Foundations of Pharmaceutical Outcomes and Policy I:
Drug Discovery, Development, and Approval
PHA 6186
3 Semester Credit Hours
Class Periods: Sundays, 6:00—8:00 PM Eastern Time
Location: Zoom

Instructor:

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Course Description:

Foundations of Pharmaceutical Outcomes and Policy I is the first course in a two-course series designed to provide students in the Master of Science in Pharmaceutical Sciences with a Focus on Pharmaceutical Outcomes & Policy an overview of drug discovery, development, approval, marketing, regulation, and use in the United States. Foundations I is designed to show how all the "US medication system" pieces 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 various 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 studies that follow this foundational course.

Course Pre-Requisites / Co-Requisites
None

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 and incentives that might overcome these barriers.
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. List and explain the various types of unapproved drugs marketed in the United States
8. Explain the creation of a drug label and its various components.
9. Identify the various types of "drug products" on the US market and regulations that affect their approval and use.
10. Explain the sources of raw materials to make pharmaceuticals, how pharmaceutical drugs are made, and how FDA regulates manufacturing before and after a drug is approved.
11. Debate current controversies in the discovery, development, and regulation of drugs.

Required Textbooks and Software

There is no required textbook for this course; however, students must subscribe to STAT+, 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 (e.g., *New York Times* and *Wall Street Journal*), and websites will be assigned for each module. 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/). Thus, students will have access to the latest in the ever-changing landscape of pharmaceutical information.

Required Materials

None

Course Schedule

Dates	Module	Topic
August 22nd	Courses Intro	Course Overview
		Writing a Paper for Your POP Course
		Using Turnitin for Written Assignments
August 29th (Week 1)	Module 1: Drug Discovery & Development	Drug discovery and development
		Industry, academia, and the government's roles in drug discovery and development
		Serendipity and drug discovery
September 5th (Week 2)		The Bayh-Dole Act
		Barriers in the drug discovery and approval process & incentives
		The cost of drug discovery, development, and approval
September 12th (Week 3)	Module 2: The FDA Approval Process	Pre-clinical testing
		Phases of Drug Approval [including INDs and NDAs]
		Types of Drugs [Biosimilars]
		ANDAs for Generics
September 19th (Week 4)		"Abbreviated" NDAs (e.g., 505(b)(2) NDAs)
		Expanded Access & Right to Try
		Emergency Use Authorizations
		"Faster" Drug Approvals (e.g., Orphan Drugs, Fast Track, Accelerated Approvals, Breakthrough Therapies, and Priority Reviews
September 26th (Week 5)	Module 3: Pharmaceutical Manufacturing	Manufacturers
		Sources of Raw Materials
		Making Finished Drug Products
		FDA Oversight of Drug Production
		Stability and Expiration Dating
October 3rd (Week 6)	Module 4: Marketed Products & Other "Drugs"	Generic and Brand Names
		Labeling
		Nonprescription Drugs
		Vitamins and Minerals
		Dietary Supplements
October 10th (Week 7)		Homeopathic Remedies
		Medical Foods
		Devices that "Look Like" Drugs
		Controlled Pharmaceutical Drugs
		Unapproved Drugs

*Attendance is optional for this session since it is a holiday weekend. Please watch the recording of the class.

Evaluation Methods

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)

Online quizzes: This course will involve mandatory readings, online assignments, and pre-recorded lectures that must be reviewed before each weekly quiz. Weekly quizzes will be available for at least 3 days before each class. Quizzes will include 10 multiple-choice or short-answer questions over 15 minutes. There will be eight quizzes [including the syllabus quz], 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 49% towards the final grade in this course (i.e., each quiz will contribute 7% towards your final grade).

Class participation: Class participation is mandatory. Discussion board participation, class attendance, and class participation 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 post to the discussion board each week. What constitutes a "substantial post" 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 student's 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). Each post must include a unique citation that is not class material, or another student has used.

Final Paper: Students will identify a topic for a paper and submit it to the course coordinator for approval. Approval must occur before the class session for Week 3. Students are encouraged to pick a subject for in-depth evaluation consistent with the topics listed in the Course Schedule. The content of the paper must be more extensive than the materials covered in class. The report should be a maximum of 10 pages and follow the *POP Online Graduate Program: Style Guide for Writing Assignments.* Proper attribution is mandatory; plagiarism will be assessed using Turnitin. References should be sequentially numbered and cited as a superscript at the end of a sentence and consecutively listed at the end of the paper. All students must watch and follow the instructions in the pre-recorded lectures, *Writing a Paper for Your POP Course,* and *Using Turnitin for Written Assignments.* All papers will be due on October 10th, 2021, by 4:00 PM Eastern Time. The final paper will determine 20% of your final grade. Refer to the Appendix for a grading rubric.

Evaluation of Grades	% of grade
Final Paper [topic approved by the course coordinator] *Grades will be based on a rubric following the assignment directions*	19%
Class Participation* *Bulletin board participation, class attendance, and live class participation will be used to award a weekly participation score*	32%
Online quizzes (6 of 7; the lowest grade will be dropped) *Dropped for technical problems or excused absences*	49%

*There will be 7 class sessions.

Attendance Policy

Unexcused absences from the live, online group discussions carry <u>a 4-point (~1/2 letter grade) reduction in the final grade.</u> Absences due to illness, job conflicts, and other emergencies must be conveyed by email to Professor 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. <u>Messages from friends or classmates will not be accepted, except under exceptional circumstances.</u> When a student has an excused absence, they will receive no deduction for participation. Excused absences require a make-up paper within 2 weeks of the missed class to obtain full participation points. This paper requires the student to listen to the recorded class session and write a reflection paper on the content covered during the missed classed.

The course instructor will address more than 2 absences; an incomplete grade (i.e., I grade) is a strong possibility.

Make-up Policy

Assignments that are not submitted by the due date will be given a zero. Make-up assignments are not usually provided but may be offered at the course instructor's discretion after evaluating the circumstances leading to the request.

Grading Policy

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

Note: this scale already reflects a rounding of grades. <u>A grade of 92.4 is not 0.1 from an A; it is 0.6 points from an A.</u> 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.

More information on UF grading policy may be found at:

UF Graduate Catalog
Grades and Grading Policies

Students Requiring Accommodations
Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the Disability Resource Center. Students need to share their accommodation letters with their instructor and discuss their access needs as early as possible in the semester.

Course Evaluation
Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Click here for guidance on how to give feedback professionally and respectfully. 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 ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students here.

University Honesty Policy
UF students are bound by The Honor Pledge, which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor 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." The Honor Code specifies a number of behaviors that violate this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Software Use
All faculty, staff, and university students are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the University of Florida community members, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

Student Privacy
Federal laws are protecting your privacy in terms of grades earned in courses and on individual assignments. For more information, please see the Notification to Students of FERPA Rights.

Recordings of weekly class sessions in Zoom are created for course teaching and learning and are used as a resource for students who miss a class session.

The use of video (or web camera) in Zoom is not used for this class. For the audio features in Zoom, you will have the option to Start or Stop these functions.

This syllabus is subject to change. The program will make every effort to post any updates promptly. However, students registered for the course should not rely on this document for course information, as changes will not be reflected immediately. Students should always refer to the Canvas course site as the authoritative source for course information.

Students who participate with their camera engaged or who utilize a profile image agree to have their video or image recorded. If you are unwilling to consent to have your profile or video image recorded, be sure to keep your camera off and do not use a profile image. Likewise, students who un-mute during class and participate orally are agreeing to have their voices recorded. If you are not willing to consent to have your voice recorded during the course, you will need to keep your mute button activated and communicate exclusively using the "chat" feature, allowing students to type questions and comments live. As in all courses, unauthorized recording and unauthorized sharing of recorded materials are prohibited.

Zoom Software Privacy Statement
Canvas (by Instructure) Privacy Policies

Appendix: 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 The 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 The content shows thinking and reasoning applied with original thoughts on a few ideas	15 It 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 Little 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 are cited in the appropriate format.	1 Poor choice of reference material cited in an inappropriate format
Total Points:	**100**		