



## **Advanced Courses 2019 – PhD in Pharmacy**

Faculdade de Farmácia, ULisboa

### **1. Biomarkers and Assay Development**

Cecília Rodrigues (Coordinator)

The Course on Biomarkers and Assay Development is designed to cover principles and applications of biomarkers and assay development, from identification to validation, to impact in drug discovery, and disease diagnosis and prognosis.

Biomarkers are now an integral part of the drug discovery and development process, acting as indicators of mechanism of action, efficacy, safety and disease progression, as well as assisting in diagnosis, and patient selection and design of clinical trials.

Biomarkers also offer the potential to inform treatment decisions and bring personalized medicine into clinical practice. In early stage drug discovery, biomarkers are used to validate in vitro target modulation. As projects progress, biomarker assays are developed for pharmacokinetic/pharmacodynamic (PK/PD) models, profiling molecules prior to testing in disease models as initial proof of concept. PK/PD models can also assist in dose-to-man scaling predictions for use in clinical trials. The biomarker assays developed during the in vitro discovery phases are frequently used as efficacy or toxicity endpoints in the clinic. Clinical trials, particularly in oncology, are frequently designed around these biomarkers, in addition to biomarkers of disease progression.

In contrast, less evidence exists to recommend the use of any biomarker of pathological processes in neurodegenerative diseases, opening the door for conducting future disease progression biomarker studies.

### **2. Biopharmaceutical and Advanced Therapies**

João Gonçalves (Coordinator)

The Course on BioPharmaceuticals and Advanced Therapies provides an overview of both classical and biotechnology derived medicinal products and on the pathways used for scientific advice, clinical trials and marketing authorizations in Europe. The course will also cover in detail the particular requirements for the CMC section, comparability packages and important safety procedures. The particular aspects of the non-clinical and clinical development of biopharmaceuticals will be presented. Case studies discussing how to develop proteins or cell therapies, such as monoclonal antibodies will illustrate the approach taken to identify benefit/risk ratio. An overview will be given on the most essential issues relating to Advanced Therapy Medicinal Products (ATMPs). A detailed presentation of the specific considerations for the development of biosimilar medicinal products will be given during the course.

### **3. Advanced Drug Delivery**

António Almeida e Helena Florindo (Coordinator)

The course on Advanced Drug Delivery trains students in the development of advanced medicinal products, covering crucial aspects that determine the fate of drugs in the human or animal body, from their fundamentals to the advanced strategies to overcome the physiological barriers, including innovative technological and therapeutic applications.

### **4. Non-Clinical Efficacy and Safety**

Beatriz Lima (Coordinator)

The course intends to provide PhD students the basis for the preclinical research behind the development of new medicines, from discovery to early development, supportive of the entry into man for First in Human clinical studies. The relevant regulatory guidelines which support these requirements as well as their scientific rationale and their use will be described and explained. All the involved Faculty has experience on the Regulatory and scientific assessment of medicinal products and are current or past regulators with high engagement in the European activities on medicines development and approval process.

### **5. Advanced Topics in Medicinal Chemistry**

Rui Moreira (Coordinator)

The course on Medicinal Chemistry covers the critical aspects of drug discovery ranging from target identification to lead identification and lead optimization strategies. Hands-on training using state-of-the-art molecular simulation software is included.

In addition, a unique overview of the drug discovery process in the pharmaceutical industry is also provided. The training program is aimed at PhD students and has slots allocated to seminars and practical workshops, including discussions with lecturers.

### **6. Pharmaceutical Biophysics**

Liana Silva (Coordinator)

This course is designed to cover the physicochemical basis of biological processes that influence the pharmacological activity of bioactive compounds and applications of state-of-the-art and emerging biophysical methodologies essential for the characterization of biological and pharmacological processes.

## **7. Pharmacoepidemiology and Pharmacovigilance in Drug Lifecycle**

Ana Paula Martins (Coordinator)

The Course on Pharmacoepidemiology and Pharmacovigilance trains students in areas of critical knowledge to an efficient management of drug risk-benefit research, specifically clinical benefits and adverse events as well as patient report outcomes related with drug exposure. It is also expected that skills for design and analysis of epidemiological studies can be significantly improved throughout this programme. This course will tackle how the principles of modern epidemiology methods are used to evaluate safety, effectiveness, and utilization patterns of drugs. Examples of the referred study designs will be drawn from recent literature to illustrate the application of relevant methods and the challenges in drug safety assessment and risk management.

## **8. Stem Cells Technologies**

Susana Solá (Coordinator)

Stem cell-based therapies are thriving. In fact, pharmaceutical companies are increasingly investing in stem cell technology to develop innovative and potentially valuable new treatments for severe human diseases, including cancer and neurological disorders, such as multiple sclerosis, Alzheimer's and Parkinson's disease, mood disorders, brain tumors and even stroke. Moreover, although seminal advances have occurred in understanding stem cell biology, further work is still needed to bridge the current gap between stem cell technologies and effective treatments in brain-related disorders. Stimulating the scientific interest on the topic will certainly accelerate and improve the successful transfer of stem cell-based discoveries from the bench to the bedside.