

PHA5176 Drug Delivery Systems

Fall, 2022

04 Credit Hours – [A-E Grading]

The primary purpose of this course is for the learner to achieve a clear and comprehensive understanding of the rational formulation and usage of drug products and preparations as they relate to development of logically sound explanations of and arguments for a particular patient's drug therapy.

Teaching Partnership Leaders

William Cary Mobley, R.Ph., Ph.D.

- Email: mobley@cop.ufl.edu
- Office: HPNP 1315
- Phone: 352-273-6282

Office Hours: See 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. Collect information to identify a patient's medication-related problems and health-related needs.
2. Analyze information to determine the effects of medication therapy, identify medication-related problems, and prioritize health-related needs.
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.
4. Implement a care plan in collaboration with the patient, caregivers, and other health professionals.
5. Collaborate as a member of an interprofessional team.
6. Fulfill a medication order.

Course-Level Objectives

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

1. Drug Development, Approval, and Manufacture
 - a. Explain the drug development and approval processes for new chemical entities, generic and orphan drugs, drugs for compassionate use, and for changes in the drug product.
 - b. Describe the most critical concepts in the manufacture of sterile and non-sterile dosage forms, the standards for good manufacturing practices, and nature of compendial standards for chemicals, devices, and drug products.
2. Biopharmaceutics
 - a. Describe the concepts important for understanding and predicting the relationships between the physicochemical properties of the drug, the drug's fate in the body after its administration as a dosage form, and the resulting onset, duration, and intensity of drug action.

- b. In the therapeutic reasoning process, assess the relevance of formulation and biopharmaceutical properties of drugs.
- 3. Fundamental Physicochemical Properties
 - a. Describe the fundamental physicochemical properties that are important for the rational design and formulation of stable dosage forms.
 - b. Develop causal explanations for the effects of fundamental physicochemical properties on the biopharmaceutical behavior of drugs and dosage forms in the body.
 - c. In the diagnostic reasoning process, determine and explain any implicated relationships between the drug's physiochemical properties or formulation and drug therapy problems.
- 4. Chemical and Physical Drug Stability
 - a. Explain the major mechanisms of drug and dosage form chemical and physical instability, including formulation ingredient incompatibilities.
 - b. Describe formulation, packaging, and storage approaches for optimizing drug and drug product stability.
- 5. Drug Dosage Forms
 - a. Explain the nature of all pharmaceutical dosage forms, including how they are designed, formulated, manufactured, compounded, and quality tested.
 - b. Assess and recommend, in the therapeutic reasoning process, the dosage form(s) and route(s) of administration that will best enable the patients to reach his or her therapeutic goal(s).
- 6. Drug Dosage Form Administration
 - a. Explain the anatomical and physiological properties important for drug delivery for all parenteral and non-parenteral routes of drug administration.
 - b. In the diagnostic reasoning process, determine and explain any implicated relationships between the dosage form or its administration and drug therapy problems.
 - c. In the therapeutic reasoning process, assess and recommend the route(s) and techniques of dosage form administration that will best enable the patient to reach his or her therapeutic goal(s) and minimize untoward effects.
- 7. Pharmaceutical Calculations
 - a. Demonstrate competence in performing pharmaceutical calculations according to standards that maximize accuracy and precision and to minimize the risk for error.
 - b. Assess the reasonableness of answers based on the understanding of the goals and purpose of the calculation.
- 8. Drug Preparation Compounding
 - a. Explain compounding skills that are used for the most common types of non-sterile preparations, employing standards of good compounding practices and compounding regulations.
 - b. Provide rational counseling advice for the proper usage of compounded preparations.
- 9. Control of Drug Delivery
 - a. Describe the rationale and approaches for the spatial and temporal control of drug delivery, describing examples, advantages and disadvantages for each route of drug administration.
- 10. Pharmaceutics of Recombinant Therapeutic Proteins and Related Biologics
 - a. Explain the production, physicochemical properties, stability, formulation, and delivery of therapeutic proteins that distinguish biologics from small molecule compounds.
 - b. Understand the development and approval process for biosimilar biological products.

- c. Recommend proper storage, handling, and administration techniques of therapeutic proteins.

Course Pre-requisites

1. Satisfactory completion of Block 1

Course Co-requisites

1. PHA5021C Personal and Professional Development I

Course Outline

See Appendix B. Please routinely check your campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/times, deadlines, and room changes.

Required Textbooks/Readings

There are no required textbooks for this course.

Required readings for will be posted on Canvas.

Suggested Textbooks/Readings

Suggested readings will be posted on Canvas.

1. Text 1: Mobley WC, Amiji MM, Cook TJ, eds. (2019). Applied Physical Pharmacy, 3e. New York, NY: McGraw-Hill.
○ Available in Access Pharmacy. [Applied Physical Pharmacy, 3e | AccessPharmacy | McGraw-Hill Medical \(mhmedical.com\)](#)
2. Text 2: Allen LV, Ansel HC. Pharmaceutical Dosage Forms and Delivery Systems, 10th Ed., Lippincott Williams and Wilkins. ISBN: 978-1-45-118876-9
3. Text 3: Washington N, Washington C, Wilson C. (2001). Physiological Pharmaceutics: Barriers to Drug Absorption, 2nd Ed, Taylor & Francis.
a. E-book available free on-line at UF library.
4. Text 4: Thompson, JE. A Practical Guide to Contemporary Pharmacy Practice, 3rd Edition. Lippincott Williams and Wilkins. ISBN: 0781783968

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/>

Other Required Learning Resources

N/A

Materials & Supplies Fees

N/A

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.]

Assessment Item	Grade Percentage
Exams 1-3: 20% each	60%
Exam 4: 17%	17%
Online Formative Assessments (6 @ 0.5% ea.)	3%
In-Class Formative Assessments (5 @ 1% ea.)	5%
In-Class Collaborative Problem-Solving Exercise (5 @ 3% ea.)	15%
Total	100%

Table 1.1 Evaluation and Grading Above

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](http://curriculum.pharmacy.ufl.edu/current-students/technical-help/) at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/technical-help/>

Pharm.D. Course Policies

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

Late Assignment Policy

Late assignments and assessments will not be accepted and will result in a grade of zero.

Makeup Assignment Policy

Makeup assignments will be required for excused absences from all Active Learning Sessions. Students will be required to complete the makeup assignment within one week of the missed session.

Respect for Diversity

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.bluer.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(s):

William Cary Mobley, R.Ph., Ph.D.

- Email: mobley@cop.ufl.edu
- Office: HPNP 1315
- Phone: 352-273-6282

Office Hours: See 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:

Robin Moorman-Li, Pharm.D., BCACP, CPE

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

Joshua Pullo, Pharm.D.

- Email: jpullo@cop.ufl.edu
- Office: Orlando Campus
- Phone: 904-866-1292

Mei He, Ph.D.

- Email: MHe@cop.ufl.edu
- Office: Gainesville Campus
- Phone: 352-273-9847

Instructional Designer:

Name: Holly Fremen

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

Academic Coordinator Gainesville Campus:

Name: TBD

- Email: TBD
- Office: HPNP 4312
- Phone: (352)-273-5617

Absence/Tardy Email (Visit the [course policy site](#) for further instructions)

Educational Coordinators

Katie Orben

- Email: korben06@ufl.edu
- Office: Jacksonville Campus

Name: Andrea Arredondo

- Email: aarredondo1@cop.ufl.edu
- Office: Orlando Campus

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 Exemplify and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.

Appendix B: Course Outline

Date / Time [Recommend ed for Independent Study]	Mod#	Activity	Activity Title	Objectiv es	Conta ct Time (hr)	Responsib le
09/26/22	1	Module	Module 1: Course Overview, New Drug Development, Introduction to Biopharmaceuti cs, Pharmaceutical Pre-formulation, Drug Stability, Parenteral Drug Delivery	(1-7)	0	Cary Mobley
09/26/22	1.1	Lecture Video	Watch: Course Overview		0.25	Cary Mobley
09/26/22		Quiz (Self- Assessme nt)	Course Introduction Quiz		0	Cary Mobley
09/26/22	1.2	Lecture Video	Watch: New Drug Development		1	Cary Mobley
09/26/22	1.3	Lecture Video	Watch: Intro to Biopharmaceuti cs I		0.75	Cary Mobley
09/27/22	1.4	Lecture Video	Watch: Intro to Biopharmaceuti cs II		1	Cary Mobley
09/27/22	1.5	Lecture Video	Watch: Pharmaceutical Preformulation I		0.75	Cary Mobley
09/27/22	1.6	Lecture Video	Watch: Pharmaceutical Preformulation II		0.75	Cary Mobley
09/28/22	1.7	Lecture Video	Watch: Pharmaceutical		0.75	Cary Mobley

			Preformulation III			
09/28/22	1.8	Lecture Video	Watch: Pharmaceutical Preformulation IV		0.5	Cary Mobley
09/30/22 DUE at 11:59pm	1.2-1.8	Quiz (Online)	Assignment: Online Formative Assessment 1: New Drug Development through Preformulation IV		0	Cary Mobley
09/29/22	1.9	Lecture Video	Watch: Drug Stability I		1	Cary Mobley
09/29/22	1.10	Lecture Video	Watch: Drug Stability II		1	Cary Mobley
09/30/22	1.11	Lecture Video	Watch: Parenteral Drug Delivery I		1	Cary Mobley
09/30/22	1.12	Lecture Video	Watch: Parenteral Drug Delivery II		1	Cary Mobley
10/04/22	1.13	Lecture Video	Watch: Parenteral Drug Delivery III		1	Cary Mobley
10/04/22	1.14	Lecture Video	Watch: Parenteral Drug Delivery IV		1	Cary Mobley
10/04/22	1	Reading	ALS Prep: Reading (See Canvas)		0.5	Cary Mobley
10/05/22 DUE at 11:59pm	1.9-1.14	Quiz (Online)	Assignment: Online Formative Assessment 2: Drug Stability – Parenteral IV		0	Cary Mobley
10/06/22 8:30am – 10:25am	1.2-1.10 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 1: Problem-Solving Exercise		2	Cary Mobley, Joshua Pullo, Robin Moorman Li
10/06/22		Quiz (In Class)	In-Class Formative		0	Cary Mobley

			Assessment #01			
10/06/22		Assignment (Graded)	In-Class Collaborative Problem Solving Exercise #01		0	Cary Mobley
10/06/22	2	Module	Module 2: Oral Drug Delivery, Powders, Granules, Capsules, Tablets, Liquids, Buccal/SL, Rectal	(5-6)	0	Cary Mobley
10/06/22	2.1	Lecture Video	Watch: Oral Drug Delivery Overview		0.75	Cary Mobley
10/06/22	2.2	Lecture Video	Watch: Powders/Granules I		0.75	Cary Mobley
10/10/22	2.3	Lecture Video	Watch: Powders/Granules II		0.75	Cary Mobley
10/11/22	2.4	Lecture Video	Watch: Capsules I		0.75	Cary Mobley
10/12/22	2.5	Lecture Video	Watch: Capsules II		0.75	Cary Mobley
10/13/22 2:00pm – 4:00pm	1	Exam	Exam 1: Module 1		2	Cary Mobley
10/13/22	2.6	Lecture Video	Watch: Tablets I		0.75	Cary Mobley
10/14/22	2.7	Lecture Video	Watch: Tablets II		0.75	Cary Mobley
10/14/22 DUE at 11:59pm	2.1-2.7	Quiz (Online)	Assignment: Online Formative Assessment 3: Oral Overview to Tablets II		0	Cary Mobley
10/14/22	2.8	Video Lecture	Watch: Oral Liquids I		0.75	Cary Mobley
10/17/22	2.9	Video Lecture	Watch: Oral Liquids II		0.75	Cary Mobley
10/18/22	2.10	Video Lecture	Watch: Oral Liquids III		0.75	Cary Mobley
10/18/22	2.11	Video Lecture	Watch: Oral Liquids IV		0.75	Cary Mobley

10/19/22	2.12	Lecture Video	Watch: Sublingual/Buccal Drug Delivery		1	Cary Mobley
10/19/22	2.13	Lecture Video	Watch: Rectal Drug Delivery		1	Cary Mobley
10/19/22	2	Reading	ALS Prep: Reading (See Canvas)		0.5	Cary Mobley
10/19/22 DUE 11:59 PM	2.7-2.13	Quiz (Online)	Assignment: Online Formative Assessment 4: Oral Liquids to Rectal		0	Cary Mobley
10/20/22 8:30am – 10:25am	2.1-2.13 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 2: Problem-Solving Exercise		2	Cary Mobley, Joshua Pullo, Robin Moorman Li
10/20/22		Quiz (In Class)	In-Class Formative Assessment #02		0	Cary Mobley
10/20/22		Assignment (Graded)	In-Class Collaborative Problem Solving Exercise #02		0	Cary Mobley
10/20/22 at 12:45pm - 1:45pm		Exam Review	Exam Review		0	
	3	Module	Module 3: Topical, Vaginal, Ophthalmic, Intranasal, Pulmonary, Advanced, Pharmaceutical Biotechnology	(5,6,9,10)	0	Cary Mobley
10/24/22	3.1	Lecture Video	Watch: Topical Drug Delivery I		1	Cary Mobley
10/25/22	3.2	Lecture Video	Watch: Topical Drug Delivery II		1	Cary Mobley
10/26/22	3.3	Lecture Video	Watch: Vaginal Drug Delivery		0.5	Cary Mobley

10/28/22 2:00pm – 4:00pm	2	Exam	Exam 2: Module 2		2	Cary Mobley
11/02/22	3.4	Lecture Video	Watch: Ophthalmic Drug Delivery I		0.75	Cary Mobley
11/03/22	3.5	Lecture Video	Watch: Ophthalmic Drug Delivery II		0.75	Cary Mobley
11/04/22	3.6	Lecture Video	Watch: Intranasal Drug Delivery		0.75	Cary Mobley
11/04/22 12:15pm - 12:45pm		Exam Review	Exam Review			
11/08/22	3.7	Lecture Video	Watch: Pulmonary Drug Delivery I		0.75	Cary Mobley
11/09/22	3.8	Lecture Video	Watch: Pulmonary Drug Delivery II		1	Cary Mobley
11/09/22	3	Reading	ALS Prep: Reading (See Canvas)		0.5	Cary Mobley
11/09/22 DUE 11:59 PM	3.1-3.8	Quiz (Online)	Assignment: Online Formative Assessment 5: Topical to Pulmonary			Cary Mobley
11/10/22 8:30am – 10:25am	3.1-3.8 & ALS Prep Reading	Active Learning Session-- VC	Active Learning Session 3: Problem- Solving Exercise		2	Cary Mobley, Joshua Pullo, Robin Moorman Li
11/10/22		Quiz (In Class)	In-Class Formative Assessment #03		0	Cary Mobley
11/10/22		Assignmen t (Graded)	In-Class Collaborative Problem Solving Exercise #03		0	Cary Mobley
11/10/22	3.9	Lecture Video	Watch: Advanced Drug Delivery I		0.75	Cary Mobley

11/14/22	3.10	Lecture Video	Watch: Advanced Drug Delivery II		0.75	Cary Mobley
11/15/22	3.11	Lecture Video	Watch: Advanced Drug Delivery III		0.75	Cary Mobley
11/15/22	3.12	Lecture Video	Watch: Advanced Drug Delivery IV		0.75	Cary Mobley
11/16/22	3.13	Lecture Video	Watch: Pharmaceutical Biotechnology I		1	Mei He
11/16/22	3.14	Lecture Video	Watch: Pharmaceutical Biotechnology II		1	Mei He
11/16/22		Reading	ALS Prep: Reading (See Canvas)		0.5	Cary Mobley
11/17/22 DUE at 12 PM	3.9-3.14	Quiz (Online)	Assignment: Online Formative Assessment 6: Advanced to Pharm. Biotechnology			Cary Mobley
11/17/22 1:55pm – 3:50pm	3.9-3.14 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 4: Problem-Solving Exercise		2	Cary Mobley, Joshua Pullo, Mei He, Robin Moorman Li
11/17/22		Quiz (In Class)	In-Class Formative Assessment #04		0	Cary Mobley
11/17/22		Assignment (Graded)	In-Class Collaborative Problem Solving Exercise #04		0	Cary Mobley
	4	Module	Module 4: Pharmaceutical Calculations and Compounding	(5,7,8)	0	Cary Mobley
11/17/22	4.1	Lecture Video	Watch: Introduction to Calculations I		0.75	Cary Mobley

11/18/22	4.2	Lecture Video	Watch: Introduction to Calculations II		0.75	Cary Mobley
11/21/22	4.3	Lecture Video	Watch: Introduction to Calculations III		0.75	Cary Mobley
11/22/22 12:00pm - 2:00pm		Exam	Exam 3: Module 3		2	Cary Mobley
11/22/22	4.4	Lecture Video	Watch: Overview of Compounding I		1	Cary Mobley
11/28/22	4.5	Lecture Video	Watch: Overview of Compounding II		1	Cary Mobley
11/29/22	4.6	Lecture Video	Watch: Compounding Selected Dosage Forms I		1	Cary Mobley
11/30/22	4.7	Lecture Video	Watch: Compounding Selected Dosage Forms II		1	Cary Mobley
11/30/22 10:30am - 11:00am		Exam Review	Exam Review			
12/01/22 8:30am – 10:25am	4.1-4.7	Active Learning Session--VC	Active Learning Session 5: Problem-Solving Exercise		2	Cary Mobley, Joshua Pullo, Robin Moorman Li
12/01/22		Quiz (In Class)	In-Class Formative Assessment #05		0	Cary Mobley
12/01/22		Assignment (Graded)	In-Class Collaborative Problem Solving Exercise #05		0	Cary Mobley
12/01/22 at 10:30am		Course Evaluation	Course Evaluation			
12/08/22 10:00am – 12:00pm	4	Exam	Exam 4: Module 4			Cary Mobley
			Total Hours		57.75	

