

CHEN E4920 Pharmaceutical Industry for Engineers Syllabus Fall 2020

Instructor: Aaron Moment, ajm2293@columbia.edu

Prerequisites: Undergraduate General Chemistry, Organic Chemistry

Course Description: This course provides students an overview of biopharmaceutical design, development, manufacturing, and regulatory requirements from an engineering perspective. The unit operations, equipment selection, and process development associated with small molecule, biologics, and vaccine manufacturing are all illustrated through examples, and quantitative engineering approaches are applied as appropriate. Small molecules, biologics, vaccines, solid oral formulations, sterile processing, and design of experiments (DoE) are treated.

Learning Objectives: Students will learn statistical and risk-assessment approaches to product development, and develop a foundational knowledge of the regulatory and engineering requirements for developing a new biopharmaceutical product. In addition, several chemical engineering transport and thermodynamic analyses will be applied to pharmaceutical unit operations including crystallization, filtration, gas-liquid mass transfer, and industrial mixing.

Lessons:

Week 1: Modalities, chemical structure, and therapy: small molecules, biologics, and vaccines

Week 2: Mixing and Scale-up in Stirred Tanks

Week 3: Filtration and Drying

Week 4: Crystallization and Polymorphism

Week 5: Powder Processing

Week 6: Solid Oral Formulation and Controlled Release

Week 7: Review

Week 8: Vaccine Processes

Week 9: Biologics Upstream Processing

Week 10: Biologics Downstream Processing

Week 11: Sterilization Technology

Week 12: Design of Experiments (DoE) in process development

Week 13: Process Validation and FDA Regulations

Week 14: Review and project presentations

Grading:

33% Mid-Term

33% Final

33% Project

Texts:

Recommended:

“Chemical Engineering in the Pharmaceutical Industry: R&D to Manufacturing” A. Am Ende
D.G., Wiley & Son, 2010

Supplemental texts provided via Courseworks.

Project:

Final projects will be assigned about ½ way through the class, and are due the last week. Projects have a ~ 5 page written report to the instructor, and a recorded video presentation to the class. A typical project will encompass a literature review and a design proposal or experimental plan. You may consult with anyone you wish to provide input on your reports and projects, but please provide documentation and acknowledgement of all your sources.

Academic Integrity: *Turning in anything that does not represent your own work or thought process is considered plagiarism and is subject to the Columbia policy on Academic Integrity. You are expected to cite and credit others as appropriate.*

Mid-Terms and Final : The mid-term and final are administered as a quizzes via Courseworks and involve multiple choice answers as well as calculations.

