

**PHRM-526S**  
**Drug Discovery and Development II**  
**3.0 Credits**

**Course Directors:**

Paul McGonigle, Ph.D., Professor, Dept. of Pharmacology and Physiology

Joanne Mathiasen, Ph.D., Professor, Dept. of Pharmacology and Physiology

**Course Description**

This course, the second of a two part series, will provide in-depth exposure to the concepts, processes and disciplines involved in the clinical and marketing stages of drug discovery and development as practiced in the biopharmaceutical industry. It covers all facets of the process ranging from Phase I Clinical Trials through to commercial, marketing and post-marketing surveillance. Discussion of unmet medical needs and case histories will also be included.

**Course Purpose and Goals**

*Drug Discovery and Development II* continues the introduction of students to the field of drug discovery and development by presenting a comprehensive overview of the clinical drug development process as well as an introduction to legal, commercial, regulatory and entrepreneurial aspects of the industry. Topics range from the design and conduct of clinical trials to the regulatory approval process and eventual commercialization and post-marketing surveillance. In addition to professional skills development activities, this course also focuses on the interdisciplinary nature of the Drug Discovery and Development process and the critical role played by each specialty. Several faculty members from the College of Medicine participate in this course as well as 19 external scientists and executives from various companies and foundations with drug discovery experience including Astellas, Relmada Therapeutics, UCB, iCeutica, In Silico Biosciences, Janssen, CHDI, PhRMA and Merck. The career opportunities presented in this course include: Clinical Research, Pharmacoepidemiology, Regulatory Affairs, Intellectual Property Management, Biostatistics, Marketing, Entrepreneurship, Contract Research, Venture Capital, Chemical Manufacturing, Commercialization and Administration of Nonprofits.

**Recommended Textbooks**

Drug Discovery and Development,  
Technology in Transition, 2<sup>nd</sup> Edition  
R.G Hill and H.P. Rang ed., 2013  
ISBN: 978-0-7020-4299-7  
Paperback, Kindle

Drug Discovery and Development,  
1<sup>st</sup> Edition  
B. Blass, 2015  
ISBN: 978-0124115088  
Format: Paperback, Kindle

## Lecture Schedule

Lecture #	Topic
1	Course Overview & Objectives
2	Overview of Clinical Development
3	Phase I Studies: Safety & Tolerability
4	Phase II Studies: Proof of Concept
5	Phase II Studies: Safety & Efficacy
6	The FDA: Regulatory Guidelines and Drug Development
7	Biomarkers and their Role in Drug Discovery & Development
8	Pharmaceutical Formulation and Manufacturing
9	The New Drug Application (NDA)
10	Drug Delivery Systems
11	Student Presentations
12	Case Study in Drug Development: Apixaban (Eliquis)
13	Predevelopment Project Presentation
14	Generics and Biosimilars
15	Overview of Commercial and Marketing
16	Project and Portfolio Management
17	Management of Risks and Resources
18	Post-marketing Surveillance
19	Outsourcing in Drug Discovery and Development
20	Business Development and Technology Transfer
21	Patent Law in the Pharmaceutical Industry
22	Entrepreneurship and Venture Capital
23	Emerging Role of Foundations and Nonprofits
24	Drug Discovery Strategy
25	Project Team Presentations
26	Round Table Discussion

## Participating Faculty

**Richard Mangano, Ph.D.**

Chief Scientific Officer  
Relmada Therapeutics

**Jeffrey Paul, Ph.D.**

Exec. Director, Clinical Pharmacology  
Astellas Pharma

**Wei Du, Ph.D.**

Professor of Psychiatry  
Drexel University College of Medicine

**Peter Basseches, Ph.D.**

Director, Regulatory Affairs  
Merck

**MaryAnn Pellemounter, Ph.D.**

Program Director  
National Institutes of Health

**Maura Murphy, Ph.D.**

Sr. Director, Research & Development  
iCeutica Corp.

**Robert Babilon, Ph.D.**

Vice President, Regulatory Affairs  
Prosoft Clinical

**Rita Raddatz, Ph.D.**

Director, Biomarker Technologies  
Teva Pharmaceuticals

**Benjamin Blass, Ph.D.**

Asst. Professor of Medicinal Chemistry  
Temple University

**David Howland, Ph.D.**

Director, In Vivo Biology  
Cure Huntington's Disease Foudation

**Patrick Lam, Ph.D.**

Consultant  
Formerly: Bristol-Myers Squibb

**Boris Polyak, Ph.D.**

Associate Professor of Medicine  
Drexel University College of Medicine

**Michael Wood, Ph.D.**

Director of Licensing  
AstraZeneca

**Felix Kim, Ph.D.**

Assistant Professor  
Drexel University College of Medicine

**Gillian Cannon, Ph.D.**

President  
UCB North America

**Randall Mack, Ph.D.**

Sr. Vice President, Development  
Recro Pharma

**James Samanen, Ph.D.**

Director, Portfolio Management  
Formerly GlaxoSmithKline

**Leslie Killion, M.D.**

Sr. Director, Immunology Safety Head  
Janssen Pharmaceuticals

**Martin Lehr, M.B.A.**

Chief Operating Officer  
Context Pharmaceuticals

**Rajesh Ranganathan, Ph.D.**

Vice President, Scientific Affairs  
Pharmaceutical Research & Mfg's Assoc.