CRN: 70994
Course: RGA6203: Food, Drug, and Medical Device Law: Topics and Cases
Fall 2017, 13-week term
September 18, 2017 – December 16, 2017
Course Format: Boston/Traditional
Time: Thursday, 5:50-8:30

Note: For courses meeting on campus, room assignments will be available online by the start of term in MyNEU/Self Service Banner.

Instructor:

Instructor Name: Wendy E. Rieder, Esq
E-mail: w.rieder@northeastern.edu
Phone Number: Available upon request

Email is the best method as a first-line of contact. If you have specific issue/concern that is better addressed live, please email times you are available and a preferred phone number for me to contact you. Please be patient.

Required Text(s)/Software/Tools:
There is one required textbook for this course – available in the bookstore on campus.

Book title: A Practical Guide to FDA's Food and Drug Law and Regulation
Author/Publisher: Edited by Kenneth R. Pena and Wayne L. Pines, published by FDLI
ISBN: 978-1-935065-70-8

Recommended Textbooks/Resources:
The department recommends:


Or


Course Prerequisites
If a student has not fulfilled the pre-requisite course requirements, he or she will not be able to register for a course.

Students must successfully complete RGA6200 or RGA6202 prior to enrollment in the course.

Course Description
Analyzes current food, drug, and medical device laws. Reviews legislation and landmark cases, as well as laws governing development, manufacture, and commercial distribution of drugs, biologics, and medical device products and how they relate to the biotechnology, pharmaceutical, and medical device industries. http://www.cps.neu.edu/ci.php/courses/detail/RGA6203
Course Outcomes

1. Understand the institutional framework, historical background and scope of authority of the U.S. Food and Drug Administration (FDA) and its relationship to other federal agencies.
2. Learn and analyze key statutory provisions, regulations and policy in major FDA areas of regulation (food and dietary supplements, drugs, medical devices, combination products, biologics, and tobacco).
3. Develop insight into how the agency responds to new scientific and technological advancements and their integration into consumer products.
4. Develop practical skills in: (1) how to interpret statutes; (2) how to read regulations; (3) how to research regulatory materials; (4) how to represent clients in front of agencies and handle enforcement actions; and (5) how to represent government agencies.
5. FDA law is a case study in regulatory practice of a major federal agency. You should be able to apply these principles when representing clients in matters involving many different regulatory agencies.

Course Methodology

Each week, you will be expected to:

1. Review the week’s learning objectives
2. Complete all assigned readings
3. Complete review of all lecture materials for the week
4. Participate in the Discussion Board
5. Complete and submit all assignments and tests by the due dates
6. Proactively contact the instructor with any questions or concerns

Participation/Discussion Board

Active participation in regulatory affairs courses is defined by both the quantity and quality of contributions. You are expected to have completed the reading and lecture material, and any assignments prior to class and given the content considerable thought. Your contributions must be submitted by stated deadlines unless other arranged beforehand.

High quality contributions advance the class discussions and do not simply summarize the material that was assigned. Quality contributions take into account not only the instructors questions but also your classmates’ contributions.

When participating in class, students are expected to be polite, respectful of other students and the instructor, and to contribute to the course at a level fitting of a graduate-level program.

The instructor reserves the right to penalize students for repeated violations of the participation policy within a course.

Additional Considerations:

Students are responsible for any communications sent to their official, NEU-husky e-mail account.
Attendance Policy:

In both on-ground and online courses, you are expected to attend all classes and discussions for the entire length of term. In addition, you will also be expected to complete assignments and group projects outside of class. Students may be penalized for all unexcused absences. The University does allow for certain types of excused absences (http://www.cps.neu.edu/student-resources/images/CPS-Stu-Handbook2013-2014.pdf). However, you will be expected to notify your instructor at least 48 hours in advance for all absences from class. Approval for absences is at the instructor's discretion. In the case of a missed course or excused absence, including during the add-drop period, students are expected to make arrangements with the instructor to make up all materials in a timely fashion.

Tardiness Policy:

In courses which meet in person, students may be marked down for lateness to class at the discretion of the instructor. Students should make all possible attempts notify the instructor at least 48 hours before missing a course meeting. Online students are expected to participate regularly and punctually in their online course and are responsible for all deadlines course announcements, e-mails, discussion board and water cooler posts or other instructions from the instructor or teaching assistant.

Communication/Submission of Work

In the Assignments folder, click on the View/Complete Assignment link to view and each assignment. Attach your completed assignments here and click Submit to turn them in to me. Once your assignment has been graded, you will be able to view the grade and feedback I have provided by clicking on My Grades in the Tools module from the Northeastern University Online Campus tab.

TurnItIn®

As per departmental policy, all written work for both on-ground and online courses must be submitted in electronic format (.doc, .docx. or .pdf) to the Blackboard site associated with the course by the specified deadline. Your written work will be reviewed by TurnItIn® in order to check for originality and correct citation practices. Additionally, your instructor or TA may request a printed paper copy for his or her records.

Online assessments:

In the case of online assessments, all of the general grading particulars apply. In addition, students are expected to be familiar with taking exams on Blackboard. They should consult with Blackboard Technical Help if additional support is required. A guidance document will be provided for students to read prior to launching each assessment. The document explains the reset policy and all expectations regarding taking quizzes and exams. Students are expected to read the document and ask any questions regarding the policies prior to launching the quiz / exam on Blackboard. In the case of technical error during an examination, NUOnline (nuonline@neu.edu or 24/7 Phone support at 1-855-836-3520) and the instructor should be notified immediately and the e-mail and help-ticket reference case retained. Grading of work affected by technical error is still at the discretion of the instructor.

Late Assignment policy:

A student should make every effort to turn his or her work in on time. No late work will be accepted without prior agreement with the instructor. Students who submit work after the deadline will be penalized at the instructor’s discretion. Academic honesty standards will be strictly enforced by the instructor and the department.

A deduction of 20% will be made for each day that an assignment is late. Work will no longer be accepted 3 days after the specified deadline, unless specific arrangements have been made with the instructor.
Grading/Evaluation Standards
Exams and quizzes may consist of true / false, multiple choice, matching, short answer and/or short essay questions. In the case of a timed assessment, it is expected that the assignment to be completed within the given period and number of sittings allowed by the instructor. Examinations and assessments may take place in class or online.

Grading Explanation

Please see the course’s Blackboard site for any rubrics or grading explanations specific to this course. Academic honesty standards will be strictly enforced by the instructor and the department.

Grading Scale:
The grades will be broken down by the following scale:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Grade</th>
<th>GPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>95-100%</td>
<td>A</td>
<td>4.0</td>
</tr>
<tr>
<td>90-94%</td>
<td>A-</td>
<td>3.7</td>
</tr>
<tr>
<td>87-89%</td>
<td>B+</td>
<td>3.3</td>
</tr>
<tr>
<td>84-86%</td>
<td>B</td>
<td>3.0</td>
</tr>
<tr>
<td>80-83%</td>
<td>B-</td>
<td>2.7</td>
</tr>
<tr>
<td>77-79%</td>
<td>C+</td>
<td>2.3</td>
</tr>
<tr>
<td>74-76%</td>
<td>C</td>
<td>2.0</td>
</tr>
<tr>
<td>70-73%</td>
<td>C-</td>
<td>1.7</td>
</tr>
<tr>
<td>69% or below</td>
<td>F</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Please remember, each student’s performance in a given course will be evaluated independently of the quality or work completed for- or the grade he or she has earned in other courses.
<table>
<thead>
<tr>
<th>Assignments</th>
<th>% of Final Grade</th>
<th>Due Date</th>
<th>Format</th>
<th>Length</th>
<th>Expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class participation</td>
<td>25%</td>
<td>Weekly</td>
<td>Class discussion</td>
<td>N/A</td>
<td>Active participation will enhance the overall class experience. Lecture materials will show certain discussion topics. Post on discussion boards for extra credit.</td>
</tr>
<tr>
<td>Assignment 1: Describe the role of the FDA and its main responsibilities</td>
<td>10%</td>
<td>October 3, 2017</td>
<td>Written report in MS Word</td>
<td>Approx 2-3 pages</td>
<td>Well written, well referenced and well reasoned papers (12 font, single spaced)</td>
</tr>
<tr>
<td>Assignment 2: Compare and contrast the FDAs role and key considerations in approving drugs, medical devices, biologics and dietary supplements</td>
<td>15%</td>
<td>November 1, 2017</td>
<td>Written report in MS Word</td>
<td>Approx 3-5 pages</td>
<td>Well written, well referenced and well reasoned papers (12 font, single spaced)</td>
</tr>
<tr>
<td>Assignment 3: You will be asked to review 5 examples of drug promotional materials to spot issues that should be addressed and suggest appropriate changes</td>
<td>25%</td>
<td>November 22, 2017</td>
<td>Written report in MS Word</td>
<td>½ page response for each example (5 total)</td>
<td>Well written responses that highlight rationale behind each suggested change</td>
</tr>
<tr>
<td>Final exam</td>
<td>25%</td>
<td>December 13, 2017</td>
<td>Multiple Choice Test</td>
<td>50 questions</td>
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</tbody>
</table>

Class Schedule/Topical Outline
<table>
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<tr>
<th>Class Schedule / Topical Outline</th>
<th>Weekly Topics</th>
<th>Weekly Outcomes</th>
<th>Lectures and Readings</th>
<th>Discussion Board and Assessments</th>
</tr>
</thead>
</table>
| Week 1                          | Overview of the US Legal System and Intro to FDA Law | • Identify the branches of US Government  
• Recognize the function of the courts in the operation of the US Government  
• Identify where in the governmental structure the various agencies sit  
• Identify how agencies derive their authority to make rules and regulations | Chapter 1 of Textbook and other readings posted on Blackboard. | Participate in class |
| 9/21/17                         |                                                   |                |                       |                                   |
| Week 2                          | Background of US Food and Drug Law, Philosophy of FDA and FDA Organization | • Identify the origins of the Food and Drug Laws in the US  
• Review the Food, Drug, and Cosmetic Act (“FDCA”)  
• Identify the various departments of the FDA, and what roles they play. | Chapter 2 3 and 4 of Textbook and other readings posted on Blackboard. | Participate in class and submit Assignment 1 by 10/3/17 |
| 9/28/17                         |                                                   |                |                       |                                   |
| Week 3                          | Approval Process for Drugs and Biologics          | • Identify the process for gaining approval to market new drugs  
• Understand the differences between drugs and biologics and how the FDA views the approval process for each  
• Explore the regulatory pathways for generic drugs and biosimilars | Chapter 5 of Textbook and other readings posted on Blackboard. | Participate in class |
| 10/5/17                         |                                                   |                |                       |                                   |
| Week 4                          | Medical Devices                                   | • Identify the process for gaining approval to market medical devices  
• Recognize the distinction between drugs and medical devices | Chapter 8 of Textbook and other readings posted on Blackboard. | Participate in class |
| 10/12/17                        |                                                   |                |                       |                                   |
| Week 5                          | Combination Products                              | • Understand the definition of combination products and how the FDA approaches the approval process | Chapter 9 of Textbook and other readings posted on Blackboard. | Participate in class |
| 10/19/17                        |                                                   |                |                       |                                   |
| Week  6 | 10/26/17 | The Regulation of Foods and Dietary Supplements | • Understand how dietary supplements are classified and how the FDA regulates their marketing and use  
• See the development of the regulation of dietary supplements over the years  
• Learn to recognize the differences between dietary supplements, food, and drugs | Chapter 11 and 12 of Textbook and other readings posted on Blackboard. | Participate class and submit Assignment 2 by 11/1/17 |
|---|---|---|---|---|---|
| Week 7 | 11/2/17 | The Regulation of Cosmetics and Tobacco | • Understand how the FDA defines cosmetics and which ingredients require approval  
• Explore how cosmetics labeling is governed  
• See the development of the FDA’s position regarding tobacco regulation and how Congress has restricted the FDA in the area of tobacco regulation  
• Understand the Tobacco Act of 2009  
• Explore the basic principles that apply to FDA regulation of advertisement and promotion | Chapter 10 and 13 of Textbook and other readings posted on Blackboard | Participate in class |
| Week 8 | 11/9/17 | Pharmacovigilance | • Understand the pharmacovigilance function  
• Review postmarketing reporting requirements | Chapter 6 of Textbook and other readings posted on Blackboard | Participate in class |
| Week 9 | 11/16/17 | Promotional Material Regulation | • Explore the basic principles that apply to FDA regulation of advertisement and promotion  
• Discuss the issues related to off-label use of drugs  
• See how the government is using other tools to control promotion of products | Chapter 14 of Textbook and other readings posted on Blackboard | Participate in class and submit Assignment 3 by 11/22/17 |
| Week 10 | 11/23/17 | THANKSGIVING BREAK  
NO ASSIGNMENTS | | | |
<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Week 11</td>
<td>11/30/17</td>
<td>FDA Inspections</td>
<td>Understand the basics of FDA inspections</td>
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<td></td>
<td>Consider cGMP concepts</td>
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<td>Chapter 15 Textbook and other readings posted on Blackboard</td>
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<td>Participate in class</td>
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<tr>
<td>Week 12</td>
<td>12/7/17</td>
<td>FDA Enforcement and Managing a Crisis</td>
<td>Learn how companies deal with a regulatory crisis.</td>
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<td>Understand the key principles of crisis management</td>
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<td>Chapter 16 and 17 of Textbook and other readings posted on Blackboard</td>
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<td></td>
<td></td>
<td>Participate in class</td>
</tr>
<tr>
<td>Week 13</td>
<td>12/13/17</td>
<td>FINAL EXAM</td>
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Academic Integrity Policy

The University views academic dishonesty as one of the most serious offenses that a student can commit while in college and imposes appropriate punitive sanctions on violators. Here are some examples of academic dishonesty. While this is not an all-inclusive list, we hope this will help you to understand some of the things instructors look for. The following is excerpted from the University’s policy on academic integrity; the complete policy is available in the Student Handbook. The Student Handbook is available on the CPS Student Resources page > Policies and Forms.

Cheating – intentionally using or attempting to use unauthorized materials, information or study aids in an academic exercise
- Unauthorized use of notes, text, the Internet, or other aids during an examination.
- Copying from another student’s academic work.
- Unauthorized communication during an examination.
- Handing in the same paper for more than one course without explicit permission from the instructor(s).

Fabrication – intentional and unauthorized falsification, misrepresentation, or invention of any data, or citation in an academic exercise

Plagiarism – intentionally representing the words, ideas, or data of another as one’s own in any academic exercise without providing proper citation
- Word-for-word quotations from a source, including another student’s work.
- Paraphrasing (using the ideas of others in your own words).
- Unusual or controversial facts not widely recognized.
- Audio, video, digital, or live exchanges of ideas, dialogues, or information.

Additionally, the Regulatory Affairs Department and its instructors would like to remind all students that proper citation requires both quotation marks and thoroughly documented references:

1. When writing, if using someone else’s exact words, these words, phrases, sentences, paragraphs, etc. must be enclosed in quotation marks and their source be properly cited in parenthetical documentation, footnote, or endnote format as specified by the instructor. Any use of the words of another person without quotation marks will be considered academically dishonest.

2. Any use of the idea of another person, even if paraphrased by the student author, must be marked by proper citation, whether parenthetical documentation, footnote, or endnote format as specified by the instructor. The use of the idea of another author without proper citation will be considered academically dishonest.

Unauthorized collaboration – instances when students submit individual academic works that are substantially similar to one another; while several students may have the same source material, the analysis, interpretation, and reporting of the data must be each individual’s independent work.

Participation in academically dishonest activities – any action taken by a student with the intent of gaining an unfair advantage

Facilitating academic dishonesty – intentionally or knowingly helping or attempting to violate any provision of this policy

For more information on Academic Integrity, including examples, please refer to the Student Handbook, pages 9-11.
College of Professional Studies Policies and Procedures
For comprehensive information, please see the Registrar University Catalogs page as well as the Student Resources page of the Northeastern University College of Professional Studies website.

Student Accommodations
The College of Professional Studies is committed to providing equitable access to learning opportunities to students with documented disabilities (e.g. mental health, attentional, learning, chronic health, sensory, or physical). To ensure access to this class, and program, please contact The Disability Resource Center (http://www.northeastern.edu/drc/) to engage in a confidential conversation about the process for requesting reasonable accommodations in the classroom and clinical or lab settings. Accommodations are not provided retroactively so students are encouraged to register with the Disability Resource Center (DRC) as soon as they begin their program. The College of Professional Studies encourages students to access all resources available through the DRC for consistent support.

End-of-Course Evaluation Surveys
Your feedback regarding your educational experience in this class is very important to the College of Professional Studies. Your comments will make a difference in the future planning and presentation of our curriculum.

At the end of this class, please take the time to complete the evaluation survey at the NEU EvaluationKit website. Your survey responses are completely confidential. Surveys will be open for the last two weeks of the class. An email will be sent to your HuskyMail account notifying you when surveys are available.

Online Proctoring
In this class, some tests may be administered remotely by an online authentication and proctoring service called Examity®, which gives you the flexibility to schedule exams at your convenience and take them wherever you want.

To prepare for using Examity®, you will need to meet the following technical requirements:

- Working webcam and microphone which can be tested at www.testmycam.net
- An Internet connection of at least 3Mbps (www.speedtest.net)
- Chrome/ Mozilla/ Safari/ Internet Explorer/ Microsoft Edge browser
- Up to date Operating system (Windows or Mac OS)

Please click on the link below to run an automated systems check: Examity Computer Readiness Check

If you do not pass the systems check or have any questions or concerns, you can contact Examity’s® technical support team 24/7 via email at support@examity.com or phone at (855) 392-6489. Please tell your instructor immediately if your computer/equipment does not meet the standard to use online proctoring.

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Instructor Biographical Sketch

**Wendy Rieder, Esq.** is an entrepreneurial, business-oriented life sciences attorney with 20+ years of experience in the industry. Wendy has been directly responsible for intellectual property, legal, compliance, human resources, quality assurance and business development activities in companies from early stage start-ups to large multinational organizations. She recently started TriUnity Law Group LLC to help emerging life science companies with their unique set of intellectual property and legal needs. Wendy was previously General Counsel and Sr. VP, Legal and IP at Synta Pharmaceuticals Corp. (NASDAQ: SNTA), a development stage biopharmaceutical company (now Madrigal Pharmaceuticals). Prior to Synta, Wendy co-founded Microbiotix, Inc., a privately-held anti-infectives company. She earlier held legal positions at Boehringer Ingelheim, Bionutrics, LipoGenics, Ceremedix, Entropin and Fish & Neave (now Ropes & Gray). Wendy holds a BA in chemistry from Barnard College, MA in organic chemistry from Columbia University and JD from Fordham University. Wendy is a Certified Compliance and Ethics Professional (CCEP), a registered US patent attorney and is licensed to practice law in NY, CT, MA, and DC.

**Recommended Writing Resources:**

Northeastern University Tutoring Services:

[http://www.cps.neu.edu/student-resources/tutoring-services.php](http://www.cps.neu.edu/student-resources/tutoring-services.php)

Services include Tutoring Center, Writing Center, and Smarthinking – available to online and on-ground students

Northeastern University Academic Integrity page:

[http://www.cps.neu.edu/student-resources/academic-integrity.php](http://www.cps.neu.edu/student-resources/academic-integrity.php)

Purdue University Online Writing Lab

Purdue University (2014). *Purdue University Online Writing Lab (OWL)*. Available: [https://owl.english.purdue.edu/owl/](https://owl.english.purdue.edu/owl/)