

2022 TUFTS CSDD

49th Annual

Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation

February 7-11, 2022

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



PROFESSIONAL DEVELOPMENT FOR INNOVATION

The **Tufts CSDD Postgraduate Course**, now in its 49th year, is the longest-running professional development program in the biopharma space, annually preparing both new and experienced drug developers, regulators, policy makers, and clinical researchers for success in the lifesciences sector. Thousands of drug development professionals are alumni of this prestigious course, where small group exercises and specialized simulations offer the only comprehensive experience of its kind. Top speakers from academia, industry, and the FDA bring their expertise to create a stimulating learning environment.

Course Overview:

Tufts CSDD's five-day Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation will resume in 2022 as a live in-person event in Boston, Massachusetts (venue to be determined). This highly acclaimed program provides advanced instruction in practical and technical problem-solving in the areas of clinical pharmacology, drug development & clinical trial strategies, biopharmaceutical development, drug safety, and new drug regulation. During an exclusive Q&A session with a senior FDA official, participants will receive first-hand insights into FDA priorities and operations and will emerge with a better understanding of the regulatory process. For more information we have provided an agenda and a detailed program description from our most recent live course in 2020.

Course Goal:

The Tufts CSDD Postgraduate Course is designed to provide students with a broad and comprehensive understanding of issues related to the development and regulation of drugs, biologics, vaccines, devices, and in vitro diagnostics. Lectures focus on basic drug development topics — such as translational medicine, clinical pharmacology, epidemiology, drug regulation, and adverse drug event reporting — as well as broader topics such as pharmacoeconomics, drug-device combinations, biosimilars, working with investigative sites, and drug marketing.

For more information please visit <https://csdd.tufts.edu/postgraduate-course>

COURSE OBJECTIVES

At the conclusion of this activity, learners will be able to:

Clinical Pharmacology:

Integrate the relevant pharmacology, pharmacokinetics, and 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, and 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:

- drug development professionals
- clinical researchers
- regulators
- consultants
- investors
- marketing executives
- physicians, pharmacists, nurses
- analysts
- professionals in the research-based drug industry

Course Co-Chairs:



Kenneth I Kaitin, PhD

Professor and Senior Fellow
Tufts Center for the Study of Drug Development
Tufts University School of Medicine



Richard I. Shader, MD

Professor Emeritus of Immunology
Tufts University School of Medicine

ADDITIONAL INFORMATION



Regular Rate:

Early Bird: Register before October 31st.....	\$4,745
Regular: November 1st – February 7th.....	\$5,145

Tufts CSDD Sponsor Rate:

Early Bird: Register before October 31st.....	\$4,545
Regular: November 1st – February 7th.....	\$4,845

Academic/Non-profit/Government Rate:	\$3,145
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**Military and Veterans included in government rate.*

Group Rate:

If your company is interested in bringing three (3) or more attendees to the program, Tufts CSDD is able to offer a group discount on all registrations. For more information, please email us at csdd@tufts.edu.

Details:

Tuition and registration is for the five-day course, included in the tuition are packaged breakfasts (Monday-Friday), lunches (Monday-Thursday), morning and afternoon refreshment breaks. Tuition does not include other meals or accommodations. Please note there is a non-refundable processing fee of \$250.

REGISTRATION, POLICIES & DISCLAIMERS

Arrival and departure:

Participants are advised to arrive on Sunday. Registration will begin that evening from 6:00 pm – 7:00 pm. Participants who arrive Monday morning may register between 8:00 am – 8:45 am. The course will begin promptly at 8:45 am on Monday and will end at 12:00 pm on Friday.

Non-endorsement statement:

The content and views presented in this educational activity are those of the faculty and do not necessarily reflect the opinions or recommendations of Tufts University School of Medicine or Tufts Center for the Study of Drug Development. Inclusion in this activity does not constitute approval or endorsement of any commercial products or services. These materials have been prepared based on the best available information, but are not exhaustive of the subject matter. Participants are advised to critically appraise the information presented and encouraged to consult the available literature for any commercial products mentioned.

Commercial support and exhibitors:

No commercial support was accepted for this course. Exhibitors will not be present.

ADA/OEO Non-discrimination policy:

Tufts University School of Medicine (TUSM) considers all applicants and participants without regard to race, color, national origin, age, religious creed, sex, or sexual orientation. TUSM is an Equal Opportunity Employer. We encourage participation by all individuals. If you have a physical disability, please inform us by January 12th, 2022 to better help us serve you.

Cancellation policy:

If you wish to cancel your registration, the full tuition will be refunded (minus a non-refundable \$250 registration fee) through January 12, 2022. Fifty percent of the tuition fee (minus the registration fee) will be refunded for cancellations received January 13–26, 2022. No tuition will be refunded for cancellations received after January 26, 2022. Substitutions may be made at any time.

Should the course be postponed due to events beyond the control of Tufts CSDD and Tufts University, tuition will be applied to the rescheduled event. Tufts CSDD and Tufts University reserve the right to alter the venue if necessary, and are not responsible for any airfare, hotel, or other costs incurred by registrants if the course is cancelled or postponed.

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FEBRUARY 7-11, 2022

Venue TBD | Boston, MA

csdd.tufts.edu/postgraduate-course | (617) 636-2170 | csdd@tufts.edu

What past participants are saying:

"Since I am new to the industry I appreciated that all the presentations provided excellent background information before examining each topic in more depth."

"The regulation overview for US, EU, Japan, and China were extremely useful. The presentation captured essential knowledge for those areas."

"The mock drug groups were very helpful because it brought together a handful of people from different backgrounds and professions. It encouraged team-building and communication - two things that are very much needed in the work field."

About the Center:

The Tufts Center for the Study of Drug Development, located in Boston, Massachusetts, helps drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops and public forums.

Tufts Center for the Study of Drug Development

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Tufts Center for the
Study of Drug Development
TUFTS UNIVERSITY