Doctorate in Pharmaceutical Sciences
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DEPARTMENT
OF PHARMACEUTICAL SCIENCES

Doctorate in Pharmaceutical Sciences

Course Program (XXXIX cycle)

Ad hoc Teaching Activities

[...ut civitas Perusii sapientia valeat elucere...]

Partner of the European Pharmacoinformatic Initiative europin
Partner of the Paul Ehrlich Euro-PhD Network

January 26 and 13 February, 2024
Prof. Benedetta Pasquini, University of Florence

Pharmaceutical Analysis and Regulatory Affairs of a new medicine: from laboratory to patient (1 CFU, 6h)

The research and development of a new drug represent a very long and complex process. After the initial screening phase of drug discovery, preclinical research in the form of laboratory experiments is carried out. If all preclinical criteria are met and regulatory approval to conduct clinical trials is obtained, the extensive clinical trial process with human volunteers and patients begins. New medicines are typically evaluated in many thousands of patients before receiving regulatory agency approval. Before new medicines are available to patients in Europe, they must undergo regulatory evaluation prior to gaining marketing authorization, and national or regional review and decisions on market access. The course aims to show the contribution of pharmaceutical analysis in preclinical and clinical research in order to guarantee quality, safety and efficacy, the three prerequisites that any medicinal product must possess at every stage. Crucial topics of regulatory sciences will be addressed: from the Quality by Design in the development and validation of analytical methods for the determination of active ingredients and their impurities for the quality control of pharmaceutical specialties up to the evaluation of these analytical methods in the European registration dossier of a new drug.

The Regulation (EU) n. 536/2014 on clinical trials of medicinal products for human use and the innovative platform clinical trial information system (CTIS) will be introduced together with real examples of documentation that Authorities are called to evaluate.

Finally, the skills required for the emerging professional figures in the regulatory field will be presented, with the final scope of supporting the employability of the participants and facilitating their future transitions towards the labour market. Good Clinical Practice (GCP) certificate could be acquired.

February 27 and 28, March 1, 2024
Prof. Vittorio Maio, Thomas Jefferson University, Philadelphia
Dr. Silvia Vernotico, Farmaceutica Younger-GUNA S.p.A. Dr. Giovanni Maurizi, Dompè Farmaceutici
Dr. Anna Tolomeo, Itelpharma
Dr. Michele Cianchini, Baxter/Takeda

Medicines: from the rules of production to therapy (2 CFU, 12h)

This course aims to follow the path of the drug from its production to its use in therapy. The rigid rules of production must guarantee efficacy and safety, while the rules of politics and economics guide medicine use in therapy. The five speakers will discuss the following topics: introduction to GMP, production of proteins in GMP, preparation and quality control of radio pharmaceuticals, health and pharmaceutical outcomes.

13 march, 10 April and 15 May, 2024
Prof. Sabine Groesch, Goethe-Universität Frankfurt, Germany

Sphingolipids in inflammation and cancer (1 CFU, 6h) (on-line)

1. Lesson: Introduction to Sphingolipids-> subgroup of lipids, components of cellular membranes, influence on cellular processes, signaling molecules, formation of membrane domains (lipid rafts, ceramide-enriched microdomains). De novo synthesis and salvage pathway, main enzymes, main products.

2. Lesson: Sphingolipids in inflammation; which cells are important, what do we know about sphingolipids and their influence on inflammatory processes (e.g. sphingolipids in T-cells, macrophages)

3. Lesson: Sphingolipids in inflammation; which cells are important, what do we know about sphingolipids and their influence on inflammatory processes (e.g. sphingolipids in T-cells, macrophages) (Continuation)

4. Lesson: Sphingolipids in cancer development, how they influence apoptosis, proliferation, cancer progression, clinical data, differences between tumors of different tissues

5. Lesson: Sphingolipids in cancer development, how they influence apoptosis, proliferation, cancer progression, clinical

data, differences between tumors of different tissues (continuation)

6. Lesson: Influence of sphingolipids on drug resistance

9,11,12, 15-19 April, 2024
Prof. Claudio Salomon, Department of Pharmacy, Faculty of Biochemical and Pharmaceutical Sciences, National University of Rosario, Rosario, Argentina

Drug delivery strategies for neglected Diseases (3 CFU, 18h)

Impact of neglected diseases in Europe and the rest of the World- 3 h
Drug Design and Discovery; Preclinical and Clinical Phases 2 h
Biopharmaceutical Classification System, Drug Properties, Solubility, Co-solvency, Case Study- 3 h
Current drug delivery systems to improve treatment outcome: Cyclodextrins, Case studies 2 h
Current drug delivery systems to improve treatment outcome: microencapsulation, polymers, methodologies, microparticles, microcapsules, Case studies – 2 h
Current drug delivery systems to improve treatment outcome: nanoencapsulation, nanoparticles, nanocrystals, methods, Case studies. – 2 h; Group discussions 1. – 2 h*;* Group discussions 2. – 2 h

June 3-6, 2024
Prof. Andrea Carotti, University of Perugia

Introduction to open source and free *in silico* tools useful in drug discovery (2 CFU, 12h)

Nowadays the drug discovery process is a complex workflow full of risks that even the majority of the big pharma company cannot deal with. In this view a big opportunity is given by the computational approaches. In the last 25 years the molecular modeling scenario was enriched by the release of open source and free modeling software. The course will provide some theoretical basis to deeper understand the applications to perform molecular visualization, docking and use artificial intelligence (AI) algorithms. Moreover, with hands-on tasks, some practical and standard scenarios in the drug discovery process will be reproduced.

July, 2024
Dr. Vittorio Maglione, IRCCS Neuromed, Pozzilli (IS)

Metabolic alterations in neurodegenerative disorders: new insight into pathogenic mechanisms and potential therapies (1 CFU, 6h)

Homeostasis of neuronal cells is largely dependent on the dynamic compartmentalization of the endomembrane system (ER, GOLGI, endosomal-lysosomes system). Emerging evidence indicates that defects in endomembrane trafficking is impaired in different neurodegenerative disorders, including both Huntington (HD) and Parkinson disease (PD). As matter of fact, proteins like LRKK2, alpha-synuclein and huntingtin are involved in vesicular dynamics, and their mutations may affect the homeostasis of both neuronal and non-neuronal cells at multiple levels. Among the lipids that make up the endomembrane compartments, (glyco)sphingolipids play a critical role. They are both regulators of the endomembrane system and a product of the same. Coherently, abnormal levels of glycosphingolipids, described in both HD and PD, are attributable to a defective homeostasis of membranes and altered lipid recycling.

In this context, over the last fifteen years, our research group has demonstrated that the alterations in (glyco)sphingolipids are shared by different HD settings, including central and peripheral tissues from human patients. Importantly, we have also developed a "lipid-based" therapy in vivo, and provided the evidence that such an approach is effective in HD pre-clinical models. Since the endomembrane compartments are also involved in the regulation of protein post-translational modification, we are currently investigating the metabolism of some glycoproteins essential for brain development and functions. A number of studies supports the concept that the alteration of glycoconjugate pathways may contribute to the pathogenesis of neurodegenerative diseases and may be eventually pharmacologically targeted.
This is supported by the evidence that some drugs, whose molecular targets belong to these pathways, are already in clinical trial for different other diseases and could be eventually repurposed for the treatment of neurodegenerative conditions and/or serve as a tool for the development of new ones.

Room and timetable, as well as any change, will be communicated to PhD students by e-mail and published on the website.

November, 2024
Dr. Anna Donnadio, University of Perugia

Solid state characterization of pharmaceuticals (2 CFU, 12h)

The course will be addressed to introduce some of the solid state characterization techniques (X-ray diffraction, thermogravimetric analysis, differential calorimetry scanning, scanning electron microscopy and hot stage microscopy) routinely utilized in the pharmaceutical field, together with examples of the information provided by each. The aim is to provide the basic principles and typical applications of these commonly employed analytical tools for characterization of pharmaceutical solids for understanding the physical properties and ensure optimal physical form.

May, 2025
Dr Luisa Mattoli, Aboca

Concepts in Metabolomic Analysis. Applications to the analysis of medicinal plants and complex natural products *(2 CFU, 12h)*

Natural substances and plant metabolites. Mass spectrometry in the Metabolomic Analysis. Identification of metabolites. Targeted and untargeted metabolomics. Identification of metabolites and their quantitative determination. Regulatory implications and study of biological activity. Analysis of metabolites by phytochemical class: the case of alkaloids and phenols. Research applications and examples for quality control.

May-June, 2025
Prof. Anna K. H. Hirsch, Helmholtz Institute for Pharmaceutical Research Saarland (HIPS), Germany
Prof. Sabatini Stefano, University of Perugia

Classical and innovative approaches to address Anti-Microbial Resistance (2 CFU, 12 h)
Antimicrobial resistance (AMR) represents a global health issue threatening our social lifestyle and the world economy. The course will show the results of some recent approaches, both classical and innovative, aimed to contrast microbial resistance. Among the innovative approaches, a particular focus will entail Target-guided synthesis (TGS), a powerful approach in which the target selects its own inhibitors, and its two main methods: kinetic target-guided synthesis (KTGS) and dynamic combinatorial chemistry (DCC).

June 23-27, 2025
Prof. Francesca Blasi, University of Perugia
Prof. Aurélie Schoubben, University of Perugia

Bioactives from Agri-Food Waste (2 CFU, 12h)

The course intends to provide information on the valorization of agri-food waste as source of bioactive compounds. Lectures will focus on bioactive compounds and their functional properties, paying particular attention on: eco-friendly methods for their extraction, analytical methods to evaluate their composition, spectrophotometric methods to determine their in vitro bioactivity. The use of bioactives from agri-food waste suffers from several hurdles such as poor stability and solubility. In the second part of the course knowledge on technological strategies proposed to overcome these limitations will be reviewed according to the hydrophilic or lipophilic nature of the bioactives. Advantages of using encapsulation approaches to solve stability problems and at the same time improve bioactive delivery will be illustrated.

July , 2025

Prof. Claudia Zadra, University of Perugia

Prof. Maria Carla Marcotullio, University of Perugia

Plant extracts (2 CFU, 12h)

Plant secondary metabolites are important leads in the drug discovery and the formulation of food supplements, and to use plant metabolites for these purposes is fundamental the correct preparation of plant extracts. Besides the traditional extracting methods, in these last years, new eco-friendly techniques have been developed with the aim of reducing the use of polluting solvents and energy-consuming strategies. Plant extracts are often used as such for the preparation of plant-based medicines and food supplements, so the occurrence of residues and contaminants in medicinal herbs and their products is of great importance. Different classes of contaminants (natural toxicants, heavy metals, pesticides, mycotoxins..) could have adverse effects on human health and also represent an index of quality for the product.
In this context, information will be provided about the legislation and the requirements for the safety assessment of these materials.

Room and timetable, as well as any integration or change, will be communicated to PhD students by e-mail and published on the website.

AA 2025-2026

January-February, ***2026***
Prof. Francesco Galli, University of Perugia

Omics technologies in drug discovery (2 CFU, 12h)

The term "omics" refers to the set of sciences and technologies that essentially derived from the completion of the genome project in 2000. It deals with the complexity of biological phenomena in all their manifestations and applications, including identification of therapeutic targets and drug development using a holistic approach. In these two decades, a growing number of software and hardware tools have developed to address "omics" problems. These involve bioinformatics for the management and interpretation of "big data" that are produced in every "omics" domain. The evolution of this area and its importance in the pharmaceutical sector will be discussed in this short course in their main aspects, also giving particular emphasis to the technical and practical aspects and to the laboratory approach and sector research projects.

February, 2026
Prof. Alessandro Fatica, Sapienza University of Rome
Prof. Mariangela Morlando, University of Perugia

Emerging Approaches using Nucleic Acids as target or therapeutic molecules for the treatment of complex diseases (2 CFU, 12h)

Small-molecules and proteins/antibodies have represented for long time the major form of drugs for medical use and the preferred modes in drug development, mainly acting on protein targets such as enzymes, receptors and ion channels. However, there are number of proteins, RNAs and genes that cannot be targeted by these conventional approaches, while they can be selectively targeted by RNA molecules. Moreover, a growing number of evidences have highlighted the contribution of altered RNA and DNA metabolism in the pathogenesis of many complex diseases, thus expanding the repertoire of suitable targets for therapeutic purposes. This course aims to provide students with knowledge of the most advanced methodologies employing RNA and DNA as novel drugs and of the most promising therapeutic strategies targeting the pathological alteration of the RNA and DNA metabolism occurring in complex diseases such as neurological disorders and cancer.

May-June 2026
Prof. Antimo Gioiello, University of Perugia

Integrated technology platforms for medicinal chemistry and organic synthesis (2 CFU, 12h)

Over last years, innovations in synthetic chemistry have greatly enabled the discovery and development of important life-changing medicines. Recent developments in enabling chemical technologies including new synthetic methods, flow chemistry, biocatalysis, chemoinformatics, and automation have the power to accelerate the pace and improve the quality of products in pharmaceutical research. Indeed, the application of new synthetic methods is rapidly expanding the realm of accessible chemical matter and there is a growing recognition that innovations in synthetic chemistry are changing the practice of drug discovery. These seminal lessons will showcase some of the most enabling recent advances in synthetic chemistry and related technologies as well as opportunities that are believed to transform the practice of drug discovery and development in the coming years.

July, 2026
Dr. Alexandros Patsilinakos, Sibylla Biotech

Rational design of small molecule degraders: from PROTAC to IFDs (1 CFU, 6h)

Targeted protein degradation (TPD) has emerged as a promising therapeutic strategy for treating a wide range of diseases, including cancer, neurodegenerative diseases, and genetic disorders. TPD enables tackling undruggable targets, and some small molecules inducing protein degradation have shown promise in preclinical and clinical trials.

However, the rational design of small molecules that effectively induce target degradation is a complex task that requires a deep understanding of the molecular mechanisms involved. This seminar will provide a comprehensive overview of the rational design of small molecules that induce protein degradation, from PROTAC to folding interfering degraders (FIDs), and medicinal chemistry strategies for optimizing their potency, selectivity, and pharmacokinetic properties.