Course Syllabus

PHR 256R

Spring 2014

Advanced Contemporary Compounding
PHR 256R

Spring 2014

256R - LECTURE
Tuesdays 9 – 11am
2.208

Instructors: Nathan Pope, PharmD
n pope@utexas.edu
Office: 512-471-5664

Andres Ruiz, PharmD, M.S.
andyruiz@stonegaterx.com
Pharmacy: (512) 707-2300

Office Hours: By appointment as requested

Unique Numbers:
Austin – 61460 – Dr. Pope
Valley – 61455 - Coordinator: Diana Laura Paz
San Antonio – 61450 – Coordinator: Veronica Young
El Paso – 61445 – Coordinator: Jose Rivera/Pat Dominguez

Table of Contents
I. Rationale…………………..
II. Course Aims and Objectives…1
   • Aims
   • Specific Learning Objectives
III. Format and Procedures……
IV. Tentative Course Schedule…
   • Feedback Statement
V. My Assumptions……………..
VI. Course Requirements
   • Attendance and participation
   • Religious Holy Days
   • Readings/Materials
   • Assignments/Assessments
     • Use of Canvas
VII. Grading Procedures
VIII. Academic Integrity
     • UT Honor Code
IX. Other University Notices and Policies………
     • Use of e-mail
     • Documented Disability Statement
     • Behavior Concerns Advice Line (BCAL)
     • Q-drop Policy

Revised 1/13/14
I. Rationale:
The art and science of compounding pharmaceutical preparations at an advanced level will be discussed. Students will build on their compounding experience in PHAR 385 and 386 to develop an advanced understanding of formulation, stability and quality of compounded pharmaceuticals and the role a pharmacist plays in the specialized practice of compounding pharmacy. Advanced compounding methods will be used to make pharmaceutical dosage forms and develop formulations as they would in the practice of compounding a pharmacy.

II. Course Aims and Objectives:
Aims
The aim of this course is to prepare the student to respond to questions from patients and other heath-care professionals regarding compounded formulations and then to prepare such compounded products.

Specific Learning Objectives:

By the end of this course, students will:
1. Determine the proper compounded dosage form for a given patient’s disease state.
2. Determine appropriate compounding method for a given formulation.
3. Determine proper formulation for a given dosage form.
4. Compound high quality dosage forms.
5. Counsel patients on the use of compounded dosage forms.
6. Evaluate the quality of a given compounded pharmaceutical dosage form.

III. Format and Procedures:
This course will involve content delivered via lecture in addition to active learning exercises. This class will be informal with no judgments to foster an active, healthy learning environment, however professionalism is expected at all times. The more you put into the work and discussion, the more prepared you will be when you are a practicing pharmacist.
IV. Tentative Course Schedule: **This syllabus represents my current plans and objectives. As we go through the semester, those plans may need to change to enhance the class learning opportunity. Such changes, communicated clearly, are not unusual and should be expected.**

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>Readings</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/14/14</td>
<td>Intro</td>
<td>Allen Ch. 1: Guidelines for Compounding Practices</td>
<td>Dr. Pope &amp; Dr. Ruiz</td>
</tr>
<tr>
<td>1/21/14</td>
<td>Regulatory &amp; Ethics</td>
<td>Read: USP795/797/TSBP compounding laws</td>
<td>Dr. Pope</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Allen Ch. 4: Records and Record Keeping</td>
<td>Dr. Ruiz</td>
</tr>
<tr>
<td>1/28/14</td>
<td>Intro to Safety &amp; Quality PCAB</td>
<td>Allen Ch. 3: Facilities, Equipment, and Supplies</td>
<td>Dr. Pope – Safety</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Allen Ch. 7: Quality Control PCAB Manual</td>
<td>Dr. Ruiz – PCAB</td>
</tr>
<tr>
<td>2/4/14</td>
<td>Compound Ingredient Considerations &amp; Stability Brief Exam Review</td>
<td>Allen Ch. 2: Compounding Ingredient Considerations</td>
<td>Dr. Pope</td>
</tr>
<tr>
<td>2/11/14</td>
<td>Exam #1 (4 weeks of material)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2/18/14</td>
<td>Men’s Health</td>
<td></td>
<td>Dr. Ruiz</td>
</tr>
<tr>
<td>2/25/14</td>
<td>Women’s Health</td>
<td></td>
<td>Dr. Ruiz</td>
</tr>
<tr>
<td>3/4/14</td>
<td>Wound Care/Hospice/Pain</td>
<td>Allen Ch. 25: Special pops(Hospice/Pain Mgmt)</td>
<td>Rene Garza</td>
</tr>
<tr>
<td>3/11/14</td>
<td>SPRING BREAK</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/18/14</td>
<td>Pediatric Brief Exam Review at end of class</td>
<td>Allen Ch 25: Special Pops(Peds) Ch. 16 &amp; 17: Solutions &amp; Suspensions</td>
<td>Dr. Pope</td>
</tr>
<tr>
<td>3/25/14</td>
<td>Exam #2 (4 weeks of material)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4/1/14</td>
<td>Veterinary</td>
<td>Allen Ch. 26: Veterinary Pharmaceuticals</td>
<td>Dr. Pope</td>
</tr>
<tr>
<td>4/8/14</td>
<td>Veterinary</td>
<td>Allen Ch. 26: Veterinary Pharmaceuticals</td>
<td>Dr. Pope</td>
</tr>
<tr>
<td>4/15/14</td>
<td>Cosmeceuticals &amp; Dermatologicals</td>
<td>Allen Ch. 28: Cosmetics for Special Populations and for Use as Vehicles</td>
<td>Dr. Pope</td>
</tr>
<tr>
<td>4/22/14</td>
<td>Ophthalmic, Otic, and Nasal Preps Introduction</td>
<td>Allen Ch. 21</td>
<td>Dr. Pope</td>
</tr>
<tr>
<td>4/29/14</td>
<td>Marketing &amp; 3rd Party Insurance Billing Brief Exam Review</td>
<td></td>
<td>Dr. Ruiz</td>
</tr>
</tbody>
</table>

EXAM #3 DURING FINAL EXAM PERIOD (5 weeks of material)
VI. Course Requirements:
1. Class attendance and participation policy:
   (a) Attendance is requested for this course.
   (b) Class participation is appreciated for this course. You can’t participate if you aren’t in class!

   Religious Holy Days
By UT Austin policy, you must notify me of your pending absence at least fourteen days prior to the date of observance of a religious holy day. If you must miss a class, an examination, a work assignment, or a project in order to observe a religious holy day, I will give you an opportunity to complete the missed work within a reasonable time after the absence.

2. Course Readings/Materials:
   • **The Art, Science, and Technology of Pharmaceutical Compounding, 4e** by Loyd Allen, Jr. – Available online at www.pharmacylibrary.com
   • Optional Textbook: Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems
   • Optional Textbook: Trissel’s Stability of Compounded Formulations – Available online
   • Optional Textbook: U.S. Pharmacopeia (USP 36-NF 31) Available online
   • Additional Text: The Merck Index

3. Assignments, Assessment, and Evaluation

256R - LECTURE

<table>
<thead>
<tr>
<th>Method</th>
<th>Points</th>
<th>% of Total Grade</th>
<th>Brief Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exam #1</td>
<td>25%</td>
<td></td>
<td>4 weeks of material</td>
</tr>
<tr>
<td>Exam #2</td>
<td>25%</td>
<td></td>
<td>4 weeks of material</td>
</tr>
<tr>
<td>Exam #3</td>
<td>25%</td>
<td></td>
<td>5 weeks of material</td>
</tr>
<tr>
<td>Standard Operating Procedure (SOP) Assignment</td>
<td>25%</td>
<td></td>
<td>Creation of a pre-assigned SOP Due 3/17/14 @ 11:59pm</td>
</tr>
</tbody>
</table>

3a. Other policies
   • Assignment policy – All assignments are due on the date noted by 11:59pm.
   • Make-up exam policy – On an as needed basis with reasonable excuse for absence.
   • Late assignments – 5% deduction per 24 hrs late.
   • Subject-to-change notice – **This syllabus represents my current plans and objectives. As we go through the semester, those plans may need to change to**
enhance the class learning opportunity. Such changes, communicated clearly, are not unusual and should be expected.

- There is no final exam for this course (Exam #3 is just that. It covers the information since Exam #2).

4. Use of CANVAS in class

In this class I use CANVAS—a Web-based course management system with password-protected access at http://canvas.utexas.edu—to distribute course materials, to communicate and collaborate online, to post grades, to submit assignments, and to give you online quizzes and surveys. You can find support in using Canvas at the ITS Help Desk at 475-9400, Monday through Friday, 8 a.m. to 6 p.m., so plan accordingly.

VII. Grades will be based on:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>&gt;= 90%</td>
</tr>
<tr>
<td>B</td>
<td>80 – 89.9%</td>
</tr>
<tr>
<td>C</td>
<td>70 – 79.9%</td>
</tr>
<tr>
<td>D</td>
<td>65 – 69.9%</td>
</tr>
<tr>
<td>F</td>
<td>&lt; 65%</td>
</tr>
</tbody>
</table>

IX. Academic Integrity

University of Texas Honor Code

The core values of The University of Texas at Austin are learning, discovery, freedom, leadership, individual opportunity, and responsibility. Each member of the university is expected to uphold these values through integrity, honesty, trust, fairness, and respect toward peers and community.

Each student in this course is expected to abide by the University of Texas Honor Code. [See the UT Honor Code above.] Any work submitted by a student in this course for academic credit will be the student's own work.

You are encouraged to study together and to discuss information and concepts covered in lecture and the sections with other students. You can give "consulting" help to or receive "consulting" help from such students. However, this permissible cooperation should never involve one student having possession of a copy of all or part of work done by someone else, in the form of an e-mail, an e-mail attachment file, a diskette, or a hard copy.

Should copying occur, both the student who copied work from another student and the student who gave material to be copied will both automatically receive a zero for the assignment. Penalty for violation of this Code can also be extended to include failure of the course and University disciplinary action.

During examinations, you must do your own work. Talking or discussion is not permitted during the examinations, nor may you compare papers, copy from others, or collaborate
Any collaborative behavior during the examinations will result in failure of the exam, and may lead to failure of the course and University disciplinary action.

X. Other University Notices and Policies

Use of E-mail for Official Correspondence to Students

- All students should become familiar with the University's official e-mail student notification policy. It is the student's responsibility to keep the University informed as to changes in his or her e-mail address. Students are expected to check e-mail on a frequent and regular basis in order to stay current with University-related communications, recognizing that certain communications may be time-critical. It is recommended that e-mail be checked daily, but at a minimum, twice per week. The complete text of this policy and instructions for updating your e-mail address are available at http://www.utexas.edu/its/help/utmail/1564.

Documented Disability Statement

Any student with a documented disability who requires academic accommodations should contact Services for Students with Disabilities (SSD) at (512) 471-6259 (voice) or 1-866-329-3986 (video phone). Faculty are not required to provide accommodations without an official accommodation letter from SSD. (Note to Faculty: Details of a student’s disability are confidential. Faculty should not ask questions related to a student’s condition or diagnosis when receiving an official accommodation letter.)

- Please notify me as quickly as possible if the material being presented in class is not accessible (e.g., instructional videos need captioning, course packets are not readable for proper alternative text conversion, etc.).

- Please notify me as early in the semester as possible if disability-related accommodations for field trips are required. Advanced notice will permit the arrangement of accommodations on the given day (e.g., transportation, site accessibility, etc.).

- Contact Services for Students with Disabilities at 471-6259 (voice) or 1-866-329-3986 (video phone) or reference SSD’s website for more disability-related information: http://www.utexas.edu/diversity/ddce/ssd/for_cstudents.php

Behavior Concerns Advice Line (BCAL)

If you are worried about someone who is acting differently, you may use the Behavior Concerns Advice Line to discuss by phone your concerns about another individual’s behavior. This service is provided through a partnership among the Office of the Dean of Students, the Counseling and Mental Health Center (CMHC), the Employee Assistance Program (EAP), and The University of Texas Police Department (UTPD). Call 512-232-5050 or visit http://www.utexas.edu/safety/bcal.

Q drop Policy
The State of Texas has enacted a law that limits the number of course drops for academic reasons to six (6). As stated in Senate Bill 1231:

“Beginning with the fall 2007 academic term, an institution of higher education may not permit an undergraduate student a total of more than six dropped courses, including any course a transfer student has dropped at another institution of higher education, unless the student shows good cause for dropping more than that number.”

Emergency Evacuation Policy

Occupants of buildings on the UT Austin campus are required to evacuate and assemble outside when a fire alarm is activated or an announcement is made. Please be aware of the following policies regarding evacuation:

- Familiarize yourself with all exit doors of the classroom and the building. Remember that the nearest exit door may not be the one you used when you entered the building.
- If you require assistance to evacuate, inform me in writing during the first week of class.
- In the event of an evacuation, follow my instructions or those of class instructors.

Do not re-enter a building unless you’re given instructions by the Austin Fire Department, the UT Austin Police Department, or the Fire Prevention Services office.

A Word about Conduct in a College Classroom

To make our time together as valuable as possible, we all have to work hard at it. The following basic principles may give us some guidelines:

Every student has the right to learn as well as the responsibility not to deprive others of their right to learn.

Every student is accountable for his or her actions.

In order for you to get the most out of this class, please consider the following:

a. Attend all scheduled classes and arrive on time.
   Late arrivals and early departures are very disruptive and violate the first basic principle listed above.

b. Please do not schedule other engagements during this class time.
   You probably wouldn't appreciate it if I did! I will try to make class as interesting and informative as possible, but I can't learn the material for you.

c. If you have trouble hearing the lecture or media presentation because of distractions around you, quietly ask those responsible for the distraction to stop.
   If the distraction continues, please let me know. It is often impossible for me to hear such things from my position in the classroom.
d. Please let me know immediately if you have any problem that is preventing you from performing satisfactorily in this class.

I am looking forward to working with you this semester.  

(Lasorsa, 1990)