Tufts Center for the Study of Drug Development

Tufts CSDD 2020 Postgraduate Course in Clinical Pharmacology, Drug Development, and Regulation

Monday, February 3, 2020

Moderator:	**Richard I. Shader, MD**
8:00-8:30 am	*Open Registration, Continental Breakfast*
8:30-8:45 am	Welcome, Orientation, Course Objectives & Introduction
8:45-9:45 am	The Basics of the Drug Development Process and its Phase
9:45-10:00 am	*Refreshment Break*
10:00-11:00 am	Translational Medicine – Discovery to Development
11:00-12:00 pm	Principles of Clinical Pharmacology
12:00-1:00 pm	*Lunch Break*
Moderator:	**Kenneth I Kaitin, PhD**
1:00-2:00 pm	Clinical Pharmacologic Evaluation of Intrinsic and Extrinsic Factor Effects in Global Drug Development
	Biosimilars: Challenges and Opportunities
2:00-3:00 pm	Drug Development Regulation Part 1: USA
3:00-4:00 pm	*Refreshment Break*
4:00-4:15 pm	Drug Development Regulation Pt. 2: Brief Overview of EU, Japan, China and Emerging Markets
4:15-5:15 pm	The Current Environment for Drug Development: Strategies for Boosting R&D Efficiency and Productivity

Tuesday, February 4, 2020

Moderator:	**Richard I. Shader, MD**
8:00-8:30 am	*Continental Breakfast*
8:30-9:15 am	The Basics of Clinical Trial Design
9:15-10:00 am	Institutional Review Boards: An Ethical and Regulatory Overview
10:00-10:15 am	*Refreshment Break*
10:15-11:15 am	The Role of Chance in Randomized Controlled Trials: Lecture
11:15-12:00 pm	Evaluating the Role of Chance in Clinical Trials: Worksho**p**
12:00-1:00 pm	*Lunch with Mock Drug Groups*
Moderator:	**Richard I. Shader, MD**
1:00-2:00 pm	The Next Wave of Adaptive Trials: Broad Implementation & Efficient Clinical Development
2:00-2:15 pm	Instant Experience in Clinical Trials
2:15-3:00 pm	Pre-Mock Drug Group Discussion
3:00-5:30 pm	Mock Drug Groups: Session I

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Wednesday, February 5, 2020

Moderator:	**Richard I. Shader, MD**
7:30-8:00 am	*Continental Breakfast*
8:00-10:00 am	Mock Drug Groups: Session II
10:00-10:15 am	*Refreshment Break*
10:15-11:15 am	Understanding the Medical Affairs Function
11:15-12:15 am	Bio/Pharm Investing 101
12:15-1:15 pm	*Lunch Break*
Moderator:	**Kenneth I Kaitin, PhD**
1:15-3:00 pm	Understanding the FDA: An Open Conversation and Q&A
3:00-4:00 pm	Pharmaceutical Marketing & the New World Order of Advertising, Social Media and Regulation
4:00-5:45 pm	Mock Drug Groups: Presentations

Thursday, February 6, 2020

Moderator:	**Kenneth I Kaitin, PhD**
8:30-9:00 am	*Continental Breakfast*
9:00-10:00 am	Optimizing Protocol Design to Improve Study Conduct Performance
10:00-11:00 am	Basics of CMC/Quality in Drug Development
11:00-11:15 am	*Refreshment Break*
11:15-12:15 pm	Regulatory Science: An Integrated Approach of Evidence Generation for Regulatory Approval & Optimal Label
12:15-1:15 pm	*Lunch Break*
Moderator:	**Richard I. Shader, MD**
1:15-2:15 pm	Pharmacovigilance, Post-Market Surveillance, and Risk Management
2:15-2:45 pm	Drug Safety Breakout Group Discussion
2:45-4:15 pm	Breakout Group Activity: Drug Safety – Stakeholder Perspectives
4:15-5:30 pm	"*MEET THE PRESS: Should This Life-Saving Medicine with Safety Issues Remain on the Market?*"
5:30-5:45 pm	Drug Safety Breakout Group Activity Wrap-Up

Friday, February 7, 2020

Moderator:	**Kenneth I Kaitin, PhD**
8:15-8:45 am	*Continental Breakfast*
8:45-9:45 am	Measuring the Value of Prescription Drugs
9:45-10:45 am	Patient Centricity's Impact on Drug Development
10:45-11:45 am	How to Select and Work with CRO's
11:45-12:00 pm	Course Wrap-Up