

New advances in alternative preclinical trials

01UCQMV

A.A. 2021/22

Course Language

Inglese

Course degree

Master of science-level of the Bologna process in Biomedical Engineering - Torino

Course structure

Teaching	Hours
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Teachers

Teacher	Status	SSD	h.Les	h.Ex	h.Lab	h.Tut	Years teaching
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Teaching assistant

▼ Espandi

Context

SSD	CFU	Activities	Area context
ING-IND/34	6	B - Caratterizzanti	Ingegneria biomedica

Anno accademico di inizio validità

2020/21

Course description

The course aims to provide knowledge in the context of preclinical testing of both biomedical devices and advanced therapies. Innovation in preclinical investigations opens new work possibilities for Biomedical Engineers.

The main aspects of the current legislation on preclinical experimentation will be illustrated, describing the tests needed for the preclinical approval of biomedical devices and advanced therapies, with particular reference to animal testing and alternative methods under development or already approved, to replace, reduce and refine (3Rs Principle: Replacement, Reduction and Refinement) animal testing (EU Directive 2010/63) (focus on EU Directives: 3 hours).

After introducing the current legislation, in vivo animal trials will be illustrated (12 hours) including aspects concerning animal welfare and applicative examples. Particular attention will be devoted to the explanation of transgenic animal models and their uses.

Alternative preclinical testing methods currently under development will be illustrated, including (22,5 hours):

- traditional 2D in vitro models (characteristics and main uses; examples from literature)
 - 3D in vitro models: spheroids and organoids (characteristics and main uses; examples from literature)
 - in vitro models by tissue engineering approaches (characteristics and main uses) with focus on skin and cardiac tissue engineering (examples of commercially available products and examples from literature)
 - organ-on-chips: general characteristics and main uses
- Basic elements of statistical analysis and its application in favour of 3R principle will be then explored (6 hours)
- Finally, in silico models will be described including molecular and computational approaches in support of 3R principle (15 hours).
- Two/three seminars from Biomedical Industries working in the sector will be included on the following subjects:
- Alternative in vitro testing
 - In vitro organ-on-chip testing
 - In silico models

Expected Learning Outcomes

Knowledge

- 1) European Standards for preclinical experimentation of biomedical devices and advanced therapies; knowledge on 3R Principle and Directive 2010/63; methods of refinement and reduction in the planning of animal studies; replacement methods for safety and biocompatibility assessments: potentialities and limitations. The concept of "significant prototype" for research and validation. Laboratory certifications and GLP methods in preclinical research.
- 2) Preclinical experimental models in vivo and their integration with those in vitro: i) examples of mouse models of tumor, inflammatory, autoimmune diseases; ii) genome editing - from preclinical to clinical studies; iii) gene therapy.
- 3) Protection of animal welfare in European legislation, according to the animal species and their native social organization.
- 4) Experimental in vitro models and their most recent applications: 2D systems, 3D cultures (spheroids and organoids), tissue engineered models, organs-on-chip.
- 5) Statistics in the 3R Principle: statistical analyses of data to replace, reduce and refine animal experiments
- 6) In silico models in preclinical experimentation and their main recent applications

The ability to apply the knowledge and understanding of the topics will be gained through classroom discussions by addressing specific recent literature case studies.

The teachers will give tips for doing excellent presentations on literature analysis.

Prerequisites

- 1) Basic knowledge of general chemistry, organic chemistry and biochemistry.
- 2) Basic knowledge of science and technology of inorganic and polymeric materials.
- 3) Basic knowledge of cell biology and physiology.
- 4) Basic knowledge of techniques for determining the surface and massive properties of materials.
- 5) Basic knowledge of statistics
- 6) Basic knowledge of mechanics of fluids and solids
- 7) Knowledge on Tissue Engineering principles

Course topics

- 1) Introduction to the course (1.5 hours)
- 2) European Standards for preclinical experimentation (3 hours)
- 2) Animal models, principles for the protection of animal welfare in European (12 hours)
- 3) In vitro models (2D, 3D, tissue engineering, organs-on-chip) (22,5 hours): introduction (1.5 hours); 2D models (3 hours); spheroids (3 hours); organoids (6 hours); tissue engineering (6 hours); organs-on-chips (3 hours)
- 3) Application of statistics for the respect of 3R Principle (6 hours)
- 4) Computational fluidodynamic and molecular models in preclinical (and clinical) experimentation and their main applications (15 hours)

Additional information

The course collects interdisciplinary topics and different teachers participate with their own module. After the first feedback on the course from students on last academic year, during the next academic year we are going to increase the interaction between the modules: each teacher will make at least one applicative example concerning the same therapeutic/regenerative medicine area (e.g. heart/cardiovascular diseases). This will allow the students to understand how the same problem can be faced by different types of investigations (in vitro and in silico models, in vivo trials, statistical approach).

The course is in English. However, if asked by all the students, it will be possible to have some of the lectures in Italian.

Sustainable development goals



Course structure

- Classroom lessons with slides projection (45 hours)
- Classroom exercises (15 hours)

Reading materials

- Slides and articles / material uploaded by the teachers

Assessment and grading criteria for online exam

Exam: Compulsory oral exam; Individual project;

The exam is oral and consists of 2 parts:

1) the presentation of a scientific article selected by the students on Course subjects. The students will select the article and send it to the approval of the reference teacher(s). They have then to send it back to the Course professor (Prof. Chiono), not later than 1 week before the exam date. Once the article has been selected and approved, the student will prepare a power point presentation following guidelines by Prof. Chiono (explained in her lectures). The presentation should last not more than 12 minutes. The Exam commission will make on average 3 questions on the scientific paper presented/presentation which will include at least one question concerning a critical evaluation of the work.

There will be a mark for the presentation part which represents 50% of the exam.

The presentation is individual and the student should demonstrate a comprehension of the contents, their relationship with the course programme and express his/her critical thinking on the work. The main teacher will publish a file on the portal with detailed information and a lecture with guidelines on how to do an excellent presentation in few minutes.

2) On average 2 questions on the course programme. This part of the exam has its own mark which represents 50% of the final mark. Questions are addressed to assess the level of comprehension and knowledge on the subjects.

The average of the two marks will be the final evaluation.

Exam is passed if the student reaches a mark equal or superior to 18.

The maximum mark 30L is possible if at least one of the two exam parts deserves 30L evaluation.

The student can refuse the mark or the mark of one part, but only once.

The language of the exam is English or Italian depending on students' individual choice.

The remote exam is generally carried out through Polito Virtual Class Room. Students are recommended to check their Internet connection and to save both a ppt and a PDF version of the presentation. In case of severe connection problems, another video platform will be used to continue the exam.

Exam committee will consist of at least 2 teachers.

**Assessment and
grading criteria for
blended exam
(online and onsite)**

Exam: Compulsory oral exam; Individual project;

The exam is oral and consists of 2 parts:

1) the presentation of a scientific article selected by the students on Course subjects. The students will select the article and send it to the approval of the reference teacher(s). They have then to send it back to the Course professor (Prof. Chiono), not later than 1 week before the exam date. Once the article has been selected and approved, the student will prepare a power point presentation following guidelines by Prof. Chiono (explained in her lectures). The presentation should last not more than 12 minutes. The Exam commission will make on average 3 questions on the scientific paper presented/presentation which will include at least on critical evaluation of the work.

There will be a mark for the presentation part which represents 50% of the exam.

2) On average 2 questions on the course. This represents 50% of the exam.

The average of the two marks will be the final evaluation.

Exam is passed whether the student reaches 18 mark.

The maximum mark 30L is possible whether at least one of the two exam parts deserves 30L evaluation (30L evaluation means at least 30.5 marks).

The student can refuse the mark or the mark of one exam part but only once in the academic year. He/She communicates it to the main teacher who has a personal register for collecting information on exams.

The language of the exam is English or Italian depending on students' individual choice.

The remote exam is generally carried out through Polito Virtual Class Room. Students are recommended to check their internet connection and to save both a ppt and a PDF version of the presentation. In case of severe connection problems, another video platform will be used to continue the exam.

If exam in presence is allowed, the power point presentation will be projected on the screen in one of Polito lecture rooms, followed by questions and discussion.

In both cases, exam committee will consist of at least 2 teachers.

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2) On average 2 questions on the course programme. This part of the exam has its own mark which represents 50% of the final mark. Questions are addressed to assess the level of comprehension and knowledge on the subjects.

The average of the two marks will be the final evaluation.

Exam is passed if the student reaches a mark equal or superior to 18.

The maximum mark 30L is possible if at least one of the two exam parts deserves 30L evaluation.

The student can refuse the mark or the mark of one part, but only once.

The language of the exam is English or Italian depending on students' individual choice.

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