

*Jointly Sponsored By Tufts University School
of Medicine and the Tufts Center for the
Study of Drug Development*

Tufts
UNIVERSITY
School of Medicine

TUFTS CSDD 2012



Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation

February 6-10, 2012
TAJ Boston Hotel
Boston, MA

POSTGRADUATE COURSE



**Tufts Center for the
Study of Drug Development**

TUFTS UNIVERSITY





EDUCATION. COLLABORATION. INNOVATION.

Now in its 39th year, Tufts CSDD's highly acclaimed, five-day Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation 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. Thousands of drug development professionals are alumni of this prestigious course, where top speakers and specialized development simulations offer the only comprehensive, CME-accredited experience of its kind.

Overview

The 2012 Tufts CSDD Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation features lectures, breakout groups, and an interactive panel discussion. Our five-day, CME-accredited program and its expert faculty focus on 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 gain a better understanding of the regulatory process.

Course Goal

The course's goal is to provide a broad and basic overview of topics related to pharmaceutical development and regulation for professionals involved in pharmaceutical and biopharmaceutical innovation. Participants include individuals employed by pharmaceutical and biotechnology companies, regulatory agencies, academic institutions, outsourcing providers, consultancy and investment firms, niche service providers, and other 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, 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

Director and Research Professor,
Tufts Center for the Study of
Drug Development, TUSM



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
Assistant Professor of Medicine
Division of Infectious Diseases
Tufts Medical Center



Judith K. Jones, MD, PhD

President & CEO
The Degge Group, Ltd.

“Overall, an exceptional course. I learned the importance of a comprehensive approach to clinical development planning.”

Additional Information

Tuition

Early registration on or before November 1, 2011	US \$4,095
Registration after November 1, 2011	US \$4,250
Tufts CSDD sponsors on or before Nov. 1, 2011	US \$3,695
Sponsor registration after November 1, 2011.	US \$3,895

Tuition and registration is for the five-day course. Included are continental breakfasts (Monday-Friday), lunches (Monday-Thursday), morning and afternoon refreshment breaks, a networking reception and dinner on Monday, February 6, and a non-refundable \$250 processing fee. Tuition does not include accommodations and other meals.

Accommodations

Course lectures will be held at the TAJ Boston Hotel, 15 Arlington Street, Boston, MA. A block of rooms at the TAJ Boston Hotel has been reserved for course participants at a preferred rate of **\$170/night**. These rooms will be available at this preferred rate until **January 22, 2012, 5:00 p.m.** Please call the TAJ Boston Hotel Reservation line at 617-536-5700 or 877-482-5267. Be sure to 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. For directions, visit <http://www.tajhotels.com/boston/>

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.



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Registration, Policies and Disclaimers

Arrival and Departure

Participants are advised to arrive on Sunday, February 5, 2012. Registration will be available from 6:00 – 7:00 p.m. Participants who arrive Monday morning may register between 8:00 – 8:45 a.m. The course will begin promptly at 8:45 a.m. on Monday, February 6th and will end at 12:30 p.m. on Friday, February 10th.

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 program. Exhibitors will not be present at this program.

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 20, 2012, 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 17, 2012. Fifty percent of the tuition fee (minus the registration fee) will be refunded for cancellations received January 18-30, 2012. No tuition will be refunded for cancellations received after February 1st. 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. Individual faculty will disclose discussion of off-label use. To view the policy on privacy and confidentiality for TUSM OCE, please visit: <http://www.tufts.edu/med/about/offices/oce/privacy.html>

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

“Great overview of each aspect of drug development.”

“The subject matter relates to my daily work.”

“Good overview of the whole clinical development process and reemphasis of certain regulations vital to drug development.”

“Puts complex concepts in terms all can understand.”

“Excellent, especially the mock drug groups.”

“As a medical doctor, I deal with literature regarding new drugs and drug safety all the time. This course gave me a view of the challenges involved in the drug industry and how they affect our practice.”

ABOUT THE TUFTS CENTER

The Tufts Center for the Study of Drug Development helps drug developers, regulators, and policy 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.

Tufts Center for the Study of Drug Development

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<http://csdd.tufts.edu>



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