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: Gabrielle Gold-von Simson, 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
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Resources:
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

Online Information:
FDA: [www.fda.gov/cder](http://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 = 30%

Feedback: ongoing; there will be a formal feedback session at the end of the term.
## SYLLABUS

### Fall 2016 Schedule

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Location</th>
<th>Faculty/Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept 7</td>
<td>10am–12:00pm</td>
<td>Verizon building 227 East 30th Street; between 2nd and 3rd Avenues—1st fl Conf Rm 120</td>
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</tbody>
</table>
| Sept 14      | 10:00 am – 11:30am | 1st fl Conf Rm 120 | Jan Vilcek, MD, PhD, NYUSOM, Professor of Microbiology  
Development of Infliximab (Remicade®)  
“Pharmaco-kid-netics: Pediatric Drug Development, obesity and metabolism, an industry perspective” |
| Sept 21      |               | 1st fl Conf Rm 120 | Martin O. Behm, MD, Merck and Co. Inc., Associate Director Clinical Pharmacology  
“Pharmacokinetics: Pediatric Drug Development, obesity and metabolism, an industry perspective” |
| Sept 28      | 10:00 am – 11:30am | 1st fl Conf Rm 120 | Dan Sherman, Assistant Research Scientist, NYUSOM  
“The discovery and optimization of macrocyclic kinase inhibitors for PK and efficacy” |
| Oct 5        | 10:00 am – 11:30am | 1st fl Conf Rm 120 | Aaron Cypess, MD MGH/Harvard  
“Brown adipogenesis as a target for new diabetes drugs” |
| Oct 12       | 10:00 am – 11:30am | 1st fl Conf Rm 120 | Ravichandran Ramasamy, PhD, NYUSOM, Associate Professor of Medicine, Biochemistry, and Molecular Pharmacology  
“Challenges in drug discovery for the treatment of diabetic complications” |
| Oct 19       |               | 1st fl Conf Rm 120 | 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 including metabolic syndrome/obesity” |
| Oct 26       | 10:00 am – 11:30am | 1st fl Conf Rm 120 | 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?” |
| Nov 2        |               | 1st fl Conf Rm 120 | 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” |
| Nov 9        |               | 1st fl Conf Rm 120 | Michael Mashaal, MD, HealthCor Partners, Managing Director  
“The New Economy and its Implications on Medical Innovation with focus on diabetes drugs” |
| Nov 16       |               | 1st fl Conf Rm 120 | Paul Below, MS, P. Below Consulting Inc., Clinical Research Consultant  
“Fraud and misconduct in clinical trials” |
| Nov 23       |               | 1st fl Conf Rm 120 | NO CLASS THANKSGIVING |
| Nov 30       |               | 1st fl Conf Rm 120 | Jay D. Kranzler, MD, PhD, Global Head – R&D Innovation – Pharmatherapeutics, Pfizer Inc.  
“Biotechnology/entrepreneurship in science” |
| Dec 7        |               | 1st fl Conf Rm 120 | Joel Dudley, PhD, Director of Biomedical Informatics, Institute for Genomics and Multiscale Biology, Icahn School of Medicine Mount Sinai  
“Genomic Medicine and Repurposing of Drugs” |
| Dec 14       |               | 1st fl Conf Rm 120 | Gabrielle Gold-von Simson, MD, MSc, NYUSOM, Assistant Professor of Pediatrics  
“The FDA and IND: the Kinetin case study of drug development in an orphan disease”  
Closing session  
Discussion of Assigned Drugs  
Feedback on speakers (written)  
Feedback, discussion  
Final thoughts |

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**Opening session and VIDEO part 1:** “Making a killing, the untold story of psychotropic drugging”  
**Gabrielle Gold-von Simson,** MD, MSc, NYUSOM  
Moderator: controversial viewpoint of the psychiatric drug industry/public opinion on prescription drugs
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**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 7: Drugs From Discovery to Approval, Chapter 1 (Introduction)

September 14: Drugs From Discovery to Approval, Chapter 5 (Drug Development and Preclinical Studies)


September 28: Drugs From Discovery to Approval, Chapter 6 (Clinical Trials)

October 5: Drugs From Discovery to Approval, Chapter 11 (Future perspectives)


October 19: Drugs From Discovery to Approval, Chapters 3 & 4 (Drug Discovery, small molecule drugs and large molecule drugs)

October 26: Drugs From Discovery to Approval, Chapter 7 (Regulatory Authorities)


AND


AND


AND

“Pfizer Subsidiary Pleads Guilty in Marketing Case” New York Times, Sept, 2009

November 16: Drugs From Discovery to Approval, Chapter 2 (Targets and Receptors)

November 23: No assignment; Thanksgiving Day
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November 30: Drugs From Discovery to Approval, Chapter 8 (Regulatory Applications)

December 7: Drugs From Discovery to Approval, Chapter 9 (Good manufacturing practice: regulatory requirement)

December 14: Drugs From Discovery to Approval, Chapter 10 (Good manufacturing practice: drug manufacturing)