Univerza *v Ljubljani Medicinska* fakulteta

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Course Regime

| Course | | | | | | | | | | |
|--|--------------------|------------------------|--|--|--|--|--|--|--|--|
| Cell Biotechnology: advanced cell-based medicines | | | | | | | | | | |
| Study Programme | Course type | Year of the Course | | | | | | | | |
| Medicine | Elective | 1. | | | | | | | | |
| Semester Summer | No. of ECTS cred | lits 4. 1 5. 6. | | | | | | | | |
| Lecturer(s) | | | | | | | | | | |
| acad. prof. dr. Robert Zorec | | | | | | | | | | |
| Participating Organisational Un | its (Departments a | nd Institutes) | | | | | | | | |
| Institute of Pathophysiology, Faculty of Medicine, UL Department of Clinical Biochemistry, Faculty of pharmacy, UL Chair of physiology, anthropology and ethology, Department of Biology, Biotechnical Faculty, UL | | | | | | | | | | |
| Parts (Modules) of the Course | | | | | | | | | | |
| 1: | | | | | | | | | | |
| 2: | | | | | | | | | | |
| 3: | | | | | | | | | | |
| 4: | | | | | | | | | | |
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Date of Issue

15. 9. 2019

A. General Part (applies to compulsory and elective courses)

1. Course objectives

The goal of the course Cell Biotechnology: advanced cell-based medicines is aimed at acquiring competences for the development and placing on the market advanced cell and tissue engineering medicines for autologous treatment.

Students' competencies are to integrate the knowledge of physiological and biological mechanisms at the level of molecules with the strategies of treating diseases with the use of cell and tissue engineering approaches. The student learns EU regulations in this area and technologies in cell and tissue engineering for the preparation of autologous medicines for human use

| 2. Comprehensive outline of the course organisation |
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| Lectures 35 hours - compulsory presence 50% Seminars 35 hours - compulsory presence 90% Laboratory work 35 hours - compulsory presence 90% Individual work 75 hours |
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3. Description of on-going assessment of knowledge and skills

On-going assessment of knowledge and skills:

- Practical Colloquium after successfully completed practical work;
- Written and oral presentation of the seminar;

Number of colloquial questions: 20

Type of colloquial questions: objective and essay;

Duration of colloquia: 2 school hours

Duration of the oral presentation of the seminar: 20 min

4. Required conditions for the final examination (Course Exam)

The condition for taking a course exam is the positive assessment of the practical colloquium and the successful presentation of the seminar. Student has several dates available for conducting a colloquium. Student arranges with the lecturer about the possibility of presenting a seminar outside the organized frame.

5. Final assessment and examination of knowledge and skills (Course Exam)

- Written exam after successfully passing the practical colloquium and seminar.

Number of questions in the written examination: 20

Type of questions in the written examination: objective and descriptive

Duration of the written examination: 90 min

Grading:

The final grade is composed of individual examinations, each examination contributs to the final evaluation differently: 30% colloquium, written and oral presentation of the seminar 10%, written examination 60%

Ratings 1-10 (1-5 negative, 6-10 positive) in accordance with the UL Statute

6. Other provisions

When carrying out the practical colloquium and the written examination, only a ball pen is permitted. When presenting a seminar, image material is allowed.

Students submit a written presentation of the seminar on 2-3 pages of A4 format, printed (up to 1300 words), the first page contains the title of the seminar, year of study, first and last name of the student presenting the seminar. Immediately after that on the first page follows the introduction, then the core of the seminar and the conclusions or summaries. The deadline for the seminar is 10.5. 2019. A written and oral presentation is evaluated.

7. Fundamental study material and Supplement reading

Basic literature:

- N. Sperelakis (1998). Cell Physiology 2nd ed. Academic Press, selected chapters (30 %). Celično inženirstvo Navodila za vaje. Authors: M. Kreft, H. Chowdhury, N. Vardjan, M. Potokar, M. Gabriiel, R. Zorec
- -Legislation on the supply of cells and tissues for human therapy and medicines and testing of new drugs.

Additional literature:

- R. P. Lanza, Robert Langer, Joseph P. Vacanti (2000) Principles of Tissue Engineering. 2nd edition, Academic Press.
- C. Ratledge in B. Kristiansen (2001) Basic Biotechnology, 2nd edition, Cambridge University Press
- F.M. Ashcroft (2000) Ion Channels and Disease, Academic Press
- J. Phillips, P. Murray, P. Kirk (2001) The Biology of Disease, 2nd ed., Blackwell Publishing
- Current periodicals and, in particular, review articles.

| 8. Exam topics, clinical presentations and skills | | | | | | |
|---|--|--|--|--|--|--|
| Exam Topics: | | | | | | |
| regulations in the field of preparation of advanced cell-based medicines, procedures and norms for carrying out a clinical study, the quality system for the preparation of advanced cell-based medicines, all of the above is adopted on the case of the preparation of a specific, advanced, cell-based medicine for the indication selected by the student. | | | | | | |
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| 9. Other information | | | | | | |
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B. Elective Courses (considered as Elective Course Annoucement)

| 1. | Partici | pating | main | and | guest | lecturers |
|----|---------|--------|------|-----|-------|-----------|
|----|---------|--------|------|-----|-------|-----------|

acad. prof. dr. R. Zorec, prof. dr. H. H. Chowdhury, dr. M. Gabrijel, assist. prof. dr. N. Vardjan, dr. S. Trkov Bobnar, assist. prof. dr. J. Jorgačevski, prof. dr. M. Kreft, prof. dr. M. Jeras

2. Estimated time period in the semester

summer semester

the first 9 weeks, 1 x weekly lectures (4 hours),

3. Maximum number of students for the elective course (if the number of students able to attend the course is limited)

The maximum number of students is 16.

Requirement for enrollment an elective course (a valid curriculum must be considered):

4. Please specify if the elective course is available in English for incoming international students (Erasmus + and others). Please specify any additional conditions in the case that the elective course is available for visiting students.

The elective course is in Slovenian, however it may be also in English.

Additional explications and notes::

- 1. The Course Regime enters in force on the date of issue and remains valid until its revocation or alteration. The Course Regime may not be altered during the academic year. Any changes to the Course Regime may only enter into force starting with the next academic year (changes must be submitted no later than 14 days prior to the start of the academic year as the new Course Regime).
- 2. The Course Regime for compulsory courses must be published no later than 14 days prior to the start of the academic year.
- 3. The Course Regime for elective courses is also considered the Elective Course Announcement and must be published no later than the 30th of July prior to the start of the academic year in which it enters in force.
- 4. The Course Regime must be published in Slovenian and English.
- 5. In the Course Regime, the »Regulations for the Assessment of Knowledge and Skills for the Single-Cycle Master Study Programmes Medicine and Dental Medicine« will be referred to as "Regulations".

case of any further questions, please contact the Study Affairs Commission of the UL MF, via e-mail: ksz@mf.uni-lj.si.