Syllabus: GS13 1111 Case Studies in Drug Development

GSBS Large Classroom (BSRB S3.8371)
10:30am - 12:00noon, Tuesdays
Spring 2017 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 10

Part I – How New Drugs Are Discovered

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

January 17

Part I – How New Drugs Are Discovered (continued)

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

January 24

Part II – Preclinical Studies

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

January 31

Part II – Preclinical Studies (continued)

- Lesson 8 – Nonclinical Safety Assessment
- Live lecture 1 – Case study: Antibody Drug Development (Dr. Zhiqiang An)

February 7

- Live lecture 2 – Case Study: Small Molecule Drug Development (Dr. Qingyun (Jim) Liu)

February 14

Part 3 – Testing Individual Drugs in Humans
• Lesson 9 – Clinical Development Plan
• Lesson 10 - Phase I Trials

February 21

Part 3 – Testing Individual Drugs in Humans (continued)

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

February 28

• Live lecture 3 – Case Study: Natural Products Drug Development (Dr. Gerald Bills)

March 7

Part 4 - Regulatory Review Process

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

March 14 – No class (Spring Break)

March 21

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

March 28

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 4

Part 5 – Postmarketing Studies & Safety Surveillance

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

April 11
• Live lecture 6 – Overview of the Drug Discovery and Development Process (Dr. Barry Morgan)

April 18
• Student presentations

April 25
• Student presentations

May 2
• Student presentations

GSBS Academic Calendar Spring 2017

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<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>January 3</td>
<td>Second Tutorial Begins</td>
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<tr>
<td>January 9</td>
<td>Spring Semester Academic Classes Begin</td>
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<tr>
<td>January 16</td>
<td>Martin Luther King Holiday (no classes)</td>
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<tr>
<td>February 20</td>
<td>Presidents Day Holiday (no classes)</td>
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<tr>
<td>March 3</td>
<td>Second Tutorial Ends</td>
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<tr>
<td>March 6</td>
<td>Third Tutorial Begins</td>
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<tr>
<td>March 13-17</td>
<td>Spring Break (no classes)</td>
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<td>April 28</td>
<td>Last Day of Classes</td>
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<tr>
<td>May 1 - 5</td>
<td>Final Exams</td>
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<tr>
<td>May 5</td>
<td>End of Spring Semester</td>
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<td>May 12</td>
<td>Third Tutorial Ends</td>
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<td>May 20</td>
<td>GSBS Commencement Exercises</td>
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