

Cover Sheet: Request 10105

Principles of Drug Therapy Individualization

Info

Process	Course New Ugrad/Pro
Status	Pending
Submitter	Beck,Diane Elizabeth beck@cop.ufl.edu
Created	2/26/2015 4:11:58 PM
Updated	2/27/2015 9:22:26 AM
Description	This course occurs during Year 1 - Spring Semester of the new 2015 Curriculum.

Actions

Step	Status	Group	User	Comment	Updated
Department	Approved	COP - Interdisciplinary Studies	Whalen, Karen		2/27/2015
College	Approved	COP - College of Pharmacy	Beck, Diane Elizabeth		2/27/2015
University Curriculum Committee	Pending	PV - University Curriculum Committee (UCC)			2/27/2015
Statewide Course Numbering System					
Office of the Registrar					
Student Academic Support System					
Catalog					
College Notified					

Recommended SCNS Course Identification

1. Prefix PHA 2. Level 5 3. Number XXX 4. Lab Code None

5. Course Title Principles of Drug Therapy Individualization

6. Transcript Title (21 character maximum) Prin Drug Ther Indiv

7. Effective Term Spring

8. Effective Year 2016

9. Rotating Topic? No

10. Amount of Credit 4

11. If variable, # minimum and # maximum credits per semester.

12. Repeatable credit? No

13. If yes, total repeatable credit allowed #

14. S/U Only? No

15. Contact Type Regularly Scheduled [base hr]

16. Degree Type Professional

17. If other, please specify: [Click here to enter text.](#)

18. Category of Instruction Select

19. Course Description (50 words maximum)

An introductory course in pharmacokinetics, pharmacodynamics, and pharmacogenomics that provides the tools and principles to individualize a patient's treatment by selecting an optimal dose and dosing regimen.

20. Prerequisites

PHA XXXX Personal & Professional Development I
PHA 5560 Pathophysiology & Patient Assessment I
PHA 5433 Principles of Medicinal Chemistry & Pharmacology I
PHA 5100 Drug Delivery Systems

21. Co-requisites

[Click here to enter text.](#)

22. Rationale and Placement in Curriculum

This is a first year course that introduces principles and concepts. These are applied during years 2 and 3 as students complete a series of body system courses.

23. Complete the syllabus checklist on the next page of this form.

Syllabus Requirements Checklist

The University's complete Syllabus Policy can be found at:

http://www.aa.ufl.edu/Data/Sites/18/media/policies/syllabi_policy.pdf

The syllabus of the proposed course **must** include the following:

- ☒ Course title
- ☒ Instructor contact information (if applicable, TA information may be listed as TBA)
- ☒ Office hours during which students may meet with the instructor and TA (if applicable)
- ☒ Course objectives and/or goals
- ☒ A weekly course schedule of topics and assignments.
- ☒ Methods by which students will be evaluated and their grades determined
- ☒ Information on current UF grading policies for assigning grade points. This may be achieved by including a link to the appropriate undergraduate catalog web page:
<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>.
- ☒ List of all required and recommended textbooks
- ☒ Materials and Supplies Fees, if any
- ☒ A statement related to class attendance, make-up exams and other work such as: *"Requirements for class attendance and make-up exams, assignments, and other work in this course are consistent with university policies that can be found in the online catalog at: <https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>."*
- ☒ A statement related to accommodations for students with disabilities such as: *"Students requesting classroom accommodation must first register with the Dean of Students Office. The Dean of Students Office will provide documentation to the student who must then provide this documentation to the Instructor when requesting accommodation."*
- ☒ A statement informing students of the online course evaluation process such as: *"Students are expected to provide feedback on the quality of instruction in this course based on 10 criteria. These evaluations are conducted online at <https://evaluations.ufl.edu>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu/results>."*

It is **recommended** that the syllabus contain the following:

- ☒ Critical dates for exams or other work
- ☒ Class demeanor expected by the professor (e.g. tardiness, cell phone usage)
- ☒ The university's honesty policy regarding cheating, plagiarism, etc.

Suggested wording: UF students are bound by The Honor Pledge which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: "On my honor, I have neither given nor received unauthorized aid in doing this assignment." The Honor Code (<http://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/>) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

- ☒ Contact information for the Counseling and Wellness Center: <http://www.counseling.ufl.edu/cwc/>, 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies

PHA XXXX Principles of Drug Therapy Individualization

Spring 2016 – Year 1 / Block 3 (8 weeks)

4 Semester Credit Hours

Course Purpose:

Individualization of drug therapy, described as tailoring drug selection and drug dosing to a given patient, has been an objective of physicians and other health-care providers for centuries. An understanding of the disease, the mechanism of the drug's action, and exposure-response relationships provides the framework for individualization. The goal of individualization is to optimize the efficacy of a drug, minimize toxicity, or both on a patient-by-patient basis.

The objective of this course is to provide students with an introductory course in pharmacokinetics (PK), Pharmacodynamics (PD) and Pharmacogenomics (PGx) that, in conjunction with other coursework, equips them with the knowledge and skills to serve as the drug expert in an interdisciplinary team of health care professionals. The knowledge acquired in this course will provide students with the tools and principles to individualize a patient's treatment by selecting an optimal dose and dosing regimen.

Course Faculty and Office Hours

Teaching Partnership Leader: Stephan Schmidt, Ph.D.

Email: sschmidt@cop.ufl.edu

Office: 467, 6550 Sanger Road, Orlando

Phone: 407 313 7012

Office Hours: By appointment

Teaching Partners:

Guenther Hochhaus, Ph.D.

Email: hochhaus@cop.ufl.edu

Office: MSB P3-33

Phone: 352 273 7861

Office Hours: By appointment

Mirjam Trame, Pharm.D., Ph.D.

Email: mtrame@cop.ufl.edu

Office: 471, 6550 Sanger Road, Orlando

Phone: 407 313 7052

Office Hours: By appointment

Reggie Frye, Pharm.D., Ph.D.

Email: frye@cop.ufl.edu

Office: HPNP room 3333

Phone: 352-273-5453

Office Hours: By appointment

Caitrin McDonough, Ph.D.
Email: cmcdonough@cop.ufl.edu
Office: HSC PG-05B
Phone: 352-273-6435
Office Hours: By appointment

Academic Coordinator

Christine Salama, M.A. Email: csalama@ufl.edu
Office: HPNP 4312 Phone: 352-273-5617
Office Hours: by email and appointment

This Course Will Prepare You to Perform the Following Activities Which the Public Entrusts a Pharmacist to Perform:

EPA A2. Interpret patient data, and identify medication-related problems and develop a prioritized problem list.

Course Objectives

Upon completion of this course, the student will:

1. Describe the influence of dosage forms, dosing regimens and dose on drug levels and to understand the relationship between drug concentration, effect and side effects.
2. Apply mathematical principles to calculate the change in a patient's drug concentration over time, the elimination rate constant, drug volume of distribution, and area under the curve (AUC).
3. Explain the following concepts: first-order elimination, zero-order elimination, half-life, volume of distribution, and clearance.
4. Determine whether a drug is predominately reabsorbed or secreted based on renal clearance and protein binding.
5. Predict the relationship between pH (and urine flow) and renal clearance.
6. Predict the effects of blood flow, intrinsic clearance, and protein binding on drug clearance for high and low extraction drugs.
7. Calculate a patient's peak and trough plasma drug concentrations after receiving multiple doses/at steady-state.
8. Recommend dosing for a patient who is receiving a continuous IV drug infusion by considering the relationships of clearance, elimination rate constant, and volume of distribution.
9. Recommend dosing for a patient who is receiving an oral drug by considering the relationships of clearance, elimination rate constant, and volume of distribution.
10. Contrast two- and three-compartment body models with the one-compartment body model with respect to assumptions, drug distribution, and drug elimination.
11. Explain the nomenclature that is used to describe genotype and phenotype.
12. Demonstrate how to use available pharmacogenomics databases.
13. Describe clinical genotype testing methods.

14. Discuss how pharmacogenetics contributes to variability in drug metabolism and transport.
15. Discuss how “OMICS” technologies can be used to stratify disease classification and personalize drug therapy.
16. Describe the purpose of the CPIC guidelines and how to use them as a clinician.
17. Describe the common special patient populations and the characteristics of each that must be considered during drug individualization.
18. Identify software and apps that may be used for decisions related to drug dose individualization/personalized medicine.

Pre-Requisite Knowledge and Skills

PHA XXXX Personal & Professional Development I

PHA 5560 Pathophysiology & Patient Assessment I

PHA 5433 Principles of Medicinal Chemistry & Pharmacology I

PHA 5100 Drug Delivery Systems

Weekly Course Outline

Course Structure. Learning activities are video lectures and students are required to come to campus for exams and active learning sessions. Multiple self-directed learning activities are required including review of videos, readings, web-based learning and completion of problem sets. These self-study activities are pre-requisite and required prior to participating in the active learning sessions.

Dates or Week	Instructor	Related Learning Objective	Learning Activities/Topic	Instructor Contact Hours
Week 1 (8 hours)	Schmidt	1	Module 1: Introduction Pharmacokinetics, Pharmacodynamics & Personalized Medicine	1 hr
	Hochhaus	2,3	Module 2: Basic Pharmacokinetics	2 hr
	Hochhaus		HW 1 / Active Learning Session	1.5 hr
	Hochhaus	3	Module 3: Distribution	2 hr
	Hochhaus		HW 2 / Active Learning Session	1.5 hr
Week 2 (9 hours)	Hochhaus	3,6	Module 4: Hepatic Clearance	3 hr
	Hochhaus		HW 3 / Active Learning Session	1.5 hr
	Hochhaus	4,5	Module 5: Renal Clearance	3 hr
	Hochhaus		HW 4 / Active Learning Session	1.5 hr
Exam 1 (Modules 1-5)				
Week 3 (10 hours)	Schmidt	7	Module 6: Intravenous Bolus Administration	4 hr
	Schmidt		HW 5 / Active Learning Session	1.5 hr
	Schmidt	8	Module 7: Intravenous Infusion	3 hr
	Schmidt		HW 6 / Active Learning Session	1.5 hr
Week 4	Schmidt	9	Module 8: Oral Administration	2 hr
	Schmidt		HW 7 / Active Learning Session	1.5 hr

(7 hours)	Trame		Module 9: Bioequivalence	1 hr
	Schmidt	10	Module 10: Compartmental Models	1 hr
	Trame		HW 8 / Active Learning Session	1.5 hr
			Exam 2 (Modules 6-10)	
Week 5 (9 hours)	McDonough	11-13	Module 11: Principles of Genetic Medicine	3 hr
	McDonough		HW 9 / Active Learning Session	1.5 hr
	Frye	14	Module 12: Pharmacogenomics of Drug Metabolizing	3 hr
	Frye		HW 10 / Active Learning Session	1.5 hr
Week 6 (8 hours)	Frye	14	Module 13: Pharmacogenomics of Drug Transporters	1 hr
	Trame	14	Module 14: Food-Drug/Drug Interactions	2 hr
	Frye		HW 11 / Active Learning Session	1.5 hr
	Frye	15	Module 15: Omics and Personalized Medicine	1 hr
	Frye	16	Module 16: CPIC Guidelines	1 hr
	Frye		HW 12 / Active Learning Session	1.5 hr
			Exam 3 (Modules 11-14)	
Week 7 (8 hours)	Trame	17, 18	Module 17: Special Patient Populations & Software/Personalized Medicine Apps	5 hr
	Trame		HW 13 / Active Learning Session	3 hr
Week 8			Final Exam (Modules 1-17)	

Active Learning Sessions

All homework must be original work by the individual student. Students must be present in the lecture room on the day the Case Study is presented. They may be asked to present parts of the case study. If the student is selected for presentation and is not present, points will be deducted from the overall grade.

Textbooks

Recommended Reading:

William J. Spruill, William E. Wade, Joseph T. DiPiro, Robert A. Blouin, Jane M. Pruemmer, *Concepts in Clinical Pharmacokinetics*, 6th Edition American Society of Hospital Pharmacists, Bethesda.

Basic Pharmacokinetics by David Bourne: <https://itunes.apple.com/us/book/basic-pharmacokinetics/id505553540?mt=11>

Malcolm Rowland & Thomas N. Tozer, *Clinical Pharmacokinetics Concepts and Applications* 4th ed. Lippincott, Williams, and Wilkins, Philadelphia, 2011 (Required Text for Spring Class)

Leon Shargel, Susanna WuPong, Andrew Yu, *Applied Biopharmaceutics and Pharmacokinetics*, 6th ed. McGraw Hill (This text is available via the UF library/Pharmacy Access)

Larry A. Bauer, Applied Clinical Pharmacokinetics, 2nd ed. (This text is available via the UF library/Pharmacy Access)

Pharmacogenomics : an introduction and clinical perspective. Bertino, Joseph S. New York : McGraw-Hill, 2013. ISBN 978-0-07-174169-9. Available through AccessPharmacy at:
<http://www.accesspharmacy.com/resourceToc.aspx?resourceID=783>

Student Evaluation & Grading

Evaluation Methods and how grades are determined

Assessment Item	Grade Percentage
Quizzes (N = 7)	7%
Case Studies – Active Learning/Class Participation (N = 13)	13%
Homework (N = 13)	13%
Midterm Exams (N = 3)	45%
Comprehensive Final Exam	22%
Total	100%

Grading Scale

> 92.5%	A
89.5-92.4%	A-
86.5-89.4%	B+
82.5-86.4%	B
79.5-82.4%	B-
76.5-79.4%	C+
72.5-76.4%	C
69.5-72.4%	C-
66.5-69.4%	D+
62.5-66.4%	D
59.5-62.4%	D-
< 59.4%	E

Rounding of grades: Final course grade will only be rounded up if the decimal is 0.5 or higher. The above scale depicts this policy.

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software. **Appendix A** outlines who to contact if you have questions about technology.

1. ExamSoft®
2. Canvas Learning Management System

Class Attendance Policy

Policy Across All 1PD-3PD courses:

Class attendance is mandatory for active learning sessions such as problem-solving sessions, case discussions, and laboratory sessions. Student attendance may be excused by the Teaching Partnership Leader in the following situations: documented illness, family emergencies, religious holidays, and other reasons of serious nature. Conflict with work schedules is an unexcused absence.

Requests for excused absences **MUST** be made by an email to the Academic Coordinator and the course facilitator prior to the scheduled session. The student is responsible for follow up and confirming whether the absence is excused or unexcused. The Teaching Partnership Leader and your campus specific director must be **CCD** in this communication. The following format is recommended:

To: Academic Coordinator and Campus Course Facilitator
CC: Teaching Partnership Leader and your specific campus director
Subject: PHA XXXX – Excused Absence request
 Dear Prof. _____,
 Professionally and politely request an excused absence.
 Explain the nature of conflict and rationale for receiving an excused absence.
 Thank the faculty member for their consideration of your special request.
 Salutation,
 Type in your full name and last 4 digits of UF-ID #, and Campus Name

Failing to follow this policy will render the absence not excusable. A request for an "excused absence" does not guarantee acceptance. No precedence can be drawn from any courses in the College of Pharmacy or any other college within University of Florida.

Makeup assignment(s) will be made for any excused absence(s) and must be submitted **within one-week of the missed session(s)**. If the situation leads to missing multiple class sessions and makeup becomes difficult, the student and Teaching Partnership Leader will meet with the Associate Dean of Student Affairs to explore options such as a remediation plan or course withdrawal.

Class attendance requires full engagement of activities and discussions. The following are unacceptable during class: 1) read non-course related materials that are either in hard-copy or web-based, 2) study for other courses, 3) use a laptop for activities that are not course-related. Class participation will be reduced in such situations.

Please refer to the University Attendance Policy at <https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>

Additional Policy Specific to This Course:

All homework must be original work by the individual student. Students must be present in the lecture room on the day the Case Study is presented. They may be asked to present parts of the case study. Class roll will be taken and if the student is not present, points will be deducted from the overall grade.

Quiz/Exam Policy

Policy across All 1PD-3PD courses:

1. Students must arrive and be seated promptly to be eligible to take the exam. Students who arrive late for the exam will not be allowed to start the exam if they are more than 30 minutes late or if another student has left the room after seeing the exam.
2. No talking or other disruptive behavior during the distribution or taking of the exam.
3. Calculators must meet the following requirements: Only nonprogrammable calculators are allowed during exams for this course.
4. If you encounter calculator problems (e.g., dead battery), contact the Proctor.
5. Nonessential materials are NOT allowed at the student's desk during examination periods. Please leave all nonessential materials outside of or in the front of the examination room.
6. Other exam rules may be instituted during the progression of the course.
7. Once the exam commences, students may not leave the room without first turning in the exam. Once the exam is turned in, the examination period for the student is considered complete and the student must leave the examination room. If there is urgent need to use the restroom, the Proctor will provide guidance.

Failure to follow exam rules may be considered as evidence of academic dishonesty.

Additional Policy Specific to This Course:

Inquiries about quiz or exam questions should be directed to the Teaching Partnership Leader. Questions about specific content contained on quizzes can be directed to the respective faculty member.

Exam format will include multiple choice, essay questions, and calculations. Questions concerning grading need to be asked not later than one week after grades were posted. The first exams will be returned. Final exams can be looked at, but will be kept. There will be 3 written exams and 6 homework assignments (representing 10% of the final grade). The homework assignments will be given on the Case Studies Days. Exams will be multiple choice, true/false, short answer, essay and problems.

Make-up Quiz/Exam Policy

Policy across All 1PD-3PD courses:

Makeup exams are given only under special circumstances. If the student is unable to take a scheduled examination, the Teaching Partnership Leader and Academic Coordinator must be notified before the examination. In addition, a written letter of explanation, requesting that the absence from the exam be excused, must be presented before the exam or immediately afterwards. An excused absence is allowable when: 1) the student is hospitalized and/or has been advised by a licensed medical

practitioner or hospital not to attend the exam, or 2) if there is a documented death of an immediate family member. All excused absences will be considered on an individual basis by the Teaching Partnership Leader. For unusual situations (e.g., wedding that was planned before admission), the faculty member will communicate with student affairs.

Depending on the decision, a comprehensive exam may be given, which will contain material from all previous exams. The questions on the makeup exam may be in the form of essay, short answer, or multiple-choice. With the exception of highly extenuating circumstances, failure to follow the prescribed procedures or failure to attend the announced comprehensive examination will result in a grade of zero for that exam. A request for an "excused absence" does not guarantee acceptance. No precedence can be drawn from any courses in the College of Pharmacy or any other college within University of Florida.

The makeup exam must be taken **within one-week of the missed exam**. In extenuating circumstances (e.g., hospitalization, faculty availability), the instructor may arrange an alternate deadline for the exam.

The student may contact the instructor to obtain details about why points were deducted. The student has two weeks following the return of the Exam to clarify any questions and appeal any possible grading errors. Any appeals on the final examination must be made in writing and submitted to your facilitator. **When an appeal is made to re-grade an Exam, the entire Exam will be reevaluated and scored.**

Additional Policy Specific to this Course:

None

Policy on Old Quizzes and Assignments

Old quizzes and assignments are available online <http://www.cop.ufl.edu/pc/education/phd/pha5127-bpdoi/>

General College of Pharmacy Course Policies

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies (Assigning Grade Points)
2. Concerns, Appeals, and Complaints
3. Academic Integrity Policy
4. Psychomotor and Learning Expectations
5. How to Request Learning Accommodations
6. Faculty and Course Evaluations
7. Computer and Other Technology Requirements
8. Expectations in Class and Other Learning Activities
9. Communications - Discussion Board Policy
10. Communications - Email
11. Religious Holidays

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12. Counseling & Student Health Services
 13. How to Access Services for Student Success
 14. Faculty Lectures/Presentations Download Policy

Please see the following URL for this information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

Appendix A. Faculty and Staff: Who to Contact

Academic Coordinator:

1. Questions about dates, deadlines, meeting place
2. Availability of handouts and other course materials
3. Assignment directions
4. Questions about grade entries gradebook (missing grades, wrong grade)
5. Assistance with ExamSoft®

Teaching Partnership Leaders

1. Issues related to course policies (absences, make up exams, missed attendance)
2. Questions about grades
3. Concerns about performance
4. Guidance when there are performance problems (failing grades)
5. General questions about content

Other Teaching Partnership Faculty Members

1. Questions about specific content

Technical Support:

Contact the College of Pharmacy MediaHelp Desk for assistance with course-related technical issues (e.g., Canvas access, video access, printing of documents). The MediaHelp Desk may be reached via the following:

Phone: 352-273-6281 (9am-4PM ET)

Email: mediahelp@cop.ufl.edu (response is delayed outside of M-F 9AM-4PM ET)

Contact the University of Florida Computing Help Desk for addresses issues related to:

1. Gatorlink accounts,
2. Gatorlink email,
3. myUFL, and
4. ISIS.

Phone: (352)-392-4357