



University of
Zurich^{UZH}

ETH zürich

PhD Program in Cancer Biology

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Translational cancer biology 2024

Regulatory aspects and entrepreneurial activities

Instructors

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Date Friday, February 9, 2024

Course Venue UZH, Irchel Campus, Y13-M-12

Abstract

The course provides an introduction into the clinical development process and entrepreneurial activities for developing a drug product.

Program

09:00 – 9:15	Introduction
09:15 – 10:30	Overview and Principles of Clinical Development Regulatory Environment in Europe and United States Tools for Dialogue with Authorities
10:30 – 10:45	<i>Break</i>
10:45 – 12:00	Bench to Clinic: First-In-Human Study Requirements
12:00 – 13:00	<i>Lunch break</i>
13:00 - 16:00	Founding a Company * Financing of Clinical Trials * IPO

Content

- Overview and principles of Clinical Development: Study phases I-IV, Study Design, Good Clinical Practice, Pharmacovigilance, Study Operations
- Regulatory Framework in Europe and the United States: Clinical Trial Applications and Tools for Dialogue
- Bench to Clinic: Set up of a First in Human Studies

Learning Outcome

Upon completion of the course, participants should have basic knowledge of the regulatory framework for clinical trials and entrepreneurial activities.