REG 6100: Fundamentals of FDA Regulation

Summer 2024

Instructor Information

Course Director
Christine Lee

Class Location & Time
Thursdays, 5 – 8 p.m.
Online

*syllabus is subject to change according to professor's discretion

General Information

Description

This introductory course provides an overview of Regulatory Affairs in relation to three key areas of development: Drugs, Medical Devices, and Biologics including gene therapy and vaccines. Students will gain insight into the pivotal role of FDA in regulating medical products, as well as explore the therapeutic product development life cycle process from initial concept to market entry. Special emphasis will be placed on formulating regulatory strategies including determining pre-clinical and clinical testing requirements for the three key areas in support of clinical trials and commercialization. Furthermore, the course will dissect different types of FDA enforcement actions and equip students with knowledge to navigate pre- and post-approval compliance challenges effectively. Practical issues encountered by regulatory specialists in collaboration with the FDA will be addressed. Real-world case studies and interactive discussions will provide students with valuable insights into overcoming regulatory hurdles and securing product approvals in a competitive domestic market.

Learning Objectives

By the end of the course, students will be able to:

- Navigate information available on the FDA website for drug, medical device, and biologic products.
- Describe how Regulatory Affairs contributes to therapeutic product development during the lifecycle of a product (pre-/post-market).
- Differentiate between 3 primary forms of medical products (drugs, biologics, medical devices) and be able to determine pathways of early interaction with the Agency.
- Formulate high level Regulatory strategies to support clinical trials and commercialization.
- Determine pre-clinical and clinical testing requirements for drugs, biologics, and medical devices.
- Determine mechanisms to implement design or manufacturing modifications to a marketed medical product
- Research complex FDA topic, critically analyze one's findings, compile a presentation, and disseminate one's discoveries to an audience

Evaluation and Due Dates

Evaluation Methods:
Students will be graded based on class attendance, participation, and assignments.

Percent of Grade	Assignment
5%	Class Participation
15%	Quizzes (5% each)
40%	Assignments (2 assignments, 20% each)
20%	Presentation
20%	Final Project

Assignment Schedule

Date	Subject
May 30, 2024	Reading assignment
June 6, 2024	Quiz 1 (due by 5pm)
June 13, 2024	Quiz 2 (due by 5pm)
June 20, 2024	Class Presentation (due by 5pm)
June 27, 2024	Assignment 1: RA Strategy
July 11, 2024	Quiz 3 (due by 5pm)
July 18, 2024	Assignment 2: Outline requirements for a clinical study
August 8, 2024	Final Project Submission & Discussion (due by 5pm)

Class participation (5%):
Participation is a crucial component in students' education in this program. Students are expected to attend and actively participate in all courses. Examples of active participation in a synchronous session may include asking or answering questions, posting comments in the chat, or collaborating with other students during group work. Examples of active participation in an asynchronous session may include asking or answering questions via Canvas or email, commenting on discussion boards, or interacting with other students outside of class.

This program is committed to providing a supportive and productive learning environment for all. Active participation requires professionalism and demonstration of respect for peers, course instructors, and guest lecturers.

Attendance Expectations:
Students are allowed 1 excused absence. If you anticipate the need to be absent, please contact the course coordinator prior to your absence. If you have other concerns about your ability to meet the attendance requirements, you must contact the course coordinator prior to your absence. All absences require students to make up content which may include watching a recording or completing an assignment or a quiz, as provided by the instructor.
Students are expected to be on time to all classes and stay for the duration of the class. If you anticipate being late to class or may need to leave early please email the course coordinator and instructor in a timely manner to let them know of may be late or need to leave early. Any student who is more than 15 minutes late will be considered absent from that class. Additionally, any student who leaves early may be marked absent. Attendance also includes keeping video feed on during synchronous sessions.

Quizzes (15%):
Students will be assigned 3 quizzes, each weighing 5% of the total grade. Students will need to navigate the FDA website to identify and summarize information for drug, device, and biologic products.

Presentation (20%):
A significant part of graduate education is learning how to research a topic, critically analyze your findings, and

then disseminate your discoveries to an audience. Presentations will be done in teams of 2 or 3 depending on how many students are enrolled. Students will present for 15 minutes with 5 minutes of allocated for questions for a total of 20 minutes. This typically works out to be approximately 15 slides of content not including references. The topic for the presentation is to provide an example of a situation where the FDA had to take enforcement action against a firm for non-compliance and the actions taken by the firm to remediate such findings. The enforcement action can be warning letters, seizures, injunctions, criminal prosecution, criminal fines, etc. Grading will be based on the pertinence of the topic, depth, and accuracy, as well as clarity of the presentation.

Final Project (20%):
The final project will be a strawman regulatory submission for a medical product (existing or made up) to support a clinical study or commercialization. The final project will build on the three assignments described below and then expanded in the areas of interest in the submission template to achieve the goals for the completed document. The final project must be 8 – 10 pages long not inclusive of references or table of contents. Format should be Times New Roman 12 font, 1.5 line spacing, and 1-inch margins. Students should be prepared to talk for 5 – 10 minutes about their project and be able to share what the project was and key learning during the process. Slides can be used but are not required.

Assignment 1 (20%) Define the Product - High level RA Strategy:

- Select drug, biologics, devices, or combination product. Describe problem to be solved (condition, disease, disorder), patient population, currently available treatments, anticipated benefit and risks of product.
- Determine whether this product is a 1) new chemical entity or biological entity or medical device 2) new indication for an existing drug, biologic, or medical device, or generic/bioequivalent or substantially equivalent to marketed product.
- Determine what type of submission may be appropriate and which phase of development is focus of the project.
- Identify what applicable guidance docs are available
- Outline requirements for pre-clinical evaluation listing and describing the preclinical testing to be performed for the selected product: what testing is required prior to entering human trials.
    - This may include laboratory testing, animal testing, and characterization of chemical or biological entities. The purpose being to establish, as much as possible the safety of the product and some probability of effectiveness prior to a clinical study.

Assignment 2 (20%) Outline Requirements for Clinical Trial:

- Outline requirements for clinical studies to include major items for a protocol such as the intended Phase of the trial (1, 2, 3, 4, Pilot or Pivotal), trial type (randomized, controlled, blinded), clinical endpoints (primary and secondary), duration of the study, number of subjects, indications and contraindications, and type of data to be collected.
- Determine if/when a pre-submission or meeting with FDA would be helpful to verify submission requirements will be met and include this as applicable, for example a meeting to discuss the study design, sample size or endpoints to ensure the study results will support a regulatory submission for the product.

Academic Policies:

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Students are expected to be on time to all synchronous classes and stay for the duration of the class.

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Course Evaluations
Course evaluations are completed in the BLUE system. These are a required part of course participation. An email from the BLUE team will be sent to students with a link and directions on how to complete the course evaluation(s).

Academic Integrity
As a student at The University of Pennsylvania, you are required to uphold the Code of Academic Integrity. Specifically, this means that materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (i.e. do not cheat, fabricate, or plagiarize, amongst others). We encourage you to reach out to the course director or coordinator if you are not clear on what potential violations are.

Course Management: Canvas
All course materials and assignments will be managed on Canvas. Log in with Pennkey and password.

Student Disabilities Services
The University of Pennsylvania provides reasonable accommodations to students with disabilities who have self-identified and been approved by the office of Student Disabilities Services (SDS). Please make an appointment to meet with me and the course coordinator as soon as possible in order to discuss your accommodations and your needs. If you have not yet contacted SDS, and would like to request accommodations or have questions, you can make an appointment by calling SDS at 215-573-9235 or accessing the **MyWeingartenCenter** portal. The office is located in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260. All services are confidential.

Course Schedule

Week	Topic	Lecturer
Week 0	**Students to complete prior to Week 1** **Reading assignment**: "Leaving the Ivory Tower – Alternative careers in science"	

Week	Topic	Lecturer
	Discussion Board: Self introduction, RA-related experience, what you hope to get out of this course	
Week 1 **May** **30**	**Course Introduction and FDA Overview** Student Introduction Class introduction Syllabus Review Discussion of Presentation and Final Project Intro to Regulations **Complete prior to class**: Reading assignment and discussion board introduction (see Week 0) Class Activity: Discussion on purpose of regulations and key events that led to evolution of FDA	Lee
Week 2 **June 6**	**Overview of Drugs and Biologics** Introduction to history, structure, and role of FDA Defining drugs and biologics Establishing high-level regulatory strategy Submission pathways (IND, NDA, BLA) Clinical Trials for drugs and biologics Class Activity: Precipitating events that led to major FDA milestones; groups to be assigned in class **Quiz 1** due by 4:59pm	Lee
Week 3 **June 13**	**Medical Device Development and Pathways** Medical device classification Medical device development and design control Submission pathways (IDE, 510(k), PMA, DeNovo, HUD, HDE) Medical device modifications & reportability **Quiz 2 due by 4:59pm** **Class Activity:** Analyze similarities and differences in regulation of medical products (clinical trial, GMP, commercialization, post-marketing requirements)	Lee
Week 4 **June 20**	**Class Presentation:** Presentation in groups of 3-4. Provide an example of a situation where the FDA had to take enforcement action against a firm for non-compliance and the actions taken by the firm to remediate such findings. The enforcement action can be warning letters, seizures, injunctions, criminal prosecution, criminal fines, etc. *Students are required to actively participate in Q&A sessions for participation*	Lee

Week	Topic	Lecturer
	points.	
Week 5 **June 27**	**Class Presentation Continued** *Students are required to actively participate in Q&A sessions for participation points.* **Assignment 1 due by 4:59pm**	Lee
Week 6 **July 4**	Optional office hours (to address questions/concerns about final project) Otherwise, students work on assignments and final project	Lee
Week 7 **July 11**	**Drug Development Overview** Drug Development Process Discovery and development Pre-clinical research **Quiz 3 due by 4:59pm**	Eileen Doyle
Week 8 **July 18**	**Drug Development Overview Cont'd** Drug Development Process – Clinical research Drug approval pathway Post-market activities Class Activity: Clinical Holds **Assignment 2 due by 4:59pm**	Eileen Doyle
Week 9 **July 25**	**Biologic Product Development** Biologic development process Biologic approval process	Naren Chirmule
Week 10 **August 1**	**Vaccines Design and Development** Vaccine Approval Process Vaccine trials underway Class Activity: Role Play - vaccine development process	Naren Chirmule
Week 11 **August 8**	**Project Discussions** Career outlook in Regulatory RA job trends **FINAL PROJECT due by 4:59pm**	Lee