Direzione Ricerca,
Innovazione e
Internazionalizzazione

UNIVERSITÀ
DI TORINO

ID

VP_169_STF

Visiting Professor Program
Academic Year 2025/2026

TEACHING COMMITMENT: **16 hours**

COURSE TITLE

Drug Development: from Research to Market

TEACHING PERIOD

II semester

SCIENTIFIC AREA

Pharmaceutical Chemistry

LANGUAGE USED TO TEACH

English

COURSE SUMMARY

Description of the preclinical regulatory approach prior to clinical development and marketing authorisation of a medicinal product. Basic knowledge of clinical trial regulations. Preparation of the Investigational Medicinal Product Dossier (IMPD) containing the Investigational Medicinal Product (IMP) data required when a clinical trial is planned to be conducted in one or more Member States of the European Union. Quality, manufacture and control of each IMP (including reference product and placebo) and data from non-clinical and clinical studies. Pharmacology and pharmacokinetic characterisation, toxic effects on target organs, dose dependency, relationship to exposure and possible reversibility of the IMP. How to plan and design a clinical trial. Required regulatory documents. Requirements for the marketing authorisation application. Content 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 overview of the basic knowledge of clinical trial regulations:
- how to plan and design a clinical trial;
- required regulatory documents;
- requirements for the marketing authorisation application.

The knowledge gained in this course is valuable for all medicinal chemists, especially those working in the pharmaceutical industry or in hospitals or involved in clinical trials.

OTHER ACTIVITIES BESIDE THE COURSE

The visiting professor will hold seminars and conferences for the students of the PhD course in Pharmaceutical and Biomolecular Sciences, the Post Graduate School of Hospital Pharmacy and for research fellows of the Department of Chemistry and Pharmaceuti

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VISITING PROFESSOR PROFILE

The visiting professor should have many years of research experience in the discovery, development and manufacture of medicinal products, both as a scientist and as a manager. Experience in drug discovery not only in academia but also in various R&D organisations including big pharma, large biotech companies, start-up companies and non-profit research institutes is highly valued. Experience in regulatory affairs and expertise in translating preclinical to clinical trials is required. Due to the intermediate level of student background (4th year of a five-year course), the visiting professor should combine rigorous presentation of topics with the ability to convey basic information as needed.

CONTACT REFERENT

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