

PHARMACEUTICAL REGULATIONS AND GMP MANUFACTURING

16:155:548

Fall 2015 (Online)

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Note: This syllabus is subject to change.

Course Description

This course studies the drug development process in the pharmaceutical industry from discovery through FDA marketing approval, reviewing the overall process and the interrelationships linking various Chemistry, Manufacturing, and Controls (CMC) disciplines. It introduces students to regulations governing the process, including interactions with the FDA, ICH, and other regulatory agencies. This course provides students with an in-depth knowledge of the major challenges facing the global pharmaceutical industry with emphasis on CMC issues. Students will learn various aspects of manufacturing pharmaceutical products under current Good Manufacturing Practice (cGMP), and the government regulations required for obtaining approvals for both investigational and marketing applications of new products. The class emphasizes basic understanding of the pharmaceutical business models, global health authority regulations, and long term planning for manufacturing of products to support both clinical studies and commercialization.

There will be a lot of writing in this class and a large part of assignments and exams will involve writing as opposed to solving equations or doing math problems.

Prerequisite

Although there is no pre-requisite for this course, it is advisable to have some working knowledge of pharmaceutical industry and drug development.

Goals and Learning Objectives

Upon successful completion of this course, students will be able to gain a basic understanding of:

- Various disciplines involved in drug development in a pharmaceutical company
- Drug Development from Chemistry, Manufacturing, and Controls (CMC) perspective
- Roles of various organizations in the pharmaceutical business including health authorities, academics, and industry
- Regulatory requirements for CMC information in regulatory submissions
- Expectations from Health authority (e.g., FDA) meetings

Textbooks

There is no required textbook for the class. Readings and relevant material will be posted on the course site. Below are some recommended textbooks:

- New Drug Development: A Regulatory Overview, 8th edition, January 1, 2008; by Mark Mathieu (Author); ISBN-13: 978-1882615858; ISBN-10: 1882615859
- Drug Discovery and Development: Technology in Transition, 2nd edition, Paperback – September 13, 2012; by Raymond G Hill (Author); ISBN-13: 978-0702042997; ISBN-10: 0702042994

- New Drugs: An Insider's Guide to the FDA's New Drug Approval Process for Scientists, Investors and Patients, 1st edition, Paperback – June 4, 2009; by Lawrence T. Friedhoff (Author); ISBN-13:978-1419699610; ISBN-10: 141969961X

Required Journal Articles

The full text of required journal articles is accessible through the Rutgers University Library web site via www.libraries.rutgers.edu. Please consult a librarian if you need assistance locating or downloading articles.

Nature of Class Sessions

This is a 100% online course. There is no face-to-face meeting; however some of the classes will be conducted “live” to facilitate class discussions and presentations. Consequently, the requirements for each class session are designed to facilitate learning independently, as well as through interaction with other students and the instructor in a structured manner. The course is scheduled as a **Tuesday** course, meeting at 7:00-9:30 pm (the lecture notes will be posted every Tuesday (every Monday evening in advance, if possible) and you can access through eCollege to download the PowerPoint lecture anytime).

Course Requirements

Email and Communication

Please check your eCollege account regularly. Course syllabus, lecture slides, additional readings, and announcements will be posted on eCollege. Periodically, communication about homework assignments or readings may be distributed using the email addresses noted in the eCollege system so it is expected that students will check their accounts regularly (daily). From time to time I adjust readings or assignments, and want you to be fully informed.

Class Participation

All students are expected to participate fully in the class by viewing PowerPoint slides (video material), reading assigned chapters and articles, and participating in online discussion threads; this implies that all assigned readings should be completed in advance. Minimum participation, typically at least 2-3 posts, is listed in each module’s discussion. For each module your first post should be submitted by Day 3, with the discussion wrapping up by Day 5.

- Treat all on-line communications as graded written assignments.
- Check spelling, grammar, and punctuation before sending your words over the network.
- Do be courteous. Avoid saying things that MIGHT be offensive to others. Sarcasm or jokes could be misunderstood.
- Avoid attacking a classmate for a point of view you disagree with. Debate should be civil. Resorting to personal attacks is a form of intellectual irresponsibility.

Discussion Extensions

The nature of the Discussions means that the deadline for completing Discussions cannot be extended. There will be no make-up Discussions. If a student fails to participate in a Discussion for a valid documented in writing medical/emergency reason, the other Discussions will be converted to make up for the missed one to calculate the final grade. If you miss a Discussion without a documented medical/emergency reason you will receive zero for that Discussion.

Quality of Remarks

- You should not respond simply to the question, but rather provide a substantial insight based on the academic materials and readings provided in this course. A simple remark

such as “I agree with Student One” or “I disagree with Student One” is not a substantial response.

- Repetition or restatements of the comments made by another student should be avoided without providing academic support based on research, personal workplace experiences, or specific readings.
- You are encouraged to reply to a comment by asking additional questions within the same topic. This will stimulate the conversation and develop high cognitive skills that will greatly contribute to the continuity of the thread.
- Please note that if I respond to a post in a manner that is constructively critical or corrective, in most instances, this does not mean that the student who posted is wrong. Rather, this is part of a critical discussion and academic dialogue.

Rubric for Discussion Participation

Use this rubric to assist you provide a substantial remark. Your participation in a discussion forum enriches learning as you share your thoughts and experiences with others in a collaborative manner.

Criteria	Unacceptable	Acceptable	Excellent
Initial Assignment Posting	There is no post.	Posts a general comment and doesn't fully address the question asked.	Posts well developed comments that fully address the questions asked.
Frequency	No participation or posts only 1 comment per week.	Posts requested number of well-developed comments.	Posts 5 or more well-developed comments.
Follow-Up Postings and content contribution	Posts lack academic support (e.g. journals, and research).	Some posts lack academic support (e.g. journals, and research).	Posts are supported by academic materials (e.g. journals, and research).
Clarity & Mechanics	Does not communicate in a professional manner and/or comments have at least 4 grammatical or spelling errors.	Communicates in a professional manner and comments have 1-3 grammatical or spelling errors.	Communicates in a professional manner and comments are clear and free of grammatical or spelling errors.

Written Assignments

It is essential that all written work be prepared to professional standards, utilizing cover sheets, headings and subheadings, and page numbers. In addition, standard formatting for papers should conform to the following: double-spaced, 12-point font, and 1-inch margins on all sides. Sentences should be clear and understandable. I expect complete sentences, good English grammar, and written compositions that are devoid of spelling and syntax errors. It is especially important in the academic and professional online settings to communicate clearly, concisely, and intelligently.

All assignments must be posted on eCollege by each Due!

Readings and assignments are to be completed in advance of the dates indicated. These

descriptions, schedules and timelines are subject to change at the Professor's discretion in order to accommodate unforeseen circumstances or to take advantage of new publications that bear significantly on the subject matter at hand.

Grading

Percentages of Final Grade:

Self-Introduction Video	5%
Home work assignments & Group discussions	25%
Quizzes	10%
Mid-term Exam	20%
Presentation*	10%
Final Exam	30%

*A 10-15 minute presentation on a topic related to current events in pharmaceutical industry, evolution of regulations, and/or pros and cons of a recently approved drug will be required. The topic must be approved by the professor.

In addition to the content of your assignments, you will also be graded on your professionalism and your ability to follow directions/instructions. All assignments need to be completed by the indicated deadlines and you need to follow directions/instructions carefully. You will lose points for not following directions, incorrect grammar and spelling mistakes.

The Definition of the Letter Grade:

A	90-100
B+	85-89
B	80-84
C+	75-79
C	70-74
F	Below 70

Course Policies

Late Work Policy

No assignments will be accepted after 11:59 p.m. E.T. on the deadline. If you have extenuating circumstances that prevent you from completing any assignment, please contact me to make alternative arrangements. Work is not an acceptable excuse for late assignments as it can be anticipated and should be accommodated in your assignment completion timetable. The possibility of alternative arrangements is at my discretion. Active communication is the key to overcoming any hurdles you may encounter during the semester.

Make-up Exams

The nature of the exams means that the deadline for completing an exam cannot be extended. There will be no make-up exams. If a student fails to take any of the exams for a valid documented in writing medical/emergency reason, the other exam(s) will be converted to make up for the missed one to calculate the final grade. If you miss an exam without a documented medical/emergency reason you will receive zero for that exam.

Incompletes

The university policy on incomplete grades will apply, and will be interpreted conservatively to prevent misuse.

Disputes about grades

I strive to be a fair and conscientious grader, but I am fallible. If you believe you received a grade in error due to my fault or oversight, I will review the work to determine if a change is warranted. Any dispute must be made in writing via a signed memo within 7 calendar days of the graded assignment being returned to the student.

Citizenship

Students are to treat each other with respect at all times. Participating in class activities without being adequately prepared to discuss the assigned readings is disrespectful and discourteous to your fellow students. I will monitor online discussion threads to gauge participation, level of understanding, and application of readings. While I will be watching, it is your responsibility to refrain from the use of discourteous, impolite or disrespectful comments. All perspectives are valued.

Attendance and Preparation

This is a graduate class. As graduate students, I expect each of you to be fully prepared for and participate in each class activity. I also expect each student to be an active participant in class discussions and exercises. Given that this course occurs in an online environment, this is especially important.

Academic Integrity Policy

The consequences for violating policies of academic integrity and the student code of conduct are serious. I expect that you will comply with standards of academic integrity (that is, all the work you present is your own) in this course. For any and all assignments no copying of any kind is allowed, unless copied text is placed within quotations and appropriately cited. Paraphrased text must be appropriately cited. The consequences of clear evidence of extensive plagiarism include, but are not limited to, a grade of F for the assignment AND the course. If you have questions about an assignment or the course content, please seek assistance. You should not turn in the same work in two separate classes. To avoid problems, do not wait until the last minute to begin an assignment.

The material on this site is copyrighted and may not be posted on any other web site at or outside of Rutgers without permission. Noncompliance with this policy will be treated as a violation of the Rutgers Code of Student Conduct and will be referred to the Office of Student Conduct for action.

For more information, read [the Academic Integrity Policy and the Student Code of Conduct at the Rutgers Academic Integrity site.](#)

Care, Respect, and Integrity

These three words apply to the written and verbal exchanges of this class. A respectful attitude is expected for class discussions and interpersonal communication with instructor and colleagues. Our classroom and learning environments are safe and open spaces. Please be respectful of each other and of your instructor.

Emails to instructor and peers should always begin by a greeting, include clear and reasonable questions and/or request, and end with salutations. I make sure to respond to emails within a couple of days (i.e., I do not always respond within the next 10 minutes, nor do I check my

messages at 3 a.m.). In the event I do not respond after a couple of days, a kind email reminder is welcome.

Netiquette

"Netiquette" is the do's and don'ts of online communication. Netiquette covers both common courtesy online and the informal "rules of the road" of cyberspace. You should be aware of some basic guidelines about how to behave in an online format, such as not using all capital letters online because that represents the vocal equivalent of shouting. If you are not, please look them up. In addition to these basics, please remember that this is a graduate course where much of the academic work is taking place online. It is not the same as communicating with friends via Facebook or Twitter, nor is it equivalent to sending text messages to friends or colleagues.

Accommodations for Disabilities

Please Note: Rutgers University welcomes students with disabilities into all of the University's educational programs. In order to receive consideration for reasonable accommodations, a student with a disability must contact the appropriate disability services office at the campus where you are officially enrolled, participate in an intake interview, and [provide documentation](#). If the documentation supports your request for reasonable accommodations, your campus's disability services office will provide you with a Letter of Accommodations. Please share this letter with your instructors and discuss the accommodations with them as early in your courses as possible. To begin this process, please complete [the Registration form on the ODS web site](#).