Tufts CSDD | 52nd Annual

Postgraduate Course *in* Clinical Pharmacology Drug Development & Regulation

January 30, February 6, 13 & 20
11 am- 3 pm EST | Virtual

The longest-running professional development program in the biopharma space linking clinical pharmacology, trial design, and the regulatory review of new drugs and biologics

COURSE OVERVIEW

The Tufts CSDD Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation is the longest-running professional development program in the biopharma space. Now in its 52nd year, this unique annual course prepares both new and experienced drug developers, regulators, policy makers, clinical investigators, and academic researchers for success in the life-sciences sector. Thousands of drug development professionals are alumni of this prestigious one-of-a-kind program. Top speakers from industry, academia, and the FDA share their expertise to create a highly stimulating and rewarding learning environment.

COURSE GOALS

The goal of the course is to provide a comprehensive overview of the pharmaceutical development process, focusing on topics vital to professionals involved in all aspects of bioinnovation. Participants include individuals employed by pharmaceutical and biotechnology companies, regulatory agencies, academic institutions, government entities, outsourcing providers, consultancies, investment firms, and other biopharmaceutical organizations involved in the research, development, regulation, and marketing of pharmaceutical products.

COURSE OBJECTIVES

At the conclusion of the course, participants will be able to...

Clinical Pharmacology

Integrate the relevant pharmacology, pharmakinetics, & statistics related to drug development and the nature of evidence required for proof of efficacy and safety.

Drug Development & Clinical Trials

Using a case-study approach, identify and solve practical, theoretical, and technical problems in human drug studies & analyze an experiment design for a new drug candidate

Regulation

Evaluate the science, laws, and regulations pertaining to the development and review of new drug products in the USA, Europe, Japan and other pharmaceutical markets.

WHO SHOULD ATTEND?

- Physicians, pharmacists, marketing executives, clinical researchers, nurses, analysts, investors, & any professional working with or in the research-based drug industry
- Professionals looking to begin work in the pharma or biotech sectors and seeking comprehensive and foundational industry knowledge and training
- Individuals eployed by regulatory agencies, academic institutions, outsourcing providers, consultancy firms, niche service providers, and other organizations involved in the research, development, and regulation of pharmaceutical products

ADDITIONAL INFORMATION

Regular Rate.....$2,750
Tufts CSDD Sponsor Rate.....$2,450
Academic/Non-Profit/Govt Rate.....$2,450

Group Rates

The postgraduate program typically receives 125 - 150 participants. Many companies choose to send multiple staff to participate in the program under a special, discounted registration rate. If you would like to learn more about registering a group (3+ colleagues), please email Sarah.Wrobel@tufts.edu

2025 TUFTS CSDD
Postgraduate Course *in*
Clinical Pharmacology,
Drug Development & Regulation

FACULTY BIOGRAPHIES

MODERATORS

Kenneth Kaitin, PhD

Professor & Senior Fellow, Tufts CSDD

Seminar Topic: Trends & Challenges Impacting Drug Development

Lindsay McNair, MD, MPH, MSB

Principal Consultant, Equipoise Consulting

Seminar Topics: Bioethical Principles & the Ethical Review Process
Novel Clinical Trial Design

Kenneth Getz, MBA

Executive Director & Research Professor, Tufts CSDD

Seminar Topic: Optimizing Clinical Trial Performance

SPEAKERS

Orest Hurko, MD

Senior Clinical Consultant, SUN Pharma; Adjunct Associate Professor, Tufts Graduate School of Biomedical Sciences

Seminar Topic: Comprehensive Overview of the R&D Process

Chris Albani, MBA

Senior Executive Advisor, PwC Strategy - Japan Healthcare

Seminar Topic: The Value of Target Product Profiles

FACULTY BIOGRAPHIES

Varun Garg, PhD

VP - Clinical Pharmacology, PureTech Health

Seminar Topic: Clinical Pharmacology & Translational Medicine

Lawrence Liberti, PhD

Director, USC D.K. Kim International Center for Regulatory Science

Seminar Topic: The Global Regulatory Landscape

Nancy Pire-Smerkanich, DRSc, MS

Assistant Professor, USC School of Pharmacy

Seminar Topic: Regulatory Documentation

Kevin Bugin, PhD

Associate Vice President for Global Regulatory Policy & Intelligence, Amgen

Seminar Topic: Regulatory Policy, Affairs & Intelligence

Sue Fish, PharmD, MPH

Professor of Biostatistics & Epidemiology, Boston University School of Public Health.

Seminar Topic: Protocol Design Strategy & Planning

FACULTY BIOGRAPHIES

Zeid Barakat, MBA

Partner, Scimitar Inc; Senior Fellow, Tufts CSDD

Seminar Topic: CMC/Manufacturing

Samir Shah, BS

Advisor & Board Member | Pharma Services & Private-Equity Life Sciences, Shah Pharma Consulting Services LLC

Seminar Topic: Collaborating with CROs & Investigative Sites

Mary Jo Lamberti, PhD

Director of Sponsored Research, Research Associate Professor, Tufts CSDD

Seminar Topic: AI Use in Drug Development

Gorana Capkun, PhD

VP, Global Head of Patient Focused Real World Evidence, Merck Healthcare

Seminar Topic: The Role of Integrated Evidence

Peter Neumann, ScD

Director, Center for the Evaluation of Value & Risk in Health, Tufts Medical Center; Professor, TUSM

Seminar Topic: Measuring & Demonstrating Prescription Drug Value