Course Syllabus

PHAR 6020
Food & Drug Law

This course syllabus is a general plan for the course; deviations announced to the class by the instructor may be necessary.

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Course Instructor:
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University of Georgia
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Course Support:

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Phone: 678-985-6808 & Fax: 770-357-3806

Program Offices:
The University of Georgia at Gwinnett
2530 Sever Road
Lawrenceville, GA  30043

When emailing faculty and staff, please allow a reply time of 24-48 hours. If you submit a question over the weekend or holiday, please allow additional response time. For assignment grades to be returned, please allow at least 72-business hours.

Disability Statement:
The University of Georgia Regulatory Sciences Program is committed to providing reasonable access and accommodations for people with disabilities upon request.

If you have a disability and require reasonable accommodations, please contact the instructor by phone, email or an appointment during office hours.

If you plan to request accommodations, please also consider registering with the Disability Resource Center.

Disability Resource Center, Division of Student Sciences
The University of Georgia, 114 Clark Howell Hall, Athens, GA 30602-3338
(706)542-8719 (voice); (706)542-7719 (fax); (706)542-8778 (tty);
email: pbertot@uga.edu and URL: http://drc.uga.edu/

UGA Gwinnett Campus Representative is Laura Crawley, Ph.D., 678-985-6805, email: lcrawley@uga.edu

Course Description:
PHAR 6020 is one of the core courses required for the Regulatory Sciences Certificate Program and for the Master of Science Degree in Pharmacy with an emphasis in Regulatory Sciences. This course provides an overview of laws and regulations governing development, manufacturing, and commercial distribution of drugs, biologic, medical device products, and animal health products and how they relate to the pharmaceutical, biotechnology, and medical device industry. This includes domestic regulatory requirements and various regulatory agencies and their jurisdiction.
Prerequisites: PHAR 6010 and Permission of Department

Credit Hours: 3 credit hours

Course Objectives:
Upon completion of PHAR 6020, students will be able to demonstrate:
1) An appreciation for federal regulation of pharmaceuticals, biologics, medical device, combination products, and animal health product-related laws, regulations and guidelines;
2) Explain how the FDA enforces the law and regulations;
3) Identify legal issues surrounding product liability, import/export, and post-marketing surveillance obligations.
4) Locate and reference information used in the role of regulatory Sciences professional, including FDA guidance documents;
5) Interpret FDA laws and regulations and write persuasively about the interpretation;
6) Understand the history of key regulations including the development and evolution of the FDA regulatory process
7) An appreciation for the subjective and interpretative aspects of regulations

Course Materials:
Required Textbooks:

1. Food and Drug Law (University Casebook Series: Cases and Materials) (Hardcover)
   Peter B. Hutt, Richard A. Merrill, and Lewis A. Grossman. May be purchased from Amazon.com.

Materials: A variety of materials and methods will be employed in providing the information for PHAR 6020. These may include audio lectures, PowerPoint presentations, reading materials, and interactive exercises.

Time Zone: All times are listed in Eastern Time Zone. If you live outside of the Eastern Time Zone, please adjust accordingly.

Equipment: Each student is required to have a computer microphone. Most laptops and newer model PCs will have a built-in microphone. If not, please purchase an external microphone. Learn to use it before class starts. We will utilize Blackboard Collaborate Classroom and Voice over IP for which each person is required to have a microphone and should know how to use it. Computer microphones can be purchased
at places like Amazon.com, Office Depot, or Staples. A decent computer microphone can be purchased for about $10.00-$20.00.

**Operating System:** Remember, we are a PC-based program. If you use an Apple Computer to develop your homework assignments or presentations, it is YOUR responsibility to ensure that your assignment is accessible or your presentation is visible to your audience. Our office does not support the Apple environment.

**Remember, we are a PC-based program.** If you use an Apple Computer to develop your course content assignment, it is YOUR responsibility to ensure that your assignment is visible to your instructor or audience. You can do this by preparing a PC-formatted version of your assignment or presentation. Our office does not support the Apple environment. If you require support, you will need to contact UGA’s EITS Office.

**Course Assignments:**

**IMPORTANT for ALL CLASSES:**
As Regulatory Sciences or Clinical Trials professionals and as UGA Graduate Students, this program expects that each assignment is submitted as though you were submitting this exercise to your company’s management, FDA, or another managing body. When you submit a research paper or written assignment, be sure that you follow the assignment directions; use your computer’s spell checking feature to assure that there are no misspellings; and proof-read your document for typographical errors. Finally, be sure that you cite all references for those ideas and quotes that are not your own.

All assignments and papers MUST BE submitted using the eLC Assignment Dropbox Tool. This is mandatory. *This is the only way to officially track your work.* Email your assignment ONLY if you receive special permission, but you must follow up then with a submission to eLC. Take care also to submit the assignment to the correct submission tool. If you turn in a late assignment and find eLC prevents you from doing so, contact the course support person before emailing your assignment.

Final course grades will be noted in eLC (unofficial) and the ATHENA (official) system.

**Course Activities:**

1) Autobiographical Summary (no more than one page)

Please write a brief autobiographical summary to share with your class and faculty. Some areas to include might be as follow:
- Current employer;
- Describe your role or position;
- What interests you most about the regulatory Sciences or clinical trials fields;
- List your professional goals, both short and longer term.

Submit this autobiography on or before **Sunday, August 18, 2019, by 11:59 p.m.** through the eLC Assignment Dropbox Tool and post it in the eLC Discussion area.
2) Midterm and Final Research Papers (20% of the final grade each):

Your papers should be double-spaced, 12-point font, and 10 pages in length excluding tables, graphs, pictures, and references. The student will be provided with a list of topics to choose from for each paper.

- The midterm paper should be submitted no later than **October 13, 2019, at 11:59 p.m.**
- The final paper should be submitted no later than **December 8, 2019, at 11:59 p.m.**

REFERENCE CITATIONS - Remember to properly document any referenced materials, including company websites, the FDA website, books, articles, quotes, etc. Failure to cite referenced works or materials is considered a violation of UGA’s Culture of Honesty Policy and could result in failure of this course. The style we recommend is the AMA style (The American Medical Association). It covers medicine, health, and biological sciences. Examples are available at [http://guides.lib.uw.edu/hsl/ama](http://guides.lib.uw.edu/hsl/ama).

**Papers and other assignments turned in without references lists or bibliographies are unacceptable. It will be considered a violation of UGA’s *Culture of Honesty Policy* to turn in a research project without noting your sources. You may receive a failing grade for the course.**

3) **Other Exercises and Midterm Exam:** Students will be expected to participate enthusiastically and effectively in threaded discussions and chat sessions. The class will also include approximately 13 web exercises that will constitute 60% of the final grade.

**Grading:**

Grading will be based on the following scale:

<table>
<thead>
<tr>
<th>100-point scale</th>
<th>Grade</th>
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<tbody>
<tr>
<td>100-94</td>
<td>A</td>
</tr>
<tr>
<td>93-90</td>
<td>A-</td>
</tr>
<tr>
<td>89-88</td>
<td>B+</td>
</tr>
<tr>
<td>87-84</td>
<td>B</td>
</tr>
<tr>
<td>83-80</td>
<td>B-</td>
</tr>
<tr>
<td>79-78</td>
<td>C+</td>
</tr>
<tr>
<td>77-74</td>
<td>C</td>
</tr>
<tr>
<td>73-70</td>
<td>C-</td>
</tr>
<tr>
<td>69&lt;</td>
<td>D</td>
</tr>
<tr>
<td>59&lt;</td>
<td>F</td>
</tr>
</tbody>
</table>

*Table 1: Grading Scale*
Grading will be based on each student completing assignments that are made during the course including web exercises, discussion boards, chat sessions, and quizzes, as applicable, and a major project. The following provides weighting for each activity:

- Online/Class Participation (Web Exercises and Quizzes) 60%
- Midterm Paper 20%
- Final Paper 20%

100%

**Academic Honesty:**
All academic work must meet the standards contained in “A Culture of Honesty.” Each student is responsible for informing themselves about those standards before performing any academic work. A Culture of Honesty is the University of Georgia’s policy and procedures for handling cases of suspected dishonesty and can be found online at www.uga.edu/ovpi. UGA Student Honor Code states “I will be academically honest in all of my academic work and will not tolerate academic dishonesty of others.” Be sure to review the section in eLC on Academic Honesty.

Prohibited conduct includes “submitting for academic advancement an item of academic work that has been submitted (even when submitted previously by that student) for credit in another course unless done pursuant to authorization from the instructor supervising the work or containing fair attribution to the original work.” Therefore, you may not submit substantially similar assignments for credit in other courses unless you receive the instructor’s permission to rework that assignment.

**Class policies:**
This is graduate school and most students are employed full-time, have families, and have positions that may require travel. As such, the following policies will be followed for the semester:

- Assignments with prior permission to be late will be accepted without penalty. Permission is given freely for international travel. If your international travel interferes with your meeting assignments/quizzes, contact the instructor or course support contact about your assignment being late before you travel. Domestic travel has been accepted as an excuse on a limited basis. Contact the instructor with any questions.

- Assignments without prior permission to be late will have 10% of the grade deducted per 24 hrs. Past the due date.
  - Experience has shown it is not in your best interest to not turn in or complete an assignment or quiz.

Remember:
- Do not be a passive student in this class.
- Feel free to ask questions.
- If you disagree with an answer, make your argument respectfully.
- There is no penalty to work ahead (you may have to wait for your grade, however).
You will be requested to THINK, not just regurgitate answers.
Look at the quizzes/assignments BEFORE you start each module. Set realistic time expectations.

From the Instructor: All students are responsible for knowing the University’s policy on academic honesty. All academic work submitted in this course must be your own unless you have received my permission to collaborate and have properly acknowledged receiving assistance. It is my responsibility to uphold the University’s academic honesty policy and to report my belief of dishonesty to the Office of the Vice President for Instruction.

Missed Assignments/Quizzes: You will have a specific length of time to take an online Assessment as well as deadlines to turn in Assignments. Absences or failure to turn in an Assignment or Assessment by the deadline will result in a failing grade for the respective test unless there is a bona fide emergency involving the student or an immediate family member. If such a case occurs, the student must contact the UGA Regulatory Sciences Graduate Education Program as soon as possible at (678) 985-6808 or email amakkar@uga.edu.

Netiquette:
In this course, and all the courses in the program, you will be required to interact with students and faculty electronically, either through email or eLC Discussion Boards or Chat Rooms. Please follow these simple guidelines of network etiquette.

1. Please always be respectful of classmates’ opinions and ideas. If you disagree on a topic, do so respectfully and with tact. These discussions are monitored by faculty and often your grade will depend on your participation and the quality and content of your posting. Should you be disrespectful, this will impact your grade.

2. Do not post anything off-topic in the designated discussion, email or chat topic areas. In each course, there will be a section referred to as the “Coffee Shop” for off-topic discussions. This discussion area is for topics related to Regulatory Sciences, but may not be directly related to your specific course. At no point are you to use any class email addresses, distribution lists or eLC programs for soliciting.

3. Take care when using humor or sarcasm in emails, discussions, and chats. Humor and sarcasm are often hard to convey electronically. It is safest to avoid using it; but if you chose to add humor, consider using emoticons like 😊, 😝, 😒.

eLC Quizzes - Helpful Hints:
Assessments (quizzes) will be posted in the related Learning Module and the Assessments sections of eLC. See each Assessment link for exact submission deadlines. Be sure to "Save Answer" for each question before submitting. Do not use your browser’s navigation buttons while using the Assessment module. If you lose your connection or close your browser, your "saved answers" will be saved until the next time you open the Assessment.
Communication:
Because we are a distance learning program, the easiest way to communicate with the department is via email. You may email us using the standard email addresses listed in the course syllabus, or you may email directly from your online course. You are also welcomed to telephone the course instructors or make an appointment for a face-to-face meeting.

Connectivity Expectations: As UGA students, you are provided with a UGA MyID account giving you access to e-mail and eLearning Commons, and other services. It is your responsibility to make sure your MyID account and password are active. All of your course materials will appear in eLC. We will use eLC to make announcements pertaining to this course. It is your responsibility to check your UGA email, eLC News, eLC email and eLC Content Modules on a regular basis to make sure you keep current with this course.
This course calendar is a general plan for the course; deviations announced to the class by the instructor may be necessary.

This course will begin Saturday, August 10, 2019. Assignments and Quizzes are generally due at 11:59 p.m.

<table>
<thead>
<tr>
<th>Saturday:</th>
<th>Topic:</th>
<th>Exercise Due date</th>
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</thead>
<tbody>
<tr>
<td>Aug 10</td>
<td><strong>Orientation Module: Review in eLC</strong>&lt;br&gt;<strong>Module 1:</strong> Historical Background of the Regulation of Food and Drugs&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 1-28; Assignment: Autobiography</td>
<td>Aug 18</td>
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<tr>
<td>Aug 17</td>
<td><strong>Module 2:</strong> Foundational Principles Surrounding the Jurisdiction of the FDA&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 29-75; Assignment: 2 Questions</td>
<td>Aug 25</td>
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<td>Aug 24</td>
<td><strong>Module 3:</strong> Foundational Principles of FDA Jurisdiction Part II&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 77-109; Assignment: 2 Questions</td>
<td>Sept 1</td>
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<td>Aug 31</td>
<td><strong>Module 4:</strong> The Boundaries of FDA Jurisdiction&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 121-162; Assignment: 1 Question</td>
<td>Sept 8</td>
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<td>Sept 7</td>
<td><strong>Module 5:</strong> FDA Regulation of Human Drugs&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 641-673; Assignment: 2 Questions</td>
<td>Sept 15</td>
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<td>Sept 14</td>
<td><strong>Module 6:</strong> FDA Regulation of Human Clinical Trials&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 673-707; Assignment: 2 Questions</td>
<td>Sept 22</td>
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<td>Sept 21</td>
<td><strong>Module 7:</strong> FDA Filing Process&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 707-751; Assignment: 2 Questions</td>
<td>Sept 29</td>
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<td>Sept 28</td>
<td><strong>Module 8:</strong> Exceptions and Variations to the Standard FDA Approval Process&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 751-801; Assignment: 1 Question</td>
<td>Oct 6</td>
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<td>Oct 5</td>
<td><strong>Module 9:</strong> Post Approval Obligations&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 802-855; Assignment: eLC Discussion</td>
<td>Oct 13</td>
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<td><strong>Semester Midterm October 7, 2019</strong></td>
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<td>Oct 12</td>
<td><strong>Module 10:</strong> Regulation of Prescription Drugs&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 855-907; 2 Questions</td>
<td>Oct 20</td>
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<tr>
<td><strong>Midterm Paper October 13, 2019, at 11:59 p.m.</strong></td>
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<td>Oct 19</td>
<td><strong>Module 11:</strong> Regulation of Drug Labeling and Marketing&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 907-956; Assignment: 1 Question</td>
<td>Oct 27</td>
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<td>Oct 26</td>
<td><strong>Module 12:</strong> Animal Drugs&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 1059-1098; 1 Question</td>
<td>Nov 3</td>
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<tr>
<td>Nov 2</td>
<td><strong>Module 13:</strong> Medical Devices&lt;br&gt;• <strong>Reading:</strong> Hutt, pp. 1193-1268; Assignment: 2 Questions</td>
<td>Nov 10</td>
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<tr>
<td><strong>Medical Devices Conference</strong>&lt;br&gt;<strong>November 6 &amp; 7, 2019</strong>&lt;br&gt;<a href="http://mdr-con.com/">http://mdr-con.com/</a></td>
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| Nov 9  | **Module 14**: 21st Century Cures Act  
|        | **Reading**: 21st Century Cures Act and FDA Work Plan | Nov 17 |
| Nov 16 | **Module 15**: FDA Law Enforcement  
|        | **Reading**: Hutt, pp. 176 – 192; 230 - 237; Assignment: 1 Question | Nov 24 |
|        | **Nov 27-29- Thanksgiving Break- No classes** |
| Dec 8  | **Work on Final Paper December 2-6, 2019**  
|        | **Final Paper Due on or Before December 8, 2019, via eLC. at 11:59 P.M.** | Dec 8 |

**Table 2: Course Calendar and Topical Outline**

**Other important dates:**
1) **Aug 14-20-** is the last day to drop or add class.
2) **Sept 2-** all UGA Offices are closed.
3) **Oct 21-** is the deadline for withdrawal.
4) **Nov 1-** Fall Break- No classes
5) **Nov 27-29-** Thanksgiving Break- No classes