Course Syllabus

PHAR 6010
Introduction to Pharmaceutical, Biotechnology and Medical Devices Industries: A Regulatory Overview

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 Faculty:

Dr. Samuel Eber Machado Silva, Associate Professor, International Biomedical Regulatory Sciences
Email: ssilva@uga.edu
Office Location: UGA - Gwinnett Campus, 2530 Sever Rd. Lawrenceville, GA 30043

Course Support:

Arvinder Makkar, Program Coordinator I, International Biomedical Regulatory Sciences
Email: amakkar@uga.edu
Office Location: UGA Gwinnett Campus, 2530 Sever Road, Lawrenceville, GA 30043
Phone: 678-985-6810 & Fax: 770-357-3804
Johnna Hodges, Assistant Director, International Biomedical Regulatory Sciences  
Email: jhodges@uga.edu  
Phone: 678-985-6808 & Fax: 770-357-3806

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

Course Lecturers:

David W. Mullis, Jr., Ph.D., RAC, FRAPS  
Frequent Guest Lecturer  
Professor Emeritus,  
College of Pharmacy, University of Georgia

Joann Pittman & Colleagues  
Special Assistant, Southeast Region  
Food and Drug Administration, Atlanta, GA

Felipe Dolz, DVM, PhD  
Former Head, Global Regulatory Sciences,  
Merial Limited, a Boehringer Ingelheim company

Kristen Kilgos, DVM  
Global Head, Pharmacovigilance  
Merial Limited, a Boehringer Ingelheim company

Grace Gowda, Ph.D., RAC  
Head of Government and Strategic Sciences (GSA),  
Global Regulatory Sciences, R&D  
Merial Limited, a Boehringer Ingelheim company

Wayne Wiley, R.Ph.  
Senior Director, Regulatory Sciences  
Recro Pharma, Inc.

Johnna Hodges  
Assistant Director, International Biomedical Regulatory Sciences  
College of Pharmacy  
University of Georgia
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 6010 is one of the core courses required for the Regulatory Sciences and Clinical Trials Certificate programs and for the Master of Science Degree in Pharmacy with an emphasis in Regulatory Sciences. This course provides an introduction to the pharmaceutical, biotechnology, medical devices, and animal health industries. The primary goal of this course is to provide the foundational information to allow a student to develop basic knowledge and understanding of the pharmaceutical, biotechnology and medical devices industries from a regulatory sciences perspective.

Students will need this course content information to support further study and to perform the tasks required of Regulatory Sciences and Clinical Trials Management professionals. The course will provide an overview of company organizations, product development, and commercialization activities with an emphasis on regulatory requirements.

Prerequisites: Permission of Department

Course Objectives:
Upon completion of PHAR 6010, students will be able to demonstrate:

1) An understanding of the product development process, including:
   • Describing various approaches to product development
   • Discussing the interrelationships among the different functions or departments involved in the product development process
   • Summarizing the impact of the regulatory process on the product development process

2) An understanding of the Food and Drug Administration, including:
   • A history of key regulations
   • The development and evolution of the FDA regulatory process
   • The FDA organization and functional components
• Interactions between and among FDA Centers
• The principles and general approaches required to obtain FDA clearance to market new products
• How to use selected FDA reference documents and websites

3) An understanding of the basic operational differences and similarities of pharmaceutical, biotechnology, medical device and animal health companies including:
• Impact on the economy
• Effect of globalization on various industries

4) The ability to locate reference materials required by individuals working as regulatory Sciences or clinical trials management professionals.

5) An appreciation for the subjective and interpretative aspects of regulations and the ability to think critically about the interaction between regulatory applications and product development.

**Course Materials and Recommended Reading:**

*Readings:* There is no required textbook for this course. The readings will come from a bibliography list and many of these will be available from the internet or library. Typically, the instructor will provide a recommended reading list on a weekly basis.

*Materials:* A variety of materials and methods will be employed in providing the information for PHAR 6010. These may include audio lectures, PowerPoint presentations, reading materials, and interactive exercises.

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

**Course Major 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 task to your Board of Directors, FDA or another managing body. With this in mind, 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.

Assignments should be submitted through the eLC Dropbox tool. Research papers and writing assignments should be in a word processing format that can be read by Microsoft Word (.doc, .docx). If warranted, you will also receive your assignment back, with inserted comments, as an attachment. Proper file extensions must be used on all files to ensure that your work can be viewed and evaluated. Work that cannot be viewed will be considered as not turned in, or missing.
1) Autobiographical Summary

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.
- How did you achieve your current position (significant assignments, schooling, etc.)?
- What interests you most about the regulatory Sciences or clinical trials field?
- List your professional goals, both short and longer term.
- Share other personal information about interests, hobbies, etc.

This autobiographical summary should be submitted on or before Sunday, August 18, 2019, by 11:59 p.m. through the eLC Assignment Dropbox and posted in the eLC Discussion area.

2) Major Research Project: Company Profile

You are to choose a company in the pharmaceutical, biologics, biotech or medical devices industry that interest you. Please choose a company that is in a different field from which you are presently employed. To prevent duplicate student presentations. Please notify Arvinder Makkar (amakkar@uga.edu) by e-mail on or before September 8 2019, with the name of the company you have chosen for your project.

You are to conduct an in-depth study of that company’s background, marketplace position, research, and development approach and regulatory history. Your research will typically involve searching the company’s website for general information about the company, reviewing annual reports, and contacting the company directly to arrange a brief interview with someone like the VP/Director of Research and Development, Director of New Product Development and/or Director of Marketing. You may also try to communicate with the head of Regulatory Sciences to gain insight into how the company interacts with FDA and other regulatory agencies.

You will submit a written report on the chosen company to include the following information:

- History of the company - how long in business, private or public and major products marketed.
- The technology platform of the product(s) - drugs, biologics, vaccines, cells, devices.
- Company’s state of development - e.g., research only, marketing products or fully vertically integrated.
- Describe the company’s product development plan or approach to creating new products - how new products are screened, reviewed and approved internally.
- How the company accomplishes each of the key tasks?
  - Discovery (chemistry, engineering, pharmacology)
  - Preclinical research (scope and how it is performed)
  - Regulatory Pathways (IND, IDE, NDA, PMA, BLA)
  - Clinical research overview (what tasks are handled internally and what are contracted to outside firms or CROs)
- Provide a summary of the products that the company currently has marketed.
- Regulatory Profile:
Review and summarize information pertaining to FDA interactions with the company that is available in the public domain. This should include reviewing the FDA websites for possible product approvals over the past two to three years, warning letters, establishment inspections reports including FDA Form 483s and/or product recalls.

- Recommendations:
  Using what you have learned in this course, please provide a recommendation for how the company could positively impact or improve its product development process and regulatory approach for bringing new products to the US marketplace.

Your paper should be double-spaced, 12-point font, and 10-15 pages in length excluding tables, graphs, pictures, and references.

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.

Papers and Presentations 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 and you may receive a failing grade for the course.

Your Final Project Parts (and logistics)

As a supplement to your paper, you will create and record a presentation highlighting your chosen company and paper. You will record your presentation using the eLC/ Collaborate Ultra Classroom system. Separate instructions for using this system will be sent early in the semester. Each student presentation should be no more than 25 minutes in length. You should deliver your presentation as though you were presenting to your professional colleagues or to your company’s board.

Recording instructions:

As a graduate student and as a working professional, it is important to remind you that you should not wait until the last minute to address your course recording assignment. Each student is responsible for creating a functioning recording as a part of this assignment. This recording is due on the due date noted in the course syllabus. No extensions will be granted. It is your responsibility to ensure that your equipment works with the Collaborate Ultra system. Following the Collaborate Ultra directions to the letter, you are to ensure your presentation has no glitches that impact negatively your message. As such, you should not wait until the last minute to create your recording. You should familiarize yourself with the Collaborate Ultra technology early in the course. You should provide yourself ample time for a few practice sessions of your presentation. Review those sessions and ensure that slides advance and your voice is audible. This means you should review your archived material. Should you have questions or encounter technical difficulties during this time, alert your course support person.
She may be able to schedule a time to assist or guide you through the process. However, if you wait until the last minute, you run the risk of not getting assistance. If the recording is due on December 6th at 11:59 pm, for example, do not wait until December 6th noon to access Collaborate Ultra for the first time. Last minute emails or phone calls, particularly over weekends, requesting help, are likely to go unanswered.

**Following the recording of the student presentations, you will pick 2 of your classmates’ presentation to review. Using the threaded discussion tool, you will discuss these presentations based on some specific questions that will be posted in the discussion area.**

**Final Project Summary (4 parts)**

1. **eLC Assignment Dropbox**: Your research paper is due on or before **Saturday, November 23, 2019, by 11:59 p.m.** via eLC Assignment Dropbox.

2. **eLC Dropbox Tool**: Your PowerPoint presentation is due on or before **Monday, November 25, 2019, by 11:59 p.m.** via eLC Assignment Dropbox.

3. **eLC Blackboard Classroom Tool**: Your Presentation Recording is due **Sunday, December 1, 2019, by 11:59 p.m.**

4. **eLC Threaded Discussion Tool**: Your threaded discussions on classmate presentations are due on or before **Tuesday, December 3, 2019, by 11:59 p.m.**

**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 eLC News and Content Modules on a regular basis to make sure you keep current with the course.

Remember, we are a PC-based program. If you use an Apple Computer to develop your presentation, it is YOUR responsibility to ensure that your presentation is visible to your audience. You can do this by preparing a PC-formatted version of your presentation. Or, you can use your Apple Laptop to deliver your presentation. If you do this, YOU will need to ensure that you have the appropriate cables and apparatus to project your presentation. Our office does not support the Apple environment.

3) **(Other Assignments) Web Exercises**

There are a series of other smaller assignments per module. Be sure to review the eLC Assignment area for the directions on these graded course activities.

During most weeks of the course, you will be required to complete web exercises that involve searching for and reviewing materials on the FDA website. The goal of these exercises is to help you become familiar with references available on the web and to help you learn some search tools/techniques when faced with new product issues. Some of these exercises may include brief essays that require you to synthesize, interpret or draw
conclusions about the materials that you have been reading and receiving during class sessions.

**Grading:** Grading will be based on the following scale:

<table>
<thead>
<tr>
<th>100-point scale</th>
<th>Grade</th>
</tr>
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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>
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<tr>
<td>87-84</td>
<td>B</td>
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<tr>
<td>83-80</td>
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<td>77-74</td>
<td>C</td>
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<td>73-70</td>
<td>C-</td>
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<td>69-60</td>
<td>D</td>
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<td>59&lt;</td>
<td>F</td>
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</tbody>
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Grading will be based on each student completing special assignments that are made during the course including web exercises, discussion boards, and quizzes, as applicable, and a major project: Company Profile plus its presentation to the class. The following provides weighting for each activity:

- Online/Class Participation (Web Exercises and Quizzes) 50%
- Written Paper on Company Profile 30%
- PowerPoint 10%
- Presentation of Paper to Class & Threaded Discussions 10%

**Assignments:** All assignments and papers MUST BE submitted using the eLC Assignment tools. 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 then follow up with a submission via eLC. Take care also to submit the assignment to the correct submission tool. If you are late turning in your assignment, and can no longer submit your assignment, contact the course support person before emailing your assignment.

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

**Policies and Academic Honesty:**

All academic work must meet the standards contained in *A Culture of Honesty*. Each student is responsible for informing him or herself 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/honesty](http://www.uga.edu/honesty). 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.

**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.

**Quizzes & Activities:**

**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) 985-6810 or email amakkar@uga.edu.

**Closed book (no notes)** - When a quiz or course activity says a **closed book (no notes)**, it means that the student is **not** to access outside resources, i.e., no unauthorized assistance. The student is to demonstrate what he/she has learned unassisted. Students should not use lecture notes, including downloaded lecture materials. Lecture notes, books, websites, collaboration with classmates, or other individuals are a few examples of outside resources, course aids, and assistance tools; therefore, must not be consulted.

**Open book** - When a quiz or course activity says **open book**, it means a student is allowed to consult outside resources. Open book activities test the student’s ability to find and apply information. Open book quizzes and activities ask students to apply, analyze, synthesize, compare/contrast, or evaluate information. They test whether the student understands the “big picture” of the course and how course concepts work together. For example, students might be given a problem or a scenario and asked to apply concepts from several parts of the course to it to develop an answer. The instructor will be looking for well-structured and presented arguments or solutions. The quiz is likely to be more challenging than others since the instructor has higher expectations for the quality of student responses and the extent of the student’s critical and analytical thinking, knowing that the student has access to course materials to formulate his/her answer.

**Timed** - Pay attention to the directions of quizzes and exams. In addition to identifying opened or closed book, some quizzes are **timed**. The number of time students is allowed to complete the quiz is noted in the quiz setting. Once a student starts the quiz, he/she will need to complete it.

**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 may 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 Assessment 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.

**Class Meetings & Attendance:**

The meeting will be via Collaborate Ultra Link for live sessions if your professor plans to have meetings. You are expected to participate in this session.

Student success is dependent upon active participation in all instructional activities. Online courses are no different. However, participation is defined in a different manner. Student "attendance" in online courses is defined as active participation in a) real-time (live) sessions; b) the submission and completion of course assignments by the posted due dates; c) completion of quizzes, tests, and other assessments; and d) communication with the instructor. Real-time (Live) sessions are defined as course webinars, face-to-face meetings, teleconferences and chat sessions, all activities that are scheduled ahead of time requiring real-time participation. Students who fail to maintain active participation will have their grades negatively impacted.

As a University of Georgia Graduate Student, you are expected to make every effort to attend pre-scheduled real-time classes in which you are enrolled. As a distance learning student, real-time course participation is rare. Thus, when a real-time class meeting is scheduled, you are expected to attend.

Professor De Gelas will also be available for group teleconferences or live chat discussions during the semester. If the group would like to participate in a live discussion, a request in the form of an e-mail to amakkar@uga.edu must be submitted at least 2 weeks prior to the requested meeting.

**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.

Course Calendar: PHAR 6010—Spring Semester 2019
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. New learning modules begin on Saturdays. Assignments and Quizzes are generally due Sundays at 11:59 p.m.

Table 2: Calendar Outline

<table>
<thead>
<tr>
<th>Saturday:</th>
<th>Topic:</th>
<th>Assignment/Assessment due</th>
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<tbody>
<tr>
<td>Aug 10</td>
<td>Start Orientation Module in eLC Module 1: Introduction to Regulatory Sciences</td>
<td>Aug 18</td>
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<tr>
<td>Aug 17</td>
<td>Module 2: The FDA: Parts One &amp; Two:</td>
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<td>• FDA Organization and Structure, Insight into the Agency Operations;</td>
<td>Aug 25</td>
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<td></td>
<td>• ClinicalTrials.gov Requirements</td>
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<td>Aug 24</td>
<td>Module 3: Pharmaceuticals: Part One:</td>
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<td></td>
<td>• Product Development Process and Regulations</td>
<td>Sept 1</td>
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<tr>
<td>Aug 31</td>
<td>Module 3: Pharmaceuticals: Parts Two &amp; Three:</td>
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<td></td>
<td>• Drug Classification &amp; Generic Drugs;</td>
<td>Sept 8</td>
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<td></td>
<td>• OTC Drugs</td>
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<td>Sept 7</td>
<td>Module 3: Pharmaceuticals: Parts Four &amp; Five:</td>
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<td></td>
<td>• Post-Marketing Activities;</td>
<td>Sept 15</td>
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<td></td>
<td>• CDER Communication</td>
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<td>Sept 14</td>
<td>Module 4: Biologics Product Development and Regulatory Overview &amp; Biosimilars</td>
<td>Sept 22</td>
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<td>Sept 21</td>
<td>Module 5: Pharmacovigilance</td>
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<td>Sept 28</td>
<td>Module 6: Medical Devices: Part One:</td>
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<td></td>
<td>• An Industry Overview</td>
<td>Oct 6</td>
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<td>Oct 5</td>
<td>Module 6: Medical Devices: Parts 2 &amp; 3:</td>
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<td></td>
<td>• Types of Submissions;</td>
<td>(Part 2) Oct 13</td>
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<td></td>
<td>• Product Development Design Control</td>
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<td>Semester Midterm October 7, 2019</td>
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<tr>
<td>Oct 12</td>
<td>Module 6: Medical Devices: Parts 3 &amp; 4:</td>
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<td></td>
<td>• Product Development (continued);</td>
<td>Oct 20</td>
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<td></td>
<td>• Overview of the Quality Systems Regulation</td>
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<tr>
<td>Oct 19</td>
<td>Module 6: Medical Devices: Parts 5 &amp; 6:</td>
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<td></td>
<td>• IVD Summary;</td>
<td>Oct 27</td>
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<td></td>
<td>• Post Market Compliance for Medical Devices</td>
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<tr>
<td>Oct 26</td>
<td>Module 7: Animal Health Products: Regulatory Overview</td>
<td>Nov 3</td>
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<tr>
<td>Nov 2</td>
<td>Module 8: Combination Products: Regulatory Overview</td>
<td>Nov 10</td>
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<tr>
<td>Medical Devices Conference November 6 &amp; 7, 2019</td>
<td><a href="http://mdr-con.com/">http://mdr-con.com/</a></td>
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<tr>
<td>Nov 9</td>
<td>Module 9: Recalls and Field Corrective Actions;</td>
<td>Nov 17</td>
</tr>
</tbody>
</table>
Nov 16 | Module 10: DEA | Nov 24
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| Work on Final Paper November 18-22, 2019 | | 
| Nov 27-29- Thanksgiving Break- No classes | | 

**Table 3: Final Project Summary**

**Final Project Summary (4 parts)**

1. eLC Assignment Dropbox: Your research paper is due on or before **Saturday, November 23, 2019, by 11:59 p.m.** via eLC Assignment Dropbox.

2. eLC Dropbox Tool: Your PowerPoint presentation is due on or before **Monday, November 25, 2019, by 11:59 p.m.** via eLC Assignment Dropbox.

3. eLC Blackboard Classroom Tool: Your Presentation Recording is due **Sunday, December 1, 2019, by 11:59 p.m.**

4. eLC Threaded Discussion Tool: Your threaded discussions on classmate presentations are due on or before **Tuesday, December 3, 2019, by 11:59 p.m.**

**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