UNIVERSITY OF KENTUCKY

Current Course Report

10/21/2014 9:56:55 AM

Course Information

Date Submitted: 8/18/2014

Current Prefix and Number: PHS - Pharmaceutical Science, PHS 760 TOPS IN PHARMACEUT SCI

Other Course:

Proposed Prefix and Number: PHS 760

What type of change is being proposed?

Major Change

Should this course be a UK Core Course? No

1. General Information

a. Submitted by the College of: PHARMACY

b. Department/Division: Pharmaceutical Sciences

c. Is there a change in 'ownership' of the course? No

If YES, what college/department will offer the course instead: Select...

e. Contact Person

Name: Jim Pauly

Email: jim.pauly@uky.edu

Phone: 859.323.8164

Responsible Faculty ID (if different from Contact)

Name:

Email:

Phone:

f. Requested Effective Date

Semester Following Approval: Yes OR Effective Semester:

2. Designation and Description of Proposed Course

a. Current Distance Learning (DL) Status: N/A

b. Full Title: TOPICS IN PHARMACEUTICAL SCIENCES

Proposed Title: TOPICS IN PHARMACEUTICAL SCIENCES

c. Current Transcript Title: TOPS IN PHARMACEUT SCI

Proposed Transcript Title:

d. Current Cross-listing: none

Proposed – ADD Cross-listing :

Proposed – REMOVE Cross-listing:

e. Current Meeting Patterns

LECTURE: 15

Proposed Meeting Patterns

LECTURE: 15

f. Current Grading System: Graduate School Grade Scale

Proposed Grading System: *Graduate School Grade Scale*

g. Current number of credit hours: 1 - 4 (variable)

Proposed number of credit hours: 1 - 4

h. Currently, is this course repeatable for additional credit? Yes

Proposed to be repeatable for additional credit? Yes

If Yes: Maximum number of credit hours: 24

If Yes: Will this course allow multiple registrations during the same semester? Yes

2i. Current Course Description for Bulletin: pharmaceutical sciences which are not being covered in other courses. May be repeated to a maximum of 10 hours.

Proposed Course Description for Bulletin: Pharmaceutical sciences which are not being covered in other courses. May be repeated to a maximum of 24 hours.

2j. Current Prerequisites, if any: Prereq: Consent of instructor.

Proposed Prerequisites, if any:

2k. Current Supplementary Teaching Component:

Proposed Supplementary Teaching Component:

3. Currently, is this course taught off campus? No

Proposed to be taught off campus? No

If YES, enter the off campus address:

4. Are significant changes in content/student learning outcomes of the course being proposed? No

If YES, explain and offer brief rational:

5a. Are there other depts. and/or pgms that could be affected by the proposed change? No

If YES, identify the depts. and/or pgms:

5b. Will modifying this course result in a new requirement of ANY program? No

If YES, list the program(s) here:

6. Check box if changed to 400G or 500: No

Distance Learning Form

Instructor Name:

Instructor Email:

Internet/Web-based: No

Interactive Video: No

Hybrid: No

1.How does this course provide for timely and appropriate interaction between students and faculty and among students? Does the course syllabus conform to University Senate Syllabus Guidelines, specifically the Distance Learning Considerations?

2.How do you ensure that the experience for a DL student is comparable to that of a classroom-based student's experience? Aspects to explore: textbooks, course goals, assessment of student learning outcomes, etc.

3.How is the integrity of student work ensured? Please speak to aspects such as password-protected course portals, proctors for exams at interactive video sites; academic offense policy; etc.

4.Will offering this course via DL result in at least 25% or at least 50% (based on total credit hours required for completion) of a degree program being offered via any form of DL, as defined above?

If yes, which percentage, and which program(s)?

5.How are students taking the course via DL assured of equivalent access to student services, similar to that of a student taking the class in a traditional classroom setting?

6.How do course requirements ensure that students make appropriate use of learning resources?

7.Please explain specifically how access is provided to laboratories, facilities, and equipment appropriate to the course or program.

8.How are students informed of procedures for resolving technical complaints? Does the syllabus list the entities available to offer technical help with the delivery and/or receipt of the course, such as the Information Technology Customer Service Center (http://www.uky.edu/UKIT/)?

9.Will the course be delivered via services available through the Distance Learning Program (DLP) and the Academic Technology Group (ATL)? NO

If no, explain how student enrolled in DL courses are able to use the technology employed, as well as how students will be provided with assistance in using said technology.

10.Does the syllabus contain all the required components? NO

11.I, the instructor of record, have read and understood all of the university-level statements regarding DL.

Instructor Name:

SIGNATURE|CHAPPELL|Joseph Chappell|PHS 760 CHANGE Dept Review|20140814

SIGNATURE|FROMA2|Frank Romanelli|PHS 760 CHANGE College Review|20140814

SIGNATURE|JDLIND2|Jim D Lindsay|PHS 760 CHANGE HCCC Review|20140917

SIGNATURE|ZNNIKO0|Roshan N Nikou|PHS 760 CHANGE Graduate Council Review|20141015

Courses | Request Tracking

Course Change Form

https://myuk.uky.edu/sap/bc/soap/rfc?services=

Open in full window to print or save

Generate R

Attachments:

Browse... Upload File

	ID	Attachment
Delete	3538	PHS 760 Drug Discovery Development and Translation

First 1 Last

Select saved project to retrieve... Get New

NOTE: Start form entry by choosing the Current Prefix and Number
(*denotes required fields)

	Current Prefix and Number:	PHS - Pharmaceutical Science / PHS 760 TOPS IN PHARMACEUT SCI	*Proposed Prefix & Number:* (example: PHY 401G) ☑ Check if **same** as current	PHS 760

* What type of change is being proposed?

- ☑ Major Change
- ☐ Major – Add Distance Learning
- ☐ Minor - change in number within the same hundred series, ex 799 is the same "hundred series"
- ☐ Minor - editorial change in course title or description which do change in content or emphasis
- ☐ Minor - a change in prerequisite(s) which does not imply a cha course content or emphasis, or which is made necessary by the significant alteration of the prerequisite(s)
- ☐ Minor - a cross listing of a course as described above

Should this course be a UK Core Course? ○ Yes ◉ No

If YES, check the areas that apply:

☐ Inquiry - Arts & Creativity	☐ Composition & Communications - II
☐ Inquiry - Humanities	☐ Quantitative Foundations
☐ Inquiry - Nat/Math/Phys Sci	☐ Statistical Inferential Reasoning
☐ Inquiry - Social Sciences	☐ U.S. Citizenship, Community, Diversity
☐ Composition & Communications - I	☐ Global Dynamics

1. General Information

a. Submitted by the College of: PHARMACY Submission Date: 8/18/2014

b. Department/Division: Pharmaceutical Sciences

c.* Is there a change in "ownership" of the course?

○ Yes ◉ No If YES, what college/department will offer the course instead? Select...

e.* * Contact Person Name: Jim Pauy Email: jim.pauly@uky.edu Phone: 859.323.8164

* Responsible Faculty ID (if different from Contact) Email: Phone:

f.* Requested Effective Date: ☑ Semester Following Approval OR Specific Term: 2

2. Designation and Description of Proposed Course.

a. Current Distance Learning(DL) Status:

- ◉ N/A
- ○ Already approved for DL*
- ○ Please Add
- ○ Please Drop

*If already approved for DL, the Distance Learning Form must also be submitted unless the department affirms (by checking this box) that the proposed chang affect DL delivery.

b.	**Full Title:**	TOPICS IN PHARMACEUTICAL SCIENCES	*Proposed Title:* *	TOPICS IN PHARMACEUTICAL SCIENCES
c.	**Current Transcript Title** (if full title is more than 40 characters):	TOPS IN PHARMACEUT SCI		

c.	*Proposed Transcript Title (if full title is more than 40 characters):*				
d.	**Current Cross-listing:**	☐ N/A	OR	Currently[3] Cross-listed with (Prefix & Number):	none
	Proposed – ADD[3] Cross-listing (Prefix & Number):				
	Proposed – REMOVE[3,4] Cross-listing (Prefix & Number):				

e. **Courses must be described by at least one of the meeting patterns below. Include number of actual contact hours[5] for each meeting patterr**

Current:	Lecture 15	Laboratory[5]	Recitation	Discussion	Indep. Stu
	Clinical	Colloquium	Practicum	Research	Residency
	Seminar	Studio	Other	Please explain:	
*Proposed: **	Lecture 15	Laboratory[5]	Recitation	Discussion	Indep. Stu
	Clinical	Colloquium	Practicum	Research	Residency
	Seminar	Studio	Other	Please explain:	

f.	**Current Grading System:**	Graduate School Grade Scale		
	*Proposed Grading System:**	○ *Letter (A, B, C, etc.)* ○ *Pass/Fail* ○ *Medicine Numeric Grade (Non-medical students will receive a letter grade)* ◉ *Graduate School Grade Scale*		
g.	**Current number of credit hours:**	1 - 4 (variable)	*Proposed number of credit hours:**	1 - 4
h.*	**Currently, is this course repeatable for additional credit?**			◉ Yes ○
*	*Proposed to be repeatable for additional credit?*			◉ Yes ○
	If YES:	*Maximum number of credit hours:*		24
	If YES:	*Will this course allow multiple registrations during the same semester?*		◉ Yes ○

i. **Current Course Description for Bulletin:**

pharmaceutical sciences which are not being covered in other courses. May be repeated to a maximum of 10 hours.

* *Proposed Course Description for Bulletin:*

Pharmaceutical sciences which are not being covered in other courses.
May be repeated to a maximum of 24 hours.

j. **Current Prerequisites, if any:**

Prereq: Consent of instructor.

* *Proposed Prerequisites, if any:*

*

k.	**Current Supplementary Teaching Component, if any:**	○ Community-Based Experience ○ Service Learning ○ Both
	Proposed Supplementary Teaching Component:	○ Community-Based Experience ○ Service Learning ○ Both ○ No Change
3.	**Currently, is this course taught off campus?**	○ Yes ◉
*	*Proposed to be taught off campus?*	○ Yes ◉
	If YES, enter the off campus address:	
4.*	**Are significant changes in content/student learning outcomes of the course being proposed?**	○ Yes ◉
	If YES, explain and offer brief rationale:	
5.	**Course Relationship to Program(s).**	
a.*	**Are there other depts and/or pgms that could be affected by the proposed change?**	○ Yes ◉
	If YES, identify the depts. and/or pgms:	
b.*	**Will modifying this course result in a new requirement[Z] for ANY program?**	○ Yes ◉
	If YES[Z], list the program(s) here:	
6.	**Information to be Placed on Syllabus.**	
a.	☐ Check box if changed to 400G or 500.	If changed to 400G- or 500-level course you must send in a syllabus and *you must include the differentiation* between under graduate students by: (i) requiring additional assignments by the graduate students; and/or (ii) establishing different grading course for graduate students. (See *SR 3.1.4.*)

[Y]See comment description regarding minor course change. *Minor changes are sent directly from dean's office to Senate Council Chair.* If Chair deems the change as "not minor," the form will b appropriate academic Council for normal processing and contact person is informed.
[Z]Courses are typically made effective for the semester following approval. No course will be made effective until all approvals are received.
[1] Signature of the chair of the cross-listing department is required on the Signature Routing Log.
[2] Removing a cross-listing does not drop the other course – it merely unlinks the two courses.
[3] Generally, undergrad courses are developed such that one semester hr of credit represents 1 hr of classroom meeting per wk for a semester, exclusive of any lab meeting. Lab meeting gene least two hrs per wk for a semester for 1 credit hour. (See *SR 5.2.1.*)
[4] You must also submit the Distance Learning Form in order for the course to be considered for DL delivery.
[4]In order to change a program, a program change form must also be submitted.

Submit as New Proposal Save Current Changes

Syllabus

Title: Topics in Pharmaceutical Sciences: Drug Discovery, Development, and Translation
Semester: Fall 2014
Course #: PHS 760-006 entire course (3 credits) or

PHS 760-007	Topics in Pharmaceutical Sciences: Discovery	08/27/2014 – 10/01/2014
PHS 760-008	Topics in Pharmaceutical Sciences: Development	10/06/2014 – 11/05/2014
PHS 760-009	Topics in Pharmaceutical Sciences: Regulatory, Clinical Pharmacology & Commercial	11/10/2014 – 12/10/2014

Course Coordinator	**Office**	**Phone**	**Email**
Linda P. Dwoskin	465 Bio Pharm	257-4743	ldwoskin@uky.edu

Module Coordinators

Brad Anderson (Module 2)	A323A ASTeCC	218-6536	bande2@email.uky.edu
Rob Lodder (Module 3)	223 Bio Pharm	955-0845	lodder@uky.edu
James Pauly (Module 1)	451 BBSRB	323-8164	Jim.pauly@uky.edu
Jon Thorson (Module 1)	463 Bio Pharm	218-0140	jsthorson@uky.edu

Coordinators will organize the schedule of topics, deliver lectures, assign readings, discuss topics, evaluate student presentations, grade term papers and assign grades for PHS 760.

Course Structure:
The Course is designed in a modular format. There are three modules each worth 1 credit. Students may sign up for either one or two modules or for the entire course. Each module is intended to be independent, but concepts presented in one Module will be relevant generally to material presented in the other Modules.

Course meetings:
Mondays & Wednesdays, 5:00 PM -6:30 PM
Fridays, October 24 & October 31, 5:00 PM -6:30 PM
Location: Bio Pharm 234

Course Objectives:
1. Provide students with an overview and introduction to major concepts and issues of importance to obtain a general understanding the multidisciplinary and translational process from discovery to commercialization of new therapeutic agents.
2. Enhance appreciation for multidisciplinary efforts in drug discovery, development, regulatory, clinical pharmacology and commercialization of therapeutic agents.
3. Enable students to think critically, interpret and evaluate research findings from different disciplines and/or levels of analysis.
4. Enhance interdisciplinary communication and presentation skills.

Course Description:
This course is designed to introduce, review and discuss major topics, concepts and the translational process from drug discovery, development, regulatory, clinical pharmacology to commercialization of therapeutic agents. The course will consist of two 90-min course meetings each week. Course meetings will consist of a combination of faculty lectures/discussion and student-led presentations. The faculty presentation will be designed to provide a general overview of the current state of knowledge (e.g., theory, methods, ethics, and review of classic and/or exemplary studies) pertaining to a particular step in the drug discovery & development pathway. At the beginning of each module, each student will be assigned an exemplar drug to follow through

the steps of the pathway throughout the module. The individual drug assignments help the student to relate the course material to an actual drug product on the market. Class members will be called upon during the student-led presentation portion of each course meeting to describe relevant activities and findings for their assigned drug germane to the specific step and milestones in the pathway being discussed. Active participation by all class members is expected during course meetings. Exemplar drugs assigned may be the same drug or a different drug for each module. For each module, a term paper will be written by each student describing and integrating the steps in the pathway for that module for their particular assigned drug. The term paper will summarize the course of events/activities for their assigned drug as it met the milestones for each step in the pathway to commercialization. The term paper also will include a reflective statement on the aspect of pathway that was most compelling for future refinement-modification for their assigned drug, and the reasons for their choice. It is expected that the term paper will integrate the steps in the pathway for each student's assigned drug within the larger framework of the discovery and development pathway for new therapeutics. The course of study will provide a strong background in the translational pathway from discovery to commercialization.

Prerequisites:
This course is an introductory graduate level course intended for students interested in one or more steps in the pathway of drug discovery, development, regulatory, clinical pharmacology and commercialization. Enrollment requires consent of the course coordinator.

Readings:
There is no text book for this course, although recommended reading material will be provided by individual instructors. Recommended readings of relevance to the faculty presentation will be accessible via PubMed and will be assigned the week prior to the discussion. Resources such as the IUPHAR guide (http://www.guidetopharmacology.org/index.jsp), Merck Manual (http://www.merckmanuals.com/professional/clinical_pharmacology.html) will be identified in class to aid in researching the assigned drug for each module.

Attendance:
Attendance at all course meetings is required. Due to the nature of the course, there is no substitute for attendance and participation in class discussions. The Course Director must be notified directly regarding absences prior to class. The course coordinator has the right to request appropriate verification. All decisions regarding excused and unexcused attendance will be at the final discretion of the Course Coordinator. Students will be expected to compensate for both excused and unexcused absences in consultation with relevant lecturers and course director. Two unexcused absences will result in a one letter grade drop for that module. In the event of an unanticipated closing of the University, all classes will be cancelled and the coursework made up during the remaining time in the semester.

Blackboard:
All of the class material will be available on line using the Blackboard system. http://ecourses.uky.edu/?bbatt=Y
All of the PowerPoint presentations and accompanying references will be located in Class Materials.

Accommodations Due to Disability:
If you have a documented disability that requires academic accommodations, please see me as soon as possible during scheduled office hours. In order to receive accommodations in this course, you must provide me with a Letter of Accommodation from the Disability Resource Center (Room 2, Alumni Gym, 257-2754, email address: jkarnes@email.uky.edu) for coordination of campus disability services available to students with disabilities.

Academic Integrity:
Per university policy, students shall not plagiarize, cheat, or falsify or misuse academic records. Students are

expected to adhere to University policy on cheating and plagiarism in all courses. The minimum penalty for a first offense is a zero on the assignment on which the offense occurred. If the offense is considered severe or the student has other academic offenses on their record, more serious penalties, up to suspension from the university may be imposed.

Plagiarism and cheating are serious breaches of academic conduct. Each student is advised to become familiar with the various forms of academic dishonesty as explained in the Code of Student Rights and Responsibilities. Complete information can be found at the following website: http://www.uky.edu/Ombud. A plea of ignorance is not acceptable as a defense against the charge of academic dishonesty. It is important that you review this information as all ideas borrowed from others need to be properly credited.

Part II of *Student Rights and Responsibilities* (available online http://www.uky.edu/StudentAffairs/Code/part2.html) states that all academic work, written or otherwise, submitted by students to their instructors or other academic supervisors, is expected to be the result of their own thought, research, or self-expression. In cases where students feel unsure about the question of plagiarism involving their own work, they are obliged to consult their instructors on the matter before submission.

When students submit work purporting to be their own, but which in any way borrows ideas, organization, wording or anything else from another source without appropriate acknowledgement of the fact, the students are guilty of plagiarism. Plagiarism includes reproducing someone else's work, whether it be a published article, chapter of a book, a paper from a friend or some file, or something similar to this. Plagiarism also includes the practice of employing or allowing another person to alter or revise the work which a student submits as his/her own, whoever that other person may be.

Students may discuss assignments among themselves or with an instructor or tutor, but when the actual work is done, it must be done by the student, and the student alone. When a student's assignment involves research in outside sources of information, the student must carefully acknowledge exactly what, where and how he/she employed them. If the words of someone else are used, the student must put quotation marks around the passage in question and add an appropriate indication of its origin. Making simple changes while leaving the organization, content and phraseology intact is plagiaristic. However, nothing in these Rules shall apply to those ideas which are so generally and freely circulated as to be a part of the public domain (Section 6.3.1).

Please note: Any assignment you turn in may be submitted to an electronic database to check for plagiarism.

Course Expectations:

1. Attendance and participation in class discussions. Due to the nature of this course, there is no substitute for attendance and participation in class discussions. The Course Director must be notified regarding excused absences prior to class. Students will be expected to compensate for both excused and unexcused absences in consultation with relevant faculty members and the Course Director.
2. Command of suggested readings. Because the course is designed to promote discussion of interdisciplinary research, students have a responsibility to the class as a whole to be prepared for discussion of suggested readings.
3. Student presentations in class on assigned drug. Students will be prepared to present the step in the translational pathway with respect to their assigned exemplar drug at each class meeting. Faculty will select the students to discuss their assigned drugs for each scheduled session.
4. Term paper. Each student will write a term paper describing and integrating the steps in the pathway for their particular assigned drug. Thus, the term paper will summarize the course of events/activities for their assigned drug as it met the milestones for each step in the pathway to commercialization. The term paper also will include a reflective statement on the aspect of pathway that was most compelling for future refinement/modification for their assigned drug. It is expected that the term paper will integrate the steps

in the pathway for each student's assigned drug within the larger process.

Grading:

Each Module will be graded independently and the grades for the three Modules will be averaged to yield an overall course grade for PHS 760. For the PHS 760 series, grades for independent Modules will stand as the grade for that Module. Grades will be determined by a combination of student presentation, term paper and class participation. The course will be graded on the basis of 500 total points. Final letter grades will be assigned by the Course Coordinator. The approximate grading scale is outlined below; however, the scale may be adjusted, according to class performance.

	Points	Letter Grade	Total Points
Student presentations	200	A	500 – 400
Term paper	200	B	399 – 300
Class participation	100	C	299 – 200
	500	E	199 & below

Student evaluations of the course are welcome at any time and will be specifically solicited at the end of the course.

Office Hours:

Individual instructors will arrange individual office hours on an as needed basis.
Syllabus is subject to change with sufficient notice.

Schedule

Module I: Discovery			
Week	Date	Topic	Faculty
1	W: Aug 27	Introduction / History of Drug Discovery Overview of the Drug Discovery / Development Process	Pauly
2	M: Sept 1	**Labor Day – No Class**	
	W: Sept 3	Targets/Validation – Enzymes, Ion Channels, Transporters, Receptors, Nucleic Acids	Pauly
3	M: Sept 8	Assay Development / Validation and Screening	Beulter (NCI)
	W: Sept 10	Systems of Pharmacology / Bioinformatics / Omics	TBN
4	M: Sept 15	Lead Sources – Natural Products, DOS, Combichem	Thorson
	W: Sept 17	Lead Sources – Biologics, Rational Design and Virtual Screening	Zhan
5	M: Sept 22	Hit MOA – Chemical Biology / Omics	Thorson
	W: Sept 24	Hit Prioritization – Models for Efficacy / Models for Toxicology	Pauly
6	M: Sept 29	Drug Resistance Mechanisms and Strategies to Counteract	Garneau-Tsodikova
	W: Oct 1	**Student Presentations**	
Module II: Development			
Week	Date	Topic	Faculty
7	M: Oct 6	PK/PD principles	McNamara
	W: Oct 8	Metabolism (Phase I/II)	McNamara
8	M: Oct 13	Transport (Phase III – efflux/uptake) relationships	McNamara
	W: Oct 15	Overview & API Characterization: Properties and Analytical Methods	Anderson
9	M: Oct 20	Formulation strategies/issues for parenteral administration	Anderson
	W: Oct 22	Physiology of GI tract/models for oral drug development	Anderson
	F: Oct 24	Nanotechnology-based drug delivery systems	Anderson
10	M: Oct 27	Oral solid dosage forms & API form selection for oral delivery	Anderson
	W: Oct 29	Controlled and extended release systems	Anderson
	F: Oct 31	**Student Presentations**	Anderson
11	M: Nov 3	Lecture rescheduled to Friday, October 24	
	W: Nov 5	Student Presentations rescheduled to Friday, October 31	
Module III: Regulatory, Clinical and Commercial			
Week	Date	Topic	Faculty
12	M: Nov 10	Regulatory – Law and Technology / Administrative Responsibilities	Kruger (Environ)
	W: Nov 12	Regulatory – R&D and cGxP	Swit (Duane Morris)
13	M: Nov 17	Regulatory – Clinical Considerations / Special Populations	Jones
	W: Nov 19	Clinical – Preclinical Trials / Clinical Trials	Ortiz (Protrials)
14	M: Nov 24	Clinical – Safety and Special Populations	Walsh
	W: Nov 26	Clinical – Monitoring and Analysis / Biomarkers	Couze (NIH)
15	M: Dec 1	Commercial – Company Pharmaceutical & Biotech Envt's / Clinical Research Organizations	Medendorp (Vertex)
	W: Dec 3	Commercial – Banking and Analysis / Investments	Harvey
16	M: Dec 8	Commercial –Law Firms and Government Agencies	Kesher (Haynes Boone)
	W: Dec 10	**Student Presentations**	