Course Syllabus

PubH 6161 Regulatory Toxicology
(taught concurrently with CVM 6545 An Introduction to Regulatory Medicine)
Spring Semester 2008

Credits: 2
Meeting Days: January 14-18, 22-25, and one additional class period to be arranged.
Meeting Time: 5:30 - 7:30 pm
Meeting Place: Most classes will be held in Room 155 Peters Hall. The January 25 class will be held in Magrath Library Room 4.
Instructor: Elizabeth Wattenberg, Ph.D.
Office Address: Division of Environmental Health Sciences, 1110 Mayo, 420 Delaware Street SE
Office Phone: 612-626-0184
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Instructor: Mike Murphy, DVM, PhD, JD
Office Address: Vet Diagnostic Medicine, E220 VetDL, 6184, 1333 Gortner Ave
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Office Hours: call or e-mail to make an appointment

I. Course Description
The course will provide students with an introduction to current issues in regulatory toxicology and regulatory affairs. This includes an overview of the discovery, preclinical, and clinical phases of medical product development. Local industry, government, and academic experts will provide product specific examples of the application of regulatory principles.

II. Course Prerequisites
Some background in toxicology or pharmacology is very useful.

III. Course Goals and Objectives
To learn how toxicology is applied in real world regulatory situations. This includes learning about the complexities and competing interests that are part of regulatory decision-making. To learn how to access Freedom of Information data and critique the premarket review process.
IV. Methods of Instruction and Work Expectations

The method of instruction is primarily lecture. Students are expected to attend all classes and participate in class discussions. Students are expected to read local and national editions of newspapers and journals to keep up with the latest news-making regulatory issues. Students are also required to complete the assignment described below.

Class assignment: Choose a product of interest. Access the Freedom of Information (FOI) web site for the appropriate agency (for example, the FDA). Critique the testing done on the product. The paper should discuss the following:

(1) A brief summary of what was done and what the studies showed were potential adverse effects;

(2) The degree to which the FOI data are what you anticipated from what you've learned in class;

(3) The strengths and weaknesses of the study design. In other words what issues do you think were appropriately addressed and what issues do you think were not appropriately addressed prior to market release;

(4) Any adverse events that have been reported on the product after it got out into the marketplace, and the suggested plan for preventing such problems in the future.

The paper should be 4-10 double-spaced pages.

Students must turn in a product name and confirmation of access to the FOI site for the product by January 18, 2008.

Assignment due February 28, 2008.

We will arrange to meet for one additional class period during Spring Semester in which students will give brief presentations on their class assignment.

V. Course Text and Readings

Highly Recommended Reading:

Dark Remedy. The Impact of Thalidomide and its Revival as a Vital Medicine.

By Trent Stephens and Rock Brynner. Students need to order and purchase this book on their own. One copy will be on reserve at the Biomedical Library.

Useful Reference:

Regulatory Toxicology, second edition. Edited by Shayne C. Gad. One copy will be on reserve at the Biomedical Library.

Additional readings may be listed during the course of the semester.

Useful Websites:

Free online course in PHARMACOGENOMICS

http://www.accp1.org/~user/index.html

Freedom of Information/FDA

http://www.fda.gov/foi/foia2.htm
VI. Course Outline/Weekly Schedule

Monday, January 14:
*Introduction and Overview of Course, Grading, Drugs, Devices, Biologics, and Food*
Betsy Wattenberg and Mike Murphy

*The Importance of Patents in Medical Product Development*
Jim Ciapetta, Patent Counsel, Boston Scientific

Tuesday, January 15:
*FDA - Organization, Inspection Practices, and Enforcement Actions*
Tim Phillips, Compliance Officer, Office of Regulatory Affairs, Food and Drug Administration

Wednesday, January 16:
*Animal Biologics*
Kim Gugisberg, D.V.M., RLATG, CMAR, Assoc. Director of Quality Assurance for Bio R&D, Fort Dodge Animal Health

*Melamine Causes Renal Failure – True or False?*
Mike Murphy

Thursday, January 17:
*Human Drug Development*
Anthony Kiorpes, Adjunct Professor, Veterinary Population Medicine

Friday, January 18:
*Labeling for the Consumer Product Safety Commission and California’s Proposition 65*
Catherine F. Jacobson, Ph.D., DABT, 3M Material EHS

*Product name and confirmation of access to the FOI site for the product due.*

Monday, January 21, Holiday

Tuesday, January 22:
*Animal Welfare & Institutional Animal Care and Use Committee (IACUC), Institutional Review Board, (IRB), Investigational Device Exemption (IDE’s), Investigational New Drug (IND’s) and Good Laboratory Practice (GLP) Audits*
Richard W. Bianco, Associate Professor of Surgery, Director of Experimental Surgery, Deputy Vice Chairman of Surgery, University of Minnesota

Wednesday, January 23:
*Neutraceuticals*
Joy Frestedt, PhD, RAC, CCTI
Independent Consultant and Vice President, Clinical Affairs
BridgePoint Medical. Inc.

Thursday, January 24:
*Food Animal Drug Development*
Scott Brown, DVM, PhD, DCVCP, Senior Director, Metabolism & Safety, Pfizer Animal Health

Friday, January 25, 2008:
*International Regulatory Affairs*
Ann Johnson, Toxicology Specialist, 3M Material EHS.
VII. Evaluation and Grading

[Enter a detailed statement of the basis for grading here. Include a breakdown of course components and a point system for achieving a particular grade. Please refer to the University's Uniform Grading Policy found at www.umn.edu/usenate/usen/policies.htm]

[If applicable, there should also be a statement on penalties for late work and/or a make-up exam policy.]

Incomplete Grade

A grade of "I" (incomplete) will not be permitted except in the case of a documented emergency (e.g., medical). If an incomplete is deemed appropriate by the instructor, the student, in consultation with the instructor, will prepare a detailed written agreement specifying the time and manner in which the student will complete the course requirements. The written contract will give explicit details for every component of the course which remains to be completed. Extension for completion of the work will not exceed one year. The written agreement must be submitted to the instructor, major coordinator and the Student Services Center prior to the date by which grades must be entered at the end of the term.

After a review of transcripts (end of semester), instructors teaching School of Public Health courses will be contacted by the Student Services Center regarding assigned grades of "I" for students. If a written agreement exists between the student and instructor, the incomplete will remain on the transcript per the terms of the agreement. If a written agreement does not exist and an incomplete was submitted for the student without a written agreement, a grade of "F" or "N" will be officially submitted by the Student Services Center. If the student does not comply and meet the deadlines as determined in the written agreement, a grade of “F” or “N” will be officially submitted by the Student Services Center.

University of Minnesota Uniform Grading and Transcript Policy

A link to the policy can be found at onestop.umn.edu.

VIII. Other Course Information and Policies

Grade Option Change (if applicable)

For full-semester courses, students may change their grad option, if applicable, through the second week of the semester. Grade option change deadlines for other terms (i.e. summer and half-semester) can be found at onestop.umn.edu.

Course Withdrawal

Students should refer to the Refund and Drop/Add Deadlines for the particular term at onestop.umn.edu for information and deadlines for withdrawing from a course. As a courtesy, students should notify their instructor and, if applicable, advisor of their intent to withdraw.

Students wishing to withdraw from a course after the noted final deadline for a particular term must contact the School of Public Health Student Services Center at sph-ssc@umn.edu for further information

Student Conduct, Scholastic Dishonesty and Sexual Harassment Policies

Students are responsible for knowing the University of Minnesota, Board of Regents’ policy on Student Conduct and Sexual Harassment found at www.umn.edu/regents/polindex.html.

Students are responsible for maintaining scholastic honesty in their work at all times. Students engaged in scholastic dishonesty will be penalized, and offenses will be reported to the Office of Student Academic Integrity (OSAI, www.osai.umn.edu).

The University’s Student Conduct Code defines scholastic dishonesty as “plagiarizing; cheating on assignments or examinations; engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; or altering, forging, or misusing a University academic record; or fabricating or falsifying of data, research procedures, or data analysis.”

Plagiarism is an important element of this policy. It is defined as the presentation of another's writing or ideas as your own. Serious, intentional plagiarism will result in a grade of "F" or "N" for the entire course. For more information on this policy and for a helpful discussion of preventing plagiarism, please consult University policies and procedures regarding academic integrity: http://writing.umn.edu/tww/plagiarism/.
Students are urged to be careful that they properly attribute and cite others’ work in their own writing. For guidelines for correctly citing sources, go to [http://tutorial.lib.umn.edu/](http://tutorial.lib.umn.edu/) and click on “Citing Sources”.

In addition, original work is expected in this course. It is unacceptable to hand in assignments for this course for which you receive credit in another course unless by prior agreement with the instructor. Building on a line of work begun in another course or leading to a thesis, dissertation, or final project is acceptable.

If you have any questions, consult the instructor.

**Disability Statement**

It is University policy to provide, on a flexible and individualized basis, reasonable accommodations to students who have a documented disability (e.g., physical, learning, psychiatric, vision, hearing, or systemic) that may affect their ability to participate in course activities or to meet course requirements. Students with disabilities are encouraged to contact Disability Services to have a confidential discussion of their individual needs for accommodations. Disability Services is located in Suite180 McNamara Alumni Center, 200 Oak Street. Staff can be reached by calling 612/626-1333 (voice or TTY).