Tufts University

Tufts Center for the Study of Drug Development

# Agenda for 2017 Tufts Annual Postgraduate Course in Clinical Pharmacology, Drug Development and Regulation

## MONDAY, FEBRUARY 6th

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| 8:00-8:30 AM | Open Registration, Continental Breakfast |
| 8:30-8:45 | Welcome, Orientation, Course Objectives & Introduction (**Kaitin**) |
| 8:45-9:45 | The Basics of the Drug Development Process, its Phases, and Typical Trial Designs (**Shader**) |
| 9:45-10:00 | **REFRESHMENT BREAK** |
| 10:00-11:00 | Pre-Clinical Phase (**Natarajan**) |
| 11:00-12:00 PM | Principles of Clinical Pharmacology (**Collins**) |
| 12:00-1:00 | **LUNCH** |
| 1:00-2:00 | Pharmacogenomics (**Court**) |
| 2:00-3:00 | Drug-Drug Interactions: Principles and Evaluation in Drug Development (**Venkatakrishnan**) |
| 3:00-3:45 | Drug Development Regulation Part 1: USA (**Grignolo**) |
| 3:45-4:00 | **REFRESHMENT BREAK** |
| 4:00-4:45 | Drug Development Regulation Pt. 2: Brief Overview of EU, Japan and Emerging Markets (**Grignolo**) |
| 4:45-5:45 | The Current Environment for Biomedical Innovation, The Changing Face of Pharma R&D (**Kaitin**) |
| 5:45-8:00 | **RECEPTION** |

## TUESDAY, FEBRUARY 7th

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|---|---|
| 8:00-8:30 AM | Continental Breakfast |
| 8:30-9:15 | Reviewing, Approaching and Managing Research Involving Human Subjects (**Russell-Einhorn**) |
| 9:15-10:00 | Protecting People in Research: Group Exercise/Workshop (**Russell-Einhorn**) |
| 10:00-10:15 | **REFRESHMENT BREAK** |
| 10:15-11:15 | The Role of Chance in Randomized Controlled Trials: Lecture (**Forrester**) |
| 11:15-12:00 PM | Evaluating the Role of Chance in Clinical Trials: Workshop (**Forrester**) |
| 12:00-1:00 | **LUNCH** |
| 1:00-2:00 | Adaptive Trials Designs: Broad Implementation & Efficient Clinical Development (**Schindler**) |
| 2:00-2:15 | Instant Experience in Clinical Trials (**Shader**) |
| 2:15-3:00 | Pre-Mock Drug Group Case Study Lecture (**Boucher**) |
| 3:00-5:30 | Mock Drug Groups: Session I (**Shader/Boucher**) |

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## WEDNESDAY, FEBRUARY 8th

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| 7:30-8:00AM | Continental Breakfast |
| 8:00-10:00 | Mock Drug Groups: Session II (**Shader/Boucher**) |
| 10:00-10:15 | **REFRESHMENT BREAK** |
| 10:15-11:15 | Integration of Diagnostics into the Therapy Business Model (**Keeling**) |
| 11:15-12:15PM | Basics of CMC/Quality in Drug Development (**Morgan**) |
| 12:15-1:15 | **LUNCH** (with Mock Drug Groups) |
| 1:15-3:00 | Understanding the FDA: An Open Conversation and Q&A (**Unger**) |
| 3:00-4:00 | Optimizing Protocol Design to Improve Study Conduct Performance (**Getz**) |
| 4:00-5:45 | Mock Drug Groups: Presentations (**Shader/Boucher**) |

## THURSDAY, FEBRUARY 9th

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|---|---|
| 8:30-9:00 AM | Continental Breakfast |
| 9:00-10:00 | BioSimilars: Challenges and Opportunities (**Taunton-Rigby**) |
| 10:00-11:00 | Vaccines and Immunotherapies (**Sardesai**) |
| 11:00-11:15 | **REFRESHMENT BREAK** |
| 11:15-12:15 PM | Pharmaceutical Marketing & the New World Order of Advertising, Social Media & Regulation (**Housman**) |
| 12:15-1:15 | **LUNCH** |
| 1:15-2:15 | PV & the Scope of Safety (**Beninger**) |
| 2:15-2:45 | Postmarketing Surveillance & Risk Management of Drugs (**Jones**) |
| 2:45-3:00 | Discussion of Postmarketing/Drug Safety Breakout Groups (**Jones**) |
| 3:00-:4:45 | Breakout Session: An Interactive Discussion on Postmarketing Surprises & Drug Safety (**Jones/Kaitin/Shader**) |
| 4:45-5:45 | Postmarketing Presentations (**Jones/Kaitin/Shader**) |

## FRIDAY, FEBRUARY 10th

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|---|---|
| 8:15-8:45 AM | Continental Breakfast |
| 8:45-9:45 | Measuring the Value of Prescription Drugs (**Neumann**) |
| 9:45-10:45 | How to Select and Work with CRO's (**Halloran**) |
| 10:45-11:45 | Portfolio Management: Managing a Diverse Company Portfolio (**Zaks**) |
| 11:45-12:00 PM | Course Wrap Up (**Kaitin**) |