PHA 6125
Introduction to Quantitative Pharmacology

FALL 2023
3 credit hours

This course consists of a series of lectures and active learning/hands on sessions (ALS) structured in 8 different modules focused on general principles of drug pharmacology. Major topics are principles of drug pharmacokinetics (PK) (including drug absorption, distribution, metabolism and elimination, ADME) and pharmacodynamics and the interpretation of pharmacology in a quantitative fashion. This course is aimed to expose students to comprehensive case examples to apply principles and concepts.

Course faculty and teaching hours

Course coordinators

Dr. Rodrigo Cristofoletti (R C)
Email: rcristofoletti@cop.ufl.edu
Office: 467/ORL
Phone: 407-313-7115
Office Hours: By appointment ONLY.

Teaching Partners:

Dr. Natalia De Moraes (NM)
Email: nataliademoraes@ufl.edu

Dr. Stephan Schmidt (SS)
Email: sschmidt@cop.ufl.edu

Dr. Richard Lalonde (RL)
Email:richard.lalonde@cop.ufl.edu

Dr. Valva Vozmediano (VV)
Email: vvozmediano@ctifacts.com

Dr. Abhisheak Sharma (AS)
Email: asharma1@ufl.edu

Dr. Sarah Kim (SK)
Email: sarahkim@cop.ufl.edu

Dr. Monica Rodriguez
Email:mrodriguez@dynakin.com

Dr. Serge Guzy
Email: poppharm2@gmail.com

ALS	Thursdays 8:30-10:00 am
Room	P4-20 (Gainesville) 334 (Lake Nona)

Course-Level Objectives

Upon completion of this course, students will be able to understand and apply the concepts and principles of pharmacokinetics and pharmacodynamics and its role in designing optimal dosing regimens. Specifically:

1. Visualize the drug development process, familiarize with the information required to build the drug label and understand how PK and PD studies help to inform it.
2. Understand and explain the following concepts: first-order elimination, zero-order elimination, half-life, volume of distribution, and clearance.
3. Understand and explain the following concepts: first-order absorption, flip-flop kinetics, and drug absorption.
4. Predict the effect of some physiological processes, as blood flow, intrinsic clearance or protein binding affect PK processes.
5. Identify whether a drug is predominately reabsorbed or secreted based on renal clearance and protein binding.
6. Predict the relationship between pH (and urine flow) and renal clearance.
7. Apply pharmacokinetic equations to derive pharmacokinetic parameters, and pharmacokinetic parameters to predict plasma concentration over time, maximum plasma concentrations and area under the curve.
8. Recommend dosing regimens in different clinical situations.
9. Understand the basic pharmacodynamics principles and models.
10. Understand how growth, aging and disease affect drug's PK and PD, and the considerations behind selecting dosing regimens for special populations.
11. Access different case examples on the application of pharmacokinetic and pharmacodynamics principles for dose selection.

Course Pre-requisites

There are no pre-requisites for this course

Course Co-requisites

There are no co-requisites for this course

Course Outline

Module 1: Generalities
Overview of the drug development process. Importance of PK/PD (RL)
Fundamental concepts and basic PK (and PD) parameters (RC)

Module 2a: ADME processes
Clearance: Renal and hepatic (SS)

Module 2b: ADME processes
Protein Binding and Drug Distribution (VV)

Module 2c: ADME processes
Absorption (RC)

Module 3: **Non-compartmental PK**
Non-compartmental PK (SK)

Module 4a: Intravenous Pharmacokinetics
One-compartment Model (AS)

Module 4b: Intravenous Pharmacokinetics
Multi-compartment Model (AS)

Module 4c: Intravenous Pharmacokinetics
Zero-order infusion and steady state (AS)

Exam 1: modules 1-4

Module 5a: Extravascular PK
Modeling absorption related processes (RC)

Module 5b: Extravascular PK
In vitro – in vivo correlations (RC)

Module 5c: Extravascular PK
Bioavailability and bioequivalence (RC)

Module 6: Pharmacokinetics of large molecules
PK of Protein Therapeutics (SS)
Nonlinear PK: Michaelis Menten kinetics and target mediated drug disposition (TMDD) (SS)

Module 7: Pharmacodynamics
Introduction to Pharmacodynamics (VV, MR)
PK/PD Applications (VV, MR)

Module 8: PBPK
Introduction to PBPK (RC)

Module 9a: PK/PD Special Populations
Pediatrics (NM)
Geriatrics (NM)

Module 9b: PK/PD Special Populations
Renal and hepatic impairment (NM)

Exam 2: modules 5-9

Course calendar

Week#	*First day of the week*	*Module*	*Topic*
Week 1	23th-Aug-2023	Module 1	Overview of the drug development process. Importance of PK/PD (RL) Fundamental concepts and basic PK (and PD) parameters (RC)
Week 2	28th-Aug-2023	Module 2	Clearance: Renal and hepatic (SS) Protein Binding and Drug Distribution (VV) Absorption (RC)
Week 3	5th-Sep-2023	Module 3	Non-compartmental PK (SK)
Week 4	11th-Sep-2023	Module 4a	One-compartment Model (AS)
Week 5	18th-Sep-2023	Module 4b	Multi-compartment Model (AS)
Week 6	25th-Sep-2023	Module 4c	Zero-order infusion and steady state (AS)
Week 7	**2nd-Oct-2023**	**Exam #1**	**Modules 1-4**
Week 8	10th-Oct-2023	Module 5a	Modeling absorption related processes (RC)
Week 9	16th-Oct-2023	Module 5b	In vitro – in vivo correlations (RC)
Week 10	23rd-Oct-2023	Module 5c	Bioavailability and bioequivalence (RC)
Week 11	30th-Oct-2023	Module 6	PK of Protein Therapeutics (SS) Nonlinear PK: Michaelis Menten kinetics and target mediated drug disposition (TMDD) (SS)
Week 12	06th-Nov-2023	Module 7	Introduction to Pharmacodynamics (MR, VV) PK/PD Applications (MR, VV)
Week 13	13th-Nov-2023	Module 8	Introduction to PBPK (RC)
Week 14	20th-Nov-2023	*Thanksgiving*	
Week 15	27th-Nov-2023	Module 9a	PK/PD Special Populations: Pediatrics (VV) Geriatrics (VV)
Week 16	4th-Dec-2023	Module 9b	PK/PD Special Populations: Renal and hepatic impairment (VV)
Week 17	**11th-Dec-2023**	**Exam #2**	**Modules 5-9**

Suggested Textbooks/Readings

- Rowland, Malcolm, and Thomas N. Tozer. Clinical Pharmacokinetics: Concepts and Applications. Philadelphia: Lea & Febiger, 1980. 5th edition. https://shop.lww.com/Rowland-and-Tozer-s-Clinical-Pharmacokinetics-and-Pharmacodynamics--Concepts-and-Applications/p/9781496385048
- Pharmacokinetic & Pharmacodynamic Data Analysis Johan Gabrielsson and Dan Weiner. 4th edition. Swedish Pharmaceutical Press 2006 http://www.amazon.com/Pharmacokinetic-Pharmacodynamic-Data-Analysis-Applications/dp/9197651001/ref=sr_1_1?ie=UTF8&s=books&qid=1198635484&sr=1-1
- Basic Pharmacokinetics by David Bourne: https://itunes.apple.com/us/book/basic-pharmacokinetics/id505553540?mt=11

- 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)

Other reading material will be provided during the course.

Assignments grading

In case of delayed assignments, a penalty of 25% reduction in the assignment grade will be applied.

Students grading

First Exam	20%
Second Exam	30%
Computer Projects	50%

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.

Class Attendance Policy

Class attendance is mandatory for all classes. Student attendance may be excused by Dr. Cristofoletti 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 prior to the scheduled session. The student is responsible for follow up.

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 Course Coordinators 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 (including the Religious Holidays policy) at https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx

Academic Integrity Policy

Students are expected to act in accordance with the University of Florida policy on academic integrity (http://www.dso.ufl.edu/sccr/honorcodes/honorcode.php). This Honor Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obliged to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult the Course Coordinators. Students are also expected to abide by the UF Honor Code.

The following is the UF Honor Pledge: We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honesty 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."

How to Request Learning Accommodations

Students with disabilities are strongly encouraged to register with Disabled Student Services in the Office for Student Services (P202 Peabody Hall) and it is recommended this to be accomplished prior to starting the course.

· 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.

· Please visit the following URL for more information: http://www.dso.ufl.edu/drc

Please note that you must arrange for accommodations in advance; grades cannot be retroactively changed

Faculty and Course Evaluations

Faculty Evaluations

You will receive an email from the Curricular Affairs Office requesting to complete the faculty evaluations. Faculty evaluations are important feedback for your course instructors and the University and receive major consideration in the tenure and promotion process. Your input via evaluations can make a difference in our College's teaching activities, so participate, evaluate and our College will be better for it.

The online faculty evaluation system is completely anonymous. When you submit an evaluation, the system marks that you have submitted an evaluation for the section (so you cannot submit multiple evaluations), but from that point on, there is no connection between you and the evaluation data. Faculty evaluations also provide useful information for students. The results of your evaluation input are made available to all students in future semesters at:

http://www.aa.ufl.edu/aa/evaluations/search/.

Course Evaluations

In the last few weeks of the course, you will receive an email with directions for completing a course evaluation. Note, course evaluations provide feedback that is different from the Faculty evaluations and both are very important to continuous improvement of our program. Course evaluations are used by the College to identify how to improve the how the course is designed and delivered. Therefore, our Courses will be better through your completion of these evaluations. You will complete Course Evaluations via a website that is different from Faculty Evaluations. These evaluations are also anonymous.