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 | Kenneth Kaitin
8:45-9:45 am   The Basics of the Drug Development Process and its Phases | Richard Shader
9:45-10:00 am  Refreshment Break
10:00-11:00 am Translational Medicine – Discovery to Development | Chandrasekhar Natarajan
11:00-12:00 pm Principles of Clinical Pharmacology | Jerry Collins
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 | Karthik Venkatakrishnan
2:00-3:00 pm  Biosimilars: Challenges and Opportunities | Alison Taunton-Rigby
3:00-4:00 pm  Drug Development Regulation Part 1: USA | Alberto Grignolo
4:00-4:15 pm  Refreshment Break
4:15-5:15 pm  Drug Development Regulation Pt. 2: Brief Overview of EU, Japan, China and Emerging Markets | Alberto Grignolo
5:15-6:00 pm  The Current Environment for Drug Development: Strategies for Boosting R&D Efficiency and Productivity | Kenneth Kaitin
6:00-8:00 pm  Networking Reception

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 | Richard Shader
9:15-10:00 am  Institutional Review Boards: An Ethical and Regulatory Overview | Susan Kornetsky
10:00-10:15 am Refreshment Break
10:15-11:15 am The Role of Chance in Randomized Controlled Trials: Lecture | Janet Forrester
11:15-12:00 pm Evaluating the Role of Chance in Clinical Trials: Workshop | Janet Forrester
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 | Jerald Schindler
2:00-2:15 pm  Instant Experience in Clinical Trials | Richard Shader
2:15-3:00 pm  Pre-Mock Drug Group Discussion | Helen Boucher
3:00-5:30 pm  Mock Drug Groups: Session I | Richard Shader, Helen Boucher & Paul Beninger
### 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 | Richard Shader, Helen Boucher & Paul Beninger  
**10:00-10:15 am** Refreshment Break  
**10:15-11:15 am** Understanding the Medical Affairs Function | Pol Vandenbroucke  
**11:15-12:15 am** Bio/Pharm Investing 101 | Les Funtleyder  
**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 | Ellis Unger  
**3:00-4:00 pm** Pharmaceutical Marketing & the New World Order of Advertising, Social Media and Regulation | Laura Housman  
**4:00-5:45 pm** Mock Drug Groups: Presentations | Richard Shader & Paul Beninger  
**5:45-7:30 pm** Mid-Week Networking Reception: Take an Opportunity to Meet Someone New!

### 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 | Kenneth Getz  
**10:00-11:00 am** Basics of CMC/Quality in Drug Development | Robert Morgan  
**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 | Iman Barilero  
**12:15-1:15 pm** Lunch Break  
**Moderator:** Richard I. Shader, MD  
**1:15-2:15 pm** Pharmacovigilance, Post-Market Surveillance, and Risk Management | Paul Beninger  
**2:15-2:45 pm** Drug Safety Breakout Group Discussion | Paul Beninger  
**2:45-4:15 pm** Breakout Group Activity: Drug Safety – Stakeholder Perspectives | Paul Beninger, Kenneth Kaitin & Richard Shader  
**4:15-5:30 pm** “MEET THE PRESS: Should This Life-Saving Medicine with Safety Issues Remain on the Market?” | Paul Beninger & Kenneth Kaitin  
**5:30-5:45 pm** Drug Safety Breakout Group Activity Wrap-Up | Paul Beninger

### 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 | Peter Neumann  
**9:45-10:45 am** Patient Centricity’s Impact on Drug Development | Kenneth Getz  
**10:45-11:45 am** How to Select and Work with CRO’s | Laurie Halloran  
**11:45-12:00 pm** Course Wrap-Up | Kenneth I Kaitin