

# PHA5176 Drug Delivery Systems

Fall, 2020

*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](mailto:mobley@cop.ufl.edu)
- Office: HPNP 1315
- Phone: 352-273-6282

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. EPA A3. Formulate evidence-based care plans. (In collaboration with an interprofessional team)
2. EPA E1. Safely and accurately dispense medications within a medication use system including supervision of pharmacy technicians.

## 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 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 physicochemical properties 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. Enter Pre-requisites here Satisfactory completion of Block 1

## Course Co-requisites

1. PHA5700C Personal and Professional Development I

## Course Outline

See Appendix. 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

1. Text 1: Amiji MM, Cook TJ, Mobley W. eds. (2013). Applied Physical Pharmacy, 2e. New York, NY: McGraw-Hill.
  - Available in Access Pharmacy. <http://accesspharmacy.mhmedical.com/Book.aspx?bookid=993>

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

Suggested readings will be posted on Canvas.

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

## Other Required Learning Resources

Enter Required Learning resources here

## Materials & Supplies Fees

Enter Materials and Supply Fees here

## 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 (4 @ 20% ea.)	80%
Online Formative Assessments (8 @ 0.5% ea.)	4%
In-Class Formative Assessments (4 @ 1% ea.)	4%

Assessment Item	Grade Percentage
In-Class Collaborative Problem-Solving Exercise (4 @ 3% ea.)	12%
<b>Total</b>	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."

## Makeup Assignments

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.

## 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/>

## 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/>

## 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(s):

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

- Email: [mobley@cop.ufl.edu](mailto:mobley@cop.ufl.edu)
- Office: HPNP 1315
- Phone: 352-273-6282

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:

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

- Email: [moorman@cop.ufl.edu](mailto:moorman@cop.ufl.edu)
- Office: Jacksonville Campus
- Phone: 904-244-9590

Joshua Pullo, Pharm.D.

- Email: [jpullo@cop.ufl.edu](mailto:jpullo@cop.ufl.edu)
- Office: Orlando Campus
- Phone: 904-866-1292

Mei He, Ph.D.

- Email: [MHe@cop.ufl.edu](mailto:MHe@cop.ufl.edu)
- Office: Gainesville Campus
- Phone: 352-273-9847

## Instructional Designer:

Name: Holly Fremen

- Email: [holly.fremen@cop.ufl.edu](mailto:holly.fremen@cop.ufl.edu)
- Office: HPNP 4309
- Phone: 352-273-5558

## Academic Coordinator Gainesville Campus:

Name: Nicole Marlowe

- Email: [nicolemarlowe@cop.ufl.edu](mailto:nicolemarlowe@cop.ufl.edu)

- Office: HPNP 4312
- Phone: 352-273-6523

Absence/Tardy Email: [absent1pd@cop.ufl.edu](mailto:absent1pd@cop.ufl.edu) (Visit the [course policy site](#) for further instructions)

## Educational Coordinators

Name: McKenzie Wallen

- Email: [mwallen@cop.ufl.edu](mailto:mwallen@cop.ufl.edu)
- Office: Jacksonville Campus

Name: Iverta Allen

- Email: [iallen1@cop.ufl.edu](mailto:iallen1@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: Course Outline: See Link Below

Date [Recommended for Independent Study]	Mod#	Activity	Activity Title	[min]	Objectives	Responsible
09/21/20	1	Module	Module 1: Course Overview, New Drug Development, Introduction to Biopharmaceutics, Pharmaceutical Pre-formulation, Drug Stability, Parenteral Drug Delivery		(1-3, 5-7)	Cary Mobley
09/21/20	1.1	Video Lecture	Watch: Course Overview	15		Cary Mobley
09/21/20		Quiz Self-Assessment	Course Introduction Quiz			Cary Mobley
09/22/20	1.2	Video Lecture	Watch: New Drug Development	45		Cary Mobley
09/23/20	1.3	Video Lecture	Watch: Intro to Biopharmaceutics I	60		Cary Mobley
09/23/20	1.4	Video Lecture	Watch: Intro to Biopharmaceutics II	60		Cary Mobley
09/24/20	1.5	Video Lecture	Watch: Pharmaceutical Preformulation I	60		Cary Mobley
09/24/20	1.6	Video Lecture	Watch: Pharmaceutical Preformulation II	60		Cary Mobley
09/25/20	1.7	Video Lecture	Watch: Pharmaceutical Preformulation III	60		Cary Mobley
09/25/20	1.8	Video Lecture	Watch: Pharmaceutical Preformulation IV	60		Cary Mobley
<b>09/30/20 DUE at 11:59pm</b>	1.1-1.6	<b>Assignment Graded</b>	Assignment: Online Formative Assessment 1: New Drug Development through Preformulation II			Cary Mobley
09/28/20	1.9	Video Lecture	Watch: Drug Stability I	60		Cary Mobley
09/28/20	1.10	Video Lecture	Watch: Drug Stability II	60		Cary Mobley
09/30/20	1.11	Video Lecture	Watch: Parenteral Drug Delivery I	60		Cary Mobley
09/30/20	1.12	Video Lecture	Watch: Parenteral Drug Delivery II	60		Cary Mobley
10/01/20	1.13	Video Lecture	Watch: Parenteral Drug Delivery III	60		Cary Mobley
10/01/20	1.14	Video Lecture	Watch: Parenteral Drug Delivery IV	60		Cary Mobley
10/07/20	1	ALS Prep	ALS Prep: Reading (See Canvas)			Cary Mobley



10/07/20 DUE at 11:59pm	1.7-1.12	Assignment Graded	Assignment: Online Formative Assessment 2: Preformulation III to Parenteral Drug Delivery II			Cary Mobley
10/08/2020 at 8:30am - 11:30am	1.2-1.10 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 1: Problem-Solving Exercise	150		Cary Mobley, Joshua Pullo, Robin Moorman Li
10/08/20		Quiz In-class Graded	In-Class Formative Assessment #01			Cary Mobley
10/08/20		Quiz In-class Graded	In-Class Collaborative Problem Solving Exercise #01			Cary Mobley
	2	Module	Module 2: Introduction to Pharmaceutical Calculations, Overview of Compounding, Compounding Powders and Granules, Capsules, Tablets		(1-3, 5-6)	Cary Mobley
10/08/20	2.1	Video Lecture	Watch: Introduction to Calculations I	60		Cary Mobley
10/08/20	2.2	Video Lecture	Watch: Introduction to Calculations II	60		Cary Mobley
10/09/20	2.3	Video Lecture	Watch: Overview of Compounding I	60		Cary Mobley
10/09/20	2.4	Video Lecture	Watch: Overview of Compounding II	60		Cary Mobley
10/15/2020 at 2:00pm - 4:00pm	1	Exam	Exam 1: Module 1	120		Cary Mobley
10/13/20	2.5	Video Lecture	Watch: Powders/Granules I	60		Cary Mobley
10/14/20	2.6	Video Lecture	Watch: Powders/Granules II	60		Cary Mobley
10/15/20	2.7	Video Lecture	Watch: Capsules I	60		Cary Mobley
10/16/20	2.8	Video Lecture	Watch: Capsules II	60		Cary Mobley
10/16/20 DUE at 11:59pm	2.1-2.6	Assignment Graded	Assignment: Online Formative Assessment 3: Calculations to Powders/Granules			Cary Mobley
10/19/20	2.9	Video Lecture	Watch: Tablets I	60		Cary Mobley
10/20/20	2.10	Video Lecture	Watch: Tablets II	60		Cary Mobley
10/21/20	2	ALS Prep	ALS Prep: Reading (See Canvas)			Cary Mobley

10/21/20 <b>DUE at 11:59pm</b>	2.7-2.10	Assignment Graded	Assignment: Online Formative Assessment 4: Capsules to Tablets			Cary Mobley
10/22/2020 at 8:30am - 11:30am	2.5-2.10 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 2: Problem-Solving Exercise	180		Cary Mobley, Joshua Pullo, Robin Moorman Li
10/22/20		Quiz In-class Graded	In-Class Formative Assessment #02			Cary Mobley
10/22/20		Quiz In-class Graded	In-Class Collaborative Problem Solving Exercise #02			Cary Mobley
10/28/20 9:00 AM			Calculations Q&A Review Session in Zoom Conference (non-mandatory)			Cary Mobley
10/29/20 at 2:00pm - 4:00pm	2	Exam	Exam 2: Module 2	120		Cary Mobley
	3	Module	Module 3: Oral Liquids, Sublingual and Buccal Drug Delivery, Rectal Drug Delivery, Topical Drug Delivery		(5-8)	Cary Mobley
10/23/20	3.1	Video Lecture	Watch: Oral Liquids I	60		Cary Mobley
10/26/20	3.2	Video Lecture	Watch: Oral Liquids II	60		Cary Mobley
10/27/20	3.3	Video Lecture	Watch: Oral Liquids III	60		Cary Mobley
10/29/20	3.4	Video Lecture	Watch: Oral Liquids IV	60		Cary Mobley
10/30/20	3.5	Video Lecture	Watch: Oral Liquids V	60		Cary Mobley
10/30/20 <b>DUE at 11:59pm</b>	3.1-3.5	Assignment Graded	Assignment: Online Formative Assessment 5: Oral Liquids			Cary Mobley
11/03/20	3.6	Video Lecture	Watch: Sublingual/Buccal Drug Delivery	60		Cary Mobley
11/03/20	3.7	Video Lecture	Watch: Rectal Drug Delivery I	60		Cary Mobley
11/04/20	3.8	Video Lecture	Watch: Rectal Drug Delivery II	60		Cary Mobley
11/04/20	3	Reading	ALS Prep: Reading (See Canvas)	15		Cary Mobley
11/04/20 <b>DUE at 11:59pm</b>	3.6-3.8	Assignment Graded	Assignment: Online Formative Assessment 6: Rectal/Buccal/Sublingual Delivery			Cary Mobley

11/05/20 at 8:30am - 11:30am	3.1-3.8 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 3: Problem-Solving Exercise	180		Cary Mobley, Joshua Pullo, Robin Moorman Li
11/05/20		Quiz In-class Graded	In-Class Formative Assessment #03			Cary Mobley
11/05/20		Quiz In-class Graded	In-Class Collaborative Problem Solving Exercise #03			Cary Mobley
11/06/20	3.9	Video Lecture	Watch: Topical Drug Delivery I	60		Cary Mobley
11/06/20	3.10	Video Lecture	Watch: Topical Drug Delivery II	60		Cary Mobley
11/09/20	3.11	Video Lecture	Watch: Topical Drug Delivery III	30		Cary Mobley
11/12/20 at 2:00pm - 4:00pm	3	Exam	Exam 3: Module 3	120		Cary Mobley
	4	Module	Module 4: Vaginal Drug Delivery, Ophthalmic Drug Delivery, Intranasal Drug Delivery, Pulmonary Drug Delivery, Advanced Drug Delivery		(5-10)	Cary Mobley
11/12/20	4.1	Video Lecture	Watch: Vaginal Drug Delivery	30		Cary Mobley
11/13/20	4.2	Video Lecture	Watch: Ophthalmic Drug Delivery I	60		Cary Mobley
11/16/20	4.3	Video Lecture	Watch: Ophthalmic Drug Delivery II	60		Cary Mobley
11/17/20	4.4	Video Lecture	Watch: Intranasal Drug Delivery	60		Cary Mobley
11/18/20	4.5	Video Lecture	Watch: Pulmonary Drug Delivery I	60		Cary Mobley
11/19/20	4.6	Video Lecture	Watch: Pulmonary Drug Delivery II	60		Cary Mobley
11/20/20	4.7	Video Lecture	Watch: Pulmonary Drug Delivery III/ Advanced Drug Delivery I	60		Cary Mobley
11/20/20 DUE at 11:59pm	4.2-4.7	Assignment Graded	Assignment: Online Formative Assessment 7: Ophthalmic to Pulmonary Drug Delivery			Cary Mobley
11/30/20	4.8	Video Lecture	Watch: Advanced Drug Delivery II	60		Cary Mobley
12/01/20	4.9	Video Lecture	Watch: Advanced Drug Delivery III	60		Cary Mobley

12/01/20	4.10	Video Lecture	Watch: Advanced Drug Delivery IV	60		Cary Mobley
12/02/20	4.11	Video Lecture	Watch: Advanced Drug Delivery V	60		Cary Mobley
12/04/20	4.12	Video Lecture	Watch: Pharmaceutical Biotechnology I	60		Me Hei
12/04/20	4.13	Video Lecture	Watch: Pharmaceutical Biotechnology II	60		Me Hei
12/02/20	4		ALS Prep: Reading (See Canvas)			Cary Mobley
<b>12/02/20 DUE at 11:59pm</b>	4.8-4.11	Assignment Graded	Assignment: Online Competency Assessment 8: Advanced Drug Delivery			Cary Mobley
<b>12/03/20 at 8:30am - 11:30am</b>	<b>3.6, 4.4-4.7, 4.10 &amp; ALS Prep Reading</b>	<b>Active Learning Session--VC</b>	<b>Active Learning Session 4: Problem-Solving Exercise</b>	<b>180</b>		<b>Cary Mobley, Joshua Pullo, Robin Moorman Li</b>
12/03/20		Quiz In-class Graded	In-Class Formative Assessment #04			Cary Mobley
12/03/20		Quiz In-class Graded	In-Class Collaborative Problem Solving Exercise #04			Cary Mobley
<b>12/08/20 at 2:00pm - 4:00pm</b>	<b>1-4</b>	<b>Exam</b>	<b>Exam 4: Module 4 and Selected Portions of Modules 1-3 [Comprehensive]</b>	<b>120</b>		<b>Cary Mobley</b>
				3945		
			<b>Total Hours</b>	<b>65.75</b>		