Advanced Models for Predictive Toxicology

Advanced Course

November 25 - 27 + December 19, 2025

Course Coordinators: Joana Miranda and Sérgio Camões **ECTS:** 6 | **Classes:** 22.5 hours

The course will be held at FFUL in a hybrid mode, with both in-person and virtual lectures (Teams platform).

Short introduction:

Drug development requires a careful balance between therapeutic efficacy and the risk of adverse reactions. Historically, *in vivo* animal studies have underpinned safety assessment, yet ethical considerations and species differences highlight the need for alternative, human-relevant models aligned with the 3Rs principle (Replace, Reduce, Refine). This course offers a systematic progression, from *in silico* to advanced *in vitro* systems (e.g., 3D cultures, microphysiological systems) and moving through emerging *in vivo* approaches (including zebrafish, humanized animals, and avatar/PDX), culminating in personalized and predictive

toxicology solutions that integrate non-clinical data. Each module combines theoretical insights with case-based discussions, culminating in a group research project presentation, where students propose novel strategies for advancing drug safety assessment.

Goals and Learning Outcomes:

- Identify emerging 3D and advanced *in vitro* approaches, recognizing the benefits of spheroids, organoids, and organ-on-a-chip systems in enhancing physiological relevance.
- Discuss the challenges of traditional animal models and describe how zebrafish, humanized mice, and avatar/PDX systems can better predict human-specific responses.
- Describe how advanced *in vitro* and *in vivo* methodologies align with the 3Rs principle by emphasizing reduced animal use, refined experimental protocols, and ethical considerations in drug safety research.
- Discuss how stem cells (including patient-derived iPSCs) can refine drug safety testing, contribute to individualized drug safety assessment and consider how computational tools can integrate diverse non-clinical data to anticipate clinical outcomes.

Assessment:

It consists in the preparation and submission of a research project (up to 8 pages) in a topic relevant within the framework of the course. Students are to be grouped in interdisciplinary groups of 2 or 3 students. The research project should be structured to address an innovative research question as follows: i) Title; ii) The problem and the innovative approach; iii) Plan and methodology; iv) Expected results and impact. The project will be evaluated according to the following criteria and weighting: a) Novelty and relevance (30%); b) Clarity and credibility of the approach to the theme/problem (30%); c) Multidisciplinary aspects of the research plan (40%).

For more Information and registration:

https://www.ff.ulisboa.pt/advanced-training-courses/advanced-models-for-predictive-toxicology/?lang=en#tab_0

PROGRAMME

The course is structured into four modules to ensure a balanced coverage of lectures on theoretical and practical case-based discussions presented during a dedicated course with limited attendance. Each module includes a combination of lectures, interactive discussions, and short workshop sessions. In the end, the students are expected to orally present a group assignment consisting of a proposal for a research project.

Day 1 – November 25th

9h30-10h Welcoming & Course introduction

Joana Miranda and Sérgio Camões, FFUL, PT

Module 1: Advanced in vitro systems in safety assessment

10h-11h Beyond 2D cell cultures: how 3D models are changing the *in vitro* studies.

Krzysztof Wrzesinski, CellVivo, DK

11h-12h 3D *in vitro* models of the human retina for drug testing and toxicity evaluation.

Sandra Tenreiro, NOVA NMS, PT

Lunch

14h-15h Heart organoids for drug screening.

Margarida Diogo, IST ULisboa, PT

15h-16h Patient-derived *in vitro* models for personalized medicine. *(Module 3)* *online*

Pau Sancho-Bru, IDIBAPS, ES

Coffee break

16h30-17h30 Advanced 3D *in vitro* models for genetic toxicology: Insights from PAH exposure. *online*

Bojana Zegura, National Institute of Biology, SI

Day 2 – November 26th

Module 1: Advanced in vitro systems in safety assessment (Cont.)

9h30-10h30 3D *in vitro* skin tests: corrosion, irritation and sensitization tests.
Sérgio Camões, FFUL, PT

10h30-11h30 Microphysiological systems for in vitro toxicology. *online*
Madalena Cipriano, Univ. Tuebingen, DE

Module 2: Emerging in vivo models

11h30-12h30 Challenges of conventional animal models. *online*
Ihsan Gürsel, IBG, TK

Lunch

14h-15h Liver spheroids and organoids: advantages and applications. *(Module 1)*
Joana Miranda, FFUL, PT

15h-16h Zebrafish as a preclinical model.
Gülçin Akdogan, IBG, TK

Coffee break

16h30-17h30 Avatar models: patient-derived xenografts (PDX).
Rita Fior, FChampalimaud, PT

Day 3 – November 27th

9h30-10h30 Humanized *in vivo* models and beyond.
Javier Cubero, University Complutense of Madrid, ES

Coffee break

Module 3: Personalized and predictive toxicology

11h-12h Bioinformatic tools in safety assessment.
Rita Guedes, FFUL, PT

Lunch

14h30-15h30 Data integration from non-clinical assays for prediction of clinical conditions.
Tiago Rodrigues, FFUL, PT

15h30-16h30 Advanced models for predictive hepatotoxicity testing.
Leonard Nelson, Edinburgh Napier University, UK

16h30-17h30 Q&A and Closing Session
Joana Miranda and Sérgio Camões, FFUL, PT

Day 4 – December 19th

Module 4. Student oral presentations of research project assignment

9h30-17h30 Projects presentation and discussion session
Joana Miranda, Sérgio Camões and Nuno Oliveira FFUL, PT


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