



PhD Advanced Course

Biologic Therapies: From Engineering to Clinics

November 23-27, 2020

Online Course through the Zoom Platform

Course Coordinator: João Gonçalves, Faculty of Pharmacy, University of Lisbon

Course Organizers:

João Gonçalves, Faculty of Pharmacy, University of Lisbon

Paula Brito, Faculty of Pharmacy, University of Lisbon

Teaching staff:

Course organizers and invited speakers as detailed in programme

Short Introduction

The Course on BioPharmaceuticals and Advanced Therapies is part of the PhD Programme in Pharmaceutical Sciences, and 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. A detailed presentation of the specific considerations for the development of biosimilar medicinal products, will be given during the course. The training program welcomes the participation of external academic and scientific community members.

Case-studies will be inserted for the practical application of knowledge gained. The training will be delivered as presentations on individual topics, interspersed by case studies and conclude with an outlook on further developments in this fast moving field.

The course intends to improve PhD students' knowledge in the discovery of potential biotherapeutics, the improvement of production and monitoring of drugs and the translation of these drugs to the clinics.

Goals and Learning Outcomes

At the conclusion of this training course, participants should be able to:

- Identify the relevant strategies for drug discovery.
- Understand the necessary steps and unique requirements in biopharmaceutical development.
- Identify the key quality issues specific to biopharmaceuticals, including implications of changes in the manufacturing process.
- Identify the required therapeutic monitoring strategies of biopharmaceuticals (Immunogenicity and pharmacokinetics).
- Know the regulatory assessment dossier aspects and considerations.
- Understand the concept and peculiarities of the biosimilar path in the EU and beyond.

- Have an outlook of clinical use of biologic drugs.

At the end of the course the PhD students must be able to demonstrate an integrated knowledge concerning the multidisciplinary of biopharmaceuticals and be able to design a new therapeutic strategy to fulfill a specific unmet need of many disorders.

Assessment

Assessment of the course consists in the preparation and submission of a research project, 10 000 characters long (including spaces). Students are grouped to build multidisciplinary teams. Each group works throughout the week on a research project that should reflect the topic of the course, including methodologies and strategies to solve an innovative research question. The project is expected to adhere to the following general structure: a) Title; b) Conceptual hurdle and innovative idea to be tested; c) Plan and methods; d) Relevance of the project (scientific and social impact).

The students will select a broad topic of research and are expected to propose a specific project. This project will be evaluated according to the following criteria and weight: a) Novelty and relevance (30%); b) approach to the problem (30%); c) multidisciplinary of the research plan (40%).

Registration and Fees

The registration is made through the [FenixEdu Platform](#) until **November 19, 2020**.

- Registration with evaluation: 125€
- Registration without evaluation: 100€

This course is free for 1st year PhD students of FFUL Doctoral Program.

PROGRAMME

Biologic Therapies: From Engineering to Clinics

MONDAY – November 23rd

9h45 Welcome - Course organizers

Fundamentals in Biopharmaceutical Discovery

10h00	New Trends in Biopharmaceutical R&D João Goncalves, iMed.Ulisboa, Faculty of Pharmacy, University of Lisbon, Lisbon. Portugal.
11h00	The role of blood-brain barrier to the development of novel biopharmaceuticals Sandra Aguiar, Faculty of Veterinary Medicine, University of Lisbon, Lisbon. Portugal.
12h00	Lunch Break
14h00	Artificial Transcription Factors as potential antiviral Pedro Perdigao,CNC – Faculty of Pharmacy, University of Coimbra. Portugal
15h00	The Development of Bacteriophage Therapy Madalena Pimentel, iMed.Ulisboa, Faculty of Pharmacy, University of Lisbon, Lisbon. Portugal.

TUESDAY – November 24th

Fundamentals in Biopharmaceuticals Design

10h00	Development of gene therapies for ocular disorders Gabriela Silva, CEDOC – Nova Medical School- Nova University, Lisbon. Portugal.
11h00	Novel technologies for purification of proteins Cecilia Roque, Faculty of Sciences and Technology - Nova University, Lisbon. Portugal.
12h00	Lunch Break
14h00	Combining phage-display and NGS for finding better variants binders through rationalisation of in-vitro maturation Khalil El Mazouari, AbnomX, Ghent Area, Belgium.
15h00	Peptides 4.0: New frontier between biotechnology and health applications Jose Leite, Brasilia University, Brasilia. Brasil. Biopropectum, Porto. Portugal
16h00	CAR-T cells at the cross-road between gene and cell therapies Joao Goncalves, iMed.Ulissboa, Faculty of Pharmacy, University of Lisbon, Lisbon. Portugal.

WEDNESDAY - November 25th

Fundamentals in Biopharmaceuticals Development and Monitoring

10h00	Scientific and regulatory aspects of immunogenicity Paul Chamberlain, NDA Advisory Board, NDA Regulatory Science Ltd, Surrey, UK.
11h00	Therapeutic Drug Monitoring in Real-Life José Germán Sánchez, Laboratorio de Farmacocinética. Universitario de Salamanca.
12h00	Lunch Break
14h00	Discussion on project writing (Meeting with students)
15h00	Chemical and physical aspects underlying the self-assembly of protein molecules Tuomas Knowles, Centre for Misfolding Diseases, Department of Chemistry, University of Cambridge, Cambridge. UK
16h00	Pharmacokinetics of biologic drugs Nuno Elvas, iMed.Ulissboa, Faculty of Pharmacy, University of Lisbon, Lisbon. Portugal.

THURSDAY - November 26th

Fundamentals in Biopharmaceutical Production and Translation

10h00	Biologic Production of Biopharmaceuticals by GMP Manuel Garrido, TechnoPhage, Lisboa. Portugal
11h00	Actual and Future trends of Biosimilars Hans Ebberts, Global Scientific Affairs Biosimilars - Biogen Netherlands

12h00	Lunch Break
14h00	Purification process development at a Microfluidic Scale Ana Azevedo, Institute for Bioengineering and Biosciences, IST, Lisboa. Portugal
15h00	Process and product design and biomanufacturing, using systems engineering approaches Jose Cardoso Menezes, Institute for Bioengineering and Biosciences, IST, Lisboa. Portugal

FRIDAY - November 27th

Fundamentals in Biopharmaceutical Clinical Use

10h00	Translational Medicine and Clinical development in Neurology Paulo Fontour, Senior Vice President - Global Head Neuroscience and Rare Diseases Clinical Development. Roche Pharmaceuticals, Basel. Switzerland
11h00	Biologic therapies in Autoimmunity/Inflammation Jose Alves Hospital Amadora Sintra, CEDOC – Nova Medical School- Nova University, Lisbon. Portugal.
12h00	Lunch Break
14h00	Biologic therapies in Breast Cancer Xavier Pivot, General Director of Paul Strauss anti Cancer Center – STRASBOURG – France
15h00	Biologic therapies in Inflammatory Bowel Disease Gionata Fiorino Pivot, Istituto Clinico Humanitas