
PHA 6935 Foundations of Pharmaceutical Outcomes and Policy I: Drug Discovery, Development, and Approval

3 Semester Credit Hours

Course Purpose:

This is the first course in a two-course series designed to provide students in the Master of Science in Pharmaceutical Sciences with Focus on Pharmaceutical Outcomes & Policy an overview of drug discovery, development, approval, marketing, regulation, and use in the United States. This course is designed to show how all the pieces of the "U.S. medication system" fit together.

These courses will provide participants with a basic understanding of topics ranging from drug discovery to disposal. This high-level overview introduces issues that are developed in detail in the Master of Science tracks (i.e., Applied Pharmacoeconomics, Managed Care Pharmacy Systems, Patient Safety in Medication Use, and Pharmaceutical Regulation). "Foundations I" will focus on before a drug is marketed.

In addition to recorded video lectures and online weekly class meetings, this course will include mandatory readings from a variety of sources and perspectives. It will provide a balanced view of controversial topics and invites discussion using the presented content, supplemental information posted to the Discussion Boards, and students' and faculty experiences. The concepts and principles in this course will provide perspective for students' various chosen specialty areas, which will be addressed in courses that follow this foundational course.

Course Faculty and Office Hours

Course Coordinator:

Randy C. Hatton, BPharm, PharmD, FCCP

Clinical Professor, Department of Pharmaceutical Outcomes and Policy

Director, Online Masters of Pharmaceutical Sciences/Patient Safety in Medication Use

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Phone: 352-262-0736

Place and Time of Class Sessions

Classes are on Sunday from 6:00 PM to 8:00 PM Eastern Time. **All times are given as Eastern Time** unless explicitly stated otherwise. Should any class be scheduled on a University of Florida holiday, it will be recorded and will be available after the next scheduled class. Live participation in the class will be optional. All classes are via the Internet through the University of Florida's Canvas system.

Course Objectives

Upon completion of this course, the student will:

1. State the role of academia, government, industry, and serendipity in drug discovery.
2. Identify the effects that the Bayh-Dole Act has had on drug discovery.
3. List barriers to drug development.

4. Explain the cost of drug discovery and development.
5. List the phases of the Food and Drug Administration's drug approval process and identify the key characteristics of each phase.
6. Compare and contrast the approval processes for drugs, biologicals, generics, biosimilars, and dietary supplements.
7. Explain the creation of a drug label and its various components.
8. Identify the various types of "drug products" on the US market and regulations that affect their use.
9. State the sources of raw pharmaceutical materials, who manufactures pharmaceutical products, and the role of FDA oversight in this process.
10. Debate current controversies in the discovery, development, and regulation of drugs.

Course Structure & Outline

Course Structure.

Learning activities

- a) Video Lectures
- b) Mandatory readings
- c) Web-based learning
- d) Preparation for weekly readiness assessments
- e) Participation in live weekly discussions during class
- f) Participation in discussion board activities
- g) An individual written paper on a topic approved by the course coordinator

Course Outline/Activities.

See the course outline in **Appendix B**. All assignments and topics are subject to change as posted on Canvas to include current issues regarding the issues of discussion.

Textbooks

There is no required textbook for this course; however, students are required to subscribe to **STAT+**, which is a pharma/health care news and analysis Website. To subscribe, go to www.statnews.com/subscribe. At the payment page, use code ACADEMIC75 to receive a 75% student discount on the subscription rate. Reading assignments from online textbooks, journal articles, lay media articles (*New York Times* and *Wall Street Journal*), and websites will be assigned for each module (see **Appendix B**). UF students have access to the *New York Times* and *Wall Street Journal* at no cost (<https://news.hr.ufl.edu/technology/did-you-know-uf-offers-free-online-subscriptions-to-the-new-york-times-wall-street-journal/>). In this manner, students will have access to the latest in the ever-changing landscape of information.

Active Learning Requirements

Participation in the live online classroom sessions is mandatory. These sessions are an essential part of this course. Students may be permitted to submit a make-up assignment for up to two **excused** absences. (See Class Attendance Policy)

Student Evaluation & Grading

Evaluation Methods

Online quizzes: This course will be a mixture of mandatory readings, online assignments, and pre-recorded lectures that must be reviewed before each weekly quiz. The weekly quiz will be available for at least three days before each class. Quizzes will include ten multiple-choice or short-answer questions over 15 minutes. There will be seven quizzes, and the lowest quiz grade will be dropped. The purpose of the quizzes will be to assess readiness for the weekly discussions and understanding of the course materials. The quiz average will contribute 48% towards the final grade in this course (i.e., each quiz will contribute 8% towards your final grade).

Class participation: Class participation is mandatory. Discussion board participation, class attendance, and participation in class will be used to award 32% of the final grade. There are eight participation grades (seven weeks plus the introductory session); thus, each week will contribute 4% towards your final grade. Each student is expected to post one substantial comment to the discussion board each week. What constitutes a “substantial comment” is described in the Introductory class session. The discussion board post may offer an opinion regarding one of the topics covered, a thoughtful reaction to another students post, an extension of the concepts covered in readings or lectures, or an addition to the general theme of the week (e.g., Drug Discovery and Development).

Final Paper: Students will identify a topic for a paper and submit it to the course coordinator for approval. Approval must occur before class session #3. Students must pick a subject for in-depth evaluation consistent with the topics listed in **Appendix B**. The content must be more extensive than the materials covered in class (i.e., video lectures, class discussion, and mandatory readings). The paper should be a maximum of 10 pages using a 10-pt font, 1.5-line spacing, and 1-inch margins for the top, bottom, and sides. Proper attribution is mandatory; plagiarism will be assessed using Turnitin. References should be sequentially numbered and listed as a superscript at the end of a sentence and sequentially at the end of the paper. All students must watch and follow the instructions contained in the pre-recorded lecture, *Writing a Final Paper*. All papers will be due on October 11, 2020. The final paper will count for 20% of your final grade. Refer to **Appendix C** for a grading rubric.

Grading	% of grade
Final Paper [topic approved by the course coordinator] <i>Grades will be based on a rubric following the assignment directions</i>	20%
Class Participation* <i>Bulletin board participation, class attendance, and class participation will be used to award a weekly participation score</i>	32%
Online quizzes (6 of 7; the lowest grade will be dropped) <i>Dropped for technical problems or excused absences</i>	48%

*There will be seven sessions from August 23, 2020, to October 11, 2020.

Grading Scale

>92.500%	A
89.500–92.499%	A-
86.500–89.499%	B+
82.500–86.499%	B
79.500–82.499%	B-
76.500–79.499%	C+
72.500–76.499%	C
69.500–72.499%	C-
66.500–69.499%	D+
62.500–66.499%	D
59.500–62.499%	D-
<59.499%	E

Note: this scale already reflects a rounding of grades! A grade of 92.4 is not 0.1 from an A; it is 0.6 points from an A. There will be no additional rounding or awarding of “extra” points because a grade is close to the cut-off. This course’s rounding policy already considers these issues.

Class Attendance Policy

Unexcused absences from the online group discussions carry a 4-point (~1/2 letter grade) reduction in the final grade. Absences due to illness, job conflicts, and other emergencies must be conveyed by e-mail to Dr. Hatton (hatton@ufl.edu) **before** the group discussion begins. Email via Canvas is preferred but a telephone text will be accepted if you cannot email. Messages from friends or classmates will not be accepted, except under exceptional circumstances. When a student has an excused absence, they will receive no deduction for participation. Excused absences will require a make-up paper within 2 weeks of the missed class to obtain your participation points. This paper requires you to listen to the recorded class session and write a reflection paper on the content covered during the missed classed.

The course coordinator will address more than two excused absences; an incomplete grade (i.e., I grade) is a strong possibility.

Quiz/Exam Policy

Make-up Quiz/Exam Policy

The course coordinator will handle make-up quizzes on a case-by-case basis. Usually, these will be considered a zero score and be the dropped quiz grade. If more than two quizzes are missed for a valid reason (i.e., medical excuse), the course coordinator will make accommodations on a case-by-case basis.

Policy on Old Quizzes and Assignments

No old quizzes, exams, or assignment examples will be provided.

Assignment Deadlines

Assignments will be posted with precise due dates. Students are responsible for complying with these deadlines. Late assignments will not be graded (0 points). Delays due to unforeseen and/or distressing events will be treated on a case-by-case basis by the course coordinator.

General College of Pharmacy Course Policies

The College of Pharmacy has a website that lists course policies that are common to all courses. This website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success

Please see the following URL for this information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

Complaints

Should you have any complaints about your experience in this course or suggestions for improvement, please visit:

<http://www.distancelearning.ufl.edu/student-complaints>

Appendix A: Directions for Contacting Faculty & Course Faculty List

Directions for Contacting Course Faculty

Canvas will be used for most communications between the faculty and students. Check for new announcements **at least once a day** for any course updates. Email will also be used occasionally for mass communication to the class, so please check your email at least once a day as well. All emails sent out to the entire class will also be posted as an announcement on Canvas.

General questions about course content (e.g., assignments or lectures) or policies should be posted to the discussion board. We expect students to help each other track down answers as best as possible. Read through all the other posts in the discussion board first before posting to make sure your question has not been addressed/answered already. Please include clear subjects for your post topics to make it clear to all what your post pertains to.

Emotions can easily be misinterpreted on a discussion board/emails, so make sure your message is clear before sending it since there are no physical gestures or voice inflections that accompany posts/emails. Any posts/emails deemed inappropriate by the faculty will be dealt with on a case by case basis with either the faculty directly or they will be sent on to the Associate Dean for Professional Affairs.

For personal issues/questions, please email Dr. Hatton (hatton@ufl.edu). Be sure to include in your subject line the course listing and then a quick subject (i.e., PHA6935 – Your Name -). This will allow coordinators to quickly identify emails related to the course amongst the plethora of junk and other emails that are received each day. Emails not correctly addressed may get lost in the shuffle and unintentionally deleted or ignored so be sure to follow the guidelines exactly. If you have any issues with the course site, please email Justin DeLeo (jdeleo1970@ufl.edu).

Appendix B. Schedule of Course Activities/Topics

Week and Date	Learning Activities/Topic
Course Overview	
8/23/20	Course Introduction
	Writing a Final Paper
Module 1: Drug Discovery and Development	
Week 1 8/30/20	Drug discovery and development
	Industry, academia, and the government's roles in drug discovery and development
	Serendipity and drug discovery
Week 2 9/6/20*	The Bayh-Dole Act
	Barriers in the drug discovery and approval process & incentives
	The cost of drug discovery, development, and approval
Module 2: FDA Approval Process	
Week 3 9/13/20	Pre-clinical testing
	Phases of Drug Approval [including INDs and NDAs]
	Investigational Review Boards [IRBs]
Week 4 9/20/20	Expanded access & Right to try
	Types of drugs (ANDAs, BLAs, biosimilars)—excluding unapproved drugs
	“Abbreviated” New Drug Approvals (505(b)(2) NDAs)
	“Faster” approvals (e.g., Orphan Drugs, Fast Track, Accelerated Approvals, Priority Review, and Breakthrough Therapy)
Module 3: Pharmaceutical Manufacturing	
Week 5 9/27/20	Manufacturers
	Source of raw materials
	Making finished drug products
	FDA oversight of drug production
	Stability and expiration dating
Module 4: Marketed Products and Other “Drugs”	
Week 6 10/4/20	Generic and brand drug names
	Labeling
	Nonprescription drugs
	Dietary supplements
	Vitamins & minerals
Week 7 10/11/20	Homeopathic remedies
	Medical foods
	Devices including those that “look like drugs”
	Unapproved drugs
	Controlled substances: scheduling, drugs of abuse, and the DEA

*Attendance is option for this session, since it is a holiday weekend.

Appendix C. Final Paper Grading Rubric

	Excellent	Acceptable	Poor
Relevance of Topic (10)	10 The topic is appropriate for the course and the student's track and is interesting	7 The topic is appropriate for the course and student's track	4 Topic is inappropriate for the course
Format (10) • E.g., # of pages, margins, spacing, etc.	10 Follows the directions and is easy to read	7 Follows most of the directions	4 Follows little of the directions
Level of content (25)	25 Content shows the synthesis of ideas, in-depth analysis, evidence of original thought, and covers the salient points	20 Content shows thinking and reasoning applied with original thoughts on a few ideas	15 Shows some thinking and reasoning, but most ideas are underdeveloped or unoriginal
Development of Main Points (25)	25 Well developed with quantity and quality support	20 Limited detail and development. Some critical thinking	15 Lacks detail with vague ideas and little evidence of critical thinking
Grammar and Mechanics (10)	10 Free of distracting spelling, punctuation, and grammatical errors	7 Limited spelling, punctuation, and grammatical errors	4 Distracting spelling, punctuation, and grammatical errors
Style (15)	15 Outstanding style beyond the usual level	12 Approaches style expected for a graduate-level paper	8 Mostly in elementary form.
Appropriate References & Format (5)	5 Excellent choice of reference material cited in the correct format with appropriate reference format at the end of the paper	3 Adequate references cited in the appropriate format.	1 Poor choice of reference material cited in an inappropriate format
Total Points:	100		