REG 6100: Fundamentals of FDA Regulation

# Summer 2023

# Instructor Information

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| Course Director | Email | Class Location & Time |
| **Christine Lee** | [Christinelee000@gmail.com](mailto:Christinelee000@gmail.com) (preferred email);  Please also CC: [Christine.Lee1@Pennmedicine.upenn.edu](mailto:Christine.Lee1@Pennmedicine.upenn.edu) | Thursdays, 5 – 8 p.m.  Online |
| **Course Coordinator** | **Email** |  |
| **Nik Kroushl** | [nkroushl@upenn.edu](mailto:nkroushl@upenn.edu) |  |

# General Information

## Description

This introductory course provides an overview of Regulatory Affairs in relation to three key areas of development: Medical Devices, Drugs, and Biologics. The course explores the rules governing medical devices, prescription and over-the-counter drugs, vaccines, and the rapidly developing arena of genetic engineering and biological product development. Throughout the course, practical issues facing regulatory professionals as they work with the FDA to secure market entry and maintain product approval will be addressed.

## 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 device development during the lifecycle of a regulated 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.
* Determine submission pathways for commercialization in the US for drugs, biologics, and medical devices.
* Determine mechanisms to implement modifications (design, manufacturing/quality) to a marketed medical device
* Understand the requirements for conducting clinical studies and associated pre-market submissions
* Research complex topic, critically analyze one’s findings, compile a presentation, and disseminate one’s discoveries to an audience
* Compile 510(k) submission and demonstrate concept of substantial equivalence to determine predicate conclusion
* Apply best practice submission writing tips and FDA interaction etiquette

## Evaluation and Due Dates

### Evaluation Methods:

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

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| **Percent of Grade** | **Assignment** |
| 15% | Class Participation and Quizzes |
| 45% | Assignments (3 assignments, 15% each) |
| 20% | Presentation |
| 20% | Final Project |

Assignment Schedule

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| --- | --- |
| **Date** | **Subject** |
| May 25, 2023 | Reading assignment |
| June 8, 2023 | Assignment 1: Draft a Regulatory Strategy Plan |
| June 15, 2023 | Class Presentation |
| June 29, 2023 | Assignment 2: Draft a Substantial Equivalence Table |
| July 13, 2023 | Assignment 3: Draft a summary DV report suitable for 510k or PMA submission |
| August 3, 2023 | Final Project & Presentation |

**Class participation (20%):**   
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.

**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%):**

Apply knowledge of regulatory processes and submission requirements to commercialize a class II medical device in the US. Compile a draft 510(k) submission that includes all required elements, including thorough evaluation of substantial equivalence and sufficient objective evidence to support the overall conclusion, and determination of applicable standards and performance testing. The final project will be built on the three assignments described below. The final project must be minimum 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.

**Assignment 1 (15%):**

* Choose a class II medical device currently cleared for market in the US. This device will be the subject of the course final project. These devices can range from orthopedic implants, catheters, medical devices containing software (such as ventilators, MR imaging systems, infusion pumps, etc.), biopsy needles, etc.
* Using FDA 510k Database, complete the Regulatory Plan using template provided.

**Assignment 2 (15%):**

* Research and choose a predicate device for the class II medical device you have chosen for the final project.
* Using the FDA 510k Database, identify an appropriate predicate device. Conduct competitive intelligence by using data provided in the 510k database and completing the SE table provided.

**Assignment 3 (15%):**

* For this assignment, a mock DV test report is provided. The objective of Assignment 3 is to present the test data as would be done in a 510k or PMA submission.
* Read and gain critical understanding of the test report. Outline the testing (~one page) at a high level and describe the following in a succinct manner:
  + Purpose of the test
  + Description of the test articles
  + Summary of test method
  + Acceptance criteria
  + Rationale for sample size
  + Summary table of raw data
  + Conclusion of data

## Academic Policies:

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### 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.

### 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](https://canvas.upenn.edu). 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**](https://urldefense.com/v3/__https:/upenn.us10.list-manage.com/track/click?u=6c89def14a1d88f5cb78518e7&id=22bdd97ae3&e=66d3273cbf__;!!IBzWLUs!TPk0vqHbPJWCqAbCO7VesoIOuzTIRx0XQlopbkilPnv5gR0wbSaeTXYnBN_6NAjVSIuRAaKPwFQXf2DnJwtfp5gVDFMNo7LhEQ2R$) 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 |
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| Week 1  May  25 | **Course Introduction and FDA Overview**  Course and Student Introduction  Role of FDA  What does FDA regulate vs. approve?  FDA structure and important Agency Centers  Determining appropriate FDA center and classification for your product  How to classify Combination Products – Request for Designation (RFD)  Day in the life of typical RA in Industry  Important skills of a RA  RA job trends and outlook  **Syllabus review**  Discussion of Presentation, Project Assignments, and Final Project  **Reading assignment**: “Leaving the Ivory Tower – Alternative careers in science”  **Quiz on reading assignment:** Please complete prior to class; 3 questions on reading assignment). Located in Canvas (Assignments Tab > Participation & Quizzes). | Lee |
| Week 2  June 1 | **Intro to Medical Device Regulation & 510k**  Medical Device definition  FDA Classification Criteria  Intended Use & Indications for Use  Requirements for commercialization (Class I, II, III)  General and Special Controls  510(k) Premarket Notification  Substantial Equivalence  Types of 510(k)’s  Determining if/when a device modification requires a submission and the type of submission  **Class Activity**: Determine the appropriate 510k submission required for different types of devices and situations  **Quiz 2 (Class II & 510k)**: **DUE Thursday, June 8, 2023; 4:59pm (complete prior to class)** | Lee |
| Week 3  June 8 | **510k Continued**  New Product Development (NPD) – Role of Regulatory Affairs  Device Classification Continued  Standards Compliance  Planning & Preparing a 510k submission  Software contained in Medical Device  Device Modifications  **Assignment 1:** Draft a Regulatory Strategy Plan using template provided.  **Class Activity:** Review examples of design and manufacturing changes for a Class II and determine reportability | Lee |
| Week 4  June 15 | **Class Presentation:** 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. | Lee |
| Week 5  June 22 | **Intro to PMA**  Device Classification Categories  Medical Device Advisory Panel  PMA Application process for Class III devices  Types of PMA  Planning & Preparing a PMA (modular)  **Case Study**: Bringing Class III Devices to Market  **Class Activity**: Review examples of design and manufacturing changes for Class III devices and determine reportability. | Lee |
| Week 6  June 29 | **PMA Cont’d + IDE**  Clinical Studies and Trials (IDE)  IDE vs. PMA  Components of IDE Clinical Trials  Expanded Access (Compassionate and Emergency Use)  Submission Writing Tips & Presentation of Data  FDA interaction etiquette  Other Device Submissions  Humanitarian Use Designation (HUD)/Device Exemption (HDE), Q-Sub, De novo, Breakthrough, etc.  Advertising and Promotion  **Assignment 2**: Determine a new primary predicate device (Device B) for the medical device you chose in Section 1 (Device A). Draft Substantial Equivalence table that would be included in a Traditional 510(k) submission. Compare, at minimum, indications for use, materials, design, sterilization method, fundamental technology / principle of operation.  Do not use the predicate already identified in the 510k Summary – choose a new predicate device! Demonstrate that device A is substantially equivalent to device B.  **Case Study**: AdPromo    **Quiz 3 (Class III & PMA): Due Monday, July 10, 2023; 11:59pm.** | Lee |
| July 6 | **Optional office hours (to address questions/concerns about final project)**  **Otherwise, students work on final project** |  |
| Week 7  July 13 | **Drug Development Overview**  Drug Development Process  Discovery and development  Pre-clinical and clinical research  IND  Submissions Process (IND, NDA, ANDA)  eCTD – overview of submission structure  Orphan Drug Designation and Benefits  **Case Study**: TBD  **Assignment 3**: Mock Design Verification (DV) report has been provided. Draft a summary of test results as would be presented in a PMA or 510k submission. | Eileen Doyle |
| Week 8  July 20 | **Biologic Product Development**  Biologic product development  Biologic approval process (BLA) | Naren Chirmule |
| Week 9  July 27 | **Vaccines Design and Development**  Vaccine development  Vaccine Approval Process  Vaccine trials underway  **Class Activity**: Role Play during drug development process | Naren Chirmule |
| Week 10  August 3 | Project Discussions  Career outlook in Regulatory  **FINAL PROJECT**: Draft an Original 510k submission for chosen medical device. |  |