Fall 2022: W4200 Section 001 : BIOPHARMACEUTICAL DEVELOPMENT & REGULATION

Meets: Thursday 4:10pm- 6:00pm, Uris, Room 301

Office Hours 2- 4 (prior to class) on Thursday, Location: TBD

Instructor: Ron Guido

Instructor Contact: rg2492@columbia.edu, ronguido@triuneadvisory.com

Course Description

The program focuses on industry perspectives on biopharmaceutical development and registration activities. It aims to provide current biotechnology, and life sciences students with an understanding of what drives the regulatory strategies that surround the development decision making process, and how the regulatory professional may best contribute to the goals of product development and approval. To effect this we will examine operational, strategic and commercial aspects of the regulatory approval process for new drug, biologic and biotechnology products both in the United States and worldwide. The topics are designed to provide a chronological review of the requirements needed to obtain marketing approval. Regulatory strategic, operational, and marketing considerations will be addressed throughout the course. We will examine and analyze the regulatory process as a product candidates are advanced from Research and Development, through pre-clinical and clinical testing, to marketing approval, product launch and the post-marketing phase. The goal of this course is to introduce and familiarize students with the terminology, timelines and actual steps followed by Regulatory Affairs professionals employed in the pharmaceutical or biotechnology industry. Worked examples will be explored to illustrate complex topics and illustrate interpretation of regulations.

Class Modules

- Basic Terminology and Concepts

- History of Regulation (incl. Regulatory Defined, Major Regulatory Bodies Worldwide)
- Basics of Drug Discovery and Development
- Pharmacokinetics / Pharmacodynamics (from a Regulatory viewpoint)
- Non Clinical Pharm/ Tox (incl. cGMP)
- Standards of Approval (Rx, OTC, Biologics, Biotech)
- IND / CTD / CTx (inc. cGCP)
- NDA / MAA (US, EU, Japan, National
- US Regulatory Filing and Approval
- EU Regulatory Filing and Approval
- Clinical Program Development / Labeling Development and Revision
- Post Approval Actions (Studies, Amendments, Supplements, Variations) EU / US
- cGMP and Inspection
- CM&C and Change Control
- Recalls and Field Actions – Product Queries
- OTC / Consumer Products
- Advertising and Promotion
- Agency Meetings and Communication
- Introduction to Regulatory Assessment and Strategy

All Topics are Supplemeted with Current Issues, and are subject to revision or change

Anticipated Grading Basis :

- **Continuous Assessment: 1-2 Take Home Assessments. May require light research and problem solving**
- **In class graded Workshop**

Textbook (optional):

Drug Discovery and Development: Technology in Transition

H.P. Rang

Churchill Livingstone (Elsevier)

NOTE: Supplemental readings will be posted

Course Summary:

Date	Details	
Wed Sep 20, 2023	Assignment Ungraded Lecture Review	due by
Fri Nov 10, 2023	Assignment Reflection	due by
Thu Dec 7, 2023	Assignment Dec 7 Workshop Prompt	due by