

UG 302 SYLLABUS: CONTEMPORARY DRUG DEVELOPMENT
Tuesdays and Thursdays, 12:30 p.m. – 2 p.m., PHR 2.208

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Office Hours: Wednesdays, 12-1 p.m., or by appointment

TO THE STUDENT

This syllabus is designed to help you navigate this course and answer questions related to all requirements needed to successfully pass this course.

Ask questions as they arise. Do not wait until the final week or the day an assignment is due. If you are having difficulties with the course, talk to me. This will enable both you and I to create a plan and implement it successfully.

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I. INTRODUCTION

This seminar is designed for students who may be interested in or curious about science, but may not be committed to pursuing scientific studies. The seminar provides an overview of the research, development and commercialization of therapeutic products serves as an introduction to understanding science at an accessible level for freshman students. It will focus on understanding the various scientific disciplines involved in pharmaceutical research and development of drug products and devices. Exploring current issues related to the development, approval, marketing and pricing of pharmaceuticals will be accomplished through readings and guest lectures by experts in their fields. Whether the student intends on majoring in science or simply curious about how medicines are developed, understanding the role of pharmaceutical sciences in the development and approval of therapeutic agents will give them knowledge and an appreciation of the many common and unique pharmaceutical products on the market.

II. COURSE OBJECTIVE

The objective of this course is to introduce students to various topics within the life cycle of the drug development process and create an awareness of how medicines are developed, approved and marketed through discussions, reading and investigation. In addition, students will integrate the concepts discussed in class and read in literature, into their writing assignments. As a writing intensive course, there are specific writing requirements that must be fulfilled.

III. COURSE POLICIES

Attendance

It is expected that you attend every class session. Class will begin promptly as scheduled. All absences must be approved in advance to be considered officially excused. An absence excused because of illness will require a written statement from the treating provider. Please plan your personal life around this course, not this course around your personal life.

Textbook

There is no required textbook for this course. It is advised to either buy or have access to E. B. White's *Elements of Style*. All materials for this course will be available via Blackboard Academic Suite. You may choose to view them all electronically or print them out.

Notes

Commercial note taking services are not allowed in this class. If you miss a class, please work with me to review missed material. Please review "Blackboard Academic Suite" (<https://courses.utexas.edu/webapps/portal/frameset.jsp>) prior to class. Readings and assignments will be posted prior to class.

Blackboard Academic Suite

The official Blackboard® web site for this course can be accessed either through UTDirect or via <http://courses.utexas.edu>. Both access points are UTEID-protected, and provide you links to the courses in which you are currently enrolled. The website will also be used for official, course-related announcements and for the exchange of class information and questions via the discussion board. Be aware that any messages posted to the discussion board are available to all enrolled students and faculty. You may also contact me directly via phone or email.

All assignments will be turned in electronically via Blackboard.

We will discuss on the first day whether to schedule an in-class demonstration.

Students with disabilities may request appropriate academic accommodations from the Division of Diversity and Community Engagement, Services for Students with Disabilities, 471-6259.

IV ASSIGNMENTS AND GRADING

Please pay attention to all emails and announcements from Blackboard, as they may pertain to a changed assignment. Check to make sure that your spam filters are set to allow Blackboard messages into your email accounts. If there have been no announcements or emails posted by the end of class each Tuesday, you may go ahead with the regularly scheduled assignment. There will be a verbal announcement in class every Tuesday to let you know if there have been any changes to that week's assignment. **All written assignments will be reviewed by SafeAssign on Blackboard to ensure original content. Plagiarized work will result in a zero (0) for that assignment and may result in an F for the course.**

My philosophy is that each student begins the class with 100 points – it's your responsibility to keep them 😊

COURSE GRADES

- 5% Attendance
- 10% Class participation
- 60% Weekly writing assignments (5% each)
- 20% Research paper
- 5% Presentation

Final course grade will be calculated according to the following scale:

A = 89.50 and greater (%)

B = 79.50 - 89.49 (%)

C = 69.50 - 79.49 (%)

D = 64.50 - 69.49 (%)

F = 0 - 64.49 (%)

EXAMINATIONS There are no exams for this course.

Grades: All test scores and final grades will be posted on Blackboard in compliance with University policy. No grades will be given in response to telephone or email inquiries.

IV-a. Weekly writing assignments should be posted to Blackboard no later than 8 a.m. on the day it is due. No exceptions. Do not wait until 7:45 a.m. to post your assignment and expect that everything will run smoothly. It is guaranteed that glitches will happen and there will not be any exception to assignments being turned in on time. I suggest that you post your assignments well in advance to avoid penalties. Writing assignments turned in after 8 a.m. on the assignment day will be considered late. Unless directed otherwise, all weekly writing assignments should be at least 300 words and quote one media source, including newspapers, speeches, and articles. Each journal assignment is worth 5% of your total grade.

Students will select an aspect of what is presented during the current week's class session for that week's writing assignment. Each journal entry should present your viewpoint on a particular topic and include information or a quote from at least one media source. Journal entries will be graded on content and form.

Late assignment policy:

- Assignments turned in on the due date between 8 a.m. and noon will need to be at least 500 words and will not result in a penalty to your grade
- Assignments turned in past noon will result in a 1-5 point deduction from your TOTAL grade

You are allowed to miss one (1) of the weekly writing assignment during the semester without penalty.

IV-b. Research Paper and Presentations – each student will select a unique topic from a suggested topic list to write a 7-10 page research paper, minimum 2,000 words. Specific directions will be provided. Students will make 5-7 minute presentations to the class on the topic of their research paper.

- **Topic selection due by Wednesday, September 23 at 5 p.m.**
- **Outline for paper due by Tuesday, October 13 at 8 a.m.**
- **Research paper due Friday, November 6, 2009, at 8 a.m.**
- **Presentations will occur during the final week(s) of class**

Papers will be graded on both content and writing style. The paper must be based on a review of relevant literature. The 2,000 words do not include the bibliography, tables, appendices, etc. Text must conform to requirements previously stated. All pages should be numbered as appropriate. This paper should be written in third person, unless approved by the instructor. The organization of the paper varies with topics, but basic elements to include are a title page, background and introduction, body, conclusion, and references. Utilize “Blackboard Academic Suite”. Under “research tools”, you will find resources on getting started, searching, writing, citing, and other help.

Late policy for Course Paper: A 10% deduction in points will be assessed for each 24-hour time period after the outline and or paper is due.

IV-c. Active participation is expected. This is a highly interactive seminar and individual participation will be counted towards your final grade.

IV-d. UNIVERSITY LECTURE ASSIGNMENT

Designed to create a campus-wide conversation, the University Lecture Series gives first-year students an opportunity to interact with leading members of our faculty—scholars, scientists, and civic leaders who are nationally and internationally renowned.

Signature Course students are required to attend at least one of the two large lectures (or watch online) and discuss in class. The large lectures will be at 7 p.m. in Bass Concert Hall, and can be viewed online within 72 hours after each lecture.

First Large Lecture: September 21, The State of the Economy, Dean Thomas Gilligan, School of Business, Bass Concert Hall

V. STANDARDS OF CONDUCT

Students at the University are expected to obey and conduct themselves in accordance with the penal and civil statutes of the local, state, and federal government and the Rules and Regulations of the Board of Regents of the University of Texas System, University regulations, and administrative rules, and to observe standards of conduct appropriate for an academic institution. § 11-101(a), *Institutional Rules on Student Services and Activities*

THE STANDARD OF ACADEMIC INTEGRITY

A fundamental principle for any educational institution, academic integrity is highly valued and seriously regarded at The University of Texas at Austin, as emphasized in the standards of conduct. More specifically, you and other students are expected to "maintain absolute integrity and a high standard of individual honor in scholastic work" undertaken at the University (*Sec. 11-801, Institutional Rules on Student Services and Activities*). This is a very basic expectation that is further reinforced by the University's Honor Code. At a minimum, you should complete any assignments, exams, and other scholastic endeavors with the utmost honesty, which requires you to:

- * Acknowledge the contributions of other sources to your scholastic efforts;
- * Complete your assignments independently unless expressly authorized to seek or obtain assistance in preparing them;
- * Follow instructions for assignments and exams, and observe the standards of your academic discipline; and
- * avoid engaging in any form of academic dishonesty on behalf of yourself or another student.

SCHOLASTIC DISHONESTY

In promoting a high standard of academic integrity, the University broadly defines scholastic dishonesty—basically, all conduct that violates this standard, including any act designed to give an unfair or undeserved academic advantage, such as:

- * Cheating * Plagiarism * Collusion
- * Unauthorized Collaboration * Falsifying Academic Records
- * Misrepresenting Facts (e.g., providing false information to postpone an exam, obtain an extended deadline for an assignment, or even gain an unearned financial benefit)
- * Any other acts (or attempted acts) that violate the basic standard of academic integrity (e.g., multiple submissions—submitting essentially the same written assignment for two courses without authorization to do so)

DISCIPLINE

As authorized by the Board of Regents of The University of Texas System, the Office of the Dean of Students is responsible for the administration of student discipline, which is implemented by Student Judicial Services (SJS).

Please refer to the SJS website for more complete information on scholastic dishonesty: <http://deanofstudents.utexas.edu/sjs/> . For matters concerning plagiarism and guidelines for acceptable paraphrasing: http://deanofstudents.utexas.edu/sjs/scholdis_plagiarism.php
An excellent resource in the LBJ School, Guide to Avoiding Plagiarism.

VI. LIST OF POTENTIAL TOPICS FOR RESEARCH PAPER

1. Access to medicine
2. Biotechnology product
3. Clinical trials – in house, outsourcing
4. Confidentiality of medical records
5. Counterfeit products
6. Disease therapies: pick a specific disease or therapy
7. Drug Pricing
8. Ethical considerations
9. FDA role, regulations, approval process
10. Generics
11. Genetic testing
12. Gene Therapy
13. Genomics
14. Legislation related to pharma/products
15. Managed Care
16. Manufacturing medical products
17. Marketing
18. Marketing, drug rep's
19. Medical ethics
20. Nationalized healthcare
21. Off label use
22. Online drug products
23. Patient protection
24. Personalized medicine
25. Pharmaceutical industry
26. Pharmacoeconomics
27. Project Teams
28. Regulations
29. Science and politics
30. Stem cell research
31. Technology Incubators
32. Translational research
33. University research and commercialization
34. Veterinary medicine

VII. TOPIC and ASSIGNMENTS
 UGS 302: CONTEMPORARY DRUG DEVELOPMENT
 FALL 2009, TTH 12:30 – 2 P.M., PHR 2.208

DATE	TOPIC	GUEST(s)	ASSIGNMENT
WEEK 1 August 27	What is Drug Development? Introduction and background; review syllabus; writing center overview	Writing Center Overview	BLACKBOARD JOURNAL: <i>What do you want to learn in this seminar?</i> <i>Short answer: 100-200 word minimum</i> <i>Due Date: Aug. 30 @ 8 a.m.</i>
WEEK 2 September 1 September 3	Navigating the Pharmaceutical Organizations The Project Team Approach: who's who? R&D, Manufacturing, Sales, Marketing, Corporate		READING: <i>Overview: The Pharmaceutical Industry</i> READING: <i>Project Team Foundation experts</i> BLACKBOARD JOURNAL: <i>300 word minimum</i> <i>Due Date: Sept. 4 @ 8 a.m.</i>
WEEK 3 September 8 September 10	Research & Development; Manufacturing Research paper overview; topic options	J. Vaughn, Ph.D. <i>PharmaForm</i>	READING: <i>To be posted</i> READING: <i>To be posted</i> BLACKBOARD JOURNAL: <i>300 word minimum</i> <i>Due Date: Sept. 11 @ 8 a.m.</i>
WEEK 4 September 15 September 17	The FDA, regulations, product approvals Marketing Practices: Competitive Analysis, Drug Pricing	R. Bell, Ph.D. <i>Drug and Biotechnology Development</i> M. Shepherd, Ph.D. <i>UT College of Pharmacy</i>	READING: <i>Review topics; prepare questions and list of favorites</i> READING: <i>To be posted</i> BLACKBOARD JOURNAL: <i>300 word minimum</i> <i>Due Date: Sept. 18 @ 8 a.m.</i>

WEEK 5 September 22 September 24	Modern Pharmaceuticals – innovation, novel delivery systems and issues NO CLASS: Attend lecture on 9/21	R. Williams, Ph.D. <i>UT College of Pharmacy</i>	READING: <i>To be posted</i> Attend lecture 9/21, The State of the Economy, Dean Thomas Gilligan, Bass Concert Hall September 23 by 12 noon: topic selection BLACKBOARD JOURNAL: <i>Pertaining to Dean Gilligan’s lecture</i> 300 word minimum Due Date: Sept. 25 @ 8 a.m.
WEEK 6 September 29 October 1	Generics Library and resource overview with M. Sitar: 12:30 – 1:45 MEET AT PERRY CASTENADA LIBRARY, PCL 1.339, which is one of the hands-on classrooms on the lower level of PCL	Meghan Sitar <i>UT Perry Castenada Library</i>	READING: <i>To be posted</i> BLACKBOARD JOURNAL: 300 word minimum Due Date: Oct. 2 @ 8 a.m.
WEEK 7 October 6 October 8	Counterfeit drug information Addressing Patients Needs	M. Shepherd, Ph.D. <i>UT College of Pharmacy</i>	READING: <i>To be posted</i> READING: <i>To be posted</i> BLACKBOARD JOURNAL: 300 word minimum Due Date: Oct. 9 @ 8 a.m.
WEEK 8 October 13	The Role of University research programs	B. Iverson, Ph.D.	READING: <i>To be posted</i>

October 15	The Role of Incubators	UT College of Nat'l Sciences J. Hanover, Ph.D. Austin Technology Incubator	October 13: Outline due READING: <i>To be posted</i> BLACKBOARD JOURNAL: <i>300 word minimum</i> Due Date: Oct. 16 @ 8 a.m.
WEEK 9 October 20 October 22	Biotech and start up's Business Development	T. Baughman UT, Office of Technology & Commercialization M. Crowley, Ph.D. Theridian Therapies	READING: <i>To be posted</i> READING: <i>To be posted</i> BLACKBOARD JOURNAL: <i>300 word minimum</i> Due Date: Oct. 23 @ 8 a.m.
WEEK 10 October 27 October 29	Role of Sales & Marketing Personalized Medicine	Jeff Cohen Performance Leaders Marie Lindner, M.D. BioAdvance	READING: <i>To be posted</i> READING: <i>To be posted</i> BLACKBOARD JOURNAL: <i>300 word minimum</i> Due Date: Oct. 30 @ 8 a.m.
Week 11 November 3 November 5	Patient Package Inserts NO CLASS Library Time: Research Paper	P. Mayer, Ph.D. Wyeth	No READING READING: <i>To be posted</i> NO JOURNAL November 6: Paper Due
Week 12 November 10 November 12	Drug Dynamics Institute Portfolio Management, Global Alliances	R. Wills, Ph.D. Johnson & Johnson	READING: <i>To be posted</i> BLACKBOARD JOURNAL: <i>300 word minimum</i> Due Date: Nov. 13 @ 8 a.m.

<p>Week 13 November 17</p>	<p>Veterinary Medicine</p>	<p>E. Caplan, D.V.M. <i>Capital Area Veterinary Specialists</i></p>	<p>READING: <i>To be posted</i></p>
<p>November 19</p>	<p>Open topics/Class Presentations</p>		<p>READING: <i>To be posted</i></p> <p>BLACKBOARD JOURNAL: <i>300 word minimum</i></p> <p>Due Date: Nov. 20 @ 8 a.m.</p>
<p>Week 14 November 24</p>	<p>Class Presentations</p>		<p>READING: <i>To be posted</i></p>
<p>November 26</p>	<p>NO CLASS</p>		<p>NO BLACKBOARD JOURNAL – Happy Thanksgiving</p>
<p>Week 15 December 1</p>	<p>Class Presentations and</p>		<p>READING: <i>To be posted</i></p>
<p>December 3</p>	<p>Course Survey</p>		<p>BLACKBOARD JOURNAL: <i>300 word minimum</i></p> <p>Due Date: Dec. 3 @ 8 a.m.</p>
<p>FINAL EXAM</p>	<p>The final exam period will be used for students who have not successfully completed assignments. Do not make plans that conflict with this period. As soon as the exam date is assigned, I will inform you.</p>		