PHA5132 Principles of Drug Therapy Individualization

Spring, 2024

4 Credit Hours – [A-E Grading]

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 dose-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.

Teaching Partnership Leaders

Guenther Hochhaus, Ph.D.

- Email: hochhaus@cop.ufl.edu
- Office: MSB P3-33
- Phone: 352 273 7861
- Office Hours: Please see the Canvas course site for posted office hours.

See Appendix A. for Course Directory of Faculty and Staff Contact Information.

Entrustable Professional Activities

This course will prepare you to perform the following activities which the public entrusts a Pharmacist to perform:

1. Patient Care Provider Domain

2. Analyze information to determine the effects of medication therapy, identify medication-related problems, and prioritize health-related needs.

    ST2.1. Interpret laboratory test results

    ST 2.1b Interpret data related to personalized medicine.

    ST2.2. Evaluate an existing drug therapy regimen

3. Establish patient-centered goals and create a care plan for a patient in collaboration with the patient, caregiver(s), and other health professionals that is evidence-based and cost-effective

    ST3.1. Develop a treatment plan with a patient (including recommend therapeutic alternatives and generic substitution).

    ST3.2. Manage drug interactions.

Course-Level Objectives

Upon completion of this course, the student will be able to:

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. Relate the volume of distribution to plasma and tissue binding of a drug
5. Predict the effects of blood flow, intrinsic clearance, and protein binding on drug clearance for high and low extraction drugs.
6. Determine whether a drug is predominately reabsorbed or secreted based on renal clearance and protein binding.
7. Predict the relationship between pH (and urine flow) and renal clearance.
8. Calculate a patient's peak and trough plasma drug concentrations after receiving single and multiple intravenous bolus doses/at steady-state.
9. 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.
10. Recommend dosing for a patient who is receiving an oral drug by considering the relationships of clearance, elimination rate constant, and volume of distribution.
11. Understand the different and typical BA/BE study designs and discuss the criteria for acceptance of BE testing.
12. Contrast two- and three-compartment body models with the one-compartment body model with respect to assumptions, drug distribution, and drug elimination.
13. Describe the common special patient populations and the characteristics of each that must be considered during drug individualization.
14. Explain the nomenclature that is used to describe genotype and phenotype.
15. Demonstrate how to use available pharmacogenomics databases.
16. Describe the purpose of the CPIC guidelines and how to use them as a clinician.
17. Discuss how "OMICs" technologies can be used to stratify disease classification and personalize drug therapy.
18. Discuss how pharmacogenetics contributes to variability in drug metabolism and transport.
19. Discuss Food-Drug/Drug Interactions and their consequences as well as understand how to change or adjust treatment plans accordingly.

Course Pre-requisites

1. Admission into the Doctor of Pharmacy program.
2. Satisfactory completion of Blocks 1 and 2.

Course Co-requisites

1. There are no co-requisites for this course.

Required Textbooks/Readings

1. There are no required textbooks for this course.

Use UF VPN to access UF Libraries Resources when off-campus.
The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the HSC Library Website at this URL:http://www.library.health.ufl.edu/

Suggested Textbooks/Readings

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

Derendorf H and Schmidt S (ed.) *Rowland and Tozer's Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications*. Fifth Edition. Wolters Kluwer, Alphen aan den Rijn, Netherlands, 2019, 1-939. https://books.google.com/books/about/Rowland_and_Tozer_s_Clinical_Pharmacokin.html?id=4OuhDwAAQBAJ

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)

David Kisor, Michael Kane, Jon Sprague, Jeffery Talbot, Pharmacogenetics, Kinetics, and Dynamics for Personalized Medicine, Burlington, Jones & Bartlett Publishers, 2013. ISBN 978-1-44496-5273-9 https://books.google.com/books/about/Pharmacogenetics_Kinetics_and_Dynamics_f.html?id=DchzGBa3AoYC

Pharmacogenomics: An Introduction and Clinical Perspective. Bertino, Joseph S. New York: McGraw-Hill, 2013. ISBN 978-0-07-174169-9. Available through Access Pharmacy at: http://www.accesspharmacy.com/resourceToc.aspx?resourceID=783

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Other Required Learning Resources

N/A

Materials & Supplies Fees

None

Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.
[The Canvas© gradebook will be set-up using the percentages below to compute the grade.]

Table 1.1 Evaluation and Grading Below

Assessment Item	Grade Percentage
Quizzes	30% (N=10 at 3% each)
Exam 1	23%
Exam 2	23%
Exam 3	24%
Total	100%

Table 1.2 Grading Scale

Percentage	Letter Grade
92.50-100%	A
89.50-92.49%	A-
86.50-89.49%	B+
82.50-86.49%	B
79.50-82.49%	B-
76.50-79.49%	C+
72.50-76.49%	C
69.50-72.49%	C-
66.50-69.49%	D+
62.50-66.49%	D
59.50-62.49%	D-
< 59.50%	E

Rounding of grades:
Final grades in Canvas will be rounded to the 2nd decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and NO EXCEPTIONS will be made in situations where a student's grade is "close."

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software.

1. ExamSoft™ Testing Platform
2. Canvas™ Learning Management System

For technical support, navigate to Educational Technology and IT Support Contact Information at this URL: http://curriculum.pharmacy.ufl.edu/current-students/technical-help/

Artificial Intelligence Use

The use of artificial intelligence (AI) text generators such as ChatGPT on assignments, projects, quizzes, and exams is prohibited in this course. Use of AI text generators is considered evidence of academic

dishonesty. If a student is uncertain about the use of AI technology, it is the student's responsibility to ask the instructor prior to beginning the assignment or assessment.

Pharm.D. Course Policies

The Policies in the following link apply to this course. Review the General Pharm.D. Course Policies carefully, at this URL: http://curriculum.pharmacy.ufl.edu/current-students/course-policies/

Attendance Policy

Attendance is mandatory for active learning sessions such as team-based learning sessions, case discussions, laboratory sessions, and other activities that the instructor designates as required. This course has 10 required sessions. A student who misses more than 2 sessions for this course (greater than 25% of the required active learning sessions) will receive an incomplete in the course and will retake the course during the next offering, resulting in delayed graduation.

Late Assignments

N/A

Makeup Assignments

N/A

Accessibility and Belonging Statement

The University of Florida College of Pharmacy strives to stimulate a culture that promotes diversity and inclusion within an exceptional community of students, faculty, and staff. It is our intent that students from all diverse backgrounds and perspectives be well served by this course, that students' learning needs be addressed both in and out of class, and that the diversity that students bring to this class be viewed as a resource, strength, and benefit.

We intend to present materials and activities that are respectful of diversity: gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture. Your suggestions are encouraged and appreciated. Please let us know ways to improve the course's effectiveness for you personally or for other students or student groups.

If any of our class meetings conflict with any of your religious events, an excused absence will be provided when requested using the standard UF COP process as detailed in the UF COP Course policies. If you feel that you have experienced or witnessed any bias/treatment that falls short of these expectations, you may submit a report through the UF COP *Student Mistreatment Report*.

Course Evaluation Process

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via https://ufl.bluera.com/ufl/.

Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/.

Appendix A. Course Directory

Teaching Partnership Leader/Course Director:

Guenther Hochhaus, Ph.D.
Email: hochhaus@cop.ufl.edu
Office: MSB P3-33
Phone: 352 273 7861
Office Hours: Please see the Canvas course site for posted office hours.

Questions to Ask:

- Concerns about performance
- Guidance when there are performance problems (failing grades)
- General questions about content

Other Teaching Partnership Faculty Members:

Emily J. Cicali, Pharm.D., BCPS
Email: emily.cicali@cop.ufl.edu
Office: DG-22R (Gainesville)
Phone: 352-273-7919

Natalia De Moraes, B. Pharm, Ph.D.
Email: nataliademoraes@ufl.edu
Office: ORL
Phone: 407-313-7048

Stephan Schmidt, B.Pharm, Ph.D., F.C.P.
Email: sschmidt@cop.ufl.edu
Office: 464/ORL
Phone: 407-313-7012
Office Hours: Please see the Canvas course site for posted office hours.

Instructional Designer:

- Name: Holly Fremen
- Email: holly.fremen@cop.ufl.edu
- Office: HPNP 4309
- Phone: 352-273-5558

Academic Coordinator Gainesville Campus:

Name: Ashley Williams

- Email: acwilliams@ufl.edu
- Office: HPNP 4312
- Phone: 352-273-5617

Absence/Tardy Email: (Visit the course policy site for further instructions)

Educational Coordinators

Name: Katie Orben

- Email: korben06@ufl.edu
- Office: Jacksonville Campus
- Phone: 904-244-9590

Name: Jessica Linares

- Email: jnoriegalinares@ufl.edu
- Office: Orlando Campus
- Phone: 407-313-4087

Questions to Ask:

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence/tardy requests (Only the Academic Coordinator handles absence requests)
- Questions about dates, deadlines, meeting place
- Availability of handouts and other course materials
- Assignment directions
- Questions about grade entries in gradebook (missing grades, incorrect grade)
- Assistance with ExamSoft® (Distance campus students may contact the Educational
- Coordinator for use of Examplify and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.

Student Dates of Study	Mod#	Activity	Unit Topic	Contact Hour	Learning Objective	Faculty
01/04/24	1	Module	Module 1: Introduction to Pharmacokinetics; Pharmacodynamics & Personalized Medicine		1	Guenther Hochhaus
01/04/24	1.1	Video Lecture	Watch: Introduction to Pharmacokinetics, Pharmacodynamics & Personalized Medicine	0.75		Guenther Hochhaus
01/09/24	2	Module	Module 2: Basic Pharmacokinetics		2-3	Guenther Hochhaus
01/09/24	2.1	Video Lecture	Watch: Basic Pharmacokinetics, Part 1	1.5		Guenther Hochhaus
01/10/24	2.2	Video Lecture	Watch: Basic Pharmacokinetics, Part 2	0.5		Guenther Hochhaus
01/11/24 3:00pm-4:50pm	1-2	Active Learning Session--VC	Active Learning Session 1:	2	1-3	Guenther Hochhaus
01/11/24	1-2	Quiz In-class Graded	Quiz 1			Guenther Hochhaus
01/12/24	3	Module	Module 3: Distribution		4	Guenther Hochhaus
01/12/24	3.1	Video Lecture	Watch: Drug Distribution, Part 1	0.75		Guenther Hochhaus
01/12/24	3.2	Video Lecture	Watch: Drug Distribution, Part 2	2.5		Guenther Hochhaus
01/16/24 8:00am-9:50am	3	Active Learning	Active Learning Session 2:	2	4	Guenther Hochhaus

		Session--VC				
01/16/24	3	Quiz In-class Graded	Quiz 2			Guenther Hochhaus
01/16/24	4	Module	Module 4: Hepatic Clearance		5	Guenther Hochhaus
01/16/24	4.1	Video Lecture	Watch: Hepatic Clearance 1	0.5		Guenther Hochhaus
01/17/24	4.1	Video Lecture	Watch: Hepatic Clearance 2	0.5		Guenther Hochhaus
01/17/24	4.1	Video Lecture	Watch: Hepatic Clearance 3	1		Guenther Hochhaus
01/18/24	4.2	Video Lecture	Watch: Hepatic clearance 4	0.5		Guenther Hochhaus
01/19/24 3:00pm-4:50pm	4	Active Learning Session--VC	Active Learning Session 3:	2	5	Guenther Hochhaus
01/19/24	4	Quiz In-class Graded	Quiz 3			Guenther Hochhaus
01/19/24	5	Module	Module 5: Renal Clearance		6,7	Guenther Hochhaus
01/19/24	5.1	Video Lecture	Watch: Drug Elimination; Renal Clearance	0.75		Guenther Hochhaus
01/22/24	5.2	Video Lecture	Watch: Renal Clearance	0.5		Guenther Hochhaus
01/23/24 10:00am-11:50am	5	Active Learning Session--VC	Active Learning Session 4:	2	6,7	Guenther Hochhaus
01/23/24	5	Quiz In-class Graded	Quiz 4			Guenther Hochhaus
			MATERIAL OF FIRST EXAM ENDS HERE			

1/26/24 3:00pm-4:00pm	1-5		Zoom Exam 1 Review	1	1-7	Guenther Hochhaus
01/30/24 10:00am-12:00pm	1-5	Exam	Exam 1, Modules 1-5	2	1-7	Guenther Hochhaus
01/30/24	6	Module	Module 6: Intravenous Bolus Administration		8	Stephan Schmidt
01/30/24	6.1	Video Lecture	Watch: IV Bolus Administration, Part 1	0.75		Stephan Schmidt
01/31/24	6.2	Video Lecture	Watch: IV Bolus Administration, Part 2	0.5		Stephan Schmidt
01/31/24	6.3	Video Lecture	Watch: IV Bolus Administration, Part 3	1		Stephan Schmidt
02/1/24 8:00am-9:50am	6	Active Learning Session--VC	Active Learning Session 5:	2	8	Stephan Schmidt
02/1/24	6	Quiz In-class Graded	Quiz 5			
02/1/2024	7	Module	Module 7: Intravenous Infusion		9	Stephan Schmidt
02/01/24	7.1	Video Lecture	Watch: Continuous Intravenous Infusion	0.5		Stephan Schmidt
02/05/24	7.2	Video Lecture	Watch: Intermittent Intravenous Infusion	0.5		Stephan Schmidt
02/06/24	7.3	Video Lecture	Watch: IV Infusion Examples	0.5		Stephan Schmidt
02/07/24 3:00pm – 3:30pm		Exam Review	Post Exam 1 Review			

02/08/24 8:00am-9:50am	7	Active Learning Session--VC	Active Learning Session 6:	2	9	Stephan Schmidt
02/08/24	7	Quiz In-class Graded	Quiz 6			Stephan Schmidt

02/13/24	8	Module	Module 8: Oral Administration		10	Stephan Schmidt
02/13/24	8.1	Video Lecture	Watch: Oral Administration	0.75		Stephan Schmidt
02/13/24	9	Module	Module 9: Bioequivalence		11	Guenther Hochhaus
02/13/24	9.1	Video Lecture	Watch: Bioequivalence	1		Guenther Hochhaus
02/14/24	10	Module	Module 10 Compartmental Models		12	Stephan Schmidt
02/14/24	10.1	Video Lecture	Watch: Compartmental Models	0.5		Stephan Schmidt
02/15/24 10:00am-11:50am	8,9,10	Active Learning Session--VC	Active Learning Session 7:	2	10-12	Stephan Schmidt Guenther Hochhaus
2/15/24	8-10	Quiz In-class Graded	Quiz 7		10-12	Stephan Schmidt
			MATERIAL OF SECOND EXAM ENDS HERE			

02/16/24 3:00pm-4:00pm	6-10		Zoom Exam 2 Review	1	8-12	Stephan Schmidt, Guenther Hochhaus
02/21/24 10:00am-12:00pm	6-10	Exam	Exam 2, Modules 7-10	2	8-12	Stephan Schmidt, Guenther Hochhaus
02/22/24	11	Module	Module 11: Special Patient Populations		13	Natalia de Moraes
02/22/24	11.1	Video Lecture	Watch: Special Patient Populations, Part 1	0.75		Natalia de Moraes
02/22/24	11.2	Video Lecture	Watch: Special Patient Populations, Part 2	0.5		Natalia de Moraes
02/23/24	11.3	Video Lecture	Pharmacokinetics and Dosage in Patients with Renal Disease	1		Natalia de Moraes
02/23/24	11.4	Video Lecture	Body-size Measure for Normalization	0.75		Natalia de Moraes
02/26/24	12	Module	Module 12: Principles of Personalized Medicine		14-17	Emily Cicali
02/26/24	12.1	Video Lecture	Watch: Introduction to Pharmacogenomics	0.75		Emily Cicali
02/26/24	12.2	Video Lecture	Watch: Principle of Genetic Medicine, Part 1	1		Emily Cicali
2/27/24	12.3	Video Lecture	Watch: Principle of Genetic Medicine, Part 2	1		Emily Cicali

2/28/24	12.4	Video Lecture	Watch: Database Tools for Pharmacogenomics	1		Emily Cicali
02/29/24 9:00am – 9:30am		Exam Review	Post Exam 2 Review			
02/29/24 10:00am-11:50am	11, 12	Active Learning Session--VC	Active Learning Session 8:	2	13-17	Natalia de Moraes Emily Cicali
02/29/24	11, 12	Quiz In-class Graded	Quiz 8			Emily Cicali Natalia de Moraes
02/29/24	13	Module	Module 13: Pharmacogenomic (1) of Drug Metabolizing Enzymes		18	Emily Cicali
03/01/24	13.1	Video Lecture	Pharmacogenomics of Drug Metabolism: Part 1	0.75		Emily Cicali
03/01/24	13.2	Video Lecture	Pharmacogenomics of Drug Metabolism: Part 2	1		Emily Cicali
03/04/24	13.3	Video Lecture	Pharmacogenomics of Drug Metabolism: Part 3	0.5		Emily Cicali
03/05/24 10:00am-11:50am	13	Active Learning Session--VC	Active Learning Session 9:	2	18a	Emily Cicali
03/05/24	13	Quiz In-class Graded	Quiz 9			Emily Cicali
03/06/24	14	Module	Module 14: Pharmacogenomics 2		18b	Emily Cicali
03/06/24	14.1	Video Lecture	Watch: Pharmacogenomics of Drug Transporters, Part 1	0.75		Emily Cicali

03/06/24	14.2	Video Lecture	Watch: Pharmacogenomics of Drug Transporters, Part 2	0.5		Emily Cicali
03/07/24	14.3	Video Lecture	Pharmacogenomics of Drug Metabolism: Part 3	0.5		Emily Cicali
			SPRING BREAK			
03/19/24	15	Module	Module 15: Food-Drug/Drug Drug Interactions		19	Natalia de Moraes
03/19/24	15.1	Video Lecture	Watch: Food and Herbal Supplement-Based Drug Interactions	0.5		Natalia de Moraes
03/20/24	15.2	Video Lecture	Watch: Enzyme and Transporter Mediated Drug-Drug Interactions	0.75		Natalia de Moraes
03/21/24 1:00pm-2:50pm	14-15	Active Learning Session--VC	Active Learning Session 10:	2	18b, 19	Emily Cicali Natalia de Moraes
03/21/24	14-15	Quiz In-class Graded	Quiz 10			Emily Cicali Natalia de Moraes
03/21/24 3:00pm-3:30pm		Course Eval	Mandatory Course Evaluations. Attendance required.			
03/22/24 3:00pm-4:00pm	11-15		Zoom Final Exam Review	1	13-19	Emily Cicali, Natalia de Moraes

03/26/24 10:00am-12:00pm	11-15	Exam	Exam 3, Modules 11-15		13-19	Emily Cicali, Natalia de Moraes
04/01/24 4:00-4:30pm		Exam Review	Post Final Exam Review.			
			Total	54.75		