Drug development in a New Era: NYU GSAS, MSc, Sackler, SOM 2012

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:
*Will be made available at NYU Health Sciences Bookstore

*PDF will be emailed to students

On line 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](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.
# SYLLABUS

## Fall 2012 Schedule

### Date and Time: Wed, 10am – 12:00pm Sept 12 through Dec 19
### Location: Verizon building 227 East 30th Street; between 2nd and 3rd Avenues--8th fl Conf Rm 818

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<tr>
<th>Date</th>
<th>Faculty/Presentation</th>
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| September 12 | **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 19 | **Jan Vilcek,** MD, PhD, *NYU SOM,** Professor of Microbiology  
“It's about time” Development of Infliximab (Remicade®)” |
| September 26 | **Shreya Jani,** BA, *Pfizer Inc.,* Head of International Media Relations  
“Medical and Science Communications: Fostering Better Dialogue through the Press” |
| October 3  | **Martin O. Behm,** MD, *Merck and Co. Inc.,* Associate Director Clinical Pharmacology  
“Pharmaco-kid-netics: Pediatric Drug Development, an industry perspective” |
| October 10 | **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” |
| October 17 | **Research Ethics Symposium,** “Are Research Ethics and Research Regulations at a Crossroads?” coordinator, **Joy Jurnack,** RN, NYU IRB education analyst  
8am – 12pm, breakout session 1pm – 2:30pm  
Farkas auditorium NYULMC  
open to all students for the full day activity |
| October 24 | **Leonard Liebes,** PhD, *NYU SOM,* Associate Professor of Medicine  
“Translational Studies leading to Phase I Clinical Studies and beyond” |
| October 31 | **Gregory Pastores,** MD, Associate Professor of Neurology, *NYU SOM,*  
“Drug development for the lysosomal storage disorders; both enzyme therapy and small molecule substrate reduction therapy (investigational)” |
| November 7 | **Paul Below,** MS, *P. Below Consulting Inc.,* Clinical Research Consultant  
“Fraud and misconduct in clinical trials” |
| November 14 | **Vilma Gabbay,** MD, MSc, Assistant Professor of Psychiatry  
“omega 3 and depression, phase II, III trials, translational research” |
| November 21 | NO CLASS |
| November 28 | **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” |
| December 5 | **Jeff Gold,** JD, MS, *Wyeth Consumer Healthcare,* Patent Counsel  
“Intellectual Property and Patent Issues Relating to Clinical Data in Drug Development; can you patent data?” |
## SYLLABUS

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<tr>
<th>Date</th>
<th>Speaker(s)</th>
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<tr>
<td>December 12</td>
<td><strong>Gabrielle Gold-von Simson</strong>, MD, MSc, <em>NYU SOM</em>, Assistant Professor of Pediatrics “The FDA and IND: the Kinetin case study” OR <strong>Jeff Greene</strong>, MD, <em>HealthCor Partners</em>, Managing Director “The New Economy and its Implications on Medical Innovation”</td>
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<tr>
<td>December 19</td>
<td><strong>Closing session</strong></td>
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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 12:** Drugs From Discovery to Approval, Chapter 1 (Introduction)
- **September 19:** Drugs From Discovery to Approval, Chapter 5 (Drug Development and Preclinical Studies)
- **October 3:** Drugs From Discovery to Approval, Chapter 6 (Clinical Trials)
- **October 10:** Drugs From Discovery to Approval, Chapter 11 (Future perspectives)
- **October 17:** CDER (Center for Drug Evaluation and Research) Update: Improving Public Health Through Human Drugs.
- **October 24:** Drugs From Discovery to Approval, Chapters 3 & 4 (Drug Discovery, small molecule drugs and large molecule drugs)
- **October 31:** Drugs From Discovery to Approval, Chapter 7 (Regulatory Authorities)
- **November 7:** IND webpage: [http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDru](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDru)

November 21: No assignment, Thanksgiving

November 28: Drugs From Discovery to Approval, Chapter 2 (Targets and Receptors)

December 5: Drugs From Discovery to Approval, Chapter 8 (Regulatory Applications)

December 12: Drugs From Discovery to Approval, Chapter 9 (Good manufacturing practice: regulatory requirement)

December 19: Drugs From Discovery to Approval, Chapter 10 (Good manufacturing practice: drug manufacturing)