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

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*Advanced Safety Sciences for Medicines*

## **I. General**

### **§ 1 Objective of the master's examination**

- (1) The development of drugs is an integrative process in which the disciplines involved need to interlink and transfer their toxicological findings. This is very important to understand the processes in this highly specialised professional area. In the Advanced Safety Sciences for Medicines Programme, students will acquire the required competences in the field of drug safety as well as drug research and development - alongside professional work.
- (2) In the master's examination, students demonstrate that they have acquired basic and advanced interdisciplinary knowledge in drug safety. With this knowledge, they 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 students have passed the master's examination, the University of Konstanz awards 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 organized in the SafeSciMET consortium offer the courses listed in the appendix. In these courses, students acquire the required knowledge in drug safety, pharmaceuticals, toxicology as well as non-clinical and clinical studies. They take the examinations leading towards the master's degree as external students 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 as per para. 2 § 15 a and the appendix of this examination regulations, as well as a written master's thesis.
- (4) Students can acquire a total of 60 ECTS credits in the master's programme. They can acquire 45 ECTS credits by successfully participating in the mandatory courses and the required elective courses as per para. 2 and 3 and § 15 a. They 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 workload of approximately 25 - -30 hours.
- (6) The curriculum of the master's programme is scheduled for four semesters. However, students can also take more time to complete the courses as this is a continuing education programme.

#### **§ 4 Examinations, Exam Administration and Deadlines**

- (1) Each module will be completed with a course-related performance assessment as per § 3 para. 2. The master's examination consists of course-related performance assessments in the modules mentioned in § 3 para. 2, and, as final module, the master's thesis as per § 17.
- (2) If the reasons for not completing an examination within the scheduled deadline are beyond the candidate's 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. Students are required to inform themselves about dates and information on examinations, at regular intervals and on specific occasions as needed. If they fail to do so, they 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 election body of the biology student council nominates the student member; the Study Commission Biology appoints this student for one year.
- (2) *StPA* decisions concerning examination procedures are made in accordance with these examination regulations. The *StPA* ensures that the examination provisions are observed and submits proposals for necessary amendments to the examination regulations. Subject to revocation, it may assign certain tasks to the chairperson.
- (3) The *StPA* members are legally bound to maintain confidentiality. Those who are not in civil service shall be instructed by the chairperson to maintain confidentiality.
- (4) The *StPA* meetings may also be held via electronic media in a videoconference.

#### **§ 6 Examiners and observers**

- (1) The *StPA* appoints the examiners for the individual examinations and for the master's theses. The Examination Board can task the chairperson with these appointments.
- (2) Course-related performance assessments are usually conducted by the course instructors.

- (3) As a rule, examinations 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 Recognition of previous studies, coursework and performance assessments**

- (1) Periods of study, coursework and performance assessments in the same study programme or other programmes at a state/state-approved institution of higher education in Germany or abroad, or a German *Berufsakademie*, are recognized upon application, 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. There is no significant difference if contents, learning objectives and examinations largely correspond to the requirements of the study programme at the University of Konstanz. When recognizing coursework and performance assessments completed outside of Germany, the following have to be considered:

- Recommendations of the Kultusministerkonferenz, Zentralstelle für ausländisches Bildungswesen (Standing Conference of the Ministers of Education and Cultural Affairs of the Länder in the Federal Republic of Germany, Central Office for Foreign Education)
- Agreements on Equivalence of the Federal Republic of Germany
- Agreements with partner universities.

The Examination Board *StPA* decides about exceptions (upon application). If applicable, students will be awarded the ECTS credits as listed in the attachment for the corresponding achievements.

- (2) If the prerequisites (as per paras. 1 and 2) are met, students are legally entitled to recognition of credits. Students must submit the required documents when applying for recognition of credit.
- (3) If recognition of credit is granted, and insofar as the grading systems are comparable, the relevant grades will be transferred and counted towards the overall grade. If the grading systems are incompatible, the grade "passed" (4.0) will be applied. Recognition of credits will be stated in the examination certificate.
- (4) The Examination Board (StPA) or an appointed representative decides on whether to recognize achievements.

### **§ 7a Recognition of non-higher education achievements**

- (1) Non-higher education achievements will be assessed as coursework and performance assessments if the following apply:
- The knowledge and skills thus acquired are equivalent to the coursework and performance assessments they stand to replace
  - The institution at which the knowledge or skills were acquired has implemented a quality assurance system

- The prerequisites for acceptance at an institution of higher education are met at the time credit is granted for such achievements
- (2) An overall view must be taken and an overall assessment made when determining whether knowledge and skills are equivalent. They are considered equivalent if there is no significant difference between the knowledge and skills acquired. There is no significant difference if the knowledge and skills achieved outside of any institution of higher education largely correspond to the contents, learning objectives and requirements of the corresponding achievement in the study programme at the University of Konstanz.
- (3) If equivalence cannot be determined, a placement test may be administered.
- (4) A maximum of 15 ECTS credits can be granted for achievements obtained outside the higher education system.
- (5) The Examination Board *StPA* decides about recognition and placement tests.
- (6) The regulations regarding recognition will come into effect only after the criteria for recognition have been verified in the context of an accreditation procedure.

#### **§ 8 Absence, withdrawal, health impairments, leave of absence for family reasons, fraud, breach of regulations**

- (1) A performance assessment will be graded "fail" (5.0) if the candidate fails to attend or withdraws from an examination after it has already started without giving compelling reasons. The same applies if the student fails to complete a written performance assessment within the set time limit.
- (2) Students must provide the Examination Board (*StPA*) with credible reasons for missing or withdrawing from an examination without delay. In the case of illness, a medical certificate has to be submitted. If the reasons are accepted, the candidate will be informed that he/she has to take the performance assessment at the next examination date. In this case, examination results acquired up to that point will be credited if they can be separated from the part of the examination that still needs to be completed.
- (3) If a candidate is able to verify by means of a medical certificate that he/she is unable to complete a performance assessment in part or in full in the designated form or time period due to a longer or permanent medical condition, the chair of the Examination Board *StPA* will allow him/her additional time or grant him/her permission to complete an equivalent type of performance assessment in a different form. The same applies for coursework assignments.
- (4) On request, the *Mutterschutzfrist* (maternity protection period), as defined by the applicable federal law in Germany on the protection of working mothers (*MSchG*) will be taken into consideration. The required documentation must be submitted with the request. The *Mutterschutzfrist* interrupts all other periods defined in these examination regulations; this means that time spent on *Mutterschutz* (maternity protection) is not counted as elapsed time within these periods.
- (5) Similarly, *Elternzeit* (parental leave) as defined in the *Bundeselternzeit- und Elternzeitgesetz BEEG* (law on parental leave allowance and parental leave) will be taken into consideration on request. The candidate must inform the Examination Board of the period(s) of *Elternzeit* to be taken no later than four weeks before the first day of planned

*Elternzeit*. This must be done in writing and include the necessary documentation. The Examination Board (*StPA*) will assess whether the legal prerequisites are met under which employees have the right to *Elternzeit* in accordance with the *BEEG*, and shall inform the candidate of their decision and, if applicable, of the new schedule for examination dates, without delay. The time period allowed for completing the master's thesis (part of the final examination) cannot be interrupted by *Elternzeit*. In this case the topic is considered not to have been assigned. After the *Elternzeit* period has ended, the candidate will be assigned a new topic.

- (6) If students have other familial obligations, they 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 a candidate attempts to influence the result of an examination through fraud, plagiarism, or the use of aids that are not permitted, the examination shall be graded fail ("fail" 5.0). The relevant examiner or supervisor can exclude a candidate who has disturbed the proper proceedings of a performance assessment from continuing the performance assessment. In this case the corresponding performance assessment is deemed to have failed.
- (8) In case of repeated or particularly serious fraud or plagiarism, the *StPA* may decide to deny the candidate permission to retake the examination, resulting in a complete loss of right to take any further examinations in this study programme.
- (9) The candidate must be notified of an incriminating decision by the *StPA* in writing and without delay, including information on available options for legal recourse. Before the Examination Board (*StPA*) decides, the candidate will be given the opportunity to comment the case.

## **§ 9 Course and examination languages**

- (1) Courses are taught in English.
- (2) Coursework and performance assessments are to be completed in English.

## **§ 10 Assessment and determination of grades**

- (1) Grades for the individual performance assessments are determined by the examiners. The following grades of the ECTS system are used:

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

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

- (2) If a performance assessment is evaluated by more than one examiner, the grade will be the arithmetic mean of the grades given by each of the examiners as per paragraph 1. Grades for individual performance assessments are calculated to only one decimal place. Additional decimal places are discarded without rounding. This also applies to the determination of the module grades and overall grade.
- (3) The final grade for a course-related performance assessment in one part of the module results from the grade for the written examination and the assessment of the case study. These two grades equally count towards the grade for that part of the module. Students have to pass each individual exam component. They need at least 50% of the possible overall points ("sufficient", E) to pass the written examination as well as the case study.
- (4) The overall grade of the master's examination is comprised of:
- a. 50 % the arithmetic mean of the grades of all module parts
  - b. 50 % the grade of the final module comprising 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:

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

X is the German overall grade that is to be calculated. (N<sub>max</sub>) is the highest grade that can be reached in the foreign system (100%, excellent), (N<sub>min</sub>) is the lowest passing grade that can be reached in the foreign system (50%, sufficient), and (N<sub>d</sub>) is the student's actual grade that is to be converted. The result is rounded to the next German grade. If a student's result is in between two German grades, the grade shall be rounded to the student's advantage.

The overall grades are as follows:

- |                                  |                |
|----------------------------------|----------------|
| – 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         |

- (1) 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) Once students have passed the master's examination and all achievements relevant for passing the examination have been recorded, they will receive a certificate with the overall grade of their study programme. The certificate also includes the grade and topic of the master's thesis.
- (2) The certificate will be awarded "with distinction" if students achieve an overall grade of 1.2 or better.

- (3) With the examination certificate, students also receive a degree certificate confirming that they have earned an academic master's degree and indicating the subject studied.
- (4) The examination and degree certificate are signed by the chairperson of the Examination Board (*StPA*) and stamped with the seal of the University of Konstanz. The date to be entered is the date on which, according to the request for issuing a certificate, the last coursework or performance assessment was completed.
- (5) A diploma supplement in line with the European Diploma Supplement Model and a transcript of records are issued as further components of the certificate. The transcript of records contains the completed modules and their components, the module grades, the ECTS credits acquired in the modules and the overall number of ECTS credits as well as the grades for the completed coursework and performance assessments; ungraded modules and achievements will be included with a remark about successful participation. Coursework and performance assessments that are not included in the master's examination will be included in the transcript of records as "Sonstige Leistungen" / "Additional voluntary course work".
- (6) In addition to that, a transcript of records as per para. 5 is issued without the grades for the individual coursework and performance assessments.
- (7) On request of the students, the duration of studies until completion of the study programme can be included in the transcript of records.
- (8) All documents mentioned in paragraphs 1, 3, 5 and 6 are issued in German and –as far as possible – in English.

## **II. Course-related performance assessments**

### **§ 12 Types of course-related performance assessments**

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

### **§ 13 Conducting and repeating course-related performance assessments**

- (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) Students have to complete the case study within six weeks after the end of the course.
- (3) Students can retake every course-related performance assessment once. Exam retakes have to take place within six weeks after failing the course-related performance assessment or in the context of the next course (agreed upon with the examiners). Students can retake each individual exam part separately.



- (4) If the student's performance in an exam retake is yet again graded "fail", the *StPA* may permit the student to retake the examination 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.

### **§ 13a Regular attendance as a special form of coursework**

- (1) In seminars and other dialogue-oriented courses as well as in practical courses such as lab courses, the instructors **may** request regular attendance in the course or participation in a lab introduction as a pre-requisite for completing coursework and performance assessments and/or for acquiring credits. In this case, it must be announced, in writing or electronically and at the beginning of the course, that regular attendance or participating in the lab introduction is an admission requirement for course-related performance assessments and/or a pre-requisite for acquiring credits.
- (2) Regular attendance means that not more than one fifth of course time or course dates was missed. Otherwise, admission to coursework and performance assessments in that course will be denied, irrespective of whether or not the student is responsible for the absences. In this case, no ECTS credits can be acquired. In justified cases it is possible to deviate from these regulations in favour of the students; corresponding requests have to be submitted to the Examination Board (*StPA*) via its secretary.

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<sup>1</sup> Cases, for which exceptions may be granted are, in particular: 1. Students with a medically certified chronic or longer-term illness who may request academic adjustments in line with these examination regulations and who cannot participate in all dates of the course for health reasons; 2. Student-parents whose child is ill as well as students with relatives in need of care if they submit corresponding documentation that the care is necessary; 3. Students who are members of a university body or the Students' Union in the current semester and consequently miss individual course dates if they submit documentation of their participation in the meeting of the committee; 4. Top athletes in the sense of the university's cooperation agreement for supporting top-class sports if they can document that they were required to participate in competitions or training camps; 5. Study abroad stays during the ongoing semester with corresponding documentation; 6. Startup founders with corresponding documentation.

### **III. External Students' Examination**

#### **§ 14 External Students' Examination**

- (1) In the continuing education master's programme "Advanced Safety Sciences for Medicines", students take the master's examination as external students.
- (2) Students can only be admitted to the external students' examination if they
  - 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 they are sufficiently prepared for the examination as per 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. have permanent residence, habitual residence or their place of work 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".

In justified exceptional cases, applicants may be admitted who do not fulfil the requirement stated in letter f).

- (3) For admission to the external student's examination, students have to apply in writing to the Examination Board, no later than the day the topic of the master's thesis is issued. Applications must include:
  - a. documentation of the admission requirements listed in para. 2 a) to f) and
  - b. a declaration whether they 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) If students can document the following, this will be seen as evidence of their being sufficiently prepared for the examination as per para 2 c): participation in
  - a. ten compulsory courses, see attachment
  - b. further required 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 consists of:

- a. course-related performance assessments 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 as per § 17.

##### **§ 16 Admission to the master's examination**

- (1) Students can apply for admission to the master's thesis after they have passed the third course-related partial module exam. They have to apply to the StPA no later than one year after the last passed partial module exam. The one-year deadline starts the day the attendance certificate is issued.
- (2) The application may include a suggestion of a topic for the master's thesis and an examiner (supervisor). There is no right guaranteeing that this suggestion will be considered.
- (3) Students can only be admitted to the master's thesis if they
  - a. have not lost the right to take examinations in this master's programme, and
  - b. have completed the required course-related performance assessments 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 a student does not fulfil the requirements stated in para. 2, the application is incomplete, or the student has finally failed a master's examination in "Advanced Safety Sciences for Medicines" or has lost the right to take examinations in this study programme.

## **§ 17 Master's thesis**

- (1) By completing the master's thesis, candidates shall demonstrate that they are able to work independently and 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 submitted on time, it shall be given the grade "fail", unless the delay is caused by circumstances beyond the student's control. The period for completing the master's thesis begins with the written assignment of the topic. The Examination Board *StPA* decides about exceptions.
- (4) If students might not be able to complete the thesis within the prescribed time limit due to circumstances beyond their control, or if they claim those circumstances even after the end of the extension deadline as per para. 2 sentence 4, the topic shall be revoked and they will be assigned a new topic no later than four weeks after these circumstances have ceased to prevail.
- (5) Students have to hand in their 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. The supervisor may specify further details.
- (6) Upon submission, candidates must provide written confirmation of being the sole author of the master's thesis and of not having used any sources or aids other than the ones stated. Candidates must retain any materials that can prove their sole authorship until the examination procedure has been concluded.
- (7) The master's thesis will be assessed by two reviewers appointed as per § 6 para.3. At least one qualified member of the Department of Biology who is entitled to hold examinations represents the University of Konstanz. The reviewers usually submit their assessment, including a grade, to the Examination Office within six weeks of 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 reviewer grades the thesis "sufficient" or better, and the other "fail", the *StPA* will appoint a third reviewer. If the third reviewer grades the thesis "sufficient" or better, the master's thesis is passed. In this case the grade will be "sufficient", (4.0), or will be calculated from the grades of the three reviewers if that value is lower. If the third reviewer grades the thesis "fail" (5.0), the master's thesis will have failed.
- (10) If the master's thesis is graded "fail" (5.0), it can be repeated once. A new topic will be assigned within three months after notification of the first result was given. A second repetition is not permitted. The second topic can only be given back within the time limit mentioned in para. 4 if the candidate did not use this option during his/her first attempt.

### **§ 18 Results of the master's examination**

- (1) The master's examination is passed if all performance assessments mentioned in § 15 are graded "sufficient" (4.0) or better.
- (2) The grade for the master's examination is calculated as per § 10 para. 4.
- (3) If one of the examinations graded "fail" (5.0) can no longer be repeated, the candidate has finally failed the master's examination.
- (4) If a student has finally failed the master's examination, the chairperson of the Examination Board *StPA* will issue a written notification containing information on the options available for legal recourse.

## **V. Final provisions**

### **§ 19 Invalidation of the master's examination**

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

## **§ 20 Inspection of examination records**

On request and within one year of the conclusion of the examination procedure, candidates are permitted to inspect their written examination records, the reviewers' assessments as well as the examination minutes.

## **§ 21 Legal recourse**

The candidate may object to decisions in the examination procedure that constitute an administrative act (§§ 68 et. seq. *VwGO*). The Vice-rector for Teaching and Curricular Affairs will issue a ruling following a recommendation of the Central Examination Board, which shall hear the Examination Board *StPA* on that matter.

## **§ 22 Effective date and transitional provisions**

These examination regulations come into effect on 01 October 2014. If students have completed courses of the SafeSciMET Programme before these regulations were effective, the achievements will be recognized as per §3 para. 2.

## **Attachment**

### Note:

These regulations were published in the *Amtliche Bekanntmachungen* (official announcements) of the University of Konstanz No. 49/2014 on 22 September 2014.

The amendments to these regulations were published in the *Amtliche Bekanntmachungen* of the University of Konstanz No. 51/2019 on 28 November 2019.

**Attachment:**

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

<b>Module title</b>		<b>ECTS Credits</b>
<b>Module 1</b>	<b>Drug Discovery and Development</b>	
MAS-SSM-101	Introduction to Safety Sciences in Drug Discovery and Development	3 / P
MAS-SSM-102	Drug Safety of Stem Cells and other Novel Therapeutics	3 / P
<b>Module 2</b>	<b>Pharmaceutical Aspects of Drug Safety</b>	
MAS-SSM-201	Pharmaceutics and Safety	3 / WP
MAS-SSM-202	Regulatory Requirements and Guidelines	3 / P
MAS-SSM-203	Pharmaco-/Toxicokinetics and Pharmaco-/Toxicodynamics	3 / P
<b>Module 3</b>	<b>Adverse Drug Reactions / Predictive Toxicology / 3 Rs</b>	
MAS-SSM-301	Biochemical and Molecular Toxicology: Biotransformation, Bioactivation and Adverse Drug Reactions	3 / P
MAS-SSM-302	Cellular Toxicology/Predictive Toxicology	3 / WP
MAS-SSM-303	Organ/Systems Toxicology	3 / P
MAS-SSM-304	Reproductive Toxicology	3 / WP
MAS-SSM-305	Mutagenesis and Carcinogenesis	3 / WP
MAS-SSM-306	Safety Pharmacology	3 / WP
<b>Module 4</b>	<b>Non-Clinical Assessment</b>	
MAS-SSM-401	Non-Clinical Safety Assessment: Strategies, Ethics and Protocols	3 / P
MAS-SSM-402	Biomolecular Analysis: From Method Development to Clinic	3 / WP
MAS-SSM-403	Predictive Cell Culture Systems	3 / WP
MAS-SSM-404	Toxicogenomics and Systems Toxicology	3 / WP
MAS-SSM-405	Pathology Interpretation in Drug Development	3 / WP
MAS-SSM-406	<i>In silico</i> ADME and Predictive Toxicology	3 / P

<b>Module 5</b>		
	<b>Clinical Safety</b>	
MAS-SSM-501	Clinical Safety: Pre-Approval	3 / P
MAS-SSM-502	Clinical Safety: Post-Approval	3 / P
MAS-SSM-503	Personalized medicine: Implications for drug development and treatment	3 / WP
<b>Module 6</b>		
	<b>Master's module</b>	
MAS-SSM-601	written master's thesis	15 / P
<b>TOTAL</b>	10 compulsory course (P) in the modules 1-5 5 out of 10 required elective courses in the modules 1-5, final module	<b>60</b>

P Pflichtkurs (compulsory course)

WP Wahlpflichtkurs (required elective course)

see also the module guide of the study programme