

## **VMFP10, Regenerative Medicine and Advanced Therapies (ATMP), 7.5 credits**

*Regenerativ Medicin och avancerade terapier (ATMP), 7,5 högskolepoäng*  
**Second Cycle / Avancerad nivå**

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### **Details of approval**

The syllabus was approved by The Master's Programmes Board on 2024-05-21. The syllabus comes into effect 2024-05-21 and is valid from the spring semester 2025.

### **General information**

The course is offered as a freestanding course.

*Language of instruction:* English

<i>Main field of study</i>	<i>Specialisation</i>
Biomedicine	A1F, Second cycle, has second-cycle course/s as entry requirements
Biomedical Laboratory Science	A1F, Second cycle, has second-cycle course/s as entry requirements

### **Learning outcomes**

The aim of the course is for students to obtain a deep understanding of the subject regenerative medicine and the overall process for developing advanced therapies – from pre-clinical research and discovery via pre-clinical development to clinical applications.

### **Knowledge and understanding**

On completion of the course, the students shall be able to:

- explain which types of drugs are included in the classification ATMP (Advanced Therapy Medicinal Product) according to the European Medicines Agency's (EMA) definitions,
- provide factual knowledge in the main field of regenerative medicine and ATMPs,

- explain current research and development in the area at an advanced level,
- describe methods that are used in regenerative medicine and ATMP research,
- identify ethical, medical, regulatory and socioeconomic challenges in relation to ATMPs.

### **Competence and skills**

On completion of the course, the students shall be able to:

- apply theoretical and practical solutions to tasks related to regenerative medicine and ATMPs,
- actively contribute to research and development in the area of regenerative medicine and ATMPs,
- apply the regulatory aspects and the quality standards that are relevant to the development and application of ATMPs in clinics.

### **Judgement and approach**

On completion of the course, the students shall be able to:

- adopt a professional approach and respect the opinions of others in discussions on regenerative medicine and ATMPs,
- evaluate different strategies to achieve scientific, health economic and regulatory goals during development of ATMPs,
- evaluate ethical considerations during development and application of ATMPs.

### **Course content**

The course covers the processes required for the development of a new advanced drug from pre-clinical discovery to final product. The course also addresses the scientific, strategic and regulatory challenges found in ATMPs as well as relevant methods and terminology. By providing students and professionals with qualified education in ATMPs results in skilled workers capable of driving development in the area and ensuring the transfer of new treatments from research to clinics. By cooperating with leading researchers and experts, the course will promote research and innovation in ATMPs and give the students the opportunity to participate in basic and translational research, both within and outside academia.

### **Course design**

The course includes seminars with lecturers primarily from Lund University and the industry but also from healthcare. The lectures will be interwoven with group activities. The working methods in the course mainly focus on active student learning, requiring student preparation prior to each teaching component. The students are expected to behave professionally and, just as in future work situations, participate constructively in the group activities. During the course, a group assignment is carried out in which the students write a project plan for the development of a new advanced drug. The group assignment is compiled in writing and presented orally for an expert panel and the other students. Written and oral feedback is given on each others' group assignments.

## Assessment

The course is examined through two assessed components:

- Course portfolio, 4.5 credits, Fail/Pass
- Multiple-choice questions, 3 credits, Fail/Pass

The course portfolio includes group work, a written group assignment in which individual contributions are to be clearly evident, an oral presentation of the assignment and critical review and feedback on other group assignments. Multiple-choice questions test learning outcomes for knowledge and understanding.

The examiner, in consultation with Disability Support Services, may deviate from the regular form of examination in order to provide a permanently disabled student with a form of examination equivalent to that of a student without a disability.

## Grades

Grading scale includes the grades: Fail, Pass

A grade of Pass on all assessed components is required to achieve the grade of Pass as a final grade for the course.

## Entry requirements

Biomedical Laboratory Science Programme 180 credits, Bachelor's degree in biomedical laboratory science, medical technology or biomedicine.