RUTGERS UNIVERSITY

Department of Chemical and Biochemical Engineering

Pharmaceutical Engineering Program

16:155:545 Synthesis, Separation and Sterile Processing in the Pharmaceutical Industry

Fall 2021 Syllabus

Instructor: Prof. Ben Glasser

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Office Location: C231, C-Wing, School of Engineering

Webpage: https://canvas.rutgers.edu

Class: Tuesdays, 5pm-8pm, Online

Office Hours: Tuesdays: 4pm-5pm, 8pm-8:30pm, or by appointment (email the instructor)

Course Description

This course provides an introduction to synthesis, separation, and sterile processing and their application to designing and optimizing pharmaceutical processes. The course focuses on the production of the drug substance or Active Pharmaceutical Ingredient (API) as one of the parts of Pharmaceutical Manufacturing.   Fundamentals of API synthesis will be discussed using industrial pharmaceutical examples including separation, distillation, crystallization, filtration, chromatography, milling, lyophilization, and drying processes. The course starts with an overview of pharmaceutical manufacturing and then delves into the API processing steps. The focus will be on chemically synthesized API's or API's that are produced using chemical processes. There will be an introduction to biologically synthesized API's or API's produced using biological processes using cell lines. There will be a lot of writing in this class and around half of the content of assignments and exams will involve writing as opposed to solving equations or doing math problems.

Course Learning Objectives

Upon the completion of this course, the student will be able to:

- Describe how pharmaceuticals are developed and brought to the market.
- Describe how the Active Pharmaceutical Ingredient is manufactured.
- Identify the processes that are used in manufacturing of the Active Pharmaceutical Ingredient.
- Compare and contrast quality attributes of the Active Pharmaceutical Ingredient and examine how these attributes are affected by processing steps.

Textbook

There is no textbook for the class. Readings and relevant material will be posted on the course site.

ASSIGNMENT AND GRADING POLICY

Assignments/Homeworks

Homework problems will be assigned most weeks. The homework problems will be posted on Canvas and submitted on Canvas. Assignments must be submitted online by the specified deadlines. Acceptable formats are pdf or MS word files – please submit a single pdf or MS word file.

Lecture Outlines

The lecture material will be posted online which will allow you go to the material at your own pace. Weekly lecture outlines (to be submitted online) will help motivate you to watch the online lectures. As you listen to the lectures please take notes, as you would if you were sitting in class listening to the lecture. As part of your notes you should also write down the main points of each lecture and thus develop a lecture outline. Acceptable formats are pdf or MS word files – please submit a single pdf or MS word file on Canvas.

Exams

There will be a midterm and final exam. Further details on the exams will be given during the semester.

Project

The project will involve a written report that you will do alone. Further details on the project will be provided once the semester starts.

Grading Scale

Final grades include A, B, B, C, C and F. An "A" will only be given for outstanding work. In addition to the content of your assignments and other graded material, you will also be graded on your professionalism and your ability to follow directions/instructions. All assignments/coursework need to be completed by the indicated deadlines and you need to follow directions/instructions carefully. You will lose points for not following directions, incorrect grammar, and spelling mistakes.

Care, Respect, Integrity and Kindness

These four words apply to the written and verbal exchanges of this class. A respectful attitude is expected for class discussions and interpersonal communication with the instructor and colleagues. Our classroom and learning environments are safe and open spaces. Please be respectful of each other and of your instructor.

Academic Integrity

Students are expected to follow the Rutgers University policies on academic integrity.