

February 14, 2011

Minutes- Senate Academic Programs Committee

February 9, 2011 3- 4 pm, Room 414 CRMS

Members in Attendance

Daniel Wermeling, Andrew Hippisley, Marilyn Duncan, Karen Badger, Esther Dupont-Versteegden, Michael Arrington, Mary Arthur

Members Absent

Greg Wasilkowski

Agenda

- **New Graduate Certificate in Pharmaceutical Science**
- New Ph.D. in Integrated Plant and Soil Science

The New Graduate Certificate in Pharmaceutical Science was presented by the Ester Dupont-Versteegden to members of the Senate Academic Programs Committee. The program offers College of Pharmacy students a pathway to study basic pharmaceutical sciences in the professional program. The goal is to encourage pharmacy students to consider a Ph.D. in pharmaceutical sciences upon graduation of the pharmacy school. The Gateway complements 2 other Gateway certificate programs offered by the College of Pharmacy. The educational requirements were not initially clear to the committee. A request was made for clarification on credits – the sponsors made a satisfactory response. The program was considered highly desirable by the committee members and well aligned with student and faculty initiatives.

A motion was made to approve the Gateway Certificate in Pharmaceutical Science. The motion was seconded and all members present voted in the affirmative – the motion carried.

The new Ph.D. program in Integrated Plant and Soil Science was presented by Greg Wasilkowski (written assessment) and Dan Wermeling (presentation) to members of the Senate Academic Programs Committee. The notion of the proposal is to integrate 5 different graduate programs under a single heading. The proposal states a number of advantages relates to critical mass of instructors, single entry point for applications and students, and single DGS, and ability to improve space management. Committee members commented that this proposal was the best submission In terms of thoughtfulness and breadth of consideration and could be a model for other submissions. The only question raised was whether the 5 current graduate programs would be eliminated. The sponsor stated that they would be suspended or withdrawn when all students in the various programs have completed or are no longer in the program.

A motion was made to approve the Integrated Plant and Soil Science Ph.D. Program. The motion was seconded and all members present voted in the affirmative – the motion carried.

April 29, 2010

TO: David Randall
Senate Council
201 Main Bldg.
CAMPUS 0032

Dear Dr. Randall,

I am transmitting to you the Proposal for the Graduate Certificate in
Pharmaceutical Science.

The Graduate Council approved this proposal on April 29, 2010.

 2010.04.30
10:46:25 -04'00'

Jeannine Blackwell, Dean
The Graduate School

Cc: Sheila Brothers

Brothers, Sheila C

From: Lindsay, Jim D.
Sent: Tuesday, April 13, 2010 10:04 AM
To: Blackwell, Jeannine; Nikou, Roshan
Cc: Romanelli, Frank; Price, Cleo; Brothers, Sheila C; LaRoche, Adrea S.; Anderson, Heidi Milia
Subject: HCCC Transmittal: Pharm. Sci. Graduate Certificate

April 13th, 2010

T R A N S M I T T A L

TO: Jeannine Blackwell, Chair and Roshan Nikou, Coordinator
Graduate Council

FROM: Heidi Anderson, Chair and Jim Lindsay, Coordinator
Health Care Colleges Council

On April 9th, 2010 the Health Care Colleges Council approved the following proposal via expedited consent agenda and is now forwarding it to the Graduate Council to approve:

College of Pharmacy

New Graduate Certificate in Pharmaceutical Science

The materials to implement the requested action are posted at: <http://www.uky.edu/curriculum/>

Cc Frank Romanelli
Cleo Price
Shelia Brothers
Adrea LaRoche
Heidi Anderson

Jim Lindsay
Health Care Colleges Council Coordinator
Associate Provost for Faculty Affairs Office
University of Kentucky, 205 Frazee Hall
Lexington, KY 40506-0031 Ph. (859) 323.6638
www.uky.edu/Provost/AcademicCouncil/council.php



UNIVERSITY OF KENTUCKY

*Dream * Challenge * Succeed*

November 16, 2009

Dr. Jeannine Blackwell
Dean, The Graduate School
University of Kentucky
Lexington, KY

Dean Blackwell:

Please accept the attached documentation as part of our application to create a "Pharmaceutical Sciences Research Gateway (PSRG) " leading to a graduate certificate in Drug Discovery and Development (GCDDD). As noted in the proposal, the purpose of the PSRG is to provide a meaningful opportunity for Pharm.D. students to gain valuable experience in the research field through graduate coursework and active participation in research activities. This curriculum will include a combination of 12 hours of graduate coursework, including three hours of independent study, with active participation in laboratory rotations, our summer research program, and part of experiential training in the fourth year of Pharmacy School. We believe that this graduate certificate will help distinguish our students, and make them more competitive for graduate school or other advanced educational opportunities.

I have been asked to serve as the Graduate Certificate Director, and have been working on this project for several months in coordination with various groups of faculty. The initial proposal was sent to all Graduate Faculty in Pharmaceutical Sciences for feedback and comment. After the proposal was approved by Graduate Faculty, it was reviewed and approved by our Graduate Program Committee, and by the College of Pharmacy Curriculum Committee. We believe the proposal is now ready for consideration by the Graduate Council. Please do not hesitate to contact me directly if you need any additional information.

Sincerely,

Jim Pauly, Ph.D.
Associate Professor of Pharmaceutical Sciences
323-8164
jpauly@uky.edu



UNIVERSITY OF KENTUCKY

**College of Pharmacy
Office of Education**
301 Pharmacy Building
Lexington, KY 40536-0082
(859) 257-5802
<http://www.mc.uky.edu/Pharmacy/depts/oei/>

MEMORANDUM

TO: Graduate School/Graduate Council

FROM: Frank Romanelli, Pharm.D., MPH, BCPS
Associate Dean and Associate Professor, Member Graduate School Faculty

RE: COP Certificate in Pharmaceutical Science

DATE: December 8, 2009

Please find enclosed a formal proposal for consideration by the Graduate School in regards to the formal establishment of a ‘Certificate Curriculum in Pharmaceutical Sciences’ to be administered by the College of Pharmacy faculty. Documents within this submission include: certificate summary and procedures, syllabi from relevant graduate courses, a description of the SURP (Summer Research Program), and supporting letters from various College officials. This proposal reflects a culmination of several months work by the Colleges faculty and administration in designing and developing this offering. The proposal was presented to and approved by the Colleges curriculum committee and subsequently the faculty as a whole.

The certificate curriculum will offer Doctor of Pharmacy students enrolled at the College of Pharmacy an opportunity to pursue and foster interests in basic science research as it relates to drugs and drug discovery. The curriculum has been developed so that students enrolled in the professional program may focus their 8 hours of elective options in pharmaceutical science coursework which can then be augmented through both the Summer Research Program (SURP) and research based clerkships (completed in the final professional year). The over-arching goal for this proposed certificate curriculum is that the availability of this educational experience will facilitate interest in and transition to formal graduate training when interested students complete the Doctor of Pharmacy program.

Thank you for your time and consideration. Should you have any questions – please feel free to contact me at any time.

Graduate Certificate in Pharmaceutical Science

Purpose/Rationale

Integration of Pharm.D. students into the research environment is expected to have benefits for both faculty and students. The PSRG will provide current Pharm.D. students and other health care professionals with a graduate-level introduction to research in the Pharmaceutical Sciences. This Gateway will be designed for students interested in research within the pharmaceutical industry, hospitals, academia, or governmental agencies. The development of this certificate curriculum is expected to increase the number and competitiveness of Pharm.D students that seek postgraduate training opportunities, including the Ph.D. program in Pharmaceutical Sciences. This program could also be the springboard for future graduate programs including the Pharm.D./Ph.D. program and possibly an new M.S. program in Pharmaceutical Sciences.

Training Faculty

Dr. James Pauly (Gateway Coordinator)
Dr. Patrick McNamara
Dr. Robert Yokel
Dr. Linda Dwoskin
Dr. Paul Bummer
Dr. Chuck Loftin
Dr. Penni Black
Dr. Greg Graf
Dr. Kim Nixon
Dr. Steven Van Lanen
Dr. Jurgen Rohr
Dr. Audra Stinchcomb
Dr. Todd Porter
Dr. Mark Leggas

Gateway Outcomes

Following completion of this Gateway, the student will:

1. Appreciate the role of drug discovery in the process of pharmaceutical product development.
2. Understand basic elements of experimental design, performance of experiments, statistical analysis and interpretation of results.
3. Have an increased understanding of the ethical use of animals in biomedical research, and the ethics of science.
4. Develop an abstract and poster presentation describing the results of their research project. The poster will be presented to at a local or national pharmacy organization meeting.

Admission Requirements

- Undergraduate transcripts
- GRE Scores
- Acceptance into UK Graduate School
- Minimum GPA of 3.0 in Pharm.D. coursework
- Personal statement
- Letters of recommendation
- Previous research experience
- Identification of a mentor
- Completion of the certificate application form

Students who do not hold an awarded bachelor's degree must have at least 90 hours of undergraduate credits to apply to the Graduate School. An undergraduate grade point average of at least 2.75 on a 4.0 scale is required. In addition to course grades, the applicant's performance on the GRE, and letters of recommendation will be considered to establish admission eligibility. Priority for admission to this certificate curriculum will be given to students currently enrolled in the Doctor of Pharmacy degree program in good standing. Students must maintain a 3.0 grade-point average within the certificate curriculum in order to qualify for successful completion.

Certificate Specific Requirements

- A minimum of 9 Hours of Graduate Coursework
- 3 Hours of independent study in pharmaceutical research
- Participation in the Pharmaceutical Sciences (PS) Summer Research Program in the Professional Year (PY) 1-PY2 and/or PY2-PY3 year
- (2) 6 week research-based rotations in PY4
- Presentation at local or national meeting

Schedule for Completion

PY1 – Fall Semester - PHS 910 - Introduction to Gateways Module [core course]

PY1 – Spring Semester - Gateway Application and Selection

Summer 1 - PS Summer Research Program (1 or 2 years) [core experience]

PY2 – Fall Semester - PHS760 (Introduction to Pharmaceutical Sciences) [course course]

PY2 – Spring Semester – PSRG elective

Summer 2 - PS Summer Research Program (1 or 2 years) [core experience]

PY3 – Fall Semester - PSRG elective

PY3 – Spring Semester - 3 Hours of independent study in Pharmaceutical research [course course]

PY4 – (2) six-week research rotations, presentation at local or national meeting [core experience]

Possible Elective Courses

PHS 545 Sterile Products

PHS 612 Quantitative Pharmacodynamics: Pharmacokinetics

PHS 620 Biosynthesis of Natural Products

PHS 630 Pharmaceutical Rate Processes

PHS 631 Equilibrium Phenomena in Pharmaceutical Systems

PHS 665 Ethical Issues in Clinical Research

PHS 760-x Neurobiology of Abused Drugs

PHS 760-x Drug Targets and Actions

PHS 762 Bioorganic Mechanisms

PHS 764 Drug Development Regulation & Clinical Research

IBS 604 Cell Signaling

IBS 605 Experimental Genetics

PHA 522 Systems Pharmacology

STA 570 Basic Statistical Analysis

STA 671 Correlation/Experimental Design

Expected Enrollment - 5 to 8 students/yr



University of Kentucky College of Pharmacy

Summer Research Programs

Date: late May 2009 — late July 2009

Description

The UK College of Pharmacy offers two different ten-week programs for talented undergraduate and professional students to participate in paid research in Pharmaceutical Policy or in Traditional Pharmaceutical Sciences. Participants perform independent research, under the supervision of faculty mentors, graduate students or postdoctoral fellows, develop a poster presentation that describes their accomplishments, and have the opportunity to contribute to front-line research in either of these areas.

Students interested in Pharmaceutical Policy ([Pharmaceutical Policy Application Form \[pdf\]](#)) will have the opportunity to apply methods and techniques of public policy planning and analysis to issues involving pharmaceuticals, pharmacy, pharmacists and pharmacies under the guidance of our nationally recognized faculty.

In the Traditional Pharmaceutical Sciences area ([PS Application Form \[pdf\]](#)), students can work with faculty who are engaged in research in areas ranging from pre-clinical studies of drug actions, to fundamental mechanisms of drug actions at the molecular level, to the design, synthesis, development and formulation of new drug products. This program allows undergraduate students to obtain hands-on laboratory experience in state-of-the-art research facilities.

Deadline

Complete applications must be received by February 19, 2010 for the Traditional Pharmaceutical Sciences area and to be determined for Pharmaceutical Policy.

Who Should Apply

Current professional (PharmD) students or undergraduates who have completed their junior year by the beginning of the summer are encouraged to apply, but highly qualified sophomore students will also be considered. Completion of courses in general biology, organic or analytical chemistry will help the student get the most from these experiences. Ideal candidates are students who are interested in entering a PhD doctoral program, who have better than a 3.3 GPA and, for the

Traditional program, are pursuing an undergraduate major in Pharmaceutical Sciences, Chemistry, Chemical Engineering, Biology, or other Life Science.

Stipend

Students will receive a stipend of \$3,000 for 10 weeks of work.

NOTE: This program IS NOT intended for students interested in pursuing the Pharm.D. degree at a College of Pharmacy.

Research Projects of Students from the Summer Program

[The Effect of Dexamethasone on Anti-tumor and Chemotherapeutic Activity \[pdf\]](#)

Student: Daniel Cornett **Mentor:** [Dr. Mark Leggas](#)

[Small Interfering RNA-Mediated Silencing of Cytochrome P450 Reductase in Rat Hepatoma Cells \[pdf\]](#)

Student: Melissa Douglas **Mentor:** [Dr. Todd Porter](#)

[Dopamine Transporter Expression in a "Two-Hit" Rat Model of Parkinsonian Syndrome \[pdf\]](#)

Student: Clarissa Harris **Mentor:** [Dr. Jim Pauly](#)

[Characterization of Dusp1 in Lung Cancer \[pdf\]](#)

Student: Josh Lester **Mentor:** [Dr. Penni Black](#)

[Transdermal Capabilities of Clonidine for Opiate Withdrawal \[pdf\]](#)

Student: Nicole Scheff **Mentor:** [Dr. Audra Stinchcomb](#)

[Memory Deficits in Relation to Neurodegeneration in a Model of An Alcohol Use Disorder \[pdf\]](#)

Student: Carey Shaner **Mentor:** [Dr. Kim Nixon](#) in collaboration with Dr. Melissa Burns-Cusato at Centre College

[3D-QSAR Analysis of BChE Inhibitors \[pdf\]](#)

Student: Carlos Silva-Rivera **Mentor:** [Dr. Chang-Guo Zhan](#)

[Optimization of Immunoproteasome-Specific Inhibitor UK-101 \[pdf\]](#)

Student: Kate Smiley **Mentor:** [Dr. Kyung Bo Kim](#)

[Exploration of 7DHCR Expression \[pdf\]](#)

Student: Emily Sparks **Mentor:** [Dr. Todd Porter](#)

[Solubility Determination of Silatecan 7-t-Butyldimethylsilyl-10-Hydroxycamptothecin \(DB-67\) in Vitamin-E TPGS in the Presence and Absence of a Secondary Excipient\[pdf\]](#)

Student: Etagegn Tadesse **Mentor:** [Dr. Brad Anderson](#)

[Polymorphism of 2-Hydroxynicotinic Acid \[pdf\]](#)

Student: Kathryn Theiss **Mentor:** [Dr. Tonglei Li](#)

[Organic Synthesis of a Gilvocarcin Oxygenase Pathway Intermediate \[pdf\]](#)

Student: May Fern Toh **Mentor:** [Dr. Jurgen Rohr](#)

[Patient Interpretation of Qualitative Statements \[pdf\]](#)

Student: Dominique Comer **Mentors:** [Dr. Karen Blumenschein](#) and [Dr. Melanie Mabins](#)

[Becaplemin \(Regranex\) Use in Patients with Non-Healing Lower-Extremity Ulcers \[pdf\]](#)

Student: Velma Henry **Mentor:** [Dr. Jeffrey Talbert](#)

[Financial Obligations of Graduating Pharm.D. Students \[pdf\]](#)

Student: Mykel Tidwell **Mentor:** [Dr. Joseph Fink](#)

For more information contact:

Catina Rossoll

SURP Coordinator

UK College of Pharmacy Graduate Program Office

725 Rose St. Room 409

Lexington, KY 40536-0082

859-257-1998

cross2@email.uky.edu

Instructors:

Tim McClintock (Course Director), Ms585 Medical Science Building, Ph. 323-1083;
mcclint@uky.edu; Office hours: by appointment

Doug Andres, 179 BBSR Building, Ph. 257-6775; dandres@uky.edu

Olivier Thibault, MS320 Medical Science Building, 323-4863, othibau@uky.edu

Ming Gong, 509 Charles T Wethington Building, 323-4933 x81361, ming.gong@uky.edu

Mariana Nikolova-Karakashian, MS571 Medical Science, 323-8210, mnikolo@uky.edu

Anthony Sinai, MN419 Medical Sciences Building, 323-6680, sinai@uky.edu

Carol Pickett, MN374 Medical Science Building, 323-5313, cpickett@uky.edu

Brian Delisle, Ms577 Medical Science Building, 323-2797, brian.delisle@uky.edu

Jason Johnston, MS435 Medical Science Building, 257-5147, jjo222@uky.edu

George Luo, MN458A Medical Sciences Building, 257- 5577, gluo0@uky.edu

Room, Date, and Time: CTW 014, MWF, 9-9:50 am.

Evening Exams: Exams are listed in the Schedule. Note times and dates to avoid conflicts.

Description: This is a 3 credit course that focuses on inter- and intracellular communication, from the generation of signaling molecules through the cellular responses. It teaches concepts central to understanding cellular signaling mechanisms. It covers the major signaling pathways and several emerging pathways. Explanations of cellular and molecular techniques that are important to understanding key advances in this area are integrated into the material presented. Class sessions will include didactic lectures and group discussions of problem sets or reading assignments.

Objectives: To convey an understanding of key concepts about cellular signaling mechanisms, about the major signaling pathways identified to date, and about the methods used to study these pathways.

Textbook: None required. A recommended reference text is: Molecular Biology of the Cell, Fifth Edition, by Alberts, Johnson, Lewis, Raff, Roberts, and Walter. Garland Publishing.

Supplementary Materials: A limited number of reviews and primary articles will be assigned. Most will be available via the electronic journals page of the Medical Center Library website (<http://sfx.uky.edu/sfxlcl3/azlist/default>). Please note that you will need to access this site from a computer with a UK IP address.

Course Website via Blackboard. You will have password-level access to selected course material via the Blackboard server. Assignments will be posted there and we will also make use of some of the communication features. Most instructors will post their lecture files (ppt or pdf format) to this site. Responsibility for generating a hard copy of a lecture files rests with the students.

Examinations and Grading: There will be four closed book examinations. Each exam will be worth 20% of the final grade. The remaining 20% of the grade will be drawn from problem set assignments. The final exam is not comprehensive. Final grade assignments will be:

A ≥ 85%, weighted total percentage.

B ≥ 65%, weighted total percentage.

C ≥ 55%, weighted total percentage.

E < 55%, weighted total percentage.

For graduate students, there is no "D" grade. Scores and percentages will not be rounded.

Regrading: Students who believe that a mistake was made in the grading of an examination should re-submit the examination and a *signed note* to the course director that describes briefly which problem they want to have re-graded and why the grading was in error. Requests for re-grading of a particular examination must be submitted before the next examination or in the case of the final exam, within 3 weeks of the final exam. The examinations will be re-evaluated and returned with the subsequent examination, or mailed to the student in the case of the final exam. Regrading of problem sets may be done if a signed note that describes which problem they want to have re-graded and why the grading was in error is delivered to the course director within 7 days of the date on which the graded problem set was first made available to students.

Rescheduling Examinations: Make-up exams will be given only in rare instances. Requests for make-up exams due to illness must be made in writing to the course director and must include a statement signed by the treating physician. Approval for make-up exams due to scientific responsibilities out of state (presentation at a conference, for example) must be obtained in advance by providing to the course director documentation that proves that the student's absence is required (presenting author is an acceptable reason, attending a conference is not). Missing a scheduled exam for any other reason (such as going home early during finals week) will result in a score of zero for the exam.

Discussion Session problem sets: Answers must be machine printed and submitted by the beginning of class. Late submission of answers will result in at least a 20% penalty. These take home questions will be slightly more difficult than the typical exam question. You may discuss them with anyone, including your classmates. However, you must write your answers in your own words and may not copy text from any source. You may not share your written answers with classmates. You are responsible for understanding that copying or close paraphrasing of an answer from a classmate or a previous student in the course is plagiarism, as is copying or close paraphrasing without citation any published source.

Academic honesty. No form of dishonesty will be tolerated. Students are encouraged to read the Student Rights and Responsibilities with regard to cheating and plagiarism (<http://www.uky.edu/StudentAffairs/Code/part2-6.html>). Plagiarism detection software will be used on materials in this course. The punishment for cheating on an exam or plagiarism on an assignment is an E for the course.

IBS 604, CELL SIGNALING, LECTURE SCHEDULE:			Exam
W JAN. 14.	Introduction to signaling	McClintock	I
F JAN. 16.	Receptors and ligands I	McClintock	I
M JAN. 19.	MARTIN LUTHER KING BIRTHDAY		
T JAN. 21.	Receptors and ligands II	McClintock	I
F JAN. 23.	G-protein coupled receptors (GPCRs)	McClintock	I
M JAN. 26.	GPCRs: heterotrimeric G-proteins	McClintock	I
W JAN. 28.	Discussion I	McClintock	I
F JAN. 30.	GPCRs: effectors I	McClintock	I
M Feb. 2.	GPCRs: effectors II	McClintock	I
W FEB. 4.	Gasous messengers: NO and CO	McClintock	I
F FEB. 6.	Wnt and Hedgehog Signaling	McClintock	I
M FEB. 9.	Discussion II	McClintock	I
W FEB. 11	Exam I; CTW 014	6-8pm	
W FEB. 11.	Tyrosine kinase receptors	Andres	II
F FEB. 13.	Cytokine receptors	Andres	II
M FEB. 16.	Src kinases	Andres	II
W FEB. 18.	ras/MAPK pathways I	Andres	II
F FEB. 20.	ras/MAPK pathways II	Andres	II
M FEB. 23.	Mitogenic signaling	Andres	II
W FEB. 25.	Notch/Delta signaling	Andres	II
F FEB. 27.	Discussion III	Andres	II
W MAR. 2.	Focal adhesion signaling	Gong	II
M MAR. 4.	Rac/rho and the cytoskeleton	Gong	II
F MAR. 6.	Discussion IV	Gong	II
M MAR. 9.	Ion Channels: I	Delisle	III
T MAR. 10.	Exam II; CTW 014	6-8pm	
W MAR. 11.	Ion Channels II	Delisle	III
F MAR. 13.	Ion Channels III	Delisle	III
MAR. 16 -20.	UK SPRING BREAK		
M MAR. 23.	Ion Channels IV	Delisle	III
W MAR. 25.	Ion Channels V	Delisle	III
F MAR. 27.	Discussion V	Delisle	III
M MAR. 30.	Toll-like receptors	Karakashian	III
W APR. 1.	TGF beta signaling	Karakashian	III
F APR. 3.	Lipid signaling I	Karakashian	III
M APR. 6.	Lipid signaling II	Karakashian	III
W APR. 8.	Lipid signaling III	Karakashian	III
F APR. 10.	Discussion VI	Karakashian	III
M APR. 13.	Calcium homeostasis	Thibault	Final
W APR. 15.	Exam III; CTW 014	6-8pm	
W APR. 15.	Calcium signaling	Thibault	Final
F APR. 17.	Kinases and phosphatases	Thibault	Final
M APR. 20.	Calcium imaging and quantification	Thibault	Final
W APR. 22.	Discussion VII	Thibault	Final
F APR. 24.	Signaling and Toxins	Pickett	Final
M APR. 27.	Bacterial pathogens and signaling	Johnston	Final
W APR. 29.	Protozoan parasites	Sinai	Final
F MAY 1.	Viral pathogens and signaling	Luo	Final
MAY 7.	FINAL EXAM, 10:30a - 12:20p in MN263		
	Med. Sci		

STERILE PARENTERALS AND DEVICES

PHR 545

Course Description

This comprehensive course provides an understanding of the overall contemporary state of the technologies associated with the preparation of parenteral drug dosage forms. The emphasis will be on obtaining a fundamental knowledge of the principals involved in the preparation, evaluation and control of parenterals and the laboratory sessions will be oriented toward techniques of most current interest, the associated regulatory requirements in general, and quality control/process validation in particular.

Learning Objectives

As a result of attending this course students will gain:

1. An understanding of how the parenteral route developed, what were some of the significant developments, and the reasons for the overwhelming acceleration of its use during the last 25 years.
2. An understanding of the various formulation approaches to obtain the desired therapeutic results utilizing the appropriate routes of administration.
3. An understanding of aseptic manufacturing processes, facility and personnel requirements fostering an appreciation of the distinctive requirements of parenterals and acquaintance with the quality control procedures and federal regulations.
4. Through selected demonstration sessions, and experience of the various phases of parenteral technology.
5. An opportunity to pursue an independent special project and write a report in manuscript form and also make a verbal presentation.
6. An understanding of and appreciation for the use of parenterals and sterile technology in the clinical setting.
7. An appreciation of the parenteral systems of the future, namely particulate systems utilizing biodegradable polymers for extended release and site specific delivery.

PHR545

The course will involve reading assignments, about 4 hours per week. There will be 8 lecture sessions of 2-3 hour duration to review the assigned topics. The laboratory component will involve select demonstrations and the conduct of a special project. The structured lab sessions will be completed by Spring break and the remainder of the time will be devoted to an independent project, in which the student will undertake a literature research effort. This will require writing a proposal and the need for such a literature project, preparing a report and making a verbal presentation to the class. The latter will be part of the final examination.

Grading:

Midterm and Final Exams		300 points
Laboratory Reports		100 points
Independent Project:		
Proposal:	due by March 7	40 points
Written Report:	week of April 25	100 points
Verbal Presentation:	following final exam	<u>60 points</u>
	Total	600 points

Faculty:

Patrick P. DeLuca, Ph.D. (7-5292) <ppdelu1@uky.edu>
Dr. Joseph Wyse (323-6899) <joe.wyse@uky.edu>
Dr. Vidam Klyushnichenko (323-8115) <vklyu2@email.uky.edu>

TA:

Caroline Strasinger (249-1849) <clstra0@email.uky.edu>

Instructors:

STERILE PRODUCTS TECHNOLOGY – PHR 545**Topical Outline of Lectures/Reviews**

1. January 15
Tuesday Introduction and Organization of Course
Pre Test
Historical Overview
2. Jan 29 General Requirements, Routes of Administration,
Types of Parenteral Products
Philosophy of a GMP, Facility Design
Personnel Requirements & Environmental Control
3. February 12 Sterilization Methods
Validation of Sterilization
4. February 26 Processing, Special Processing, Freeze Drying
5. March 4 Formulation Principles
Principles Involve in Selection of Vehicles and Added
Substances for Small Molecules and Proteins (Buffers,
Antioxidants, Other Stabilizers, Solubilizers, Preservatives,
Tonicity Adjustors), Overview of Packaging for Parenteral
Products
- Week of March 3 Midterm Exam *to be scheduled*
Review Independent Projects
- March 10 Spring break
6. March 18 Quality Control
Sterility Testing, Pyrogen Testing (Rabbit and LAL)
Particulate Matter Testing, Container/Closure Integrity
Testing
7. April 1 FDA Inspections, Current Regulatory Trends
8. April 15 Sterile Technology in the Clinical Setting
Administration Devices, Techniques and Requirements, Total
Parenteral Nutrition and Fat Emulsions, Expectations and
Problems Associated with Contamination During
Administration
(Dr. Rapp)
9. April 29
or May 5 Final Exam – *date to be scheduled*
Presentation of Independent Projects

STERILE PRODUCTS TECHNOLOGY – PHR 545

Reading Assignments and Lecture and Review Schedule

Location for Lectures and Reviews: Coll of Nurs 214, Tuesdays, 9:00 – 10:50 AM

Principally from Pharmaceutical Dosage Forms: Parenteral Medications

<u>Week of:</u>	<u>Assignment:</u>	<u>Review Session¹:</u>
January 14	Microcontamination Control Reprint Chapters 1 – Vol. 1	January 15 (Drs Klyushnichenko/Wyse)
January 28	Chapter 2 – Vol. 1 Chapters 4, 6 and 7 – Vol. 2	January 29 (Drs Klyushnichenko/Wyse)
February 11	Chapters 8 – Vol. 2	February 12 (Drs Klyushnichenko/Wyse)
February 25	Chapter 4 – Vol. 3 Chapter 1 & 3 – Vol. 2	February 26 (Dr. DeLuca)
March 3	Chapters 4 and 5 – Vol. 1	March 4 (Dr. DeLuca)
Wk of Mar 3	Midterm Exam <i>date to scheduled</i> Review Independent Projects	
Spring Break – March 10 - 14		
March 17	Chapter 3 – Vol. 3	March 18 (Dr. DeLuca)
March 31	Chapters 5 and 6 – Vol. 3	April 1 (Dr. DeLuca)
April 14	Chapter 12 – Vol. 1	April 15 (Dr. Rapp)
April 28 - May 2	Final Exam – <i>date to be decided</i> Independent PROJECT PRESENTATIONS	

¹Reviews will be 1 hr 50 min on the dates designated. Additional sessions may be added if necessary to cover the material.

January 2008

STERILE PRODUCTS TECHNOLOGY - PHR 545

Laboratory Schedule: Fridays, 1:00-5:00 PM in 1st floor lab

Faculty: Joseph Wyse & Vadim Klyushnichenko
Teaching Assistant: Caroline Strasinger
Instructor:

<u>Date</u>	<u>Laboratory</u>	<u>Topic</u>
January 18	1	cGMPs Facility Design, Cold Stream Contamination Control
January 25	2	Component Processing & Testing For Non-Sterile Fill
February 1	3	Process Non-Sterile Fill, Autoclave & Term Sterilization Methods
February 8	4	QC Terminally Sterilized Product (Content Uniformity, Particulate Matter) Gowning Procedures. (Component Processing for Aseptic Fill)
February 15	5	Discuss and Prepare for Aseptic Fill & Lyophilization
February 22	6	Process Aseptic Fill, Lyophilize
February 29	7	QC Aseptically Filled Product (Reconstitution, Content Uniformity, Moisture Analysis, Particulate Analysis)
March 7	8	Media Fill Midterm Exam, Review of Special Projects
March 10 - 14		Spring Break
March 17 – April 25		Independent Projects

A 1-2 page laboratory report will be required for each session.

LEARNING OBJECTIVES FOR LECTURES ON PARENTERAL DRUG TECHNOLOGY, PHR 545

A. GENERAL

1. Differentiate between Small Volume Parenterals (SVPs and Large volume Parenterals LVPs).
2. List 4 types of SVPs and 5 LVPs.
3. Know the reasons why the injectable drug products have increased and will continue to increase.
4. Differentiate how the various routes of administration influence the design of the dosage form.
5. Name five basic characteristics or requirements of parenteral products.
6. Have an understanding of the therapeutic need for injectables and some of the disadvantages.
7. Describe how a parenteral dosage form can be formulated to effect a prolonged action. Show the relative order of absorption of the various dosage forms.

B. FORMULATION

1. List the phases of the Parenteral Product Development Process.
2. List five acceptable parenteral co-solvents and state the advantages and disadvantages of each.
3. List five non-aqueous (oil) vehicles used in parenterals. How would these be sterilized?
4. List the types of water and the requirements for Parenteral Products.
5. List three approaches to enhancing the solubility of a drug.
6. Name five commonly added substances to parenteral products and describe the purpose of each.
7. List three preservatives used in injectable projects.
8. List five buffer systems used in parenteral products and state the effective pH range.
9. Be able to calculate the relative amounts of sodium acetate and acetic acid required to provide a buffered solution at pH 4.5.

10. State the purpose of an antioxidant and how the free radical process is catalyzed and mediated.
11. State why tonicity adjusters are used in parenteral formulations and understand the relationship between osmolarity and tonicity and what toxicological issues are associated with parenterals which are not isotonic.

C. STERILIZATION AND VALIDATION

1. Name and describe the various sterilization methods. List their application.
2. List the lethal action of the various sterilization methods.
3. Name three factors which influence the lethal effectiveness of the thermal sterilization methods.
4. Why is steam sterilization more effective than dry heat sterilization?
5. What are the temperature-time requirements for the thermal methods of sterilization?
6. Discuss four measures which assure the adequacy of the sterilization cycle and the integrity of the resulting product.
7. Name two methods of Radiation Sterilization and discuss advantages and disadvantages of each.
8. Name a gaseous sterilization technique and understand its application.
9. Know when Aseptic Filtration would be used.
10. Understand the reasons and concepts for Validation.
11. Describe Validation of the Steam Sterilization Process.

D. OTHER

1. Understand the problem of people in a Sterile Product Processing Area.
2. Describe Laminar Air Flow and list the specifications for Critical and Controlled Processing Areas.
3. Describe the Freeze Drying Process. Be able to draw typical Temperature Times and Pressure Time curves for a freeze drying cycle.
4. Describe the Aseptic Processing of a Parenteral.

PHR 631 Equilibria in Pharmaceutical Systems

Spring 2008

Paul M. Bummer, Ph.D.

Rm A270 ASTeCC, telephone 218--6522, e-mail pbumm01@email.uky.edu

Class is held from 11 AM to 12:15 PM on Tuesdays and Thursdays in Room 211 Nursing (except Jan 31 and April 24 where we will meet in Room 501B Nursing).

This course probes in detail the physical chemical basis of a variety of equilibrium phenomena of particular interest to the pharmaceutical sciences. Topics include aqueous solubility of drugs, colligative properties of aqueous solutions, multiple ionic equilibria, molecular associations, macromolecular binding and complexation, and adsorption. The use of chemical thermodynamics in practical problems encountered in drug product formulation and drug delivery to biological systems will be highlighted. A prerequisite of the course is physical chemistry.

Textbook:

Ionic Equilibrium; Solubility and pH Calculations, James N. Butler; John Wiley, New York, 1998. (or equivalent).

Topics:

Unit 1: Homogeneous Equilibria

Write and solve mathematical models to characterize the concentrations of various ionized and un-ionized species in solution as a function of conditions (pH, ionic strength, etc).

To become familiar with the various methods of measuring pKa values and how the values are influenced by ionic strength, organic solvents, temperature and chemical structure. Emphasis will be on applying the appropriate method to the experimental conditions and on advantages and disadvantages.

Write and solve mathematical models to characterize microscopic equilibrium constants.

Unit 2. Solubility

Master the thermodynamic basis of ideal solubility of non-electrolytes in aqueous and nonaqueous systems

Estimate solubility through calculations employing regular solution theory, solvatochromic approaches and semi-empirical approaches. Be able to evaluate the advantages and limitations of each approach.

Write and solve mathematical models to characterize the solubility of species in solution as a function of conditions (pH, ionic strength, etc)

Design experiments for the determination of solubility for stable and unstable molecules

Unit 3. Solubilization

A. pH Control

Learn the theory behind the use of pH control as a means of enhancement of solubility.

Understand the physics underlying the methods of pH measurement and relate to proper use and care of pH-probes.

Write and solve mathematical models to characterize the concentrations of various species in solution as a function of pH.

B. Cosolvents

Learn the theory behind the use of co-solvents as a means of enhancement of solubility

Entropic and enthalpic interpretation to the use of co-solvents and pH control

C. Complexation

Learn the theory behind the use of inclusion complexes as a means of enhancement of solubility

Entropic and enthalpic interpretation to the structure-activity relationships of inclusion complexes

Write and solve mathematical models to characterize the concentrations of various species in solution as a function of macromolecular binding and multi-state models

Unit 4. Self-Association

Understand the relationship of the properties of water, the hydrophobic effect and self-association of molecules (drugs and lipid assemblies) in aqueous solution.

Unit 5. Surface Adsorption

Understand the thermodynamic basis of adsorption to surfaces
Learn the theory of surface states of matter

Characterization of liquid surfaces and insoluble monolayers.

Examinations

Midterm examination: 25 % of grade

Final examination: (non-inclusive) 25 % of grade

Term paper: 20% of grade (topics to be assigned after the midterm examination).

The term paper will be due 1 week prior to the final examination.

Literature Critique: 3 short papers at 10% each

Homework will be assigned as needed, but not graded.

Midterm examination on 5 March 2008

Spring Break 10-14 March 2008

Term paper due 9 April 2008

Final Examination on 16 April 2008

Attendance

Class attendance is not required and will not be monitored. However, class attendance is highly encouraged. If there is to be a late submittal of the term paper or an inability to attend an examination, the student is expected to communicate with the professor as soon as is practical. Other arrangements will then be made to carry out the assigned tasks.

**PHR 760-008: Molecular Neurobiology of Abused Drugs (3 credits)
Spring Semester, 2008**

Syllabus

Class meetings:

This course meets once per week for 2.5 hrs (Thursday, 3:00-5:30 pm)
Location (BBSRB, 202A)

<u>Coordinator:</u>	<u>Office</u>	<u>Telephone</u>	<u>e-mail</u>
Linda P. Dwoskin	B343 BBSRB	257-4743	ldwoskin@email.uky.edu

Dr. Dwoskin will organize the schedule of topics, deliver lectures, assign readings, and assign grades for PHR 760-008.

Instructors:

Other PHR 760-12 Faculty:	Office	Phone	Email
Bardo, Michael T.	B447 BBSRB	257-6456	mbardo@email.uky.edu
Crooks, Peter	501B Col Pharmacy Bldg	257-1718	pcrooks@uky.edu
Gerhardt, Greg	311 Whitney-Hendrickson Facility	323-4531	gregg@uky.edu
Hersh, Louis B.	B283 BBSRB	323-5549	lhersh@uky.edu
Maragos, William	262 HSR Bldg	323-6702 x240	maragos@uky.edu
Nixon, Kimberly	B351 BBSRB	323-3038	kim-nixon@uky.edu
Pauly, Jim	B451 BBSRB	323-8164	jpauly@uky.edu
Prendergast, Mark A.	B449 BBSRB	257-6120	prender@uky.edu
Rodgers, David W.	B269 BBSRB	257-5205	david.rodgers@uky.edu
Snow, Diane M.	MN212 Med Sci Bldg	323-2613	dsnow@pop.uky.edu
Stinchcomb, Audra	459 Wethington Bldg	323-6192	astin2@email.uky.edu
Taylor, Palmer	UCSD		pwtaylor@ucsd.edu
Walsh, Sharon	643 Maxwellton Court	323-6126	sharon.walsh@uky.edu
Welch, Sandra P.	Virginia Commonwealth Univ		swelch@vcu.edu
Zhan, Chang-Guo	B355 BBSRB	323-3943	czhan6@email.uky.edu

Faculty will give lectures, assign readings, evaluate class discussions and grade term papers.

Objectives:

1. Introduce students to major concepts and issues of general importance with respect to the molecular neurobiology of drug abuse and dependence.
2. Enable students to interpret and evaluate research findings from different disciplines and/or levels of analysis.
3. Enhance appreciation for multidisciplinary efforts in drug abuse and dependence research.
4. Enhance interdisciplinary communication skills.

Course Description:

This course is designed to review major topics, concepts and issues pertinent to the molecular neurobiology of drug abuse and dependence. The course will consist of weekly presentations (90 min) by faculty and open discussions (60 min) led by class members regarding assigned readings of relevance to the faculty presentation. Active participation by all class members is expected. Each weekly faculty presentation is

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) in a given area of drug abuse and dependence research. Student-led open discussions will review recent literature on the topic assigned by the faculty member. Discussions are intended to integrate the information across traditional disciplinary boundaries. A term paper will be written by each student on a topic of the student's choice and approved by the course director, which is focused on recently reported research findings in drug abuse and dependence. The focus of the term paper will be to interpret the new findings in light of the currently accepted understanding of the topic. Taken together, the proposed course of study will provide a strong background in neuroscience and students will be informed about current trends in our understanding of the molecular neurobiology of drug abuse research.

Prerequisites:

This course is an introductory graduate level course intended for students pursuing focused research training in one or more areas of drug abuse and dependence. No special prerequisites, other than graduate standing, are necessary.

Readings:

There is no textbook for this course. Assigned readings will be accessible via Pubmed.

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. Students will be expected to compensate for both excused and unexcused absences in consultation with relevant faculty members.
2. Command of assigned readings. Because the course is designed to promote discussion of interdisciplinary research publications, students have a responsibility to the class as a whole to be prepared for discussion of assigned readings (1-2 papers) during class sessions.
3. Regarding leadership of assigned class discussions, students will take the responsibility to coordinate class discussions on assigned literature (1-2 papers) during at least one class meeting of the semester. As discussion leaders, it will be the student's responsibility to stimulate productive discussion related to the assigned literature. Faculty will select the literature to be discussed for the scheduled session. It is expected that the discussion topics will integrate information across disciplines.
4. Regarding the term paper, each student will write a term paper on a topic of the student's choice, approved by the course director, and focused on recently reported research findings in drug abuse and dependence. The focus of the term paper will be to interpret the new findings in light of the currently accepted, scholarly understanding of the topic; and, it is expected that the discussion will integrate these new findings across disciplines. The topic of the term paper should be chosen in consultation with the course director. It is the responsibility of the student to contact the course director well in advance for consultation to review the literature options.

Grades:

Grades will be determined by a combination of leadership of assigned discussions, class participation and term paper.

	<u>% of grade</u>
Class Participation	20
Discussion Leadership	40
Term paper	<u>40</u>
	100

Progress reports will be provided to the students for class participation and discussion leadership every four weeks. Student evaluations of the course are welcome at any time and will be specifically solicited at the end of the course.

The course will be graded on the basis of 500 total points. Final letter grades will be assigned by Dr. Dwoskin. The approximate grading scale is outlined below; however, the scale may be adjusted, according to class performance.

<u>Letter Grade</u>	<u>Total Points</u>
A	500 – 400
B	400 – 300
C	300 – 200
E	below 200

Schedule of Topics:

Jan 10	Orientation to molecular and cellular mechanisms of drug abuse and dependence (Dwoskin)
Jan 17	Drug abuse during neural development – prenatal and adolescent nicotine and cocaine exposure (Pauly and Snow)
Jan 24	Drug disposition: Pharmacokinetic concepts relevant to abused drugs (Stinchcomb)
Jan 31	Molecular and cellular mechanisms/adaptations of psychostimulant abuse: methamphetamine (Dwoskin)
Feb 7	Molecular and cellular mechanisms/adaptations of cannabinoids abuse (Welch)
Feb 14	Molecular and cellular mechanisms/adaptations of psychostimulant abuse: cocaine (Bardo)
Feb 21	Molecular and cellular mechanisms/adaptations of opioid abuse (Hersh)
Feb 28	Molecular and cellular mechanisms/adaptations of psychostimulant abuse: nicotine (Dwoskin and Crooks)
March 6	Molecular and cellular mechanisms/adaptations of alcohol abuse (Prendergast and Nixon)
March 13	Modeling and structural contributions: nicotinic receptors (Taylor)
	Spring Break
March 20	Modeling and structural contributions: opioids (Rodgers)
March 27	Modeling and structural contributions: cocaine (Zhan)
April 3	Neuropathogenesis of drugs of abuse (Gerhardt)
April 10	Drugs of abuse and interaction with HIV/AIDS (Maragos)
April 17	Development of novel pharmacotherapies for the treatment of drug abuse: cannabinoids (Stinchcomb)
April 24	Development of novel pharmacotherapies for the treatment of drug abuse: methamphetamine or opioids (Crooks and Walsh)
May 1	EXAM WEEK

College of Pharmacy
PHR 762
Bioorganic Mechanisms

Professor Peter A. Crooks, Instructor

Course Policy

No textbook has been recommended for this course. Students are advised to consult the collection of typed lecture notes provided by faculty members involved in the teaching of the course. A set of lecture notes is available to students.

It must be emphasized that the lecture notes do not cover all of the subject matter to be given in the course, and it is recommended that students use them to supplement their notes taken in class. **Taking class notes and attending classes are of paramount importance. Typed lecture notes alone could not possibly cover all the material.**

Compulsory attendance is required for the course.

Lectures will be given at 5pm on Mondays and Wednesdays in Room 222, College of Pharmacy, and will be 75 minutes duration. Course assessment will take the form of three exams/take home projects, placed at suitable intervals during the course. Each of these is like a final examination with equal weighting toward the final grade. In case of an excused absence from an examination, the student must take a make-up within two weeks following the exam.

MAKE-UP EXAMS ARE CONSIDERABLE MORE DIFFICULT THAN THE ORIGINAL EXAM.

UNIVERSITY OF KENTUCKY
COLLEGE OF PHARMACY

SYLLABUS
PHR 762 – BIOORGANIC MECHANISMS
SPRING 2009

<u>Number of Lectures</u>	<u>Date</u>	<u>Title of Lecture</u>	<u>Professor</u>
		<u>Enzyme Kinetics</u>	<u>Dr. Tai (10.5 hours, 7 lectures)</u>
1	Jan. 14	Kinetics of unireactant: Michaelis-Menton equation	
2	Jan. 21	Kinetics of unireactant and multireactants: derivation of rate equations	
3	Jan. 26	Kinetics of multireactants: kinetic mechanisms	
4	Jan. 28	Inhibitor and substrate effects: I. Competitive, non-competitive and uncompetitive inhibition	
5	Feb. 2	Inhibitor and substrate effects: II. Product inhibition and abortive complex	
6	Feb. 4	Inhibitor and substrate effects: III. Substrate inhibition and complex mechanisms	
7	Feb. 9	Isotope exchange studies; pH effects	
		<u>Receptor Mechanisms and Kinetics</u>	<u>Dr. Dwoskin (1.5 hours, 1 lecture)</u>
1	Feb. 11	Receptor mechanisms and kinetics	
<u>EXAM:</u>	Feb. 16		
		<u>Chemical Catalysis</u>	<u>Dr. Crooks (15 hours, 10 lectures)</u>
1	Feb. 18	General concepts and strategies; in-depth treatment of selected samples	
2	Feb. 23	Active site-directed mechanism-based inhibitors; suicide inhibitors	
3	Feb. 25	Transition state analogs and multi-substrate inhibitors	
4	Mar. 2	Stereospecificity in bioorganic reactions	
5	Mar. 4	Pyridoxal-dependent reactions I	
6	Mar. 9	Pyridoxal-dependent reactions II	

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| 7 | Mar. 11 | S-Adenosylmethionine-dependent reactions;
in vitro model reactions; mechanisms of enzymic reactions |
| 8 | Mar. 23 | Methyltransferases, aminopropyltransferases;
C-methyltransferases, N- and O- methyltransferases |
| 9 | Mar. 25 | Folate-dependent reactions;
thymidylate synthase;
mechanism of inactivation by 5-flourouracil |
| 10 | Mar. 30 | Kinase and phosphorylase enzymes;
mechanism and stereochemistry |

EXAM: **Apr. 1**

Chemical Approaches to Cell Biology **Dr. Kim (12 hours, 8 lectures)**

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|---|---------|--|
| 1 | Apr. 6 | Chemical genetics overview |
| 2 | Apr. 8 | Protein kinases
a. Kinases as regulators of signaling pathways
b. Modulators |
| 3 | Apr. 13 | Microtubules
a. Target as pharmaceuticals
b. Inhibitors |
| 4 | Apr. 15 | Immunophilins
a. Immunosuppressive natural products: FK-506 and Cyclosporin A
b. Modulators |
| 5 | Apr.20 | Chromatin remodeling
a. Controlling gene transcription
b. Modulators: natural products and small molecules |
| 6 | Apr. 22 | Ubiquitin-proteasome pathways
a. Protein degradation machinery
b. Small molecule inhibitors |
| 7 | Apr. 27 | Angiogenesis
a. Starving cancer cells
b. Small molecule inhibitors |
| 8 | Apr. 29 | Screening bio-active small molecules: new approaches |

EXAM: **May 6**

PHS 612 Monday, Wednesday, Thursday			Rm. College of Pharmacy 206; 5:00-6:00 pm		8/24 to 12/10/2009
Day	Date	Module	Specific Topic	Instructor	Reading
Mon.	8-24-09	1	Overview	Wedlund	NA
Organizational Meeting, Structure, Expectations			Therapeutic range, Infusion rate, Maintenance dose, Loading Dose, PK development		
Wed.	8-26-09	2	Mathematical & Chemical Kinetics	Wedlund	NA
			Mathematical principles, Laplace Transformations, Chemical Kinetics Review, Zero Order and First Order Processes		Assignment #1
Thur.	8-27-09	3	Analytical Issues	Wedlund	NA
			Sensitivity, Specificity, Quality Controls, importance of assay in PK and PD research		
Mon.	8-31-09	4	Parameter Estimation	Wedlund	361-388 G&W
			Minimizing variation in data on PK parameters, Non-linear regression		
Wed.	9-02-09	5	Computer Workshop	Leggas	
Class in Leshaft Lab 3rd Floor COP			Experience with Excel, Prism, WinNonlin, Adapt and Stella		
Thur.	9-03-09	6	One Compartment Models	Wedlund	11-51 G&W
			Differential equations and integrated forms for 1 cmpt. Model with IV bolus and infusion		Assignment #2
Mon.	9-07-09	LABOR DAY	NO CLASS TODAY		Work on HW
Wed.	9-09-09	7	One Compartment Models	Wedlund	11-51 G&W
			Absorption parameters, non-parental dosing, multiple dosing		
Thur.	9-10-08	8	Modeling Strategies	Leggas	389-463 G&W
			Initial estimates, goodness of fit, Discrimination between models		
Mon.	9-14-09	9	Multi-compartment models	Wedlund	63-84 G&W
			Two compartment model IV bolus & infusion, non-parental dosing, multi-compartment general form		
Wed.	9-16-09	10	Clearance Models	Wedlund	51-54 G&W
			Clearance concepts, blood flow, intrinsic clearance, protein binding		Assignment #3

PHS 612 Monday, Wednesday, Thursday			Rm. College of Pharmacy 206; 5:00-6:00	8/24 to 12/10/2009	
Day	Date	Module	Specific Topic	Instructor	Reading
Thur.	9-17-09	11	Clearance Models	Wedlund	86-104 G&W
			Well stirred, parallel tube and dispersion models of hepatic clearance, in-vivo & in-vitro implications of models, first pass effects		
Mon.	9-21-09	12	Clearance Models	Wedlund	
			Renal parameter estimation, prediction, role in clearance		
Wed.	9-23-09	13	Model Independent methods	Wedlund	161-176 G&W
			AUC, AUMC, MRT, MAT and use in place of cmpt. models		
Thurs.	9-24-09	14	Non Linear Pharmacokinetics	Wedlund	125-157 G&W
			Capacity limited and time limited, flow and binding		Assignment #4
Mon.	9-28-09	Exam #1	Material 8-24 through 9-23	Wedlund & Leggas	EXAM #1
Wed	9-30-09	15	Turn over Models	Wedlund	105-123 G&W
			Turnover concepts, Feedback mechanisms in PK		
Thurs.	10-01-09	16	Metabolite Kinetics	Wedlund	177-179 G&W
			Metabolite profiles, formation & elimination clearance		
Mon.	10-05-09	17	Metabolite Kinetics	Wedlund	
			Assumptions and effects on predictions of metabolites		
Wed.	10-07-09	18	Exposure & Interspecies Scaling	Leggas	181-222 G&W
			Exposure, flow models, interspecies scaling and allometry		
Thur.	10-08-09	19	Ligand – Protein interaction	Wedlund	225-234 G&W
			Protein binding, metabolism, transport, affinity and capacity, plotting and assessments		
Mon.	10-12-09	20	Pharmacodynamic Models	Lee	236-250 G&W
			Linear and Log-Linear Models, Emax and Hill Modification		
Wed.	10-14-09	21	Interaction Models	Lee	251-289 G&W
			Competitive & Non-competitive, Antagonism, Kinetics of response		Assignment #5
Thurs.	10-15-09	22	Indirect Response Models	Lee	261-289 G&W
			Reversible and Irreversible mechanisms, Alternative models		

PHS 612 Monday, Wednesday, Thursday			Rm. College of Pharmacy 206; 5:00-6:00	8/24 to 12/10/2009	
Day	Date	Module	Specific Topic Area	Instructor	Reading
Mon.	10-19-09	23	Other Models	Lee	221-257 G&W
			Dose-response, time models, Tolerance, Rebound, baseline		
Wed.	10-21-09	24	Population Pharmacokinetics	Leggas	NA
			Bassian Pharmacokinetics, NONMEM Approaches		
Thurs.	10-22-09	25	Study Design Elements	Leggas	464-484 G&W
			Tools for experimental Design, General design issues		Assignment #6
Mon.	10-26-09	27	Bioavailability Assessment	Wedlund	43 and handouts
			Rate and extent of absorption, Bioequivalence study, Statistics		
Wed.	10-28-09	28	Factors affecting Drug Absorption	Wedlund	NA
			Oral Route of Administration, other routes of dosing and effects		
Thur.	10-29-09	29	Drug movement across membranes	McNamara	Handouts
			BCS & BDDCS; Membrane transfer; Diffusion, Active and passive, transporter systems		Assignment #7
Mon.	11-02-09	30	Drug Movement across Membranes	McNamara	Handouts
			Transporters on PK/PD; In-vitro-In vivo systems to study transport		
Wed.	11-04-09	31	Drug Movement across Membranes	McNamara	Handouts
			Transporters ; IV and IV systems, models to study transporter s		
Thurs.	11-05-09	Exam #2	Material 9-24 through 10-28	Wedlund	Exam #2
				Leggas	
				Lee	
Mon.	11-09-09	No Class	AAPS Meeting	No Class	AAPS Meeting
			Los Angeles, CA		
Wed.	11-11-09	No Class	AAPS Meeting	No Class	AAPS Meeting
			Los Angeles, CA		
Thurs.	11-12-09	No Class	AAPS Meeting	No Class	AAPS Meeting
			Los Angeles, CA		
Mon.	11-16-09	32	Reversible metabolism issues	Wedlund	
			PK equations to describe reversible metabolism and impact on clearance		
Wed.	11-18-09	33	Reversible metabolism issues	Wedlund	
			PK equations and their assumptions regarding inter-conversion processes		

PHS 612 Monday, Wednesday, Thursday			Rm. College of Pharmacy 206; 5:00-6:00	8/24 to 12/10/2009	
Day	Date	Module	Specific Topic Area	Instructor	Reading
Thurs.	11-19-09	34	Stereochemistry on PK and PD	Wedlund	
			How stereochemistry can affect drug PK and PD, how to identify		
Mon.	11-23-09	35	Enzyme induction time course	Wedlund	
			Models and implications of enzyme induction on drug PK		
Wed.	11-25-09	Vacation	Thanksgiving Break – No Class	No Class	School Break
Thur.	11-26-09	Vacation	Thanksgiving Break – No Class	No Class	School Break
Mon.	11-30-09	36	Drug Metabolism	Wedlund	
			Techniques to study, various enzymes, classification, limits		
Wed.	12-02-09	47	Drug Metabolism	Wedlund	
			In-vitro, In-Vivo predictions of metabolism, issues, problems		
Thur.	12-03-09	38	Pharmacogenomics	Wedlund	Assignment #8
			Causes of genetic variation, extent of variation, predictions		
Mon.	12-07-09	39	Pharmacogenomics	Wedlund	
			Applications and limits to use of genetics, cost and re-use, hype		
Wed.	12-09-09	40	Biological Therapeutics	Wedlund	
			PK of proteins, biotechnology products, elimination assessment		
Thur.	12-10-09	41	Review of class material	Wedlund	
				Leggas	
				Lee	
Wed.	12-16-09	FINAL	Material 11-04 through 11-09	FINAL	FINAL EXAM

PHS 760
Introduction to Pharmaceutical Science
2009 SYLLABUS

Course Description:

PHS 760 is a required course of all new graduate students in Pharmaceutical Sciences. This course has two objectives: 1) to introduce the student to the discipline of pharmaceutical science and 2) to introduce a set of 'scientific life skills' necessary for success in graduate level research. Two series of lectures on these topics will be presented, along with presentations by faculty on their research projects. The course will conclude with short presentations by the students on their first 6-week research laboratory rotation. These presentations, along with a short paper describing this research experience, written in the form of a scientific manuscript, will allow the students to practice two of the most important skills necessary for a successful career in science (writing and presentation), and will form the basis for the course grade.

Class Meeting Time:

Tuesdays and Thursdays, 11:00-11:50 am, 222 College of Pharmacy.

Course Coordinator:

Dr. Todd Porter, 446 College of Pharmacy. Office hours: 9-5, M-F. Contact: 257-1137;
tporter@email.uky.edu

Attendance:

Attendance at all presentations is mandatory. Students who miss a class must notify the coordinator, preferably in advance, with a valid excuse to avoid an unexcused absence. Excused absences are defined by the Academic Ombud: <http://www.uky.edu/Ombud/policies.php>. Two or more unexcused absences will result in lowering of the grade by one letter.

Course grading:

The short paper and oral presentation describing the first 6-week research rotation constitute the bulk of the grade for this class, and so this first rotation should be chosen carefully and begun as soon as possible.

A 250-word abstract of the research paper summarizing the work carried out in the first rotation will be due at mid-term. This and the final paper will be graded on overall clarity, grammar, and readability; avoidance of plagiarism is of utmost importance. The final paper should be limited to no more than 5 pages, with 1.5x-line spacing and 0.75 in. margins. It should follow standard scientific paper format and include an abstract, introduction, methods, results, discussion, and bibliography in a proper format. The objective of the work should be clearly evident, as should the relationship of the research undertaken to published literature in the area, and should be described in the 'Introduction'. Methods should be described in sufficient detail such that the reader does not have to refer to the literature to

understand how the experiments were done. If results are limited or not available the discussion section should reflect how the expected or possible results would confirm, extend, or refute current knowledge in the area, and what the implications of the findings are or would be for future research in the area.

The in-class presentation should be no longer than 10 min and formatted in Microsoft PowerPoint. It will be followed by a 5 min discussion and questions/answers. The presentation should present the goals of the research undertaken, a brief background that shows how the research fits into current knowledge in the area, present the results in visually understandable format (graphs, images, diagrams), and provide a brief conclusion and perspective to the work. The presentation will be graded on clarity, visual appeal, scientific accuracy, and the ability of the presenter to speak clearly and concisely, as well as to answer questions posed by the audience.

This course will follow a standard grading scale: 90%>= A; 80%>= B; 70%>= C. Grades will be assigned by the course coordinator, with input from other faculty who attend the talks and/or read the papers, on the following basis: 10% for attendance and participation in class; 40% for the research paper; 10% for the abstract/summary of the research due at mid-term; and 40% for the in-class presentation.

Course Schedule:

Day	Date	Lecture Topic	Presenter
THU	8/27/09	Course overview	Todd Porter
TUE	9/1/09	Lab infomercials: Lee and Van Lanen	
THU	9/3/09	Lab infomercials: Bae and Graf	
TUE	9/8/09	Lab infomercials: Black and Loftin	
THU	9/10/09	Lab infomercials: Kim and Elliot	
TUE	9/15/09	Lab infomercials: McNamara and Littleton	
THU	9/17/09	How to read and evaluate a scientific paper	Penni Black
TUE	9/22/09	Recording data: Keeping a laboratory notebook	Brad Anderson
THU	9/24/09	Fundamentals: Drug receptors and pharmacodynamics	Linda Dwoskin
TUE	9/29/09	Fundamentals: Computational design of drugs	Chang-Guo Zhan
THU	10/1/09	Fundamentals: Whole animal pharmacological studies	Chuck Loftin
TUE	10/6/09	Scientific writing and how to avoid plagiarism	Jim Pauly
THU	10/8/09	How to write a scientific paper	Greg Graf
TUE	10/13/09	Fundamentals: Neuropharmacology	Jim Pauly
THU	10/15/09	Guidelines for scientific presentations: posters and slides	Todd Porter
TUE	10/20/09	Fundamentals: Natural Products and Combinatorial Synthesis	Steve Van Lanen
THU	10/22/09	Fundamentals: Medicinal chemistry	Greg Elliott
FRI	10/23/09	<i>Abstract of research rotation due @ 5 pm</i>	Todd Porter
TUE	10/27/09	Fundamentals: Gastrointestinal drug absorption and delivery	Paul Bummer
THU	10/29/09	Fundamentals: Pharmacokinetics	Woojin Lee
TUE	11/3/09	Fundamentals: Pre-formulation	Tonglei Li

THU	11/5/09	Fundamentals: Drug delivery and formulation	Younsoo Bae
TUE	11/10/09	Fundamentals: Drug metabolism	Todd Porter
THU	11/12/09	How to choose a mentor and be a successful graduate student	Student panel
TUE	11/17/09	Fundamentals: New approaches in drug formulation and delivery	Courtney Swadley
THU	11/19/09	Preparing for your Qual Exam: Writing the grant proposal	Porter and Steinke
TUE	11/24/09	Student presentations - <i>Research papers due in class</i>	
THU	11/26/09	THANKSGIVING HOLIDAY	
TUE	12/1/09	Student presentations	
THU	12/3/09	Student presentations	
TUE	12/8/09	Student presentations	
THU	12/10/09	Student presentations and pizza lunch	

Syllabus

STA570 401-402, Basic Statistical Analysis

University of Kentucky, Spring 2007

Instructor: Kert Viele

Office: 803 Patterson Office Tower

Phone: 257-4803

E-mail: viele@ms.uky.edu

Office Hours: Whenever I'm in

Lectures: TR 6:00-7:15, CB 201

Labs: Sec 401 M 6:00-7:50pm CB307 , Sec 402 M 8:00-9:50pm CB307

Text: Fundamentals of Biostatistics, by Bernard Rosner

Lab Instructor: Chris Hammons, 859 POT, 257-4423, hammons@ms.uky.edu

Course Web Page: <http://www.ms.uky.edu/~viele/sta570s07/sta570.html>

Overview

This course provides an introduction to many basic statistical techniques for the analysis of quantitative data, including exploratory data analysis, the normal distribution, estimation, hypothesis testing, regression, analysis of variance, and analysis of categorical data. Much of our discussion will consist of determining which of these many techniques is appropriate for a particular experiment, and how to design an experiment in advance to be sure you'll actually get relevant answers. Finally, in the lab sections we will discuss how to use SAS Analyst, a graphical user interface for SAS, to implement the techniques discussed in lecture.

Grading

I will assign approximately weekly homeworks (avoiding weeks with exams, for example). Most weeks will also have a lab assignment. The homeworks are worth 20% of the grade and the lab exercises are worth 20% of the grade. Homeworks will be graded on a traditional percentage scale, but the lab exercises will only be graded as either "check" (50%), "check-plus" (100%), or "check-minus" (0%). The "check-minus" will only be given for not showing up to lab or leaving the lab unfinished. Note that receiving a "check-plus" does not indicate you did everything perfectly, simply that you got most answers correct. Considering you will have the lab instructor available in lab to help, my hope is that everyone will have a perfect lab grade at the end of the semester. Homeworks may be emailed electronically in Word or turned in on paper in class on the due date. Lab assignments must be emailed in Word at the completion of the lab session.

There will be two exams, a midterm (Feb. 27 in class) and a final (Tuesday, May 1, 6:00-8:00pm). Each of these exams will be worth 30% of the course grade.

The course percentage will translate into a letter grade according to the scale 90-100=A, 80-89=B, 70-79=C, 60-69=D (exception - for undergraduate students 60-69 corresponds to a D, graduate students are not eligible for D's). These are minimum requirements, thus, interpret 80-89 as "at least a B".

Late homework and other missed work may only be made up in the case of a university excused absence. Attendance is required to the extent that any student missing 20% of the course for any reason may be asked to withdraw at the discretion of the instructor. If you will be missing any days due to religious holidays, the instructor must be informed in writing by the end of the add period.

STA 580-001 (Biostatistics I)

The last laboratory session, on Thursday 30 April at 6 p.m., will be held in BE (Business and Economics) 105 instead of NURS 602J because of a room reservation conflict.

I will hold extended office hours, from 12 Noon to 3 p.m., on Thursday 07 May.

The final examination, on Thursday 07 May at 3:30 p.m., will be held in the usual classroom CTW 014.

Syllabus (DOC), posted 08 January 2009

Entrance Survey (DOC), posted 08 January 2009

Lecture 1 (PS PDF), posted 08 January 2009

data from Table 2.13 (XLS), posted 08 January 2009

SAS output for Lecture 1 (PDF), posted 08 January 2009

Lecture 2 (PS PDF), posted 14 January 2009

Lecture 3 (PS PDF), posted 16 January 2009

Lecture 4 (PS PDF), posted 03 February 2009

data from Table 6.12 (XLS), posted 03 February 2009

SAS output for Lecture 4 (PDF), posted 03 February 2009

Lecture 5 (PS PDF), posted 03 February 2009

Lecture 6 (PS PDF), posted 06 February 2009

Lecture 7 (PS PDF), posted 11 February 2009

data for Lecture 7 example (XLS), posted 11 February 2009

SAS output for Lecture 7 example (PDF), posted 11 February 2009

Lecture 8 (PS PDF), posted 19 February 2009

Lecture 9 (PS PDF), posted 27 February 2009

SAS output for Lecture 9 example (PDF), posted 27 February 2009

Lecture 10 (PS PDF), posted 02 March 2009

SAS output for Lecture 10 example (PDF), posted 02 March 2009

Lecture 11 (PS PDF), posted 20 March 2009

Lecture 12 (PS PDF), posted 01 April 2009

blood pressure data (XLS), posted 01 April 2009

SAS output for Lecture 12 (PDF), posted 01 April 2009

Lecture 13 (PS PDF), posted 01 April 2009

SAS output for Lecture 13 (PDF), posted 01 April 2009

Lecture 14 (PS PDF), posted 01 April 2009

smoking recidivism data (XLS), posted 01 April 2009

SAS output for Lecture 14 (PDF), posted 01 April 2009

Computing Guide (PS PDF), posted 08 January 2009

SAS code for descriptive statistics (TXT), posted 08 January 2009

SAS code for computing binomial probabilities (TXT), posted 08 January 2009

SAS code for computing normal probabilities (TXT), posted 08 January 2009

SAS code for computing quantiles of distributions (TXT), posted 08 January 2009

SAS code for one-sample problems (TXT), posted 08 January 2009

SAS code for two-sample problems (TXT), posted 08 January 2009

SAS code for nonparametric techniques (TXT), posted 08 January 2009

SAS code for analysis of variance (TXT), posted 08 January 2009

SAS code for simple linear regression (TXT), posted 08 January 2009

SAS code for relative risks and odds ratios (TXT), posted 08 January 2009

SAS code for survival analysis (TXT), posted 08 January 2009

Written Assignment 1 (PS PDF), posted 08 January 2009

data for Written Assignment 1 (XLS), posted 08 January 2009

Solutions (PS PDF), posted 09 February 2009

Written Assignment 2 (PS PDF), posted 03 February 2009

data for Written Assignment 2 (XLS), posted 03 February 2009

description of data (XLS), posted 03 February 2009

Solutions (PS PDF), posted 23 February 2009

Written Assignment 3 (PS PDF), posted 06 February 2009

Solutions (PS PDF), posted 08 March 2009

Written Assignment 4 (PS PDF), posted 19 February 2009

Solutions (PS PDF), posted 07 April 2009

Written Assignment 5 (PS PDF), posted 03 March 2009

Note: To do exercise 1g, assume that $r_1 = 1051.5$, $r_2 = 821.5$, $r_3 = 694$, and $r_4 = 673$. Also assume that there are nine two-way ties and one three-way tie.

Solutions (PS PDF), posted 20 April 2009

Written Assignment 6 (PS PDF), posted 06 April 2009

Solutions (PS PDF), posted 01 May 2009

Preparation for your Midterm Examination

Practice Test in Fall 2007 (PS PDF), posted 19 February 2009

Actual Test in Fall 2007 (PS PDF), posted 19 February 2009

Actual Test in Fall 2008 (PS PDF), posted 19 February 2009

Preparation for your Final Examination

Practice Test in Fall 2007 (PS PDF), posted 12 April 2009

Actual Test in Fall 2007 (PS PDF), posted 12 April 2009

Actual Test in Fall 2008 (PS PDF), posted 12 April 2009

Syllabus

Regression and Correlation

STA 671 410-411

University of Kentucky, Summer I, 2006

Instructor: Kert Viele

Office: 803 Patterson Office Tower

Phone: x7-4803

E-mail: viele@ms.uky.edu

Lectures and Labs: TR 6:00-8:30, CB307 (alternate time available for lab)

Course Web Page: <http://www.ms.uky.edu/~viele/sta671u06/sta671.html>

Overview

Regression is one of the most commonly used statistical methods. As such, it is probably also one of the most misused statistical methods. We will discuss

1. Regression allows you to describe a linear relationship between a set of covariates (explanatory variables) and a single, continuous response.
2. Before you use the results of a regression analysis, you need to make sure a linear relationship actually exists. This may be done through the use of plots, analysis of residuals, and other means.
3. Some things (such as outliers) can make a regression analysis look more or less accurate than it actually is. We'll discuss methods for identifying possible problems and dealing with them.
4. Some things that don't originally look like linear patterns can be transformed into linear relationships, such as by using transformations or polynomial models.

There is a wealth of mathematics lying behind the techniques we will discuss. We will simply trust that the people who did that mathematics knew what they were doing and programmed SAS correctly, focusing primarily on practical matters involving interpreting plots and regression output.

Grading

The course grade is based upon the following:

Homeworks : 15%

Labs : 15%

MidTerm Exam (date TBA) : 35%

Final Exam (date TBA) : 35%

Each day class will begin with a lecture, typically 60-90 minutes long. This will be followed with an introduction to the lab material by the course teaching assistant, Matthew Leichter (leichter@ms.uky.edu). The labs will be taught in SAS. After the lab introduction, students will be given a lab exercise to do on their own for the remainder of the class session, assisted by both me and Matt. The labs are due at the end of class.

Homework will be assigned roughly weekly (keep in mind this is an accelerated class, and some homework may be assigned on a Thursday and due the following Tuesday). Homework will consist of analyzing datasets on your own and providing a written analysis. We'll talk about prototypes for these analyses as the semester continues.

Syllabus

Experimental Design

STA 672

University of Kentucky, Summer II, 2009

Instructor: Kert Viele

Office: 803 Patterson Office Tower

Phone: x7-4803

E-mail: viele@uky.edu

Lectures: TR 6:00-7:30, CB333

Labs: TR 5:00-6:00 or TR 7:30-8:30 CB309

Course Web Page: <http://web.as.uky.edu/statistics/users/kviele/courses/sta672u09/sta672.html>

Overview

With your previous courses in statistical inference (such as STA570 or STA580) and Regression (STA671), you have a foundation to analyze most standard experimental designs. We will begin with by covering reviewing oneway ANOVA (with multiple comparisons), regression, and ANCOVA. We will then discuss factorial experiments, randomized block designs, nesting, Latin squares, and split plot designs. Our goal will be to place all these standard designs within the regression/ANOVA framework we have already developed, so that they may easily be compared. The main purpose behind these techniques is to most efficiently use experimental resources to answer scientific questions. You have a finite amount of observations available to use, and you must assign this observations to treatment in a manner that acquires the most information. The techniques in STA672 address how to accomplish this in a variety of common experimental settings.

Grading

The course grade is based upon the following:

Homeworks : 15%

Labs : 15%

MidTerm Exam (tentative date July 14) : 35%

Final Exam (tentative date August 6) : 35%

If the exam dates create a conflict for you, let me know as soon as possible and we will try to work something out. I realize many of you have other obligations during the summer (field work, internships, etc.)

Each lab session will contain it's own assignment that must be emailed to me at the completion of lab (lab attendance is required, though of course we will allow people with university excused

absences to make up labs, and in addition I will try to work with all students who need to miss a lab provided they speak to me before the absence). Labs will be graded as one of “full credit”, “half credit”, or “no credit”. Full credit will be given for an honest attempt at the lab regardless of the quality of your answers.

Homework will be assigned periodically. Homework will consist of analyzing datasets on your own and providing a written analysis. We’ll talk about prototypes for these analyses as the semester continues.

STA 673

Distribution-Free Statistical Inference and Analysis of Categorical Data

Spring Semester 2005

Class Instructor

Name : [Dr. Arne Bathke](#)
Address : 875 Patterson Office Tower (POT)
Telephone : 257-3610
Email : arne@ms.uky.edu
Office Hours : 2:00-4:00 AM on Mondays or by appointment.

Lab Instructor

Name : Bob Loos
Address : 857 Patterson Office Tower (POT)
Telephone : 257-9202
Email : loos@ms.uky.edu
Office Hours : 2:00-4:00 PM on Mondays.

Course Information

Class time : March 7 - May 6, 2005, *Lecture* MWF 12:00 - 12:50 AM, *Computer Lab* W 2:00 - 3:50 PM
Class room : *Lecture* **CB (Classroom Building) 235**, *Computer Lab* CB (Classroom Building) 307
Textbook : G. Noether, *Introduction to Statistics the Nonparametric Way*, Springer.
Website : <http://www.ms.uky.edu/~arne/sta673/>

This website will be updated regularly. **Please keep checking** it for announcements and homework information.

Course Policies

Description: This is a 2 credit hour course about nonparametric statistical methods. These are methods that usually require less assumptions than their parametric counterparts, while being almost as powerful. More specifically, topics of STA 673 are envisioned to include *inference for population quantiles, sign tests, Wilcoxon tests, Kruskal-Wallis and Friedman tests, Kendall and Spearman rank correlation; goodness-of-fit tests for completely and partially specified distributions, $r \times c$ contingency tables, McNemar and Cochran's Q tests for matched proportions; three dimensional tables and tests of partial and multiple associations*. The use of computer library routines (SAS) will be discussed. Other special topics may be discussed according to the interests of the class and the available time.
Prerequisites: STA 570 or STA 580.

Learning Objectives: Upon successfully completing this course, you will be able to

- articulate the role of nonparametric statistics in statistical science
- apply binomial test methods and explain how the binomial test is the basis for simple nonparametric tests of hypotheses
- apply contingency table methods and derive the exact distribution of simple tables
- apply rank-based methods of correlation and hypothesis testing and articulate their relationship to better-known parametric methods
- apply simple goodness-of-fit-tests
- implement all supported methods in SAS

Course Goals: Apart from the knowledge of the STA 673 topics mentioned above, the course is intended to enhance analytic and problem-solving skills and the capacity to make wise decisions.

Attendance: Consistent attendance is strongly recommended. Each student is responsible for obtaining all material missed when absent.

Grading: Your grade will be divided into three parts: Two exams (25% each), and homework (50%). The homework assignments, midterm exam and final exam must be your own work. Late homework will not be accepted (i.e., given full credit) without a university excused absence.

Exams: The two exams are scheduled for April 15 and **May 2 (Final Exam)**. Make-up exams will be allowed only in extreme circumstances and are subject to proper documentation. Unless it is an emergency situation, you need to notify me **ahead of time** either by phone or via [email](#).

Syllabus

Date	Topics	Book Sections	Handouts/Assignments
Mon, Mar 7	Syllabus, Introduction		
Wed, Mar 9	Advantages and Disadvantages of Nonparametric Methods, Review of Some Statistical Concepts		
Fri, Mar 11	Two-Sample Problem	6, 7	Homework 1, due Friday, March 25: 6.2, 6.9, 7.3(g), 7.10, 7.13
Mon, Mar 14	Spring Break - No Classes!		
Wed, Mar 16			
Fri, Mar 18			
Mon, Mar 21	Wilcoxon-Mann-Whitney Test for Two Independent Samples	6, 7	
Wed, Mar 23	Exact and Asymptotic WMW Test		
Wed, Mar 23	First Lab Session		
Fri, Mar 25	Relation of WMW Test to Other Statistical Tests	8	Homework 2, due Friday, April 1: 8.48, 8.49, 8.50
Mon, Mar 28	One-Sample Problem	11	
Wed, Mar 30	No Lecture Today		

Wed, Mar 30	Second Lab Session		
Fri, Apr 1	Two Dependent Samples	12	Homework 3, due Friday, April 8: 11.27, 11.47, 12.6, 12.30, 12.31, 12.32
Mon, Apr 4			
Wed, Apr 6	Median Regression	13.1	
Wed, Apr 6	Third Lab Session		
Fri, Apr 8	Spearman Rank Correlation	13.3.3	
Mon, Apr 11	Tests for k Independent Samples	15.1	
Wed, Apr 13	Tests for k Dependent Samples	15.2	
Wed, Apr 13			
Fri, Apr 15	Tests for k Dependent Samples, Bonferroni-Holm Procedure		Midterm Exam Due
			Last Homework, due Friday, April 22: 13.3, 13.25 (Spearman), 15.7, 15.23, 17.6
Mon, Apr 18	Analysis of Categorical Data	17	
Wed, Apr 20		18	
Wed, Apr 20	Fourth Lab Session		
Fri, Apr 22	2x2 Tables	18	
Mon, Apr 25	Fisher's Exact Test		
Wed, Apr 27	McNemar Test Nonparametric Alternative to ANOVA		
Wed, Apr 27	No lab today!		
Fri, Apr 29	Review		
Mon, May 2	Final Exam (1-3pm)		

Lindsay, Jim D.

From: Romanelli, Frank
Sent: Wednesday, March 31, 2010 12:21 PM
To: Lindsay, Jim D.
Cc: Pauly, Jim; McNamara, Patrick; Morgan, Belinda
Attachments: GSmemo.doc; IBS 604.pdf; PHR545 Syllabus Schedule 2008.doc; PHR760-008 Molecular NeuroBiol of Abused Drugs spring 08 Final.doc; PHR 762 Bioorganic Mechanisms Spring 2009 FINAL2.doc; PHS 612 Pharmacokinetics and Pharmacodynamics Course outline Fall 2009.doc; PHS 760 Syllabus 2009.doc; PS Research GatewayFinal.doc; PSRGCoverLet.pdf; STA671syllabus.doc; STA 570 syllabus.doc; SURP.doc; Syllabus PHR 631 Spring 2008.doc

J:

Please find attached documentation and background regarding a Graduate Certificate Program in Pharmaceutical Science originating from the College of Pharmacy.

The proposal was originally submitted (per The Graduate Schools instructions) to the Graduate School on December 9, 2009. It has recently come to our attention that following a lengthy delay and some mis-information, the proposal needed to pass through HCCC.

I am also forwarding hard-copies (letter from Interim Dean McNamara and Dr. Bob Kuhn (Chair of COP Curriculum Committee)).

Specifically please find:

A cover memo, course syllabi, and a proposal description.

Thank you.

FR

Frank Romanelli, Pharm.D., MPH, BCPS

Associate Dean and Associate Professor of Pharmacy, Health Sciences, & Medicine
College of Pharmacy
University of Kentucky

Jim ...

Thank you for the expedited review! Here are the answers to aforementioned questions:

1. Students will potentially enroll in the Program at the conclusion of the Spring semester ... 910 is not part of the certificate program other than being the required course where the Gateway will be introduced to students as a potential option in their future coursework. We will have at least the Fall semester of the PY1 year completed prior to enrollment.
2. I can provide this syllabus however as mentioned in item #1 910 is not part of the coursework for the Certificate ... it is only the venue where the Certificate (and other differentiation options are formally presented to students).
3. I apologize for the syllabi mis-match ... we were told by the Graduate school (initially) that these not need be provided as part of the submission. Dr. Pauly has made the 'stats' related revisions to the Gateway proposal and collected all necessary syllabi ... I will forward those under separate cover.

AGAIN ... thank you ... what is next?

FR

Frank Romanelli, Pharm.D., MPH, BCPS

Associate Dean and Associate Professor of Pharmacy, Health Sciences, & Medicine
College of Pharmacy
University of Kentucky

From: Lindsay, Jim D.

Sent: Monday, April 12, 2010 9:49 AM

To: Romanelli, Frank

Subject: RE: Proposal

Hi Frank...

The HCCC has approved your proposal provided that the questions below from one of the HCCC members be addressed. As soon as I receive your response I will transmit the proposal to the Graduate Council.

Thanks,

Jim

1. Page 6 says that "All applicants must be enrolled in the Pharm.D. program at the UKCOP" and, moreover, that applicants must have a "Minimum GPA of 3.0 in Pharm.D. coursework", while page 7 seems to indicate that PPS 910 will be taken in the first semester of the first year of the Pharm.D. program. How can the GPA requirement be assessed before the first semester of the first year?
2. I did not see a syllabus for PPS 910 in the accompanying materials, which I think would be more important to this proposal than syllabi for potential electives.
3. Can an actual syllabus for STA 570 be provided on pages 37 and 38 rather than a list of web links to the lectures?

4. There seems to be a mismatch between the list of electives on page 7 and the potential electives for which syllabi are provided. For example, syllabi are provided for PHR 545 and STA 671, which do not appear on page 7. Also, since STA 671 is only a two-credit-hour course (meeting for seven weeks), one would need to follow it with STA 672 or STA 673 to meet the credit hour requirements for the certificate.

5. Will the three-hour methods course STA 580 be considered as an elective alongside STA 570? The content of STA 580 is similar to that of STA 570, but some people find STA 580 easier to enroll in because there is only one lecture per week. A syllabus from a recent offering of STA 580 is available at {<http://www.richardcharnigo.net/STA580S09/index.html>}.

Jim Lindsay
Health Care Colleges Council Coordinator
Associate Provost for Faculty Affairs Office
University of Kentucky, 205 Frazee Hall
Lexington, KY 40506-0031 Ph. (859) 323.6638
www.uky.edu/Provost/AcademicCouncil/council.php

From: Romanelli, Frank
Sent: Tuesday, March 30, 2010 10:38 AM
To: Price, Cleo
Cc: Pauly, Jim; Lindsay, Jim D.
Subject: RE: Proposal

See attached ... I also submitted copies of all the course syllabi as well as memo of support from our Dean and Curriculum Committee.

I am very disappointed as I repeatedly checked in and asked what was needed regarding the proposal. Had I not checked in again I don't know if anyone would have followed up.

The other day I was directed to the proposal status website and found no listing of our submission and now this AM I was told this needed to go to HCCC (something I had specifically asked about in December). Our Graduate Faculty are (understandably) going to be very angered by this.

FR

Frank Romanelli, Pharm.D., MPH, BCPS
Associate Dean and Associate Professor of Pharmacy, Health Sciences, & Medicine
College of Pharmacy
University of Kentucky