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

## Spring 2023

**Instructor Information**

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| Course Director | Email | Class Location and Time |
| **Michele A Roy, RN, MS**  | micheleroy06@yahoo.com610-217-7536 | Online (Zoom)Thursdays, 5 p.m. |
| **Course Coordinator** | **Email** |  |
| **Nik Kroushl** | nkroushl@upenn.edu |  |

## 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/participation, class assignments, a midterm exam, and a final exam.

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| **Due Date** | **Assignment Title** | **% of Grade** |
| 2/2/2023 | **Label Section Overview**Short presentation | 10 |
| 2/9/2023 | **Accelerated Approval – Pros and Cons**In class informal debate  | 5 |
| 2/23/2023 | **Risk Evaluation and Mitigation Strategy (REMS) Overview**Short presentation | 10 |
| 3/16/2023 | **Post-Marketing Safety Report Case Studies**Small group in-class activity | 5 |
| 3/23/2023 | **Chemistry, Manufacturing, and Controls (CMC) – NDA Post-Approval Changes**Short writing assignment | 10 |
| 3/23/2023 | **Quiz – Chemistry, Manufacturing, and Controls (CMC)** | 5 |
| 4/13/2023 | **Advertising and Promotion – Untitled and Warning Letters**Short discussion | 5 |
| 4/27/2023 | **Final Project** | 25 |
| Ongoing | **Class Participation** | 25 |

**Academic Policies**

## Attendance

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.

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.

**Participation Expectations**

Participation in class is crucial to 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.

## Academic Integrity

As a student at the University of Pennsylvania, you are required to uphold the Code of Academic Integrity. Specifically, materials that you submit either online or in person should be independent works created by you that uphold all tenets of academic integrity (e.g., 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 constitutes a potential violation.

## Course Management: Canvas

All course materials and assignments will be managed on Canvas. Log in with Pennkey and password at <https://canvas.upenn.edu>.

**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).

## 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](https://upenn-accommodate.symplicity.com/). 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

| 2023 Schedule | Topic | Assignment Due |
| --- | --- | --- |
| Jan 19Week 1  | Course introduction and overview of FDA regulatory environment following marketing application approval, including Prescription Drug User Fee Amendments (PDUFA) | Pre-reads  |
| Jan 26Week 2  | FDA-approved product labeling | Pre-readsFDA website search |
| Feb 2Week 3  | FDA-approved product labeling – how changes are made to labeling post-approval | Label Section Overview Presentations |
| Feb 9Week 4  | Post-marketing requirements, part 1 – accelerated approvals and other situations where PMRs are utilized | Pre-reads |
| Feb 16Week 5  | Post-marketing requirements, part 2 – pregnancy, lactation, pediatrics | Pre-reads |
| Feb 23Week 6  | Risk evaluation and mitigation strategy (REMS)Xyrem case study | REMS Product Presentations |
| Mar 2Week 7  | Pharmacovigilance/safety surveillance – post-approval safety reporting requirementsPostmarking safety report case studies | Pre-reads |
| Mar 9Week 8 | **Spring Break – no class** |  |
| Mar 16Week 9  | Annual ReportsChemistry, manufacturing, and controls (CMC) Part 1 | Pre-reads |
| Mar 23Week 10  | Chemistry, manufacturing, and controls (CMC) Part 2 | Pre-readsManufacturing Changes writing assignmentCMC/cGMP Quiz |
| Mar 30Week 11  | Device post-approval landscape (Guest Facilitator: Monica Lockard) |  |
| Apr 6Week 12  | Advertising and promotion of approved products | Pre-readsUntitled/Warning Letter Presentations |
| Apr 13Week 13 | Commercial – sales and marketing (Guest Facilitator: Dave Knouft) |  |
| Apr 20Week 14 | Lifecycle management | Pre-reads |
| Apr 27Week 15 | Final presentations & discussion | Final Presentation |