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

11h30-12h30 Liver spheroids and organoids: advantages and applications.
Joana Miranda, FFUL, PT

Lunch

Module 2: Emerging in vivo models

14h-15h Challenges of conventional animal models. *online*
Ihsan Gürsel, IBG, TK

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


HaltRONIN
Funded by European Union


EXCHEP


UNIVERSIDAD
COMPLUTENSE
MADRID


IZMIR BIOMEDICINE
AND GENOME CENTER


Edinburgh Napier
UNIVERSITY


NOVA
UNIVERSIDADE NOVA
DE LISBOA


Celvivo