

# REG 6150: Post-Approval Maintenance of Drugs, Biologics, and Devices

Spring 2025

## Instructor Information

### Course Director

Michele A Roy, RN, MS

### Class Location and Time

Online (Zoom)

Wednesday, 5 p.m.

\*syllabus is subject to change at professor's discretion.

## General Information

### Description

Drug development is complex, time consuming, and resource intense across multiple disciplines that require subject matter expertise. The goal is to obtain FDA-approval of a marketing application, which, once achieved, is a major accomplishment. However, marketing approval brings significant Sponsor responsibilities as FDA continues to enforce strict regulatory requirements to ensure marketed products maintain their favorable benefit/risk profiles and therefore continue to offer safe and effective options for patients.

This course is designed to provide students with an in-depth understanding of the multiple regulatory requirements and marketing activities that take place following FDA approval, throughout the lifecycle of a marketed product. Topics include:

- Post-marketing requirements
- Pharmacovigilance/safety surveillance
- Manufacturing throughout product lifecycle
- Device regulations
- Labeling considerations
- Sales, marketing, advertising, and promotional activities
- FDA inspections
- General lifecycle management, label expansion, patent and exclusivity considerations

### Objectives

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

- Identify key post-marketing FDA regulations across specific pharmaceutical disciplines
- Explain key post-marketing FDA reporting requirements
- Describe post-marketing safety reporting
- Interpret FDA-approved product labeling
- Discuss post-marketing studies
- Analyze ongoing manufacturing changes and their impact on the approved application
- Discuss sales and marketing activities and the requirements regarding advertising and promotion
- Describe lifecycle management strategies for marketed products

## Evaluation and Due Dates

### Evaluation Methods:

Students will be graded based on class attendance, active engagement and participation, and assignments.

Due Date	Assignment Title	% of Grade
2/5/2025	<b>Label Section Overview</b> Short presentation	10
2/12/2025	<b>Accelerated Approval - Pros and Cons</b> Canvas discussion board	5
3/5/2025	<b>Risk Evaluation and Mitigation Strategy (REMS) Overview</b> Short writing assignment	10
3/5/2025	<b>Post-Marketing Safety Report Case Studies</b> Small group in-class activity	5
3/26/2025	<b>Chemistry, Manufacturing, and Controls (CMC) - NDA Post-Approval Changes</b> Short writing assignment	10
3/26/2025	<b>Quiz - Chemistry, Manufacturing, and Controls (CMC)</b>	10
4/9/2025	<b>Advertising and Promotion - Untitled and Warning Letters</b> Short discussion	5
4/30/2025	<b>Final Project</b>	20
Ongoing	<b>Class Participation</b>	25

## **Program and Course Policies:**

### **Community Standards and Program Expectations**

All students taking ITMAT Education online and hybrid courses must ensure that their learning environment for synchronous course meetings is appropriate and free from distractions to themselves, other students, and instructors. Specifically, participate in the session in a physical space and surrounding environment that allows you to devote your full attention to the course meeting. Remain stationary in that location for the duration of class. You are expected to log on using a computer, with working microphone and video capabilities. During class, your video must be operational and be on at all times, with your background blurred and your microphone muted to minimize unexpected distractions to you and your fellow students. If you identify issues that compromise your ability to meet these expectations, contact the course director to seek ways to resolve the situation in a timely manner.

Two general rules are (i) if you wouldn't expect your instructor to facilitate a class under any condition or set of conditions, it is equally unacceptable for a student to attend class under those same conditions; (ii) if you would not do something in an in-person classroom environment, it should not be done in a synchronous online class. Some examples of unacceptable conduct during synchronous sessions include attending class while driving; attending class while walking; attending class while also working; attending class while being physically located in a busy environment or an environment likely to be disrupted by other people or significant background noise; attending class using your cell phone. Course directors will, at their discretion, include course-specific policies articulated in the course syllabus.

### **Attendance**

Students are allowed 1 excused absence. Beyond the excused absence, you must contact the course director for a makeup assignment. Missing 4 or more synchronous classes will result in a maximum final grade of C+.

If you will be absent, please contact the course director prior to your absence. If you have other concerns regarding attendance requirements, contact the course coordinator as soon as possible. Beyond the excused absence, grade impacts are at the discretion of the course director.

Students will be on time, keep their video feed on, and remain present engaged in class for the duration of the class. If you will be late to class or need to leave early, please email the course coordinator and instructor prior to class. Any student more than 15 minutes late or who does not keep video on will be considered absent from class. Additionally, any student who leaves early may be marked absent. Please contact the course instructor regarding any extenuating circumstances.

Students who are absent from any class are at a minimum always responsible for reviewing the class recording and other materials covered during a synchronous class.

### **Participation and Active Participation**

Participation in class is crucial to students' success. Students will attend and actively engage with the content and participate in discussion all courses.

Examples of active participation in a synchronous session:

- asking or answering questions during class
- posting comments in the chat

- collaborating with other students during group work
- sharing relevant expertise with other students and the instructor
- incorporating knowledge or information from out-of-class readings and videos to enrich the conversation
- please consider speaking up in every synchronous class period to gain full participation points

Examples of active participation in an asynchronous session:

- asking or answering questions after class via Canvas or email
- interacting with other students outside of synchronous class
- commenting on discussion boards
- completing short reflective assignments

This program is committed to creating a supportive, respectful, and productive learning environment for all students. Students will remain professional and respectful of their peers, course instructors, and guest lecturers. An important principle code of conduct is to behave in the virtual space in the same way you would during an in-person class and/or a work meeting. **If you wouldn't do it in a work meeting or in-person class, don't do it in the virtual space.**

Students are expected:

- Refer to “[Community Standards and Program Expectations](#)” (above) for details on creating a quiet, distraction free environment
- Keep video on
- Be appropriately attired (casual wear is fine)
- Approach debates and disagreements in a thoughtful and respectful manner

If you have questions regarding appropriate behavior in a synchronous class, contact the course coordinator.

### Student Disability 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 your instructor and the course coordinator as soon as possible to discuss your accommodations and your needs. To request accommodations or ask questions, you can make an appointment by calling SDS at 215-573-9235 or accessing the [MyWeingartenCenter](#) portal. The office is in the Weingarten Learning Resources Center at Hamilton Village, 220 S 40th St Suite 260. All services are confidential.

Learn more about the [types of services and accommodations offered by Weingarten](#).

## Grading, Late Work, Extension, and Resubmission

### Grading

The grading system is: A, excellent; B, good; C, fair; D, poor; and F, failure.

LETTER GRADE	PERCENT SCORE
A	93-100
A-	90-92
B+	87-89
B	83-86
B-	80-82
C+	77-79
C	73-76
C-	70-72
D+	67-69
D	63-66
D-	60-62
F	0-59

At the graduate level for students enrolled in Regulatory Affairs programs, **the minimum standard for satisfactory work in each course is a B-.**

### Course Evaluations

Course evaluations are an opportunity to share feedback on the strengths of the course, and opportunities for improvement. We welcome constructive feedback in the BLUE system. Completing evaluations is a required part of course participation. An email from the BLUE system is sent to students with a link and directions on how to complete the course evaluation(s).

### Course Management: Canvas

All course materials and assignments will be managed on [Canvas](#). Log in with Pennkey and password. Additional information on configuring and using Canvas will be provided in the Canvas site.

### Student Conduct

ITMAT Ed students must comply with the University's Code of Student Conduct and other University policies related to student conduct that appear in [The PennBook: Resources, Policies and Procedures Handbook](#). These include, but are not limited to, policies on sexual harassment, acquaintance rape and sexual violence, appropriate use of electronic resources, open expression, and drug and alcohol usage.

Additional codes of conduct and expectations students should be familiar with are the [nondiscrimination statement](#), the [sexual misconduct policy and resource offices](#), and [student grievance procedures](#).

### Academic Integrity

The fundamental value of our academic community is intellectual honesty; accordingly, our academic community relies upon the integrity of every member. Students are responsible not only for adhering to the highest standards of truth and honesty but also for upholding the principles and spirit of the Academic Code. Violations of the Code include but are not limited to plagiarism, cheating, and fabrication.

If you have questions regarding what is considered a violation of academic integrity, please review The [Code of Academic Integrity](#) in the PennBook.

Alleged violations of the Code of Academic Integrity are reviewed by the Program Director and as necessary referred to the Penn Office of Student Conduct. If a student is unsure whether their action(s) constitute a violation of the Code of Academic Integrity, it is that student's responsibility to consult with the instructor to clarify any ambiguities.

### Use of Generative AI

It is plagiarism to submit work produced by a generative artificial intelligence (AI) service as your own without citing the source. Any use of generative AI services must be in alignment with course requirements and restrictions. Course Directors have full discretion to allow or deny use of ChatGPT or similar AI tools in their courses. Ask the course director for permission before using these tools for course assignments.

### Religious and Cultural Holidays

Religious and cultural holidays are listed on the [University of Pennsylvania's Chaplain website](#). If a student observes any of the listed holidays and they conflict with a class date, please contact program staff with class date with which the holiday coincides.

If an assignment is due during a holiday, program staff and faculty will work with the student to determine an alternative due date.

### Course Schedule

<b>Class: Wednesday at 5pm</b>	<b>Topic</b>	<b>Assignments</b>	<b>Due</b>
Jan 22 Week 1	Course introduction and overview of FDA regulatory environment following marketing application approval, including Prescription Drug User Fee Amendments (PDUFA)	Pre-reads	
Jan 29 Week 2	FDA-approved product labeling	Pre-reads	
Feb 5 Week 3	FDA-approved product labeling - how changes are made to labeling post-approval	Label Section Overview Presentations	Wednesday, 2/5 at 5PM
Feb 12 Week 4	Post-marketing requirements, part 1 - accelerated approvals and other situations where PMRs are utilized	Pre-reads  Accelerated Approvals: Canvas Discussion Board	Wednesday, 2/12 at 5PM
Feb 19 Week 5	Post-marketing requirements, part 2 - pregnancy, lactation, pediatrics	Pre-reads	

<b>Class: Wednesday at 5pm</b>	<b>Topic</b>	<b>Assignments</b>	<b>Due</b>
Feb 26 Week 6	Risk evaluation and mitigation strategy (REMS)  Xyrem case study		
Mar 5 Week 7	Pharmacovigilance/safety surveillance - post-approval safety reporting requirements  Post-marketing safety report case studies	Pre-reads  REMS Product Assignment  Post-marketing safety report case studies (in class assignment/discussion)	Wednesday, 3/5  Writing: 5PM Case Studies: (in class)
Mar 12 Week 8	<b>Spring Break - No Class</b>		
Mar 19 Week 9	Annual Reports Chemistry, manufacturing, and controls (CMC) Part 1	Pre-reads	
Mar 26 Week 10	Chemistry, manufacturing, and controls (CMC) Part 2	Pre-reads  Manufacturing Changes writing assignment  CMC/cGMP Quiz (after class)	Wednesday, 3/26  Writing: 5PM Quiz: 11:59PM
Apr 2 Week 11	Device post-approval landscape (Guest Facilitator)		
Apr 9 Week 12	Advertising and promotion of approved products	Pre-reads  Untitled/Warning Letter Presentations	Wednesday, 4/9 at 5PM
Apr 16 Week 13	Commercial - sales and marketing (Guest Facilitator)		
Apr 23 Week 14	Lifecycle management	Pre-reads	
Apr 30 Week 15	Final presentations and discussion	Final Presentation	Wednesday, 4/30 at 5PM