Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation

Ritz-Carlton | Boston, MA
The Tufts CSDD Postgraduate Course, now in its 46th 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 life-sciences sector. Thousands of drug development professionals are alumni of this prestigious course, where small group exercises and specialized simulations offer the only comprehensive, CME-accredited experience of its kind. Top speakers from academia, industry, and the FDA bring their expertise to create a stimulating learning environment.

OVERVIEW

The 2019 Tufts CSDD Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation features lectures, drug design simulations, and interactive post-marketing panel discussions. Our five-day program and its expert faculty present the latest in clinical trial ethics, outcomes research, epidemiology, vaccines and device development. Using a case-study approach, mock drug groups provide participants with a unique and highly interactive opportunity to develop and analyze an experimental drug design protocol. 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.

COURSE GOAL

The goal of the Postgraduate Course is to provide a fundamental overview of pharmaceutical development and regulation, focusing on topics vital to professionals involved in bioinnovation. Participants include individuals employed by pharmaceutical and biotechnology companies, regulatory agencies, academic institutions, outsourcing providers, consultancies, law firms, niche service providers, investment firms, and other biopharmaceutical organizations involved in the research, development, regulation, and marketing of pharmaceutical products.

For more information on faculty and to view the full schedule, please visit our website: 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:

RICHARD I. SHADER, MD
Professor Emeritus of Immunology
Tufts University School of Medicine

KENNETH I KAITIN, PHD
Professor of Medicine and Director
Tufts Center for the Study of Drug Development
Tufts University School of Medicine
REGULAR
Early Bird: Register before September 1st................................................................................... $4,595
Advance: September 2nd - December 1st...................................................................................... $4,795
Regular: December 2nd - January 31st.......................................................................................... $4,995

SPONSOR
Early Bird: Register before September 1st................................................................................ $4,395
Advance: September 2nd - December 1st..................................................................................... $4,595
Regular: December 2nd - January 31st........................................................................................ $4,695

ACADEMIC/NON-PROFIT/GOV’T................................................................................................. $2,995

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

ACCOMMODATIONS
Course lectures will be held at the Ritz-Carlton Hotel Boston. A block of rooms has been reserved for course participants at a preferred rate of $209/night. These rooms will be available at this preferred rate until January 4, 2019. Please call the Hotel Reservation line at (617) 574-7100 and mention the Tufts CSDD Postgraduate Course to obtain the preferred room rate. Taxi cabs are available from Boston’s Logan Airport for transportation to and from the hotel. The hotel provides valet parking and self-parking for vehicles. For directions and additional information, visit www.ritzcarlton.com/en/hotels/boston
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.

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, 2019. Fifty percent of the tuition fee (minus the registration fee) will be refunded for cancellations received January 13-26, 2019. No tuition will be refunded for cancellations received after January 26, 2019. 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.
FEEDBACK FROM PAST PARTICIPANTS IN THE PHARMA INDUSTRY

“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, MA, 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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