CRN: 70941  
Course: RGA6001: Introduction to Food Drug Administration Medical Device Regulation  
Section: 02  
Fall 2017 CPS Quarter - Second Half / 6 Weeks  
October 30, 2017 – December 16, 2017  
Course Format: Online  
Meeting Time: Virtual  

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

Your Instructor for the course:

Instructor Name: Kathryn Reddig  
NEU E-mail: k.reddig@neu.edu  
Phone Number: available upon request  

Best mode of contact is email. Will respond within 24-48 hours

See Biographical sketch on page 10 for more details regarding your instructor.

Required Text(s)/Software/Tools:


This course utilizes audio lectures as well as other audio material. Students should have access to or should purchase a headset. The Logitech ClearChat Comfort USB Headset, or the Plantronics Audio 470 or 500, or comparable brands/models, are recommended. Headsets can be purchased from online vendors such as amazon.com, bestbuy.com, or newegg.com.

Recommended Textbooks/Resources:

[ISBN: 978-0226823379]

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.

RGA6100 prerequisites: none (this course should be one of your first in the Master’s degree)

Course Description

Provides students with an overview of the medical device development process, and the function of the Food and Drug Administration (FDA) as it relates to device product commercialization. Through course work and participation, the course offers students an opportunity to develop an understanding of fundamental medical device regulatory affairs from a U.S.-centric perspective. Topics include a review of the historical development of significant U.S. medical device legislation, including the 1976 Medical Device Amendments Act. In addition, the subject of Quality System Regulations (QSRs) as they relate to device product design, clinical development, and compliance are introduced

http://cps.neu.edu/courses/detail/RGA6001

Course Outcomes

• Identify and summarize information available on the Food and Drug Administration website
• Describe critical milestones and events in the history of the Food and Drug Administration
• Differentiate between the three primary forms of medical products (drugs, biologics, medical devices) and the emerging area of combination products
• Identify and explain the role and requirements for conducting clinical studies to support marketing applications and post-approval product modifications
• Apply through case study assignments the regulation of manufacturing and quality assurance process

Course Methodology

Each week, you will be expected to:

1. Review the week’s learning objectives
2. Complete all assigned readings (inclusive of CDRH Learn Videos)
3. Complete all lecture materials for the week (1-2 Lectures per 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 online 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 arrangements have been made beforehand.
Each week students are expected to provide one primary response by Wednesday 11:59 PM EST for each discussion question posted. Additionally, there should be a minimum of one secondary response to your classmate’s discussion to be completed by Sunday 11:59 PM EST.
  o For most weeks there will be two DB questions posted and the minimum participation expected is 3 posts (2 primary, 1 secondary).

- Participation in the discussion board contributes to 30% of your final grade.
- 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 as well as your own research on the topic.
  o NOTE: While responses of “Great post”, “Thanks for the information” or similar, is welcomed these posts will not count towards your overall participation (i.e., will not be counted towards your minimum of 3 responses).
- Please check each posting before you press submit to make sure that there are no errors in spelling and grammar, and that your contribution is relevant and adds value to the discussion. The automatic spell check should be on, but proofreading your work prior to posting, is very useful.
  o Please also use appropriate citation methods if you have used materials other than your own thoughts.
- The instructor reserves the right to penalize students for repeated violations of the participation policy within a course.

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.

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. In most cases, 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.

Technical Issues:

In the case of technical issues for online assignments, 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. Please note, technical issues are not a sufficient excuse for missing deadlines, therefore students may or may not receive credit for late material at the discretion of the instructor.

Late Assignment policy:

A deduction of 20% percent 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

There will be one short quiz, two written assignments and one final exam in this course. The overall details on the assignments will be provided below. The specifics of the assignments will be provided during the course.

Exams 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 will take place online.

Content, organization, and mechanics all will be considered in grading final versions of written assignments. Quality contributions are comprehensive and insightful in nature, and draw upon all resources specified by the course, assignment, and the instructor. There is the expectation that students’ written work will be clear, comprehensible and competently produced as fitting of graduate student work. For more information on grading standards, students should reference the CPS Student Handbook at http://cps.neu.edu/student-resources/ or http://www.cps.neu.edu/images/CPS-Stu-Handbook2012-2013.pdf.
Assignments:

Assignment Title: Assignment 1  
Format: PowerPoint  
Length: 5-7 Slides  
Description: Research presentation on a Class II device  
Due Date: 11/19/17

Assignment Title: Assignment 2  
Format: PowerPoint  
Length: 5-7 Slides  
Description: Perform a literature/advertising/promotional review and assess risks for the organization based upon a marketing collateral document and offer alternative choices  
Due Date: 12/10/17

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<thead>
<tr>
<th>Assignment</th>
<th>Length</th>
<th>Points/Percentage</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Quiz</td>
<td>Short Essay</td>
<td>10 pts</td>
<td>11/05/17</td>
</tr>
<tr>
<td>Participation</td>
<td>See above</td>
<td>6 pts/wk 30 pts</td>
<td>Weekly</td>
</tr>
<tr>
<td>Writing Assignments(2)</td>
<td>5-7 pages/slides</td>
<td>15 pts/ea 30 pts</td>
<td>See Above</td>
</tr>
<tr>
<td>Final Examination</td>
<td>See below</td>
<td>30 pts</td>
<td>12/16/17</td>
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Final Exam – The final exam will be worth 30% of your final grade. This exam will test your knowledge of what you learned throughout the course. The exam will consist of short essay questions.

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 will be 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>Grade Range</th>
<th>Letter Grade</th>
<th>GPA</th>
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</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.

Class Schedule / Topical Outline

<table>
<thead>
<tr>
<th>Week</th>
<th>Weekly Topic(s)</th>
<th>Weekly Outcomes</th>
<th>Readings and Lectures</th>
<th>Discussion Board, Assignments and Assessments</th>
</tr>
</thead>
</table>
| Week 1 10/30/17 – 11/5/17 | Regulation of Medical Device Products | • Explain the role of the US Food and Drug Administration (FDA) in the healthcare product commercialization process  
• Describe critical milestones in the history of the FDA, as well as the FDA's organizational structure, mission and product jurisdiction  
• Cite key product parameters reviewed by the FDA during the submission evaluation process  
• Define "medical device" & identify FDA Centers with jurisdiction for medical devices  
• Explain the criteria that determine the extent of FDA jurisdiction over the commercialization of medical device products  
• Define combination product  
• Identify the four basic types of combination product  
• Describe the FDA Center jurisdiction designation process | **Textbook** Pisano & Mantus Chapters 1,4, 5 (pgs 125-135) & Chapter 12  
**CDRH Learn:** Overview of Regulatory Requirements: Medical Devices  
**CDRH Learn:** Product Codes: Making the Connection  
Lecture (slides and audio) | Short Quiz  
Post an introduction in the discussion board (Introduction Section)  
Discussion Board two Initial Postings and one follow up Postings |
| Week 2 11/6/17 – 11/12/17 | Quality System | • Identify and describe the key testing requirements during device development  
• Describe the objectives of the | **Textbook** Pisano & Mantus Chapter 5 pgs 137-141 | Discussion Board two Initial Postings and one follow up Postings |
| Regulation                                                                 | Quality System Regulations (QSR’s) and understand where their essential components are described in the Code of Federal Regulations  
• Explain where and how device design controls fit within a manufacturer's quality system  
• List the stages of design control and describe the objective(s) of each stage | Section on Design Controls & pgs 159 - 163  
**CDRH Learn:** Quality System Regulation 21CFR820 Basic Introduction  
Lecture (slides and audio) |
|---|---|
| Week 3  
11/13/17 - 11/19/17 | Premarket Notification (510k)  
Premarket Approval (PMA)  
Device Modifications  
• Determine which types of medical devices require a 510(k) premarket notification or a PMA  
• Discuss the content of a 510(k) and a PMA submission  
• Describe the potential outcomes of a submission  
• List and describe the required elements and review process for a complete PMA Application  
• Identify the alternatives to filing "standard" PMAs to the FDA for approval of class III medical devices and explain the expedited review process  
• Discuss device modifications and triggers for supplement filings practices for drug, biologic and medical device products | Textbook  
Pisano & Mantus  
Chapter 5 (pgs 135-137) & (pgs146-157) & (pgs 163-165)  
**CDRH Learn:** Overview of the Premarket Notification Process  
Lecture (slides and audio)  
Assignment 1 Due 11/19 @ 11:59 PM EST  
PowerPoint presentation 5-7 slides  
Points = 15  
Discussion Board two Initial Postings and one follow up Postings |
| Week 4  
11/27/17 - 12/03/17 | Clinical Studies  
Investigational Device Exemptions  
• Discuss the types of Investigational Studies  
• Define the elements of the IDE  
• Explain Clinical Study Design | Textbook  
Pisano & Mantus  
Chapter 5 (pgs 141-145) & Chapter 9  
Discussion Board two Initial Postings and one follow up Postings |
<table>
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<tr>
<th>Week 5</th>
<th>Compliance</th>
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| 12/04/17 – 12/10/17 | Discuss establishment and device listing  
| | Define a Medical Device Reporting (MDR) event  
| | Explain the MDR event FDA notification requirements for manufacturers and user facilities  
| | Understand Medical device recalls, corrections and removals  
| | Describe the FDA’s definition of labels and labeling  
| | Enforcement of Compliance and consequences discussed  
| | Understanding the concepts of misbranding, advertising and promotion of medical device for medical device products  |

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<tr>
<th>Week 6</th>
<th>Final Exam</th>
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<tr>
<td>12/11/17 – 12/16 (Saturday)</td>
<td>This exam will cover all the materials covered in the course</td>
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</table>

**Final examination** will be comprised of Short Answer questions.

Final Exam Point Value = 30

No Discussion board Posting this week
Please complete your CPS Class Evaluation

You can find term dates with your contract documents or on the Registrar website/Calendar page.
http://www.northeastern.edu/registrar/calendars.html

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.

Northeastern University Online Policies and Procedures
For comprehensive information please go to http://www.cps.neu.edu/online/

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Instructor Biographical Sketch

Kathryn Reddig has a Master's of Science in Regulatory Affairs from Northeastern University and a Bachelor of Science – Pre-medical in Biology from Rivier College in New Hampshire. In addition to being a part-time lecturer at Northeastern, she is employed as the Director of Global Regulatory Affairs at ConMed Corporation. She is also a member of the board of directors for the Orthopedic Surgical Manufacturers Association (OSMA). Prior to this she worked in both Clinical and Regulatory Affairs positions at both Smith & Nephew Inc. and Medtronic Vascular. She holds Lead Auditor and RAC certification and pursues her professional growth through continuing education. She lives in sunny St Petersburg, Florida with her twin fourteen-year-old boys and Australian Cattle Dog.

Recommended Writing Resources:

Northeastern University Tutoring Services:

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

Purdue University Online Writing Lab

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