**PHC 502 Drug Development**

**Friday, 1 pm- 3:45 pm**

**Pharmacy Building, Room 180**

**Fall 2017 Syllabus**

**Location:** Class is located in the Pharmacy Research and Education Building, Room 180.

**Course Description**

This course provides an overview of the scientific and regulatory aspects of drug development from discovery to market. A requirement for all College of Pharmacy graduate students, the course will allow students to gain an appreciation of the varied aspects in researching, producing and marketing pharmaceuticals. Lecturers from the College faculty will provide expertise on a range of topics, including clinical trials, metabolism, pharmacokinetics, pre-formulation, pharmacoepidemiology and pharmacoeconomics.

**Course Coordinators** Angela Slitt, Ph.D

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Office Hours: by appointment

Jie Shen, Ph.D.

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Office Hours: by appointment

**Course Student Learning Outcomes**

Students who have completed this course will be able to:

* Identify the key steps in bringing a drug to market in the United States
* Recognize key regulatory and governmental agencies that affect drug approval, manufacturing and the health care industry
* Identify types of new chemical entities and the strategies utilized for drug discovery
* Identify key steps in the pre-clinical drug development such pharmacodynamics, and pharmacokinetics, and drug metabolism and disposition, and drug safety
* Appreciate the role of the clinical trials, and their strengths and limitations

**Textbook**

Drugs: From Discovery to Approval, by Rick Ng; Wiley -Blackwell Publishing;

ISBN 978-0-470-19510-9.

**Attendance Policy**

Please come to class – missing class equates to missing an entire week. In the event of illness or emergency, please notify Dr. Slitt ([aslitt@uri.edu](mailto:aslitt@uri.edu)) or Dr. Shen ([jie\_shen@uri.edu](mailto:jie_shen@uri.edu)). Missed exams due to excused absences may be excluded without penalty, with additional weight applied to the corresponding section of the final exam.

**Student Term Paper**

The student term paper accounts for 25% of the course grade. The term paper topic must pertain to a domain of the drug development process, as discussed or mentioned in class. Ideally, the student should focus on a particular issue or novel area of drug development. Students are encouraged to contact the faculty participating in this course for guidance in shaping their ideas for paper topics. Papers should provide a thorough yet concise exploration of the topic, including both what is known, and of what gaps in knowledge exist. Students are encouraged to offer personal viewpoints and supporting rationale. Examples from previous semesters include:

* Issues in the design and interpretation of non-inferiority clinical trials
* Mitigating drug interactions with oral anticoagulants
* Gene therapy: Where are we going from here?
* FDA regulation of biologics

The paper should note important literature published to date, and referencing primary sources predominantly. The paper shall be typed single-spaced, be no longer than 4000 words in length, and cited according to a journal typical to your field of study (examples: *NEJM*, *JAMA*, *Drug Metabolism Disposition*, *Journal of Pharmacology and Experimental Therapeutics*) style. Use of citation software is recommended, such as Reference Manager or Endnote.

**Pipeline Presentation**

The last week of class, students will provide a 5-7 presentation on a particular pharmaceutical drug under development. More detail regarding this assignment will be provided during the first week of class.

**Course Grading**

Exam 1 25%

Student paper 25%

Exam 2 25%

Pipeline presentation 15%

Attendance / Participation 10%

***General policies and principles***

**Illness:** Flu epidemics may impact classes this semester. If any of us develop flu-like symptoms, we are being advised to stay home until the fever has subsided for 24 hours. If you exhibit such symptoms, please do not come to class. Notify Dr. Slitt of your status, and we will work together to ensure that course instruction and work is completed for the semester. The Centers for Disease Control and Prevention have posted simple methods to avoid transmission of illness. These include: covering your mouth and nose with a tissue when coughing or sneezing; frequently washing your hands to protect from germs; avoiding touching your eyes, nose and mouth; and staying home when you are sick. For more information, please view [www.cdc.gov/flu/protect/habits.htm](http://www.cdc.gov/flu/protect/habits.htm). URI flu information is posted on the URI website at [www.uri.edu/news/h1n1.html](http://www.uri.edu/news/h1n1.html), with links to the [www.cdc.gov](http://www.cdc.gov) site.

**Dress Code Policy** Professional dress is exemplified by the avoidance of extremes in dress and grooming. Even though current dress code policy does not specifically require adherence to the professional dress standard in the classroom, students are expected to maintain a neat, clean appearance in the classroom, such that visitors and faculty members might discern they are in the presence of students within a professional program. Therefore, avoidance of extremes of dress and grooming, and adherence to personal cleanliness should be maintained in the classroom, or in any situation when the student represents the College of Pharmacy.

**Professional Misconduct Policy** We expect professional conduct from all students, faculty, and staff. Individuals are expected to represent the College, professional program or profession in a positive, professional manner. Violation of any professions’ codes of ethics is a violation of professional conduct.

Examples of misconduct can be found in the Professionalism Guidelines of the URI College of Pharmacy (http://www.uri.edu/pharmacy/professionalism).

**Policy on Adjudication of Unprofessional Conduct.** The procedure for adjudication of alleged unprofessional conduct is handled by the Professionalism Committee. Conduct that is generally considered unprofessional or unethical (as listed in this manual) is typically considered unprofessional conduct for students.

**Misconduct Reporting** Anyone can report professional misconduct to the Director of Student Affairs in writing. Verbal reports must be followed up with a written form that lists the name of the reporter (anonymous reporting will not be permitted), the student violator, a detailed description of the offense(s), and the date(s). These forms serve as the basis for the complete documentation of the conduct adjudication process. All confirmed misconduct reported to the Committee will lead to some action by the Director and/or the Committee. The Director has 10 business days from receipt of the form to address the alleged misconduct, assemble the Committee (if needed), and decide on an appropriate disciplinary action. Offenses may require that the student meet with the Committee prior to a decision. The decisions of the Committee range from a letter in the student’s professional file to a recommendation for immediate expulsion from the College.

**Appeals Process** From the day the student is notified of the Director’s or Committee’s decision, the student has 10 business days to submit a written appeal to the Associate Dean for Student Affairs. The Associate Dean may choose to uphold, change, or override the Committee’s decision, also within 10 business days of receipt of the appeal. The student may further appeal the Dean’s decision to the University’s Ombudsman. Students who are disciplined three times are subject for dismissal from the College.

**Professionalism Expectations (Adapted from the APhA Professionalism Toolkit and the University of Georgia College of Pharmacy)**

As defined in the 1999 APhA-ASP/AACP White Paper on Student Professionalism, pharmacists and pharmacy students act professionally when they display the following traits:

1. Knowledge and skills of a profession

2. Commitment to self-improvement of skills and knowledge

3. Service orientation

4. Pride in the profession

5. Covenantal relationship with client

6. Creativity and innovation

7. Conscience and trustworthiness

8. Accountability for his/her work

9. Ethically sound decision-making

10. Leadership

A full description of the traits can be found in the Professionalism Guidelines of the URI College of Pharmacy (http://www.uri.edu/pharmacy/professionalism).

**Academic Misconduct:** while also considered professional misconduct, will be adjudicated as outlined in the URI Student Handbook (http://www.uri.edu/judicial/Student Handbook/handbook.html, portions included here) and, in some cases, heard by the Professionalism Committee.

Students are expected to be honest in all academic work. A student's name on any written work shall be regarded as assurance that the work is the result of the student's own thought and study. Work should be stated in the student's own words, properly attributed to its source. Students have an obligation to know how to quote, paraphrase, summarize, or reference the work of others with integrity. While intent or negligence may affect the seriousness of the sanction, the following examples of academic dishonesty apply regardless.

The following are examples of academic dishonesty.

**1.5 Procedures** The following procedures apply when there is an allegation of academic dishonesty.

a. The instructor has the following options when dealing with a case of academic dishonesty (a-d):

i. May fail the student for the assignment;

ii. May fail the student for the course, with authorization from the instructor's dean; and/or

iii. May request conduct action. This request may be made in lieu of or in addition to a grade adjustment.

b. The instructor is required to:

i. Notify the student of the allegations; and,

ii. Send written notice to the instructor's dean, the student's academic dean and the dean of students.

c. The dean of students notifies the student in writing of the academic dishonesty violation. If it is a first offense and no conduct action is requested, students are sent an official warning letter. Repeat infractions will have conduct action initiated against the student. Conduct action on an allegation of academic dishonesty may be requested by the instructor's dean or by the instructor with a statement of position from the instructor's dean. Appeals for conduct action will be followed in accordance with Section 26 of this handbook.

d. Students accused of academic dishonesty within the drop period may be denied the opportunity to drop the course. This requires authorization from the instructor's academic dean. If the accusation is not upheld in an academic appeal, the student will be given the same options available before the end of the drop period without penalty.

e. The student may appeal the allegation of academic dishonesty to the instructor's dean. The student or instructor may appeal the dean's decision to the Provost and Vice President for Academic Affairs whose decision on the appeal shall be final. For further academic appeal options students may consult the University Manual.

**1.6 Records** A cumulative file on student violations will be maintained in the Office of Student Life.

**Plagiarism:** Plagiarism is defined in both the University Manual and the Student Handbook – RAMPAGES. Students should carefully read sections 8.27.12-8.27.20 of the University Manual. Faculty have the explicit duty to take prompt action when they suspect cheating or plagiarism. The range of action includes, but is not limited to: failure on the assignment, failure in the course, or suspension or dismissal from the University (resulting from action within the University Judicial system). Students are expected to do their own work independently of their classmates. When preparing written and or oral work for this class, students should pay special attention to guideline 8.27.12.

*8.27.12 : In preparing papers of themes, a student often needs or is required to employ sources of information or opinion. All such sources used in preparing to write or in writing a paper shall be listed in the bibliography. It is not necessary to give footnote reference for specific facts which are common knowledge and have obtained general agreement. However, facts, observations and opinions which are new discoveries or are debatable shall be identified with correct footnote references even when restated in the student’s own words. Material taken word for word from the written or oral statement of another person must be enclosed in quotation marks or otherwise clearly distinguished from the body of the text and the source cited. Paraphrasing or summarizing the contents of another’s work usually is acceptable if the source is clearly identified but does not constitute independent work and may be rejected by the instructor.*

**Disability Services** Any student with a documented disability is welcome to contact me early in the semester so that we may work out reasonable accommodations to support your success in this course. One should also contact Disability Services for Students, Office of Student Life, 330 Memorial Union, 874-2098.

**Academic Enhancement Center** The work in this course is complex and demanding. To do well, it is best to attend all classes, stay on top all assignments, review your notes regularly, and work with the students at the Academic Enhancement Center (AEC) in Roosevelt Hall. AEC tutors are students like you who have succeeded in this course and understand how challenging it can be. They can answer questions, clarify concepts, test your understanding, and show you how to study in the most effective ways possible. You can make an appointment or walk in anytime during office hours -- Monday through Thursday from 9 am. to 9 pm, Friday from 9 am to 1 pm, and Sunday from 4 pm. to 8 pm. For a complete schedule -- including when tutors are available specifically for this class -- go to www.uri.edu/aec, call (401) 874-2367, or stop by the fourth floor in Roosevelt Hall.

**Academic Accommodations:** Any student with a documented disability is welcome to contact me as early in the semester as possible so that we may arrange reasonable accommodations. As part of this process, please be in touch with Disability Services for Students Office at 330 Memorial Union, 401-874-2098. All accommodations are on a case-by-case basis and depend on discussions with the student, current documentation, and university policy.

**Course Schedule Fall 2016**

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| **Date** | **Class topics/itinerary** | **Readings / Assignments** |
| 9/8 | * Course introduction (Shen and Slitt) * Term paper expectations * The drug approval process: Introduction to the pharmaceutical sciences and the drug development process. (Dr. Susanna Tse, Pfizer) | Ng: Chapter 1,2 |
| 9/15 | * Chapter 3 *Small Molecule Drugs* * Review chapter with Dr. Slitt * Natural Products (Dr. Rowley or Bertin, URI) | Ng: Chap. 3 |
| 9/22 | * Review of Chapters 3 and 4 *Large Molecule Drugs* * Development of Large Molecular Drugs and New Biological Entities (Dr. Deng, URI) | Ng: Chap. 4 |
| 9/29 | * Putting the Drug Discovery and Development Process Together: Challenges, Decisions, and Victories at Alexion Pharmaceuticals * Guest: Dr. Steve Uden, Alexion | Ng: Chap. 5 |
| 10/6 | * Introduction to ADME (Dr. Fatemeh Akhlaghi, URI) * Preclinical studies: Impact of metabolism (Dr. Amit Kalgutkar, Pfizer Global Research) * Ayman El-Kattan | Ng: Chap. 5 |
| 10/13 | * Review of Chapter 6 * Small molecule safety (Dr. Jeffrey Moffit, Forum Pharmaceuticals) * **Paper drafts due** | Ng: Chap. 6,7 |
| 10/20 | * **Exam I** * Topics: Chapters 1-7 and guest lecturers Topics: Chapters 1-7 and guest lecturers through 10/13 |  |
| 10/27 | * Large molecule safety (Dr. Laura Andrews, Abbvie) |  |
| 11/3 | * Clinical Study Design (Dr. Dufresne, University of Rhode Island) * Biomarkers? | Ng: Chap.8 |
| 11/10 | * Phase III and IV studies: Pharmacoepidemiology: The FDA and drug safety Dr. Ami Vyas, University of Rhode Island * Pharmacoeconomics and outcomes research (Dr. Kogut, URI) * **Final Paper drafts due** | Ng: Chap. 9, 10 |
| 11/17 | * Good Manufacturing Process |  |
| 11/24 | * No Class – Thanksgiving Break |  |
| 12/1 | * **Exam 2** * Cumulative * Multiple choice and written responses |  |
| 12/8 | * Pipeline Presentations * FDA Guest Webinar |  |

*In lieu of a final examination, we will have class presentations*