

PHARMACEUTICAL RESEARCH, DEVELOPMENT AND APPROVAL
CHEM 1011 SECTION M12
Spring 2020

**Faculty
Contact
Information**

Prof. Mariana P. Torrente
Class Time: M 12:50-3:30PM
Classroom: 2310 Ingersoll
Office: Ingersoll Hall 3151
Office hours: M10:00-11:00am or by appointment
Email: mariana.torrente@brooklyn.cuny.edu, **note CHEM1011** in subject line.

**Course
Description**

This course will study the procedure by which medications are developed, tested, and approved for sale. Through selected case studies, we will explore the biochemical basis for drug action and analyze the role of the Food and Drug Administration and the federal government in assuring drug safety. We will also discuss the ethical issues surrounding the pharmaceutical industry, drug development and marketing. Course assessment includes one mid-term assignment and one final assignment as well as short writing assignments throughout the semester and class participation.

**Course
Materials**

1. *Overdosed America: The Broken Promise of American Medicine* by J. Abramson
2. *Drugs for Life: How Pharmaceutical Companies Define Our Health* by J. Dumit
3. *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs* by J. Avorn
4. *Blockbuster Drugs: The Rise and Decline of the Pharmaceutical Industry* by J. J. Lee
5. *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients* by B. Goldacre
6. *The Quest for the Cure* by B. Stockwell
7. *Saving Normal: An Insider's Revolt against Out-of-Control Psychiatric Diagnosis, DSM-5, Big Pharma, and the Medicalization of Ordinary Life* by A. Frances
8. Primary scientific literature papers and news articles will be posted in Blackboard prior to class sessions.

**General
Education
Objectives**

- **Gather, interpret, and assess information from a variety of sources and points of view.** *You will be required to read primary scientific literature and a range of books and overviews of topics related to healthcare and medicine. Furthermore, you will be gathering relevant background data in support of policy modifications suggestions of your own in two assignments throughout the term.*
- **Evaluate evidence and arguments critically or analytically.** *We will review case studies related to drug development, including the procedures used by the US FDA to ensure safety and efficacy. You will be asked to critically assess evidence of drug action. You must pay attention to conflicts of interest for entities carrying out pre-clinical and clinical studies, critically assess control and treatment populations, and individual and statistical success of treatments. We will discuss both technical and ethical issues.*
- **Produce well-reasoned written or oral arguments using evidence to support conclusions.** *You will have one mid-term assignment and one final assignment in which you will either write or present about a topic of your choosing. Grading rubrics will assess completion of the course objectives.*
- **Identify and apply the fundamental concepts and methods of a discipline or interdisciplinary field exploring the scientific world.** *We will study the mechanism of action of different drugs and their role in human health. Lectures and readings activities will describe fundamental concepts in drug development, the biochemistry behind the action of selected pharmaceuticals and the statistics supporting their efficacy. We will discuss the nature of a range of illnesses and the mechanisms of drug action that address them. Methods by which mechanisms of action are elucidated will be briefly discussed. Biochemical and concepts will be applied to the interpretation of clinical studies supporting drug approval.*

- General Education Objectives (continued)**
- **Articulate and evaluate the empirical evidence supporting a scientific or formal theory.** *You will be required to a range of materials covering topics related to biochemistry, healthcare and medicine. You will evaluate the studies' validity based on the statistical data presented.*
 - **Understand the scientific principles underlying matters of policy or public concern in which science plays a role.** *We will review case studies related to drug development and marketing and their influence on population health, including the procedures used by the US FDA to ensure safety and efficacy. In-class discussion will include both technical and ethical issues.*

- Course Learning Objectives**
- Understand the scientific evidence behind drug approval, and how it is evaluated by federal agencies to ensure drug safety and efficacy.
 - Understand the relationship between science and policy.
 - Understand how physical science is used to justify policy decisions impacting public health.
 - Suggest policy revisions in light of changes in science.
 - Understand the legal and ethical issues that are involved in pharmaceutical drug development and regulation.

- Course Obligations**
- **Attendance**
 - ⇒ You are expected to **attend all class meetings** of this course. A grade of "0" will be assigned to all missed assignments.
 - ⇒ If you must miss class, you are responsible for all material covered during your absence. Make arrangements to get any missed lecture notes and/or handouts from a classmate.
 - **Participation**

You are **EXPECTED** to participate in class and voice your opinion on the topics covered. Various assignments throughout the semester will facilitate participation. Participation and short unannounced quizzes will heavily factor into the final grade for the course.

Grading Your final grade will be calculated as follows:

Midterm Assignment*	20%
Final Assignment*	30%
Short Writing Assignments: Question of the Day	15%
One Page Written Reports	15%
In-Class Participation	20%

*Specific assignments will be chosen by class on the first day of lecture

- Grading Policies**
- Assignments must be submitted during the class period on the assignment deadline. All missed assignments will receive a grade of zero.
 - If you are unable to submit an assignment **due to a documented extenuating circumstance**, you will be given the opportunity to turn in your assignment late.
 - ⇒ If you are unable to submit a assignment, you must contact the instructor prior to the assignment deadline.
 - ⇒ In the event of unpredictable extenuating circumstances, other arrangements may be made after discussion with the instructor and possibly the Dean as warranted. At the instructor's discretion, a grade of "0" will be assigned to any quizzes and/or writing assignment where academic dishonesty is displayed.

Important Information

- **Academic dishonesty is prohibited in the City University of New York.**

Cheating, plagiarism, internet plagiarism and obtaining unfair advantages are violations of policies of academic integrity and are punishable by penalties, failing grades, suspension and expulsion. For more information about CUNY policy on academic integrity see

<http://www.brooklyn.cuny.edu/bc/policies/pdt7CUNY%20PolicyAcademicIntegrity.pdf>

- **Student Withdrawals**

⇒ **If you decide to withdraw from this course, it is your responsibility to do so by the Deadline for Student Withdrawals (April 1st, 2020).**

- **Library Services**

All course books are on reserve at the Library. Some are also available as electronic books. Librarians can help you access them.

- **Students with Disabilities**

In order to receive disability-related academic accommodations students must first be registered with the Center for Student Disability Services. Students who have a documented disability or suspect they may have a disability are invited to set up an appointment with the Director of the Center for Student Disability Services, Ms. Valerie Stewart-Lovell at 718-951-5538. If you have already registered with the Center for Student Disability Services please provide your professor with the course accommodation form and discuss your specific accommodation with her.

- **No part of lecture can be recorded without the instructor's written permission.**

A student requiring this particular accommodation must follow the procedures for students with disabilities detailed above.

- **Immigrant Student Success Office**

The Immigrant Student Success Office (ISSO) is to recruit, enroll, and retain students, with an emphasis on new immigrants like the students granted Deferred Action for Childhood Arrivals (DACA) who identify with the Development, Relief and Education for Alien Minors act (DREAMERS), and first-generation students by providing the necessary academic and non-academic support to ensure graduation from Brooklyn College in a timely manner.

Course Assessment

Assessment of the knowledge of the course material:

Short writing assignments, one midterm assignment, and one final assignment will assess students' understanding of terminology and concepts associated with pharmaceutical drug approval.

Assessment of the communication skills:

Students are expected to participate heavily in class discussion, drawing from the assigned readings and their own experiences and critical analysis.

Students will have two longer assignments as well as short writing assignments throughout the term.