

2024 Tufts CSDD | 51st Annual

Postgraduate Course in Clinical Pharmacology Drug Development & Regulation

February 7, 14, 21, 28 & March 1
12 - 4 PM EST | Online Synchronous

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 51st 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.



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COURSE OBJECTIVES

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

Clinical Pharmacology

Integrate the relevant pharmacology, pharmacokinetics, & 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 employed 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



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 Topic: Bioethical Principles & the Ethical Review Process

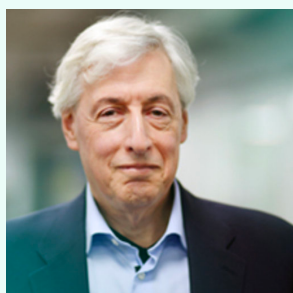


Kenneth Getz, MBA

Executive Director & Research Professor, Tufts CSDD

Seminar Topic: Optimizing Clinical Trial Performance

SPEAKERS



Lawrence Friedhoff, MD, PhD

CEO Pharmaceutical Special Projects Group, LLC

Seminar Topic: Comprehensive Overview of the R&D Process

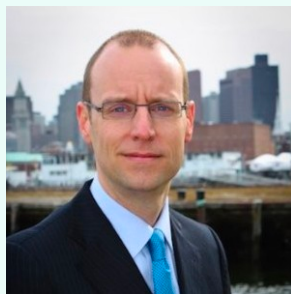


Chris Albani, MBA

Senior Executive Advisor, PwC Strategy - Japan Healthcare

Seminar Topic: The Value of Target Product Profiles

FACULTY BIOGRAPHIES



Koene R.A. Van Dijk, PhD

Consultant, KVD Consulting

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



Ameeta Parekh, PhD

Senior Advisor for Scientific Collaborations, FDA CDER

Seminar Topic: Collaborating & Engaging with the FDA



John Balser, PhD

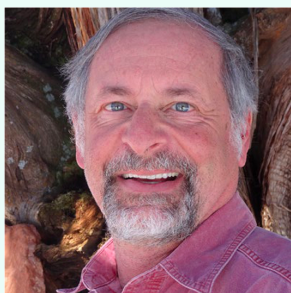
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Seminar Topic: Protocol Design Strategy & Planning



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Robert Franco, PhD

President, Coe Point Associates LLC ;
Senior Fellow, Tufts CSDD

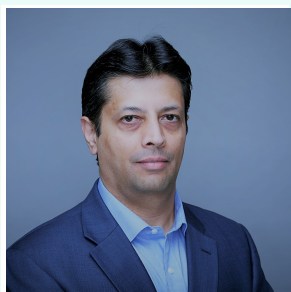
Seminar Topic: CMC/Manufacturing



Samir Shah, BS

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

Seminar Topic: Collaborating with CROs & Investigative Sites



Prasanna Rao, BMS

Senior Director, Global Head of AI/ML Data Monitoring
& Management, Pfizer

Seminar Topic: AI Use in Drug Development



Gorana Capkun, PhD

Global Head of Patient Focused Real World Evidence,
Merck KGaA

Seminar Topic: The Role of Integrated Evidence



Jennifer Kim, PhD

Assistant Research Professor, Tufts CSDD

Seminar Topic: Diversity, Equity & Inclusion



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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



Anita Patel, PharmD

VP Pharmacy Services Development, Walgreens

Seminar Topic: COVID Vaccine Development - Lessons Learned



Chandresh Harjivan, MBA, MPH, PharmD

Associate Director for Domestic Preparedness & Response to Pandemic & Biological Threats, The White House

Seminar Topic: The New White House Pandemic Preparedness Commission



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