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Visiting Professor Program
Academic Year 2024/2025

TEACHING COMMITMENT: **16 hours**

COURSE TITLE

Drug Development: from Research to Market

TEACHING PERIOD

2nd term

SCIENTIFIC AREA

Medicinal Chemistry

LANGUAGE USED TO TEACH

English

COURSE SUMMARY

Description of preclinical regulatory approach before clinical development and marketing authorization of medicinal product. Basic knowledge on regulations on clinical studies. Preparation of the Investigational Medicinal Product Dossier (IMPD) containing the Investigational Medicinal Product (IMP) related data required whenever the performance of a clinical trial is intended in one or more European Union Member States. Quality, manufacture and control of any IMP (including reference product and placebo), and data from non-clinical and clinical studies. Pharmacology and pharmacokinetic characterization, toxic effects concerning target organs, dose dependence, relationship to exposure, and potential reversibility of the IMP. How to plan and design a clinical study. Required regulatory documents. Requirements for market authorization application. Contents First-in-human, bioavailability/bioequivalence studies, phase II/III studies, post-marketing studies pharmacovigilance.

LEARNING OBJECTIVES

The aim of this course is to provide an outline of basic knowledge on regulations on clinical studies. How to plan and design a clinical study. Required regulatory documents. Requirements for market authorization application. The knowledge gained from this course will be valuable to any medicinal chemists, particularly those working in the pharmaceutical industry or in hospitals, or those involved in clinical trials.

OTHER ACTIVITIES BESIDES THE COURSE

Visiting Professor will give seminars and conferences addressed to the students of the PhD course in Pharmaceutical and Biomolecular Sciences, of the Post Graduate School og Hospital Pharmacy as well as to research fellows of the Department of Chemistry and Pharmaceutical Technology of the Turin University.

VISITING PROFESSOR PROFILE

The visiting professor should have a long research experience in the field of drug discovery, development, and manufacturing both as a scientist and as a manager. Experience in drug discovery not only in academia but also in multiple R&D venues, including big pharma, large biotech, start-up ventures and nonprofit research institutes will be highly appreciated. Experience in regulatory affairs and expertise in translation from preclinical to clinical studies is require. Due to the intermediate level of the background of the students (4rd year of a five-year course), visiting professor should combine the rigorous presentation of the topics with the ability to give the basic information, when required.

CONTACT REFERENT

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