed in § 3 para. 2 as well as in the attachment to these examination regulations.
- (4) The *StPA* decides about admissions. Admission must be denied if you do not fulfil the requirements stated in para. 2, your application is incomplete or you have finally failed or lost the right to examination in the master's programme "Advanced Safety Sciences for Medicines".

§ 17 Master's Thesis

- (1) With your master's thesis you shall demonstrate that you are able to work independently according to scientific principles on a problem in the area of drug safety within a certain period of time.
- (2) The *StPA* assigns the topic of the master's thesis, appoints the examiners and documents this information.
- (3) The time period allotted for the master's thesis is six months. In exceptional cases the chair of the *StPA* may extend this deadline by up to two months. If the thesis is not turned in on time it shall be given the grade "fail", unless the delay is caused by circumstances beyond your control. The period for completing the master's thesis begins with the written assignment of your topic. The *StPA* shall decide about exceptions.
- (4) If you might not be able to complete the thesis within the prescribed time limit due to circumstances beyond your control, or if you claim those circumstances even after the end of the extension deadline according to para. 2 sentence 4, the topic shall be revoked and you will be assigned a new topic no later than four weeks after these circumstances have ceased to prevail.
- (5) You have to hand in your master's thesis via the chair of the *StPA* in three bound or stapled copies as well as in electronic form within the prescribed time limit. One of the submitted copies shall remain with the *StPA* until the examination procedures are completed. The master's thesis has to be in one and a half line typescript, font size 12, and should not exceed 50 pages. Your supervisor may specify further details.
- (6) When submitting the thesis you must affirm in writing that you have completed the thesis alone, with no aids or sources other than those explicitly stated. You shall keep materials which can prove your sole responsibility in preparing the thesis available until the completion of the examination procedures.
- (7) Your master's thesis will be assessed by two examiners appointed according to § 6 para.3. At least one qualified member of the Department of Biology who is an authorised examiner represents the University of Konstanz. Usually the examiners present their assessment (containing a grade) to the Examination Office within six weeks after submission of the master's thesis.
- (8) A master's thesis is passed if the grade is "sufficient" or better. It is not passed if the grade is "fail".
- (9) If one examiner marks the thesis "sufficient" and the other "fail", the *StPA* will appoint a third examiner. If the third examiner marks the thesis "sufficient" or better, you will have passed the thesis. In this case the grade is "sufficient", (4.0), or is calculated from the grades of the three examiners if that figure is better than 4.0. If the third examiner marks the thesis "fail" (5.0), you have failed the master's

thesis.

- (10) If the master's thesis is marked "fail" (5.0), you can repeat it once. You shall be assigned your new topic within three months after receiving the first result. A second repetition is not permitted. You can only give the second topic back within the time limit mentioned in para. 4 if you did not use this option while writing your first master's thesis.

§ 18 Results of the Master's Examination

- (1) You have passed the master's examination if each grade for all coursework and all examinations mentioned in § 15 is "sufficient" (4.0) or better.
- (2) The grade for the master's examination is calculated according to § 10 para. 4.
- (3) If you can no longer re-sit an examination marked "fail" (5.0), you have irrevocably failed the master's examination.
- (4) If you have irrevocably failed the master's examination, the chair of the Examination Board *StPA* will issue a written confirmation containing information on the options available for legal recourse.

V. V. Final Provisions

§ 19 Invalidation of the Master's Examination

- (1) If a candidate has cheated on an exam and this fact is discovered after the certificate has been issued, the *StPA* may correct the grades for the exam on which the candidate cheated, and may declare all or part of the examination failed.
- (2) If the prerequisites for an exam taken were not met, and this fact is discovered after the certificate has been issued, the deficit shall be deemed to have been rectified by the passing of the exam, provided the candidate had no intent to deceive. If the candidate intentionally practised deceit to obtain admission to the exam, the *StPA* will decide.
- (3) Before a decision goes into effect, the candidate shall be given opportunity to make a statement.
- (4) The incorrect examination diploma shall be revoked and, if appropriate, a new diploma issued. If the master's examination is declared "fail" due to deceitful practices, the examination certificate shall be revoked as well as the degree certificate.
- (5) Revocation of the academic degree shall be handled in accordance with statutory provisions.

§ 20 Inspection of Records

Within one year of the conclusion of the examination procedure, you will be permitted to inspect your written examination records, the evaluations by the examiners, and the minutes of the examinations on request and within a reasonable period of time.

§ 21 Legal Recourse

You can object to decisions in the examination procedure that constitute an administrative act (§§ 68 et. seq. VwGO). The Vice Rector of Study Programmes shall issue a ruling on the matter following a recommendation of the Central Examination Board, which shall hear the *StPA* on that matter.

§ 22 Effective Date and Interim Regulations

These study requirements and examination regulations go into effect on 01 October 2014.

If you have completed courses of the SafeSciMET Programme before these regulations were effective, your achievements will be recognised according to §3 para. 2.

Appendix

Note:

These examination regulations were published in the Official Bulletin of the University of Konstanz No. 49/2014 of 22 September 2014.

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Appendix:

Modules in the Master's Programme Advanced Safety Sciences for Medicines

| Module title | | ECTS-Credits |
|---------------------|---|---------------------|
| Module 1 | Drug Discovery and Development | |
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| MAS-SSM-101 | Introduction to Safety Sciences in Drug Discovery and Development | 3 / CC |
| MAS-SSM-102 | Drug Safety of Stem Cells and other Novel Therapeutics | 3 / CC |
| | | |
| Module 2 | Pharmaceutical Aspects of Drug Safety | |
| | | |
| MAS-SSM-201 | Pharmaceutics and Safety | 3 / CEC |
| MAS-SSM-202 | Regulatory Requirements and Guidelines | 3 / CC |
| MAS-SSM-203 | Pharmaco-/Toxicokinetics and Pharmaco-/Toxicodynamics | 3 / CC |
| | | |
| Module 3 | Adverse Drug Reactions / Predictive Toxicology / 3 Rs | |
| | | |
| MAS-SSM-301 | Biochemical and Molecular Toxicology: Biotransformation, Bioactivation and Adverse Drug Reactions | 3 / CC |
| MAS-SSM-302 | Cellular Toxicology/Predictive Toxicology | 3 / CEC |
| MAS-SSM-303 | Organ/Systems Toxicology | 3 / CC |
| MAS-SSM-304 | Reproductive Toxicology | 3 / CEC |
| MAS-SSM-305 | Mutagenesis and Carcinogenesis | 3 / CEC |
| MAS-SSM-306 | Safety Pharmacology | 3 / CEC |
| | | |
| Module 4 | Non-clinical Assessment | |
| | | |
| MAS-SSM-401 | Non-Clinical Safety Assessment: Strategies, Ethics and Protocols | 3 / CC |
| MAS-SSM-402 | Biomolecular Analysis: From Method Development to Clinic | 3 / CEC |
| MAS-SSM-403 | Predictive Cell Culture Systems | 3 / CEC |
| MAS-SSM-404 | Toxicogenomics and Systems Toxicology | 3 / CEC |
| MAS-SSM-405 | Pathology Interpretation in Drug Development | 3 / CEC |

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| MAS-SSM-406 | <i>In silico</i> ADME and Predictive Toxicology | 3 / CC |
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| Module 5 | | |
| Clinical Safety | | |
| | | |
| MAS-SSM-501 | Clinical Safety: Pre-Approval | 3 / CC |
| MAS-SSM-502 | Clinical Safety: Post-Approval | 3 / CC |
| MAS-SSM-503 | Personalized medicine: Implications for drug development and treatment | 3 / CEC |
| Module 6 | | |
| Master's module | | |
| MAS-SSM-601 | written master's thesis | 15 / CC |
| Total | | |
| | 10 compulsory courses (CC) from modules 1-5 5 out of 10 compulsory elective courses (CEC) from modules 1-5, plus thesis module | 60 |

CC compulsory course (Pflichtkurs, P in the German language document)

CEC compulsory elective course (Wahlpflichtkurs, WP in the German language document)

see also the module guide of the study programme