

## **Syllabus: GS13 1111 Case Studies in Drug Development**

GSBS Large Classroom (BSRB S3.8371)  
10:30am- 12:00noon, Mondays  
Spring 2019 semester

### **Instructor**

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### **Office Hours**

By appointment

### **Course description**

The course covers the entire spectrum of drug discovery ranging from target identification, pharmacokinetics, pre-clinical and clinical safety, final design and objectives of each phase of the drug development process encountered in industry and regulatory agencies, and tracking of clinical outcomes in Phases III and IV as well as post launch surveillance for toxicity. This course provides the necessary training in knowledge, logic, and steps for successful approval of a drug and ethical, conflict of interest, and intellectual property issues involved throughout the process.

The course integrates a video based drug development course developed by Merck and Yale with live lectures from faculties with drug discovery experience and scientists from the biotech and pharmaceutical industry.

*The course is designed to:*

- Improve/Create formal education about the pharmaceutical industry
- Role of pharma in delivering innovative medical products/devices that provide value to improve human health
- Role of academic medical centers' collaboration in this process

- Educate students about how to interact with the pharmaceutical industry

*Additional goals of the course include:*

- Dispel myths about drug development and the pharmaceutical industry & academic interactions
- Show in a positive light the critical nature of academic-industry collaboration;
- Present pharmaceutical industry as a valid career option

## **Course Details**

### **January 14**

*Part I – How New Drugs Are Discovered*

- Lesson 1 – Target Identification
- Lesson 2 – Target Validation

### **January 21 Martin Luther King Holiday (no classes)**

### **January 28**

*Part I – How New Drugs Are Discovered (continued)*

- Lesson 3 – Lead Identification
- Lesson 4 – Lead Optimization
- Lesson 5 – Biologics

### **February 4**

*Part II– Preclinical Studies*

- Lesson 6 – Formulation Activities
- Lesson 7 – Drug Metabolism and Pharmacokinetics

### **February 11**

- Live lecture 1 – Case Study: Small Molecule Drug Development (Dr. Qingyun (Jim) Liu)

### **February 18 Presidents Day Holiday (no classes)**

### **February 25**

- Live lecture 2 – Case Study: Natural Products Drug Development (Dr. Gerald Bills)

## **March 4**

### *Part II– Preclinical Studies (continued)*

- Lesson 8 – Nonclinical Safety Assessment
- Live lecture 3 – Case study: Antibody Drug Development (Dr. Zhiqiang An)

## **March 11**

### *Part 3 – Testing Individual Drugs in Humans*

- Lesson 9 – Clinical Development Plan
- Lesson 10 - Phase I Trials

## **March 18 Spring Break (no classes)**

## **March 25**

### *Part 3 – Testing Individual Drugs in Humans (continued)*

- Lesson 11 – Phase II Trials
- Lesson 12 – Phase III Trials

## **April 1**

### *Part 4 - Regulatory Review Process*

- Lesson 13 – Who Regulates?
- Lesson 14 – Drug Labeling
- Lesson 15 – Global Regulatory Strategy

## **April 8**

- Live lecture 4 – Case Study: Vaccines Discovery and Development (Dr. Tong-Ming Fu)

## **April 15**

### *Part 4 - Regulatory Review Process (continued)*

- Lesson 13 – New Drug Application
- Lesson 14 – FDA review and Approval Process
- Live lecture 5 – Case Study: Assay Development (Dr. Ningyan Zhang)

## **April 22**

### *Part 5 – Postmarketing Studies & Safety Surveillance*

- Lesson 15 – Phases 3b and 4
- Lesson 16 – Post Market Regulatory Activities

### **April 29**

- Live lecture 6 – Overview of the Drug Discovery and Development Process (Dr. Barry Morgan)

### **May 6**

- Student presentations

### **GSBS Academic Calendar Spring 2019**

January 2	Second Tutorial Begins
January 14	Spring Semester Academic Classes Begin
January 21	Martin Luther King Holiday (no classes)
February 18	Presidents Day Holiday (no classes)
March 8	Second Tutorial Ends
March 11	Third Tutorial Begins
March 18-22	Spring Break (no classes)
May 3	Last Day of Classes
May 6-10	Final Exams
May 10	End of Spring Semester
May 17	Third Tutorial Ends
May 18	GSBS Commencement Exercises

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