

Drug development in a New Era: NYU GSAS, MSCI Program, Sackler, SOM 2017
Syllabus

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

Resources:

Updated as of 9/1/2017

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Text: Ng, Rick. **Drugs: From Discovery to Approval.** 2009 Wiley-Blackwell.

*Will be made available at NYU Health Sciences Bookstore

PDF text: CDER (Center for Drug Evaluation and Research) Update: Improving Public Health Through Human Drugs.

*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:

1. "From Fish to Pharmacies: The Story of a Drug's Development" at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm>
2. IND webpage: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>
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.