TUFTS CSDD 2014
Postgraduate
Course in Clinical
Pharmacology,
Drug Development,
and Regulation

FEBRUARY 3-7, 2014
Ritz-Carlton, Boston Common
Boston, MA
Overview

The 2014 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, CME-accredited program and its expert faculty present the latest in clinical trial ethics, outcomes research, epidemiology, and information technology in clinical 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. In the 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.

The following ABMS/ACGME/IOM competencies will be addressed: Medical Knowledge and Work in Interdisciplinary Teams.

For more information on faculty and to view the full schedule, please visit our website: http://csdd.tufts.edu/courses/postgraduate_course
Course Objectives

- **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 and 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

This course is intended for drug development professionals, clinical researchers, regulators, consultants, investors, marketing executives, physicians, pharmacists, nurses, analysts, and professionals working with the research-based drug industry.

Course Co-Chairs

**Kenneth I Kaitin, PhD**  
Professor and Director, Tufts Center for the Study of Drug Development, Tufts University School of Medicine

**Richard I. Shader, MD**  
Professor Emeritus of Molecular Physiology and Pharmacology, Tufts University School of Medicine

Breakout Groups Co-Moderators

**Helen W. Boucher, MD, FACP**  
Director, Infectious Diseases Fellowship Program, Associate Professor of Medicine, Division of Infectious Diseases, Tufts Medical Center

**Judith K. Jones, MD, PhD**  
President & CEO, The Degge Group, Ltd.
Additional Information

Regular Registration:
Early Bird (Register before Sep. 15th): \$3,795 USD
Advance (Register Sep. 16th – Nov. 15th): \$3,995 USD
Regular (Register Nov 16th—Jan 30th): \$4,325 USD

Sponsor Registration:
Early Bird (Register before Sep. 15th): \$3,595 USD
Advance (Register Sep. 16th – Nov. 15th): \$3,795 USD
Regular (Register Nov 16th—Jan 30th): \$4,125 USD

Academic/Gov’t/Non-Profit: \$2,895 USD

Tuition and registration is for the five-day course. Included in the tuition are continental breakfast (Monday-Friday), lunches (Monday–Thursday), morning and afternoon refreshment breaks, a networking reception and dinner on Monday, February 3rd, and a non-refundable $250 processing fee. Tuition does not include other meals or accommodations.

Accommodations
Course lectures will be held at the Ritz-Carlton Hotel, 10 Avery Street, Boston, MA 02111. A block of rooms has been reserved for course participants at a preferred rate of \$199 USD/night. These rooms will be available at this preferred rate until January 17, 2014, 5:00 p.m. Please call the Ritz-Carlton Hotel Reservation line at 1-800-542-8680 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 http://www.ritzcarlton.com/en/Properties/BostonCommon/Information/Default.htm

Accreditation

Physicians
This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Tufts University School of Medicine (TUSM) and Tufts Center for the Study of Drug Development. TUSM is accredited by the ACCME to provide continuing medical education for physicians.

TUSM designates this live activity for a maximum of 32.75 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Requirements for successful completion
To receive CE credit, participants must sign in, attend the entire activity, and complete and submit the activity evaluation provided in syllabus materials. Certificates/statements of credit will be issued within 4-6 weeks after the activity.
Registration, Policies and Disclaimers

Arrival and Departure
Participants are advised to arrive on Sunday. Registration will begin that evening from 6:00 p.m. - 7:00 p.m. Participants who arrive Monday morning may register between 8:00 a.m. - 8:45 a.m. The course will begin promptly at 8:45 a.m. on Monday and will end at 12:00 p.m. 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 17, 2014, 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 10, 2014. Fifty percent of the tuition fee (minus the registration fee) will be refunded for cancellations received January 11-24, 2014. No tuition will be refunded for cancellations received after January 24, 2014. 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.

Disclosure
Disclosure information from faculty and all other persons in control of content will be provided to participants prior to the beginning of the educational activity. To view the policy on privacy and confidentiality for TUSM OCE, please visit: http://md.tufts.edu/Education/Continuing-Ed-Microsite/Privacy-and-Confidentiality-Policy

For more information regarding certification, please contact Tufts University School of Medicine Office of Continuing Education at med-oce@tufts.edu or 617-636-6579.
Tufts CSDD’s Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation

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In the Words of Past Participants

“This course provides an opportunity to engage with seasoned & experienced faculty for 5 solid days of learning.”

“It is a carefully designed and thorough — yet concise — course on the different functions involved in drug development.”

“The opportunity to interact with others in the industry or supporting the industry is invaluable. The mock exercises are by far the greatest tool for reinforcing the material.”

“The experience of the faculty is tremendous.”

“The [Tufts Course] brings together national and international scientists from academia, the pharmaceutical industry, the biotechnology industry and regulatory agencies for the opportunity to learn and discuss better ways to develop drugs as well as to improve the quality of existing drug products.”

ABOUT THE TUFTS CENTER

The Tufts Center for the Study of Drug Development, located in Boston, MA, helps drug developers, regulators, and policy makers succeed in the global marketplace, through its in-depth makers succeed in the global marketplace, through its in-depth analyses of pharmaceutical issues. Tufts CSDD publishes bi-monthly, quarterly, and annual publications, hosts on-site senior executive roundtables, and offers postgraduate level courses and training workshops.

For more information, please visit our website: http://csdd.tufts.edu