

Drug Development Issues
Monday: 4.00 ~ 6.00 PM
8 September 2008 – 1 December 2008
Jefferson Alumni Hall M-61
1020 Locust Street
Thomas Jefferson University

Course Number: GC 625 (CRN 70388)

Course Coordinator: Dennis M. Gross, M.S., Ph.D.
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Credit: Two credit hours

Prerequisites: None

Objectives/Goals: To provide students with an overview and understanding of the drug and vaccine development enterprise from the bench through the registration process. The impact of the various cGxP regulations will be presented as well as discussions of legal, outcomes and Pharmacoeconomics issues.

Text and Materials: **Zenobia: The Curious Book of Business: A Tale of Triumph Over Yes-Men, Cynics, Hedgers and Other Corporate Killjoys.**
Matthew Emmens and Beth Kephart
Berrett-Koehler Publishers, San Francisco, 2008

Copies of the PowerPoint slides of the presentations will be distributed at each class and posted on the Blackboard site. Additional text and reading materials will either be distributed in class and/or posted on the class Blackboard site.

Suggested for your professional library (Not Required for the Class)

New Drug Development: A Regulatory Overview. Mark Mathieu, Anne Evans, 389 pgs, Parexel International Corp., 8th. Edition (Jan 2008) \$145.00 @ Amazon.com

Biologics Development: A Regulatory Overview. Mark Mathieu, 283 pgs., Parexel International Corp., 3rd Edition (Jan 2004) \$164.00 @ Amazon.com

JCGS Academic Integrity Policy (From the JCGS Policy: The full document is available on the JCGS web page at www.jefferson.edu/jcgs/policies)

The Administration and Faculty of the Jefferson College of Graduate Studies believe that academic integrity is one of the most important values and behaviors that should be practiced by students during their studies. Because we are committed to training future scientists and educators who perform the highest quality of research, the College Administration and Faculty are equally committed to mandating and enforcing the practice of academic integrity by all students.

Grading and Evaluation Standards:

Midterm Exam	30%	150 points
Class participation	10%	50 points
Final Exam	60%	300 points

- The midterm exam will be a take-home examination of short answer essays covering each of the topics in the first 6 lectures.
- The midterm exam will be e-mailed to all students at their TJU e-mail address.
- The midterm should be returned electronically *via* email in MS Word format.
- The final exam is in the format of a research paper. Each student will be assigned a marketed pharmaceutical product that can be found in the Physicians Desk Reference (PDR) though you will regard the drug as never having been marketed before. Using a drug from the PDR ensures that you will be able to find real data on it. If you cannot find a PDR, most drug monographs are available now on the Web.
- Your research paper will reflect a synthesis of the entire term and will represent a development plan that will take an assigned product from the bench through the entire enterprise of drug discovery, development and registration addressing all of the critical issues in the path forward to approval.

Lecture #	Lecture Date	Activity and Lecture Topic	Lecturer
1	September 8, 2008	Course Introduction & Good Laboratory Practices (cGLP) and Preclinical Issues	Dr. Dennis M. Gross- TJU
2	September 15, 2008	Good Manufacturing Practices (cGMP): Synthetics & Biologicals	Dr. Dennis M. Gross - TJU
3	September 22, 2008	cGCP: Good Clinical Practices	Dr. Dennis M. Gross - TJU
4	September 29, 2008	Computers in Industry: Quality Audits and Quality Assurance	Mr. Harry Huss - Charles River Labs
5	October 6, 2008	Legal Issues in Drug Development	Dr. Frank Bigley - NovoNordisk
6	October 13, 2008	Vaccine R&D: From the Fermentor to the Recipient	Dr. Charbel Haber, PTC Therapeutics
	October 13, 2008	Midterm Exam Distributed	DMG
	October 20, 2008	Midterm Exam Submitted via E-mail	DMG
7	October 20, 2008	Tech Transfer: The View from Academe	Ms. Katherine Chou - TJU Tech Transfer Office
8	October 27, 2008	The Drug Development Process from a Labeling Perspective	Dr. Peter Basseches - Merck Research Labs
9	November 3, 2008	The International Registration Process	Dr. Romi Singh - Amgen
	November 10, 2008	Final Project Assignment Distributed	DMG
10	November 10, 2008	Public Policy Issues: Lecture and Discussion	Dr. Robert Hunter, Merck US Pharma
11	November 17, 2008	Outcomes Research: Lecture and Workshop	Dr. Kim Brodovicz- Merck Research Labs
12	November 24, 2008	Pharmacoeconomics	Dr. Erik Dasbach - Merck Research Labs
	December 1, 2008	Final Course Wrap-up and Discussions If Needed	DMG
	December 5, 2008	Final Project Due via email at COB	