Nikou, Roshan

From: Graduate.Council.Web.Site@www.uky.edu
Sent: Wednesday, October 31, 2007 11:27 AM
To: Nikou, Roshan
Cc: Price, Cleo
Subject: Investigator Report

AnyForm User: www.uky.edu
AnyForm Document: http://www.research.uky.edu/gs/GCInvestigatorReport.html
AnyForm Server: www.uky.edu (/www/htdocs/AnyFormTurbo/AnyForm.php)
Client Address: 128.163.70.200

College/Department/Unit: = PHR 564
Category:_ = New
Date_for_Council_Review: =
Recommendation_is:_ = Approve
Investigator: = Dexter Speck
E-mail_Address = dfspeck@uky.edu
1__Modifications: = NOne
2__Considerations: = Dr. Wermeling has taught this course twice under special topics during the time this application has been working its way through the system! In Fall 2006 there were 13 students and there are 10 students taking it this semester. According to Dr. Wermeling, in our region, there is only 1 other school with a similar course. It has been favorably received by students and serves an important role for the professional students interested in careers in government and commercial agencies.
Under the grading policies in pharmacy, there are no D and E grades for the professional students so the syllabus seems appropriate.
3__Contacts: = listed above
4__Additional_Information: = I will be out of town the week of Nov. 5-12, but I think the application is clear and I recommend we go ahead.

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APPLICATION FOR NEW COURSE

1. Submitted by College of Pharmacy Date January 25, 2006

   Department/Division offering course Pharmacy Practice and Science

2. Proposed designation and Bulletin description of this course

   a. Prefix and Number PHR 564 b. Title* Introduction to FDA and the Drug Development Process

   *NOTE: If the title is longer than 24 characters (including spaces), write
   A sensible title (not exceeding 24 characters) for use on transcripts FDA & Drug Development

   c. Lecture/Discussion hours per week 2 d. Laboratory hours per week

   e. Studio hours per week f. Credits 2

   g. Course description

   A broad overview of the regulatory and scientific principles employed in pharmaceutical development including the regulatory framework and pre-clinical experimentation necessary to initiate a first time in human (Phase 1) trial through the objectives, principles, study designs, methods and reporting to evaluate a new pharmaceutical in a human. Students will develop an understanding of how certain forms of translational, or "bench to bedside" research must be organized and executed . Pre-req: enrollment in the Colleges of Pharmacy, Dentistry, Law, Medicine or Public Health, the NIH K-30 program, a junior or senior undergraduate, or consent of instructor.

   h. Prerequisites (if any)

   Enrollment in the Colleges of Pharmacy, Dentistry, Law Medicine, or Public Health, the NIH K-30 program, a junior or senior undergraduate, or consent of instructor

   i. May be repeated to a maximum of N/A (if applicable)

4. To be cross-listed as

   Prefix and Number Signature, Chairman, cross-listing department

5. Effective Date Fall 2006 (semester and year)

6. Course to be offered ☒ Fall ☐ Spring ☐ Summer

7. Will the course be offered each year? ☒ Yes ☐ No
   (Explain if not annually)

8. Why is this course needed?

   Many health profession students are directly impacted by the manner in which new pharmaceutical products are developed, marketed and used by their patients. Moreover, many health profession and biology/chemistry trained students will be employed in this industry. There is no other course on campus to provide the framework for health product development to these students.

   OCT 17 2007

9. a. By whom will the course be taught? Dr. Daniel Wermeling & a few guest lecturers

b. Are facilities for teaching the course now available? ☒ Yes ☐ No
If not, what plans have been made for providing them?

APPLICATION FOR NEW COURSE

10. What enrollment may be reasonably anticipated? 10-30 students

11. Will this course serve students in the Department primarily? ☒ Yes ☐ No

    Will it be of service to a significant number of students outside the Department? ☒ Yes ☐ No
    If so, explain.

    The College has had requests from the AG Biotech Program for the course and interest from other campus programs

    Will the course serve as a University Studies Program course? ☐ Yes ☒ No

    If yes, under what Area? _____

12. Check the category most applicable to this course

    ☐ traditional; offered in corresponding departments elsewhere;

    ☐ relatively new, now being widely established

    ☒ not yet to be found in many (or any) other universities

13. Is this course applicable to the requirements for at least one degree or certificate at the University of Kentucky? ☒ Yes ☐ No

14. Is this course part of a proposed new program: ☐ Yes ☒ No
    If yes, which?

15. Will adding this course change the degree requirements in one or more programs?* ☐ Yes ☒ No
    If yes, explain the change(s) below

16. Attach a list of the major teaching objectives of the proposed course and outline and/or reference list to be used.

17. If the course is a 100-200 level course, please submit evidence (e.g., correspondence) that the Community College System has been consulted. ☐ Check here if 100-200.

18. If the course is 400G or 500 level, include syllabi or course statement showing differentiation for undergraduate and graduate students in assignments, grading criteria, and grading scales. ☒ Check here if 400G-500.

19. Within the Department, who should be contacted for further information about the proposed course?

    Name Daniel Wermeling, Pharm.D., Associate Professor Phone Extension 3-7499

*NOTE: Approval of this course will constitute approval of the program change unless other program modifications are proposed.

APPLICATION FOR NEW COURSE

Signatures of Approval:

Department Chair	4/21/06 Date
Dean of the ~~College~~ Associate Academic Affairs	4-21-06 Date
*Undergraduate Council	Date of Notice to the Faculty 10-2-07 Date
;ity Studies Jeannine Blackwell Digitally signed by Jeannine Blackwell DN: cn=Jeannine Blackwell, c=US, o=University of Kentucky, ou=Graduate School, email=jeannine.blackwell@uky.edu Date: 2007.11.13 13:55:15 -05'00'	Date
*Graduate Council	Date
*Academic Council for the Medical Center	5.11.06 Date
*Senate Council (Chair)	Date of Notice to University Senate

*If applicable, as provided by the Rules of the University Senate

ACTION OTHER THAN APPROVAL

Rev 3/04

Introduction to the FDA and Drug Development Process
PHR 564
Two Credit Hours

Course Outline

Course Director: Daniel Wermeling. Pharm.D.
Associate Professor
231 A College of Pharmacy
Tel: 3-7499
Email: dwermel@uky,edu
Office hours via appointment

Course Schedule: Two One-hour Lectures per Week, Room TBA

Prerequisites

Enrollment in the Colleges of Pharmacy, Medicine, Dentistry, Law or Public Health, the NIH K-30 program, junior or senior undergraduate student, or consent of instructor

Course Overview

This course is designed to provide a broad overview of the regulatory and scientific principles employed in pharmaceutical development. The first segment of the course, through Exam 1, is designed to demonstrate the regulatory framework and pre-clinical experimentation necessary to initiate a first time in human (Phase 1) trial. The second segment of the course, through Exam 2, is designed to focus on human clinical research objectives, principles, study designs, methods and reporting to evaluate a new pharmaceutical in a human. Integration of the two segments permits an understanding of how certain forms of translational, or "bench to bedside", research must be organized and executed.

Course Objectives:

This course offering provides education in drug development, regulation and clinical research. Upon completion of this course a student shall be able to:

1. Describe the history and regulation of the drug approval process for different types of pharmaceutical products
2. Describe the scientific considerations in designing human research studies that meet specific drug development goals
3. Apply the information obtained in class to contemporary drug development problems

Blackboard Discussion Group

The course director will provide a document of interest by handout, direction to a web address, or place the article in the Course Documents section of Blackboard for review by all students. Question(s) will be posted about the article and responses are to be placed in the Blackboard Discussion section. There will be three discussion documents throughout the semester, approximately one per month. A grade will be assigned for participation and thoughtfulness of Blackboard answers.

Grading

Exam # 1	35%
Exam # 2	35 %
BlackBoard Discussion	30%
Total	100%

Exam format will be multiple-choice, short answer and essay responses. There are two exams scheduled and will be up to 1 hour in duration.

Specific exam questions may be reconsidered upon request of a student. The instructor reserves the right to re-review the question and the entire exam with the final results applying to all students. Exams graded incorrectly must be brought to the attention of the instructor in writing within five days of receiving the graded exam. Five days after the exam grade is returned all grades become final and no corrections will be made, except for an incorrect entry in the grade book.

A course letter grade assignment is determined by summing the weighted points allocated for exam and discussion board scores. The letter grade assignments are:

A = 90 – 100 points
B = 80-89 points
C= 70-79 points
F= $\leq$ 69 points

Graduate Student Requirements

Graduate students enrolled in the course are required to complete an additional assignment. The instructor will provide direction to write an outline of how they would approach a drug development problem. The problem will be derived from contemporary issues in drug development and appropriate for the background and degree being sought by the student. The grade will be determined by the student demonstrating understanding of the problem, the issues being raised, approaches that could be taken along with a rationale, and, finally, their recommendation for the way they would handle the problem. The final course grade for a graduate student will be determined by their scores on exams, Blackboard and the writing assignment. The breakdown of weighting is:

Exam 1	**25%**
Exam 2	**25%**
Blackboard	**25%**
Assignment	**25%**
Total	**100 %**

Course/Instructor Evaluations

Course evaluations are a part of the course requirements; therefore, if you do **not** complete an evaluation, **you will receive an incomplete grade ("I") for the semester**. When you complete the course evaluation, the incomplete grade will be changed to the grade earned in the course.

Regular course and instructor evaluations are required by state, university, college and accreditation regulations. These evaluations are essential for improving student learning by providing feedback to faculty about their classroom presentations. Based on your feedback, important decisions are made about courses and how they are taught. This process CANNOT work without your input. The College of Pharmacy administers these evaluations electronically through a web-based program. You will receive email notifications from the Office of Education Innovation (OEI) about when to complete a course and/or an instructor evaluation(s) for this course. Since these evaluations are completed electronically and each survey will be posted only for a limited time, you should check your university email account regularly. Please note that your individual responses are completely **anonymous**. However, the Office of Education Innovation can track who has or has not completed each evaluation and send reminder notices. Summary reports of aggregate data will be provided to the faculty after the semester is completed.

Course Meeting Schedule

The course meets for a 50 minute lecture two times per week. The course topic listing, instructor and dates are attached to the syllabus for reference.

Reading Assignments and Blackboard

Blackboard is utilized to provide access to the syllabus and course materials. Class announcements may be generated and posted. Reading assignments, useful references and lecture materials will also be posted. Students are encouraged to regularly check their Blackboard account.

PHR 564 Introduction to FDA and the Drug Development Proces

Course Schedule

Lecture #	Date	Faculty	Topic
1	TBA	Wermeling	Introduction & Government and Economic Influences on Pharma R & D
2		Fink	Pharmaceutical Patents & Market Exclusivity
3		Wermeling	Pharmaceutical Regulation 1938 to 1984
4		Wermeling	Pharmaceutical Regulation 1984 to Present
5		Wermeling	New Drug Application (505 b 1 NDA) and Biologic License (BLA) Process
6		Wermeling	Generic Drug Approval Regulation, Process and Science (ANDA 505 j)
7		Wermeling	Drug and Delivery Sytem Regulation, Process and Science (505 b 2 NDA)
8		Wermeling	OTC Drug and Nutraceutical Regulation and Process
9		Wermeling	Orphan Drug Regulation, Process and Science
10		Foster	Medical and Humanitarian Device Regulation & Science (IDE/PMA/510k)
11		Wermeling	Elements and Submission of an Investigational New Drug (IND) Application
12		Wermeling	Preclinical Pharm/Tox Requirements and Protocols
13		Wermeling	Preclinical Chemistry, Manufacturing and Controls (CMC) Requirements
14		Jay/Mumper	Good Laboratory Practices (GLP)
15		Jay Mumper	Good Manufacturing Practices (GMP)
16		Jay/Mumper	Process Analytical Technology Regulation and Science
17		Wermeling	Exam 1
18		Wermeling	Elements of an NDA or BLA Marketing Approval Submission
19		Wermeling	Post NDA Approval Requirements
20		Wermeling	Regulation of Labeling, Marketing and Advertising
21		Wermeling	FDA Inspections, 483 Process, Product Withdrawals
22		Foster	Research In Humans - Good Clinical Practices
23		Foster	Role of the IRB in Overseeing Clinical Research
24		Wermeling	Clinical Pharmacology - Objectives of Phase 1 Trials
25		Wedlund	Pharmacogenomics in Drug Development
26		Wermeling	Special Population Studies
27		Wermeling	Phase 2 and 3 Trial Objectives and Designs
28		Wermeling	Use of Surrogate Markers in Phase 2/3 Research
29		Wermeling	Clinical Study Logistics and Operations
30		Wermeling	Principles of Data Management
31		Hatton	Authorship, Report and Manuscript Writing
32		Wermeling	Exam 2

Brothers, Sheila C

From: Wermeling, Daniel
Sent: Thursday, November 15, 2007 3:51 PM
To: Brothers, Sheila C
Subject: RE: New Course Proposal for PHR 564

Sheila, thank you for calling to clarify my intent in the syllabus. It was my intent to have a single grading scale for all students regardless of their year in school. Students may complete assignments and tests to earn an A, B, or C as passing grades. It was not my intent to have "D" as a grade. I have had one undergraduate student from AG Biotech take the course and this did not seem to be an issue for him from the syllabus. He did make an "A" in the course for Fall 06. Hope this helps. Dan

Daniel Wermeling, Pharm.D.
Associate Professor
University of Kentucky College of Pharmacy
725 Rose Street
Lexington, KY 40536-0082
Tel: 859-323-7499
Fax: 859-257-9838
e: dwermel@uky.edu

From: Brothers, Sheila C
Sent: Thursday, November 15, 2007 3:21 PM
To: Wermeling, Daniel
Subject: New Course Proposal for PHR 564

Good afternoon, Daniel. I am writing in regards to the new course proposal for PHR 564 (attached).

There is one small problem with the syllabus that must be corrected before this can receive final reviews by the Senate Council and Senate.

On the syllabus, there is a grading scale for graduate students, but no undergraduate student grading scale. Because this course is open to undergraduates, such an inclusion is necessary.

If you could please send me a revised syllabus that includes both the graduate and undergraduate grading scales, I can put this on the next web transmittal and have this approved in time for spring 2008.

If you have any questions, please don't hesitate to let me know!

Thank you,
Sheila

Sheila Brothers
Office of the Senate Council
Administrative Coordinator
203E Main Building, -0032
Phone: (859) 257-5872
Fax: (859) 257-8375
sbrothers@uky.edu
http://www.uky.edu/USC/New

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Memorandum

TO: David Watt, Ph.D.
Associate Provost for Academic Affairs

FROM: William C. Lubawy, Ph.D.
Associate Dean for Academic Affairs
College of Pharmacy

DATE: April 21, 2006

RE: New courses, changes in existing courses and change in academic rules.

Attached are forms and syllabi for the following new courses: PHR 910, 920, 930, 940, 950, 953, 960 and 564. Also attached are course change forms for PHR 919, 929, 939, 949, 959 and 969 and the list of topics to be included in each. In this package is the rationale for these new courses in the page titled "Redesign of Contemporary Aspects of Pharmacy Practice (CAPP) Rationale.

Also attached is a recommendation and rationale for a change in the academic rules of the College of Pharmacy.

The material included in this package has been approved by the faculty of the College of Pharmacy and is submitted for consideration by the HCCC.

Redesign of Contemporary Aspects of Pharmacy Practice (CAPP) Rationale

CAPP was originally designed as a six semester sequence of courses consisting of lectures, laboratories and small group discussions, beginning in the fall of PY1 and ending in the spring of PY3, representing 33 credit hours across 6 individual courses. Its intent was to integrate all material in the curriculum around contemporary aspects of pharmacy practice.

A proposal to redesign the course sequence, maintaining the original intent of integration, but shifting the focus to patient-centered pharmacy practice, has been developed and was recently discussed by the College Curriculum Committee which has recommended it's approval by college faculty. The redesign is needed to meet ACPE accreditation standards. Specifically, information related to health and human behavior, ethics, public health and management have been missing from the CAPP curriculum. The absence of these topics from our curriculum has been documented during the past two accreditation site visits and must be addressed prior to our next accreditation site visit.

The new proposal splits the 33 credit hours into 13 individual courses across the 6 semesters - 7 didactic courses and a 6-semester laboratory course sequence. The didactic course modules coupled with the patient-centered laboratory course sequence will provide the background and experiences necessary for students to meet the practice outcomes as indicated in the College's approved outcomes documents.

There are four documents related to these changes

1. This one entitled "CAPP Rev 1 Rationale, Lec Descrip & Topics" providing the Rationale and the Lecture Description and Topics
2. A second entitled "CAPP Rev 2 Lab Descrip & Topics" containing the Lab description and topics
3. A third entitled "CAPP Rev. 3 Lecture Portion Forms" containing the New Course forms for #1 above.
4. A fourth entitled "CAPP Rev 4 Lab Portion Forms" containing the Course Change forms for # 2 above.

Number 1 and #2 are the SUMMARIES of the changes, including the topic sequences. These are the most important of the four documents to review. Number 2 also contains the templates for the integrated patient care laboratory, self-instructional laboratory content and the skill sets learned during each semester of the lab portion of the revision.

The Lecture Description and Topics list follows.