Approaching 3R teaching in biomedical engineering

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Abstract

Since its adhesion to Centro3R, Politecnico di Torino has approached 3R teaching through a new Master course, entitled "New advances in alternative preclinical trials". This is a multidisciplinary optional course for Master students in Biomedical Engineering, with the contribution of different teachers, who are experts on different aspects of preclinical testing of biomedical devices: European Standards for preclinical experimentation; preclinical animal models; protection of animal welfare in the European legislation; the role of statistics on the application of the 3R principle; preclinical experimental models *in vitro*; *in silico* models. This contribution describes the subjects faced by the course and their importance in the context of the 3R Principle.

Introduction

Politecnico di Torino has recently joined Centro 3R and is now approaching 3R teaching through the introduction of the new Master course "New advances in alternative preclinical trials", as an optional course for Master students in Biomedical Engineering, starting from the next academic year (2019/20). The course aims to provide knowledge in the context of preclinical testing of biomedical devices. Main aspects of the current legislation on preclinical experimentation will be illustrated, as well as the tests currently needed for the preclinical evaluation of biomedical devices, with particular reference to *in vitro* trials and animal testing. Attention will be then devoted to new alternative methods currently under development, to replace, reduce and refine animal testing, according to the 3R Principle: Replacement, Reduction and Refinement. Such alternative models include: i) *in vitro* models of organs – organoids; ii) *in vitro* models of tissues/organs by tissue engineering techniques; iii) *in silico* models.

Expected results

The course is expected to give knowledge on:

- European Standards for preclinical experimentation: relationship between safety according to ISO 10993-1 and preclinical performance aspects; methods of refinement and reduction in the planning of animal studies; replacement methods for safety and biocompatibility assessments: potentialities and limitations; concept of "significant prototype" for research and validation; sample preparation; Laboratory certifications and GLP methods in preclinical research.
- Preclinical experimental models *in vivo* and their integration with trials *in vitro*: i) examples of mouse models of tumor, inflammatory, autoimmune diseases; ii) genome editing - from preclinical to clinical studies; iii) gene therapy.
- Protection of animal welfare in the European legislation: based on animal species and their normal social organization, environmental factor, such as cage size and its structure, light (intensity, wavelength, photoperiod, frequency), sound, ventilation *etc*., are as important as the presence or absence of subjects of the same species, their sex and the predictability and controllability of the environment.
- Statistical elements for a correct evaluation of the number of animal tests required; integration with the ISO 10993-1 regulatory requirements to guarantee the regulatory adequacy of the tests.
- Preclinical experimental models *in vitro* (organoids, tissue engineering) and their main applications.
- *In silico* models in preclinical experimentation and their main applications.

To achieve the aims, the course will be hold by a group of teachers with complementary expertise, including Prof. Alice Ravizza (European Standards), Valeria Poli (animal models and animal welfare), Giuseppa Alfano (statistical analysis), Lucia Napione (organoids), Valeria Chiono (tissue engineering models), Marco Deriu and Diego Gallo (*in silico* models).

The talk will illustrate the topics faced by the course and their meaning in the context of the 3R Principle.

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