MIT/Harvard Principles and Practice of Drug Development
Fall 2015


MIT, Building 56, room 114

Thursdays, 3:00 – 6:00 pm

Instructors:
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CLASS SCHEDULE

This course serves as a description and critical assessment of the major issues and stages of developing a pharmaceutical or biopharmaceutical. Topics covered include drug discovery, preclinical development, clinical investigation, manufacturing and regulatory issues considered for small and large molecules, and economic and financial considerations of the drug development process. A multidisciplinary perspective is provided by the faculty, who represent clinical, life, and management sciences. Various guests from academia and industry also participate.

September 10  Introduction (Faculty)
State of the Industry (Finkelstein)
Scientific History of Pharmaceuticals (Sinskey)

September 17  Drug Development and Development Processes (Rubin)
Brief economic history of the pharmaceutical industry (Finkelstein)

September 24  Business of Biopharmaceuticals
Guests: Robert Mulroy, M.P.P.M., Director, President & CEO, Merrimack Pharmaceuticals
Sumit Khedekar, Director, Global Healthcare Group, Bank of America, Merrill Lynch

October 1   Toxicology (Sinskey)
CRISP-Cas: Scientific History and Path to Clinic
Guest: Chad Cowan, PhD, Harvard Dept of Stem Cell and Regenerative Biology
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(continued)

October 8  Neurodegeneration: From Yeast to Neurons to Yumanity
Guest: Vikram Khurana, MBBS, PhD
Attending Neurologist, MGH; Scientific Co-founder, Yumanity Therapeutics
Modified RNA
Guest: Derrick Rossi, PhD
Harvard Dept of Stem Cell and Regenerative Biology & Boston Children’s Hospital

October 15  Drug Discovery: Organs on a Chip
Guest: Anthony Bahinsky, PhD, MBA, FAHA, The Wyss Institute of Harvard University
Discovery and Development of Cystic Fibrosis Drugs
Guest: Eric Olson, PhD, Chief Scientific Officer, Syros Pharmaceuticals

October 22  From Cell paper to clinic: Translating Basic Stem Cell Science to a Transformative Therapy
Guests: Robert Millman, CEO Semma Therapeutics
Felicia Pagliuca, Scientific Co-founder and Director of Technology and Corporate Development, Semma Therapeutics

October 29  Drug Delivery Systems
Guests: Luís Almeida, PhD & João Nuno Moreira,
University of Coimbra, Portugal

November 5  The Future of Drug Discovery in Neuroscience
Guest: Ricardo Dolmetsch, Global Head of Neuroscience
Novartis Institutes for Biomedical Research

November 12 Manufacturing I (Charles Cooney)

November 12  Manufacturing II (GK Raju)
Pharmaceutical Quality (GK Raju)
Manufacturing III (Guest)

November 19  Control of Limb Regeneration: Drugs of the Future?
Guest: Jessica Whited, PhD, Brigham Regenerative Medicine Center, BWH
Zebrafish Screening: How to Use Model Organisms to Discover Human Therapeutics
Guest: Leonard Zon, MD, Boston Children’s Hospital/HHMI and Harvard’s Dept of Stem Cell and Regenerative Biology

November 26  Thanksgiving Day – No Class

December 3  Use of Stem Cells in Modeling and Treating Disease (Rubin)
Guest: Brock Reeve, MPhil, MBA, Executive Director
Harvard Stem Cell Institute

December 10  Student Presentations