CRN: 70888  
Course: RGA6207 FDA and the Electronic Common Technical Document (eCTD)  
Fall 2017, 12-week term  
Course Format: Online/Virtual  
Meeting Time: Week of September 18th, 2017 – December 11, 2017

Instructor Name: Stephen F. Amato, PhD, MBA, RAC (US/EU)  
E-mail: s.amato@northeastern.edu  
Phone Number: (781) 640-0553

In general, please contact me by e-mail and you will get a response within 24-48 hours. In emergency situations ONLY send me a text at the number provided above or call me. I will most likely respond to texts at any point that I am available, but will take phone calls between the hours of 7 am to 7 pm only.

Required Text(s)/Software/Tools:

There is no required textbook for this course. However, readings will be assigned throughout the course. If readings are not directly provided, they will be available through your myNEU account. In order to ensure that you remain current with respect to the appropriate regulations specific to your concentration, additional readings may be assigned but will be made available to you.

Course Description

The Common Technical Document (CTD) structure is the mandatory format for new drug applications (NDA) in the EU and Japan, and also the required format for NDAs submitted to the US Food and Drug Administration (FDA). The CTD format was co-internationally developed to assemble all Quality, Safety and Efficacy related information in a common format. It has eliminated the need to restructure the aforementioned information for submission to various International Conference on Harmonization (ICH) regulatory authorities. As of May 2017 NDA, ANDA and BLA submissions must be published and delivered to FDA in electronic CTD (eCTD) format. In addition, beginning in May 2018 all commercial IND submissions to FDA as well as Drug Master Files (DMF’s) must also be filed in eCTD publishing format. Students in this course will examine the structure of CTD format documents through study of both regulatory requirements as well as example submissions. In addition, students will have an opportunity to develop an understanding of FDAs geographically specific eCTD submission requirements. The course curriculum also reviews the basic structure and format of an eCTD submission and the differences between the electronic format and former paper based CTD submissions.

Course Prerequisites

RGA6000, RGA6001, RGA6101

Course Outcomes

Through enrollment in this course, students will have the opportunity to:
• Demonstrate an understanding of the framework upon which Common Technical Document (CTD) format is based, as well as the extent to which the framework is harmonized across various regions of the globe

• Differentiate between the types of regulatory documents that must be submitted to FDA in electronic Common Technical Document (eCTD) format and describe how this differentiation impacts the content of specific electronic submissions

• Describe how to prepare and navigate through an FDA compliant eCTD submission through utilization of a modular approach

• Demonstrate expertise in understanding, processing, and writing of complex scientific documents in eCTD format that are compliant with clinical investigation and registration requirements of FDA and ICH regions

Course Methodology
Each week, you will be expected to:

1. Review the week's learning objectives
2. Complete all assigned readings
3. Complete or attend all lecture materials for the week
4. Participate in class and/or discussion board
5. Complete and submit all assignments by the due dates
6. Proactively contact the instructor with any questions or concerns

For specific details for each week, please see the class schedule below.

Participation/Discussion Board
Active participation in graduate regulatory affairs courses is defined by both the quantity and quality of contributions. You are expected to have completed the reading and viewed the lecture, and any assignments prior to class and given the content considerable thought.

Participation in the Discussion Board each week is mandatory. If a discussion board is posted for the week, the following is expected: primary responses must be submitted by Wednesday 11:59 EST of each week. Primary responses should address the Instructor's discussion question/topic. At least two (2) secondary responses must be submitted by Sunday 11:59 Eastern Time of each week. Secondary responses should address student responses to the discussion topic. Brief, on-line responses with no substance (e.g., Great post, I agree, etc.) are not acceptable and discouraged. Discussion responses do not require formal references, but references to your source within the post may be appropriate (e.g., As stated in 21 CFR 640…).

Place references from reputable sources, e.g., fda.gov, diahome.org/en-US/News-and-Publications, raps.org/focus-online/news/, dia.bulletinhealthcare.com/, DIADaily@dia.custombriefings.com, smartbrief.com/, fdalawblog.net/, http://www.policymed.com/ at the end of the post. Please convert your research to ‘take-away’ messages and answer in your own words (cutting and pasting directly from references is not permitted). Please take care with grammar, spelling, and sentence and paragraph construction as the ‘mechanics’ of how you build your post will be taken into consideration for grading. You must be compliant with the NEU ‘Academic Honesty’ policy.

Class Participation Policy
Students are expected to participate in all Blackboard discussions and complete all assignments each week. Any unexcused absences or excessive tardiness in assignments will result in a grade deduction at the discretion of the instructor. In the event of legitimate and unavoidable situations, such as personal illness, urgent family or work-related issues, students should reach out to the instructor.

Communication/Submission of Work
In the Assignments folder, click on the View/Complete Assignment link to view each assignment. Attach your completed assignments here and click Submit to TurnitIn® in order to check for originality and correct citation practices. You must be with TurnitIn® prior to the start of the course.

All written work must be submitted in electronic format (.doc, .docx. or .pdf) to the Blackboard site associated with the course by the specified deadline. Once your assignment has been graded, you will be able to view the grade and feedback provided by clicking on Tools, My Grades from the Northeastern Online Campus tab.

Additional Considerations
Students are responsible for any communications sent to their official, NEU-husky e-mail account.

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 Issue
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 15% 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
Grades for Discussion Board/Class Participation will consider how well you apply the regulatory guidance and content discussed in the reading as well and in the lecture material, as well as the
quality and clarity of your writing. For Discussion Board posts, it is expected that you elaborate on your written responses and reference applicable sources as necessary. See Participation/Discussion Board above.

Grades for the written assignments will also consider how well you apply the regulatory guidance and content discussed in class, in addition to the quality and clarity of your writing. The writing assignments should be no more than 5-7 pages long (excluding references), double-spaced using 12 pt. font and must have references. Please be sure that references are provided in an acceptable format. See Recommended Textbooks/Resources above. Each written assignment will have a separate assignment sheet with more specific instructions.

Grading will be based on accuracy and presentation (readability, spelling/grammar, conciseness, effective word usage, and inclusion of appropriate references) of responses. 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/

General assistance in writing may be found at the following:

- **Smarthinking** (available free in Tool section of Blackboard) – this allows students to submit written material in any subject and have it reviewed by an e-instructor within a 24-hour window (in most cases).
- **Writing Center** on Northeastern Campus – contact the center to schedule an appointment.
- **The Purdue Online Writing Lab** (http://owl.english.purdue.edu/owl/) is a valuable source of information about grammar, sentence structure, and general writing skills

**Written Assignments**
Assignments will involve writing components of Common Technical Document compliant submissions for pharmaceutical and biologic products designated by the instructor. It is critical that students keep up with the material presented each week to be able to complete Discussion Board posts and all of the writing assignments.

**Grading Scale & Rubric**

<table>
<thead>
<tr>
<th>Type of Assessment</th>
<th>Notes</th>
<th>Percentage of Final Grade</th>
</tr>
</thead>
</table>

## Written Assignments
Length may vary according to assignment – instructions given each week 40%

## Final Project
Instructions to be Given at the Start of the Fall 2017 Term 30%

## Discussion Board Participation
Basis for grading described 30%

### Writing Assignment and Final Project Grading Rubric

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95-100 A</td>
<td>Outstanding, insightful work demonstrating a thorough and accurate understanding of the context and purpose of assigned task and course concepts. Goes beyond requirements of the tasks to develop a response, which is thoughtful, reflective, flows logically, and considers alternative views and makes connections among ideas and information from different sources or from different aspects of the course. Well researched and documented (with appropriate citations). Displays creativity and originality. Very skillful control of syntax and mechanics of building and integrating components of assignment.</td>
</tr>
<tr>
<td>90-94 A-</td>
<td>Very good work. Good understanding of course concepts. Purposefully and logically developed and focused on correctly responding to the assigned tasks. Thoroughly addresses all aspects of the task with excellent content development. Synthesis of details and concepts from various sources or topics shows evidence of sound understanding and thoughtful examination. Assigned tasks are consistently researched and appropriately cited. Good control of syntax and mechanics of building and integrating components of assignment.</td>
</tr>
<tr>
<td>87-89 B+</td>
<td>Good work. Generally clear and relevant. Adequately addresses all requirements of the tasks. Demonstrates good understanding of task context, purpose, and course concepts, with evidence of some thoughtful examination and reflection. Content development is generally logical, facts generally correct. Tends to focus on one interpretation. Generally shows control of syntax and mechanics of building and integrating components of assignment.</td>
</tr>
<tr>
<td>84-86 B</td>
<td>Satisfactory work. Shows basic understanding of task context, purpose, and course concepts with minimal evidence of reflection or thoughtful analysis. Complies with the basic requirements, relies on limited sources of information, modest integration of concepts. Addresses most, but not all, of the requirements of the tasks. Some lapses in appropriate content development and accuracy. Demonstrates an attempt to control syntax and mechanics of building and integrating components of assignment.</td>
</tr>
<tr>
<td>80-83 B-</td>
<td>Minimally satisfactory work. Shows some understanding of course concepts with little reflection or analysis. More than occasional lapses in accuracy of task content. Barely meets basic requirements of assignment with some focus on content development and some control of syntax and mechanics of building and integrating components of assignment.</td>
</tr>
</tbody>
</table>
Unsatisfactory work. Fails to address the topic in a meaningful way. May be extremely brief, inaccurate, illogical or undeveloped. Inconsistent to poor control of syntax and mechanics of building and integrating components of assignment.

*Please note that CPS does not award grades below a C- for graduate level courses.*

<table>
<thead>
<tr>
<th>Week</th>
<th>Topic</th>
<th>Notes (Details of Written Assignments to be Provided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Regulatory Operations and its Function Within Biomedical Product Commercialization</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>FDA Overview of the eCTD Guidance and its Implementation</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Module 1 – Regional Requirements and Administrative Documents</td>
<td>Written Assignment #1 Due</td>
</tr>
<tr>
<td>4</td>
<td>Module 2 – Summary Documents</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Module 3 – Chemistry, Manufacturing and Controls (CMC) Documents</td>
<td>Written Assignment #2 Due</td>
</tr>
<tr>
<td>6</td>
<td>Module 4 – Nonclinical Reports</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Module 5 – Clinical Reports and Datasets</td>
<td>Written Assignment #3 Due</td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>8</td>
<td>Best Practices in Navigating an eCTD Submission</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Planning, Preparing &amp; Building an FDA Compliant eCTD Submission</td>
<td>Written Assignment #4 Due</td>
</tr>
<tr>
<td>10</td>
<td>eCTD Compliant Investigational New Drug (IND) Submissions</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>The eCTD and its Harmonization Across the Globe</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>eCTD Review and Final Presentation</td>
<td>Final Project Due</td>
</tr>
</tbody>
</table>

**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

*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

*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/](http://www.cps.neu.edu/online/)

**Northeastern University Online Copyright Statement**

Northeastern University Online is a registered trademark of Northeastern University.

All other brand and product names are trademarks or registered trademarks of their respective companies.

This course material is copyrighted and Northeastern University Online reserves all rights. No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system, or translated into any language or computer language, in any form or by any means, electronic, mechanical, magnetic, optical, chemical, manual, or otherwise, without the express prior written permission of Northeastern University Online.

Copyright 2017 © by Northeastern University Online
All Rights Reserved