

Study programme regulations

- ***“Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel***
- ***“Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” at the University of Basel***
- ***“Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel***

of 25 May 2020 (Faculty resolution)

This is a translation of the German original “Studiengangreglement” for information and orientation purposes only. Only the German version of this document is legally binding.

The Faculty of Medicine at the University of Basel issues the following study programme regulations subject to approval by the Rectorate and having regard to the University’s provisions governing further education.

§ 1. Purpose and scope

¹ These study programme regulations govern the post-graduate study programmes “Master of Advanced Studies (MAS) in Medicines Development”, “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” and “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel that are pursued in parallel with employment.

² They apply to all students pursuing the post-graduate study programmes “Master of Advanced Studies (MAS) in Medicines Development”, “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” and “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel.

³ The curriculum provides details of the post-graduate study programmes.

§ 2. Responsible bodies

¹ The Faculty of Medicine at the University of Basel sponsors the study programmes.

² For administrative and financial purposes the study programmes form part of Advanced Studies at the University of Basel.

§ 3. Admission to the study programmes

¹ The following conditions must be met for admission to the study programmes:

- a) Completed programme of university study at Master level in medicine, veterinary medicine, pharmacy, pharmaceutical science, sciences in which chemistry, biology or biochemistry are examined subjects, mathematics and related fields.
- b) At least two years of comprehensive professional experience in the field taught in the study programme.
- c) Good spoken and written knowledge of English.

² In justified exceptional cases, candidates may be admitted to the study programme if they can demonstrate an appropriate professional background and a relevant professional qualification and submit a written recommendation.

³ Admission to the study programme “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” at the University of Basel requires prior participation in and successful completion of the study programme “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel.

⁴ Admission to the study programme “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel requires prior participation in and successful completion of the study programme “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” at the University of Basel.

§ 4. *Content of the study programmes*

¹ The content of the consecutive study programmes is based on the internationally recognised PharmaTrain syllabus. The CAS study programme teaches the core subjects that are covered in more depth in the DAS and MAS programmes.

² The study programmes contain the following modules:

- a) Discovery of Medicines
- b) Development of Medicines: Planning
- c) Non-Clinical Testing
- d) Pharmaceutical Development
- e) Exploratory Development (Molecule to Proof of Concept)
- f) Confirmatory Development
- g) Clinical Trials
- h) Ethics and Legal Issues
- i) Data Management and Statistics
- j) Regulatory Affairs
- k) Drug Safety, Pharmacovigilance and Pharmacoepidemiology
- l) Information, Promotion and Education

m) Economics of Health Care and Health Care Systems

³ The content of the study programmes takes into account the current state of research, teaching and practice in the development of medicines.

⁴ The study programme commission reserves the right to modify the content.

§ 5. *Scope and duration of the study programmes*

¹ The study programme “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel comprises 60 ECTS credit points and a study duration of 5 years.

² The study programme “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” at the University of Basel comprises 30 ECTS credit points and a study duration of 2 years.

³ The study programme “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel comprises 20 ECTS credit points and a study duration of 2 years.

§ 6. *Structure of the study programmes*

¹ The study programme “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel comprises teaching in the following modules:

- a) Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine
- b) Elective modules in the fields covered by the PharmaTrain syllabus
- c) Final MAS examination consisting of a written dissertation and an oral examination.

² The study programme “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” at the University of Basel comprises teaching sessions in the following modules:

- a) Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine
- b) Final DAS examination.

³ The study programme “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel comprises teaching sessions in the following modules:

- a) Module 1: From Molecule to Marketplace
- b) Module 2: From Non-Clinical Testing to First-in-Human
- c) Module 3: Planning, Collecting and Managing Clinical Data
- d) Module 4: Clinical and Safety Data Evaluation and Biostatistics
- e) Module 5: Global Registration and Approval Process
- f) Module 6: Integrated Product Development, Healthcare Marketplace and Marketing
- g) Final CAS examination.

⁴ The curriculum informs students about the teaching sessions for the modules and the ECTS credit points that can be earned with each session.

§ 7. *Successful completion of the study programme*

¹ Successful completion of the study programme “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel requires the acquisition of the following ECTS credit points:

- a) Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine (30 ECTS)
- b) Elective modules in the fields covered by the PharmaTrain syllabus (20 ECTS)
- c) Final MAS examination (written: 9 ECTS, oral examination: 1 ECTS); total 60 ECTS.

² Successful completion of the study programme “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” at the University of Basel requires the acquisition of the following ECTS credit points:

- a) Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine (20 ECTS)
- b) Final DAS examination (written: 5 ECTS, oral examination: 5 ECTS); total 30 ECTS.

³ Successful completion of the study programme “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel requires the acquisition of the following ECTS credit points:

- a) Completion of the modules a) to f) listed in section § 6, point 3 (18 ECTS in total)
- b) Final CAS examination: (multiple choice, 2 ECTS); total 20 ECTS.

§ 8. *Format of teaching sessions*

¹ The following teaching formats are offered in the study programmes:

- a) Lectures
- b) Group assignments in a face-to-face setting and online
- c) e-Learning modules
- d) Case studies

² The programmes are taught in English.

§ 9. *Assessment formats*

¹ The following assessment formats are used in the study programmes:

- a) Active participation in discussions
- b) Presentation of case studies
- c) Written assignments
- d) Final CAS examination
- e) Final DAS examination
- f) Final MAS dissertation

² Assessments with a negative outcome may be repeated twice, the final MAS examination only once.

§ 10. Active participation in discussions

¹ Attainment in Modules 1-6 is demonstrated by active participation in discussions during face-to-face teaching.

§ 11. Presentation of case studies

¹ Additionally, attainment can be demonstrated in Modules 1 to 6 and the elective modules in the form of a presentation of a case study, unless this is done as a written assignment as described in § 12.

§ 12. Written assignments

¹ Attainment in the elective modules is demonstrated in the form of a written assignment or a presentation (described in § 11).

§ 13. Final CAS examination

¹ The “CAS in Pharmaceutical Medicine” at the University of Basel concludes with a written examination in multiple-choice format.

§ 14. Final DAS examination

¹ The “DAS in Pharmaceutical Medicine” at the University of Basel concludes with an examination comprising a written part and an oral part. The written part consists of an examination based on an open question (essay). The oral examination at the conclusion of the “DAS in Pharmaceutical Medicine” at the University of Basel consists of a discussion of a scientific publication. The publication forms the starting point of a discussion which is expanded to include further subjects described in the PharmaTrain syllabus.

§ 15. Final MAS examination

¹ Students in the “Master of Advanced Studies (MAS) in Medicines Development” programme at the University of Basel write a concluding dissertation, preferably at the end of the programme of post-graduate study. Permission to write the concluding dissertation is granted if they have acquired at least 30 ECTS credit points from the modules listed in § 6 and if their supervisor is willing to supervise the MAS dissertation on the basis of the student’s knowledge of the specific field in question.

² The MAS dissertation is written under the supervision of a lecturer authorised by the head of the study programme. The subject of the dissertation is determined in consultation with the head of the study programme and must meet the requirements of the PharmaTrain syllabus. A study agreement covering the written MAS dissertation is signed.

³ The written MAS dissertation is assessed independently by the supervising lecturer and an external expert. The written MAS dissertation may be revised once.

⁴ A written MAS dissertation that has been assessed as being inadequate is examined and evaluated by another member of the Faculty chosen by the head of the study programme or an external expert.

⁵ An unsuccessful written MAS dissertation may be repeated once. A second failure leads to the exclusion of the student from the post-graduate study programme “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel.

⁶ The final MAS examination includes a presentation of the written dissertation followed by a discussion and questions about subjects in the PharmaTrain syllabus. An unsuccessful final oral MAS examination may be repeated once. A second failure leads to the exclusion of the student from the post-graduate study programme “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel.

§ 16. Assessment of attainment

¹ A student’s attainment is either awarded grades or is assessed as having passed or not passed.

§ 17. Right of inspection

¹ After the assessment of a written assignment has been completed, the candidate may inspect the assessment on request and within the period of time granted for this review.

§ 18. Recognition of study and examination attainments

¹ Of the 20 ECTS credit points that must be earned within the elective modules, up to 20 ECTS credit points may be replaced by elective modules offered outside the MAS at the University of Basel.

² The content of elective modules attended outside the “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel must meet the requirements of the PharmaTrain syllabus and their learning objectives must fulfil the criteria for the award of ECTS.

³ The study programme commission decides on the recognition of other study and examination attainments and of ECTS credit points earned in another study programme or at another university.

§ 19. Certificates for the “Master of Advanced Studies (MAS) in Medicines Development”, “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” and “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel

¹ Students who have successfully completed the “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel are awarded the title “Master of Advanced Studies

(MAS) in Medicines Development” of the University of Basel and receive a corresponding Diploma Supplement. This contains details of the teaching sessions and modules, the ECTS credit points earned and the subject of the written MAS dissertation.

² Students who have successfully completed the “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” at the University of Basel are awarded the title “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” of the University of Basel and receive a corresponding Diploma Supplement.

³ Students who have successfully completed the “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel are awarded the title “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” of the University of Basel and receive a corresponding Diploma Supplement.

² Diploma of Advanced Studies (DAS) or Certificate of Advanced Studies (CAS) certificates issued by the University of Basel that were earned previously in modules of the post-graduate study programme “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” or “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel must be returned to the head of the study programme before the “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” or “Master of Advanced Studies (MAS) in Medicines Development” certificate is awarded.

³ Students who have not completed the study programme successfully receive written documentation of their attainments.

§ 20. Hardship

¹ In case of hardship, the study programme commission may, in justified exceptional cases, grant exceptions to the provisions set out in these regulations provided that these do not fundamentally fall within the Faculty’s sphere of competence.

§ 21. Exclusion

¹ Students may be excluded from the study programme “Master of Advanced Studies (MAS) in Medicines Development”, “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” or “Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” at the University of Basel if they fail to observe the university’s regulations or have definitively failed the attainment assessments set out in these study programme regulations.

§ 22. Costs

¹ The fee for the study programme “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel is CHF 30,000. The fee for the study programme “Diploma of Advanced Studies (DAS) in Pharmaceutical Medicine” is CHF 15,500. The fee for the study programme

“Certificate of Advanced Studies (CAS) in Pharmaceutical Medicine” is CHF 14,750. The payment details are set out in the curriculum.

² The fee for the study programme includes the fee for the final CAS examination. Repetition of the final CAS examination attracts an additional examination fee of CHF 500.

³ The fee for the DAS study programme includes the fee for the final DAS examination, consisting of a written part and an oral part. Participants who do not pass the final DAS examination at the first attempt pay a fee of CHF 750 to repeat the examination.

⁴ The fee for the MAS study programme includes the fees for the elective modules that can be studied at the University of Basel as part of the MAS.

⁵ The cost of elective modules attended outside the university (see § 18) is not included in the fee for the MAS study programme. The fee for the study programme “Master of Advanced Studies (MAS) in Medicines Development” at the University of Basel may, however, be reduced by not participating in elective modules at the University of Basel as part of the MAS.

⁶ The fee for repeating the final MAS examination, comprising a written final dissertation and presentation and discussion of this dissertation, is CHF 3,500.

⁷ If a student fails a required attainment step or an examination at the third attempt or the written MAS dissertation at the second attempt (cf. § 14. point 5.) and consequently ends the study programme prematurely, or else discontinues the study programme or is excluded from it, there is no entitlement to reimbursement of the study fee or part of it.

§ 23. *Entry into force*

¹ These study programme regulations enter into force immediately after approval by the Rectorate of the University of Basel.¹

² These study programme regulations replace the study programme regulations dated 25 May 2009. The study programme regulations in force at the time when the student registered for the programme shall apply.

¹ Approved on 23 June 2020, in force since 24 June 2020