PHAR 7220: Therapeutic Drug Monitoring (TDM) and Clinical Pharmacokinetics
Fall Semester 2024

Course Description
This course prepares the student to apply and incorporate therapeutic drug monitoring and clinical pharmacokinetics into the patient care process.

Additional Course Information
This course introduces representative medications that require monitoring for maximal therapeutic benefits while minimizing potential adverse events. Students apply foundational knowledge of pharmacokinetics acquired in PHAR 7302, Principles of Pharmacokinetics and Biopharmaceutics, to make clinically appropriate, patient-centered therapeutic drug dosing and monitoring recommendations.

Course Credit: Two (2) credit hours

Pre-Requisites: PHAR 7302: Principles of Pharmacokinetics & Biopharmaceutics

Co-Requisites: None

Class Meeting Days, Time & Location:
- Mondays, 2:00 pm – 3:50 pm CST; W.T. Brookshire Hall room # 234
- Supplemental Instruction (Optional): Select Wednesdays, 10-11 am, via Zoom (see schedule below)

Course Coordinator:
Winter J. Smith, Pharm.D., BCPS
W.T. Brookshire Hall Room 247
Email: wsmith@uttyler.edu
Office hours:
- **MUST** make appointment: Mondays, 1-2 PM and Wednesdays, 12-2 PM (may be virtual or in-person)
- Other days/times by appointment
- Preferred method of contact: email

Fisch College of Pharmacy (FCOP) and UT Tyler Policies
This is Part 1 of the syllabus. Part 2 contains UT Tyler and the FCOP course policies and procedures. These are available at https://www.uttyler.edu/pharmacy/academic-affairs/files/fcop-syllabus-policies.pdf. For experiential courses (i.e., IPPE and/or APPE), the Experiential Manual contains additional policies and instructions that supplement the Syllabus Part 1 and 2. Please note, the experiential manual may contain policies with different deadlines and/or instructions. The manual should be followed in these cases.

Required Materials

Most course required materials are available through the Robert R. Muntz Library. These materials are available either online* (http://library.uttyler.edu/) or on reserve.

1. Beringer PM, ed. Winter's Basic Clinical Pharmacokinetics, 7e. Wolters Kluwer, 2024. **Available through LWW Health Library**. Access to Muntz online library resources is required.
2. Lexi-Drugs Online [database on the Internet]. Hudson (OH): Lexicomp, Inc.; 2024. **Available through Access Pharmacy**. Access to Muntz online library resources is required.
3. Other required materials will be posted on the course Canvas site.

Recommended Materials

1. Bauer LA. ed. Applied Clinical Pharmacokinetics, 3e. McGraw Hill; 2015. **Available through Access Pharmacy.** Access to Muntz online library resources is required.
2. Cohen H. eds. Casebook in Clinical Pharmacokinetics and Drug Dosing. McGraw Hill; 2015. **Available through Access Pharmacy.** Access to Muntz online library resources is required.
3. DiPiro JT, Yee GC, Haines ST, et al, eds. DiPiro's Pharmacotherapy: A Pathophysiologic Approach, 12e. McGraw-Hill; 2023. **Available through Access Pharmacy.** Access to Muntz online library resources is required.
4. Other supplemental materials may be posted on the course Canvas site.

Course Format

The course may include, but are not limited to, the following activities:

The course may include, but is not limited to, the following activities:

1. Independent study of selected readings
2. Active learning strategies:
    a. In and out of class applications
    b. Pharmacokinetic dosing and monitoring consult notes

Course Learning Outcomes (CLOs)

CLOs	PLO(s) Assessed for this CLO (1-15)	EPAs (1-13)	ACPE Std. 11 & 12 (1-4)	Grading Method	Assessment Methods
1. Define basic pharmacokinetic parameters including volume of distribution, clearance terms, extraction ratio, elimination half-life, and unbound fraction.	1	N/A	4	ES	1,2
2. Explain the clinical significance of linear and non-linear pharmacokinetic profiles of representative medications.	1,2,5	N/A	4	ES	1,2
3. Describe how pharmacokinetic changes in select special patient populations impact drug dosing and monitoring: pediatric, obese, elderly, critically ill, and renal impairment (including renal replacement therapy)	1,2	1,2,3,9,12	4	ES	1,2
4. Apply pharmacokinetic principles to recommend patient-specific initial dosing regimens and monitoring parameters for	1,2,6	2,3,6,9	4	ES	1,2

medications in the following medication classes: a. Select anticoagulants b. Select antibiotics c. Select antifungals d. Select anti-epileptic agents e. Digoxin f. Select immunosuppressant agents					
5. Recommend dose adjustments and monitoring parameters based on renal function, plasma drug concentrations, and other laboratory results.	1,2,6	2,3,6,9	4	ES	1,2
6. Document medication dosing and monitoring recommendations with appropriate lab assessments in a pharmacokinetic consult note.	2,6,9,11	4,6	1	RUB	3
7. Understand the genetic basis of drug response variability, the impact of genetic variations on drug disposition, efficacy, and safety, and the clinical applications of pharmacogenetic testing.	1,6	1,2	4	ES	1,2

ES = ExamSoft; RUB = Rubric

Course Assessment Methods

	Assessment method	Description
1	Midterm and Final Exam Multiple Choice or Multiple Select Question(s)	Standard MCQ, true/false, matching, and select all that apply
2	Midterm and Final Exam Open Ended Questions	Fill-in-the-blank, essay, and handwritten calculations.
3	Individual Project	Pharmacokinetic dosing and monitoring consult note

Grading Policy & Grade Calculation

Grades will be determined based on evaluation of individual and team readiness assessment tests (iRATs, tRATs), individual and team cumulative assessment tests (iCATs, tCATs), midterm examinations, final written examinations, skills assessments, graded application assignments, participation in team-based projects, peer evaluations and other assessment methods that may include, but not limited to, Objective Structured Clinical Examinations (OSCEs). Examinations, RATs and CATs may consist of, but not limited to, multiple-choice, true/false, fill in the blank, short-answer, essay, and problem-based questions.

All examinations, tests, and assignments, including the final examination, may be **cumulative.** Students are responsible for material presented during prior courses. The grading scale for all graded material is below. The final course grade will be assigned according to the calculated percentage and the percentages will not be rounded upward or downward. For additional information, see Part 2 of the syllabus (https://www.uttyler.edu/pharmacy/academic-affairs/files/fcop-syllabus-policies.pdf).

During the time the course is in progress, students who obtain less than 75% on any summative assessment or a total course grade of less than 75% during a particular semester will receive an academic alert from the course coordinator and the Office of Academic Affairs and be subject to weekly in-course remediation with the course instructor(s).

Standard Grade Calculation	
Individual component	**100%**
Individual applications (includes in-class and take-home assignments)	8%
Pharmacokinetic consult note	5%
Major assessments (Midterms/Final exams) Midterm 1 = 20% Cumulative Midterm 2 = 27% Cumulative Final Exam = 40%	87%
Total	**100%**

The final course letter grade will be determined according to the following grading scheme:

A	90 - 100 %
B	80 - 89.999 %
C	70 - 79.999 %
D	65.0 - 69.999 %
F	< 65.0 %

FALL 2024 PHAR 7220: TDM + Clinical Pharmacokinetics Schedule of Topics*

Date	Topic	Instructor	CLO	Disease State(s)
MON 8-26-2024 2-3:50 pm	Course Overview Pharmacokinetics: Foundational review	Smith	1,2	S20.99
WED 8-28-2024 10-11 am	Supplemental Instruction (Optional)			
MON 9-2-2024	***NO CLASS (Labor Day Holiday)***			
MON 9-9-2024 2-3:50 pm	Clinical pharmacokinetics: Dosing considerations in renal dysfunction, renal replacement therapy, hepatic disease, and critical illness	Smith	3	S04.04 S04.08 S04.12
WED 9-11-2024 10-11 am	Supplemental Instruction (Optional)			
MON 9-16-2024 2-3:50 pm	Clinical pharmacokinetics: Dosing considerations in pediatric, pregnant, obese, and elderly patients	Smith	3	S18.04 S18.09 S18.14
WED 9-18-2024 10-11 am	Supplemental Instruction (Optional)			
MON 9-23-2024 2-3:50 pm	Clinical pharmacokinetics: Anticoagulants	Smith	1,3,4,5,6	S01.11
WED 9-25-2024 10-11 am	Supplemental Instruction (Optional)			
9-30-2024 2 – 4 pm	***Midterm Examination 1 – assessment of 8-26 through 9-23 material***			
MON 10-7-2024 2-3:50 pm	Clinical pharmacokinetics: Vancomycin 1	Smith	1,3,4,5,6	S15.16
MON 10-14-2024 2-3:50 pm	Clinical pharmacokinetics: Vancomycin 2	Smith	1,3,4,5,6	S15.16
WED 10-16-2024 10-11 am	Supplemental Instruction (Optional)			
MON 10-21-2024 2-3:50 pm	Clinical pharmacokinetics: Aminoglycosides	Smith	1,3,4,5,6	S15.16
WED 10-23-2024 10-11 am	Supplemental Instruction (Optional)			

Date	Topic	Instructor	CLO	Disease State(s)
MON 10-28-2024 2-3:50 pm	Clinical pharmacokinetics: Azole antifungals	Smith	1,3,4,5	S15.16
WED 10-30-2024 10-11 am	Supplemental Instruction (Optional)			
11-4-2024 2 – 4 pm	***CUMULATIVE* Midterm Examination 2 – assessment of 08/26 through 10/28 material**			
MON 11-11-2024 2-3:50 pm	Clinical pharmacokinetics: Phenytoin, fosphenytoin, valproic acid, and carbamazepine	Smith	1,2,3,4,5	S05.08
WED 11-13-2024 10-11 am	Supplemental Instruction (Optional)			
MON 11-18-2024 2-3:30 pm	Clinical pharmacokinetics: Digoxin and immunosuppressant maintenance therapy	Smith	1,2,3,4,5	S01.11 S10.03
WED 11-20-2024 10-11 am	Supplemental Instruction (Optional)			
MON 11-25-2024	***NO CLASS (Thanksgiving Break)***			
MON 12-2-2024 2-3:30 pm	Pharmacogenomics/genetics: Introduction to pharmacogenomics	Smith	7	S20.99
WED 12-4-2024 10-11 am	Supplemental Instruction (Optional)			
FRI 12-13-2024 **9 am – 12 pm**	***CUMULATIVE* Final Examination – assessment of 8-26 through 12-2 material**			

Please note that dates, topics, and assignments are subject to change. In the event of a change, you will be given ample notification of the change.