**Supplemental Materials**

**Questionnaire 1**

1. What kind of careers exist in research?
2. Do you have any research experience? If yes, please describe.
3. What job do you hope to have with your major?
4. Circle one: I am a freshman, sophomore, junior, senior.
5. Why are you interested in this class?

**Questionnaire 2**

1. Are science exams as stressful as other exams, or more?
2. Does this class have the same amount of opportunities for presentations as other classes, or more?
3. Is this class format similar or different compared to your other science classes?
4. How many careers in the research field can you name?
5. Has this class introduced you to careers in research that you did not know about?
6. Up until now, has this class influenced/changed your career goals?

**Questionnaire 3**

1. Should this class be required?
2. When should a student take the class?
3. Do you think your class trajectory would have changed if you had taken this class earlier?
4. How confident were you in your communication skills before?
5. What soft skills have you acquired?
6. Do you think your presentations skills improved/did you think presenting so often helped you learn?
7. How much did you improve your science communication skills?
8. To whom would you be comfortable presenting a scientific paper?
9. What can we do to improve this class?
10. What was this class most successful at? Why?
11. Was there anything you did not like in the class but found helpful?
12. Did this class help you become more aware of careers in STEM? How?

# **Image result for dna helix no background“The Pipeline of Drug Development: From Basic Research to Your Medicine Cabinet”**

**Category:** Biology*;* Oral communication

**Instructor:** Laura Laranjo, MS

**Email:** llaranjo@brandeis.edu

**Target Audience:**

This course is designed for students majoring in Biology, HSSP, Biotechnology, and Biochemistry. Students aiming to go to medical/ graduate school are highly encouraged to take it.

# **Prerequisites**

Basic knowledge of molecular and cell biology will be expected, therefore, Biol 14a and 15b or Biol 22a/b are prerequisites for this course.

# **Course Description and Objectives**

We all have extensive access to many different FDA approved drugs that are useful in treating multiple injuries and diseases – many of which have become so commonplace that they can be readily found at bedsides and medicine cabinets across the globe. However, we might not often consider how these drugs are discovered and how they impact our biology. In this course, we will explore the biology and ethics behind specific drugs to better understand drug development and treatment. We will focus on cancer and antiviral drugs, their mechanism of action, and how scientists decide drug benefits versus drug risk. In addition, we will explore the role that society and science policy play in drug development pipeline. The class format will consist of lectures and group discussions. Lectures will focus on the biology of drug development, and group discussions on interpreting scientific articles, to engage students in understanding and critiquing past and current scientific research. Students will have the opportunity to practice and improve their oral communication and writing skills by presenting scientific papers, writing technical science pieces, peer review, and interacting with different audiences.

# **Learning Goals**

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

* Explain how drugs are designed to target cellular processes.
* Compare and contrast targeted and off target effects of different chemotherapeutic and antiretroviral drugs.
* Analyze and critique scientific research articles.
* Distinguish between ethical and unethical scientific behaviors and thoughtfully discuss potentially controversial grey areas.
* Engage in scientific discussions in the drug development pipeline across different fields.
* Utilize verbal and written skills to effectively convey scientific ideas to a target audience.

# Course Plan

**Topic 1: Introduction: Overview of the Pharmaceutical Development Pipeline (08/29) Day 1: From Molecules to Medicine**

Students will be exposed to the main six steps of the pharmaceutical development pipeline: Discovery and development, preclinical research, clinical research, FDA review, FDA post- market safety monitoring and clinical trials.

**Assignment:** Students will read the article “The Biomanufacturing Career Track” from Science 2009, and write a one-page paper about different roles scientists have in the Pharmaceutical Development Pipeline. \*\*In class: Literature Scavenger Hunt.

**(09/05) Day 2: Careers in the field.** Class will be divided into different profession focus groups and they will debate the role of each professional role along the pharmaceutical development pipeline, and will come up with ethical concerns belonging to each position. Those concerns will be revisited and studied later on the semester.

# **Topic 2: Research and Development**

**(09/06) Day 1: Drug Discovery:** The history of Taxol (chemotherapy) and Azidothymidine (HIV drug) will be covered, where students will learn cell pathways, drug targets, and the two most popular methods of drug discoveries: small molecule library and natural antibiotic resistance.

**Assignment:** Students will choose one article out of two options, and come to class with a “lobbyist” 3 minutes elevator speech to present to congress their views on new approaches on drug discoveries.

Option 1: A Majorly Unexplored Domain for Drug Discovery, 2017

Option 2: Leveraging Traditional Knowledge for Drug Discovery, 2017

**(09/12) Day 2: Basic Research & Drug Design**. In a journal club style, as a class we will go over the main methods and findings of each paper where each student will have the opportunity to explain a figure from the paper or to ask questions.

**Topic 3: Antibacterial drugs**

**(09/17) Day 1: Superbugs:** Class will focus on epidemic superbugs in history and what mechanisms bacteria use to be resistant towards multiple antibiotics.

**Assignment:** Students will choose one article out of two options and come prepared to discuss major findings.

Option 1: Nanomedicine and Biotherapeutics for Antibiotic Resistance Bacteria, 2015 Option 2: Future Antibiotics: New Weapons against Emerging ‘Superbugs’?, 2013

 **(09/25) Day 2:** Antibiotic design. Class will focus on major targets of antibiotic design and mechanism of bacterial resistance. Findings from papers will be reviewed and discussed in a journal club style.

**Topic 4: Viral Diseases**

**(09/26) Day 1:** Virus: Mode of infection. Lecture will focus on the different types of viruses and modes of infection.

**Assignment:** Students will choose one paper, and write a one page summary for a general audience about the virus studied and its mode of infection.

Option 1: Conserved HIV Epitopes for an Effective HIV Vaccine, 2017

Option 2: Immunogenicity & Protective Efficiency in Mice of a Smallpox DNA Vaccine, 2017

**(10/03) Day 2:** Virus: Vaccines and treatment development. Lecture will focus on vaccine development, and how some viruses cannot be prevented by vaccination. Side effects as well as vaccine accuracy will be discussed.

**Topic 5: Drug specificity**

**(10/08) Day 1: Off- label usage: Specificity of Action.** Class will be exposed to the mechanisms behind drug specificity as well as off target effects. Drugs such as Viagra and 5-azacytidine will be studied.

**Assignment:** Students will read both articles assigned and come to class ready to discuss each of their main findings in a journal club style.

#1: How sildenafil (Viagra® ) may cause melanoma: a histopathologic study providing a potential physiological/etiopathological mechanism, 2017.

#2: Induction of complete remission by azacitidine in a patient with myelodysplastic syndrome- associated inflammatory bowel disease, 2017.

**(10/10) Day 2: Mechanisms of Action - Drug Effect**. In a journal club style, class will discuss the mechanisms of actions described in the articles assigned.

**Topic 6: The impact of DNA sequencing in Drug Development**

**(10/15) Day 1: Genomics and Drug Discoveries:** Lecture will focus on new genomics techniques and how DNA sequencing has been advancing drug development.

**Assignment:** Students will write a one page paper about the relationship between genomics and drug discoveries. Students can choose, but are not limited to using both papers assigned.

#1: A Step towards Advancing Clinical Trials. J Pharmacogenomics Pharmacoproteomics, 2017

#2: Genomics, Epigenetics and Molecular Considerations in Esophageal Adenocarcinoma, 2017

**(10/17) Day 2: Personalized Medicine.** Class will focus on current personalized medication options for treatment of immune diseases and late stage cancer.

# **Topic 7: Drug Schedule**

**(10/22) Day 1: Drug Classification**. Lecture will focus on the six different drug categories and how they are classified.

**Assignment:** Students will read both articles below and in pairs present (5 minutes) 1 PowerPoint slide on an assigned branch of the Opioid Epidemic.

#1: Prospective, Longitudinal Study to Evaluate the Clinical Utility of a Predictive Algorithm to Detect Opioid Use Disorder in Chronic Pain Patients, 2017

#2: Medical Response to the Opioid Epidemic. J Alcohol Drug Depend, 2017

**(10/24) Day 2: The Opioid Epidemic.** Class will focus on the molecular and biological responses a human body goes through after opioid exposure and addiction.

**Topic 8: Review and Presentations**

**(10/29) Day 1: Group Presentation**. Groups selected during the first day of class, will choose a lecture of their choice and present a short review of the material to the class.

**(10/31) Day 2: Midterm.** Exam will include biological fundamentals of drug development, as well as different types of drugs and new pharmaceutical science techniques.

**Topic 9: Clinical trials**

**(11/05) Day 1: Clinical Research.** Lecture will include biomedical research studies used to determine drug efficiency. Biological response between preclinical research and clinical research will be compared and debated.

**Assignment:** Students will choose one of the articles below and write a 1-2 pages summary of the major findings of their chosen paper.

#1: Global Challenges in Cardiovascular Drug Discovery and Clinical Trials, 2017.

#2: Innovations in Outcomes & Designs of Clinical Trials for Respiratory Drug Development, 2017

**(11/07) Day 2: The Usage of Clinical Trials as Primary Treatment.** Class will focus on the biological pathways and the body’s response to drugs that are currently used in clinical trials for late stage cancer treatments.

**Topic 10: Drug Safety**

**(11/12) Day 1: The Food and Drug Administration (FDA) Approval – Drug Recall and Safety.** Students will be exposed to the rules and regulations of the FDA in order to approve a drug. Biological concerns will be revisited and used to determined risk and benefits.

**Assignment:** Students will read both papers prior to class. Class will be divided in groups. Each group will receive a fake drug name. Although the name will be fake, the actual biological pathways, and clinical studies will be real. Students will have the same information presented to the FDA for drug approval, and then they will decide if the drug is safe or not.

#1: FDA Approved Drugs as Potential Ebola Treatments, 2015

#2: FDA-Approved Drugs That Are Spermatotoxic in Animals & the Utility of Animal Testing for Human Risk Prediction, 2017

**Topic 11: Off to the Public**

**(11/14) Day 1: Marketing and Advertising, Pricing & Accessibility.** The impact of the media in drug administration will be discussed focusing on drugs that are under appreciated due to lack of advertisement versus drugs with little effect that are popular. Issues related to drug accessibility in the U.S. and in the world will be discussed.

**Assignment:** Students will read both articles and come to class prepared to engage in discussion.

#1: Drug Affordability and Prescription Noncompliance in the United States, 2004

#2: Prescription Drug Accessibility and Affordability in the United States and Abroad, 2010

# **Topic 12: Time for a New Drug**

**(11/19) Day 1: Public Perception and Interest in Development and Drug Distribution**. Class will focus on major social issues that affect drug development. Cases of superbugs that caused a rise in antibiotic development, and cases of virus epidemic that influenced quick vaccine development will be addressed.

**Assignment:** Students will watch the movie “Lorenzo’s Oil” and write a two-page essay about the movie and how it relates to this week’s topic.

**Case studies from the NSF - 2010 National Center for Case Study Teaching in Science.** Class will be divided in groups to discuss case studies in this topic.

Case study 1: “When Drug Sales and Science Collide”

Case study 2: “Agony and Ecstasy Party Drug or Breakthrough Treatment for PTSD?”

**Topic 13: Science Policy**

**(11/26) Day 1: Science Policy and Drug Development.** The role of politics in drug development will be studied, as well as how the public can contribute to changes in regulation.

**Assignment:** Read before class: WHO and UNDP Change in Leadership: What Views on Drug Policy and Harm Reduction, 2017

**Topic 14: Ethics in Drug Development**

**(11/28) Day 1: Ethics and Oversights.** Lecture will focus on ethical concerns during the drug development pipeline.

**(12/03) Review.**

**(12/05) Topic: Final Presentations:** Students will present in groups a PowerPoint style talk about a drug of their choice, including drug safety, public and ethical concerns, and the biological aspects covered throughout the semester. \*Review sheet for the final exam will be given out and extra office hours will be announced.

**Final Exam:** Date determined by Brandeis.

 **Evaluation**

|  |  |  |
| --- | --- | --- |
| **Categories** | **Points** | **Percentage** |
| Class attendance and participation | 26 | 5% |
| Homework Assignments | 120 | 10% |
| Group presentation | 100 | 20% |
| Final Presentation | 100 | 20% |
| Midterm Exam | 100 | 20% |
| Final Exam | 100 | 25% |
| Total | 546 | 100% |

# **Course Materials**

All reading materials will be posted on Latte and will consist of scientific reviews, articles, and chapters from the book “Molecules and Medicine” by Corey, Czakó and Kürti. Grading will be determined by attendance, participation, reading assignments, literature review, exams and presentations.

**Class attendance and participation (1 point per day):** The nature of this course mandates class participation, therefore students will be required to attend every class. Excused absences will require signed documentation to the instructor.

**Homework assignments (10 points each, 120 points total):** Assignments will assess the ability of each student to understand the material and to practice the skills learned. Each week students will be assigned tasks towards a corresponding lecture.

**Group Presentation (100 points), and Final Presentation (100 points):** As an oral communication course, this class will combine the knowledge learned and presentation skills acquired throughout the semester. Students will present in a PowerPoint format to an audience. All presentations will be scored by instructors and guests and the ability of each student to orally explain the selected topic will be evaluated.

**Midterm (100 points), and Final Exam (100 points):** Students will be tested on their knowledge of the material taught. Exams will focus on the biological processes covered in lectures used by drugs in targeting their goal. Final exam will also include ethical concerns and public safety issues related to drug development.

**Extra credit:** “Drugs in the news”. We will discuss this fun activity in class!

# **Disabilities**

If you are a student with a documented disability on record at Brandeis University and wish to have a reasonable accommodation made for you in this class, please see me immediately\*.

# **Academic Integrity**

You are expected to fulfill Brandeis rules and regulations in all of your academic work. Please see Brandeis University Rights and Responsibilities for all policies concerning academic integrity. Students may be required to submit work to TurnItIn.com software to verify originality. Allegations of alleged academic dishonesty will be forwarded to the Director of Academic Integrity. Sanctions for academic dishonesty can include failing grades and/or suspension from the university. Citation and research assistance can be found at LTS - Library guides\**.*

**Privacy**

This class requires the use of tools that may disclose your coursework and identity to parties outside the class. To protect your privacy you may choose to use a pseudonym/alias rather than your name in submitting such work. You must share the pseudonym/alias with me and any teaching assistants as needed. Alternatively, with prior consultation, you may submit such work directly to me\*.

**Title IX**

This is a reminder that Brandeis is in common agreement with the rules of Title IX of the Education Amendments of 1972.

# **Communications**

# Any syllabus changes or accommodations for snow days/unexpected events will be sent by email.

**Critical Dates**

Final exam will take place on the University assigned time slot.

**Credit Hours**

Success in this four- credit course is based on the expectation that students will spend a minimum of 9 hours of study time per week in preparation for class (readings, papers, discussion sections, preparation for exams, etc.)\*.

**\****Taken from the Brandeis website: http://www.brandeis.edu/registrar/faculty/docs/1819/course\_approval\_revised\_103017.pdf*