Course Description: Bringing a new chemical entity, drug, or device to the consumer market is a necessary but intricate, expensive, complicated, and time-consuming process. There are different avenues of drug discovery and product development (industry vs. academic), and many aspects of development focus on satisfaction of regulatory requirements mandated by the FDA and other regulatory agencies. The FDA’s CDER asserts that their mission is, “to promote and protect public health by ensuring that safe and effective drugs are available to Americans.” As such, preclinical, pharmacokinetic, pharmacodynamic, stability, toxicity trials, as well as clinical trials (I-IV) and post marketing surveillance are elements that are important for researchers (and those who propose to gain expertise in the basic and environmental health sciences) to understand as prerequisites for US/global market approval. Furthermore, protocol planning, safety monitoring, data and cost analysis are essential parts of this interdependent and collaborative process involving individuals from a diverse range of disciplines, including basic and clinical sciences, statistics, management, legal, and marketing departments.

As we enter a new decade of discovery, it is essential that translational researchers, medical, biological, and basic scientists have a prerequisite understanding of the process of drug and device development. Core tenants involve integration of resources within the global economy and public health domain. This course will provide an overview of this innovative, multidisciplinary process.

To ensure that an interesting and broad range of topics will be covered, invited lecturers are from the academic and private sectors and are comprised of physicians and non-medical professionals. Presentations range in content from bench discoveries to marketing strategies and will run for 90 min., followed by a 30 min. discussion period.

Coordinator: , MD, MSc, Assistant Professor of Pediatrics. You can reach me via email at: gabrielle.gold-vonsimson@nyumc.org by phone: 212-263-5759 or 917-301-1862

Learning Objectives: To have a basic understanding of the following:

1) The steps involved from product discovery to final market approval
2) The role of toxicology and pharmacokinetics in drug development in both adults and children
3) Significance of intellectual property, patent regulations, and disclosure/conflicts of interest
4) Ethics in clinical trials and reporting of misconduct/fraud
5) Protocol design, biostatistical analysis, and safety monitoring in clinical trials
6) Cost analysis, funding, and economic and public ventures associated with new drug development and marketing
7) The regulatory aspects of new drug development such as the IND and be able to navigate the FDA website

Resources:
SYLLABUS

Text: Ng, Rick. Drugs: From Discovery to Approval. 2009 Wiley-Blackwell.
*Will be made available at NYU Health Sciences Bookstore

*PDF will be emailed to students

On line Information:
FDA: www.fda.gov/cder for information regarding IND, currently approved drugs, and clinical trials information:
  3. Running clinical trials webpage: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

Evaluation: Student evaluation is mainly based on class participation, but will also be based on completion of assignments, project, and final exam. The breakdown is as follows:

  Participation = 60%
  Weekly Homework Assignments = 10%
  Final Project/Exam = 30%

Feedback: ongoing; there will be a formal feedback session at the end of the term.
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| September 11 | 10-11:30     | Opening session and VIDEO part 1: “Making a killing, the untold story of psychotropic drugging”  
Gabrielle Gold-von Simson, MD, MSc, Moderator                                                                 |
|            |               |                                                                                   | controversial viewpoint of the psychiatric drug industry/public opinion on prescription drugs    |
| September 18 | 11:30-12:00   | Jan Vilcek, MD, PhD, NYU SOM, Professor of Microbiology                            | “Development of Infliximab (Remicade)”                                                           |
| September 25 |               | Martin O. Behm, MD, Merck and Co. Inc., Associate Director Clinical Pharmacology  
“Pharmaco-kid-netics: Pediatric Drug Development, an industry perspective”                                |
| October 2   | 10-11:30     | Vilma Gabbay, MD, MSc, Assistant Professor of Psychiatry                           | “neurobiology of obesity, novel therapeutic targets”                                              |
| October 9   |               | Ravichandran Ramasamy, PhD, NYUSOM, Associate Professor of Medicine, Biochemistry,  
and Molecular Pharmacology                                                                     | “Challenges in Drug Discovery for the treatment of diabetic complications”                        |
| October 16  |               | Manfred Hauben, MD, Pfizer, Lead Safety Monitor,                                  | “pharmacoepidemiology, pharmacovigilance and drug safety, concentrating on the application of statistical data mining techniques to monitor and predict drug safety” |
| October 23  | 10-11:30     | Knut Wittkowski, PhD, DSc, Rockefeller University, Center for Clinical and       
Translational Science, Senior Research Associate                                                  | “Biostatistics and Study Design; new statistical approaches and application to new drug targets” |
<p>| October 30  |               | Jeff Gold, JD, MS, Pfizer Consumer Healthcare, Patent Counsel                    | “Intellectual Property and Patent Issues Relating to Clinical Data in Drug Development; can you patent data?” |
| November 6  | 10-11:30     | Michael Mashaal, MD, HealthCor Partners, Managing Director                        | “The New Economy and its Implications on Medical Innovation”                                     |
| November 13 |               | Leonard Liebes, PhD, NYU SOM, Associate Professor of Medicine                     | “Translational Studies leading to Phase I Clinical Studies and beyond”                            |
| November 20 |               | Paul Below, MS, P. Below Consulting Inc., Clinical Research Consultant            | “Fraud and misconduct in clinical trials”                                                        |
|            |               | Shreya Jani, BA, Pfizer Inc., Head of International Media Relations               | “Medical and Science Communications: Fostering Better Dialogue through the Press”                |</p>
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<tr>
<td>November 27</td>
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<td>NO CLASS THANKSGIVING</td>
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<td>December 4</td>
<td>V. Craig Jordan, PhD, Scientific Director, Lombardi Comprehensive Cancer Center, Vincent T. Lombardi Chair of Translational Cancer Research, and Vice Chairman, Department of Oncology Georgetown University Medical School, “Oncologic drug development and repurposing of drugs”</td>
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<td>December 11</td>
<td>Bert Spilker, MD, PhD</td>
<td>“The FDA and new drugs/devices”</td>
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<td>December 18</td>
<td>Gabrielle Gold-von Simson, MD, MSc, NYU SOM, Assistant Professor of Pediatrics “The FDA and IND: the Kinetin case study of drug development in an orphan disease”</td>
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**Closing session**
- Discussion of Assigned Drugs
- Feedback on speakers (written)
- Feedback, discussion
- Final thoughts

**Gabrielle Gold-von Simson, MD, MSc, NYU SOM, Assistant Professor of Pediatrics “Closing session, feedback”**

**Brown Bag Lunch sessions:** At 12:00pm each Wednesday after class, there will be a one-hour lunch session for students to meet and discuss relevant topics with the course director and lecturer(s). Each student will be required to attend at least 4 sessions during the semester and are encouraged to attend more.

**Assignments:**

- **September 11:** Drugs From Discovery to Approval, Chapter 1 (Introduction)
- **September 18:** Drugs From Discovery to Approval, Chapter 5 (Drug Development and Preclinical Studies)
- **October 2:** Drugs From Discovery to Approval, Chapter 6 (Clinical Trials)
- **October 9:** Drugs From Discovery to Approval, Chapter 11 (Future perspectives)
- **October 16:** CDER (Center for Drug Evaluation and Research) Update: Improving Public Health Through Human Drugs.
SYLLABUS

October 23: Drugs From Discovery to Approval, Chapters 3 & 4 (Drug Discovery, small molecule drugs and large molecule drugs)

October 30: Drugs From Discovery to Approval, Chapter 7 (Regulatory Authorities)


November 20: No assignment, Thanksgiving

November 27: Drugs From Discovery to Approval, Chapter 2 (Targets and Receptors)

December 4: Drugs From Discovery to Approval, Chapter 8 (Regulatory Applications)

December 11: Drugs From Discovery to Approval, Chapter 9 (Good manufacturing practice: regulatory requirement)

December 18: Drugs From Discovery to Approval, Chapter 10 (Good manufacturing practice: drug manufacturing)