ChE/EID 475 - Pharmaceutical Engineering
Fall 2011
Department of Chemical Engineering
The Cooper Union for the Advancement of Science and Art

Instructor: Daniel Lepek, Ph.D., Assistant Professor of Chemical Engineering

Contact: Office: Room 418, Phone: +1.212.353.4379, Email: `lepek@cooper.edu`

Office Hours: Tuesdays 10-11am, Thursdays 11am-12pm, and by appointment

Textbook: *Chemical Engineering in the Pharmaceutical Industry: R&D to Manufacturing.* Edited by David J. am Ende. 1st ed. Wiley (2010)

Prerequisites: ChE121, ChE142, and Ch262, or permission of instructor

Catalog Description

ChE/EID 475 - Pharmaceutical Engineering Introduction to Pharmaceutical Engineering. Overview of the pharmaceutical industry and drug discovery and development. Clinical trials, regulation, and validation. Scientific principles of dosage forms including solutions, disperse systems, dissolution, stability, and surface phenomena. Drug dosage form and drug delivery system design. Biopharmaceutical principles of drug delivery. Pharmacodynamics, pharmacokinetics, and biopharmaceutics. Unit operations for solid and liquid dosage forms. Pharmaceutical plant design.

Course Introduction

The design, development, engineering, and manufacture of pharmaceuticals and drug products encompasses a wide variety of chemical engineering principles. This course will introduce students to the fundamentals behind how drugs are engineered in the pharmaceutical industry. An overview of the pharmaceutical industry, including concepts on drug discovery and development and regulatory and approval processes will be provided. The principles behind pharmacodynamics, pharmacokinetics, and biopharmaceutics will be presented to show how dosage forms are linked to drug delivery systems. The course will culminate in a survey of pharmaceutical unit operations used to develop, engineer, and manufacture active pharmaceutical ingredients, as well as the solid and liquid dosage forms of the drug product.

Grading Scheme

Graded Assignments – 10 %
Midterm Exam – 35 %
Final Exam – 35 %
Project/Presentation – 20 %

Final Course Grade Scheme
From the Cooper Union Course Catalog:

A - superior and comprehensive grasp of the course principles
B - good degree of familiarity with the course principles
C - average knowledge of the course principles and fair performance
D - minimum workable knowledge of the course principles
F - unsatisfactory understanding of the course principles

Final letter grades will be determined based on the above grading scheme and definitions of the final course grade scheme. Curving is at the discretion of the instructor. For those students whose weighted average is in a *gray area* between two letter grades, the following factors will influence your grade: (a) class attendance and participation in class, and (b) whether your performance has been improving or declining during the course period.

Policies

1. **Class Attendance:** Students must attend all classes. Absences from class will inhibit your ability to fully participate in class discussions and can therefore affect your grade. Tardiness to class is very disruptive to the instructor and students and will not be tolerated.

2. **Assignments:** Assignments are due on the date assigned and will be collected at the *beginning* of class. Late assignments will only be accepted under extraordinary circumstances and might be penalized. Students are expected to work on all assignments (including computer assignments) independently. Graded assignments (and exams) must be written legibly in an organized, structured fashion.

3. **Exams:** The format of the exams may be open or closed notes and/or text. Cell phones and other electronic devices are **not** permitted during exams. Make-up exams will only be given under extraordinary circumstances and at the sole discretion of the instructor. It is the student's responsibility to inform the instructor of any conflicts.

4. **Plagiarism:** Plagiarism will **not** be tolerated. According to the Cooper Union Course Catalog, "plagiarism is the presentation of another persons 'work product' (ideas, words, equations, computer code, graphics, lab data, [*solutions manual*], etc...) as one's own. Whether done intentionally or unintentionally, plagiarism will not be tolerated in the School of Engineering." Please refer to the Cooper Union Course Catalog for more information.

5. **Technology:** Students are expected to bring a calculator to all classes (including for exams). The use of laptop computers and other electronic devices during class will be not allowed, unless approved by the instructor. For some assignments, computational software such as COMSOL and MATLAB might be required. Course materials will be posted on the The Cooper Union Moodle website (`http://moodle.cooper.edu/moodle/`). Lastly, students are expected to check their e-mail on a **daily** basis.

Course Outline

- Introduction to Pharmaceutical Engineering (Ch. 1, 2)
  - The Pharmaceutical Industry
  - Drug Discovery and Development
  - Clinical Trials
  - Regulation and Validation
- Scientific Principles of Dosage Forms
  - Dissolution and Stability
  - Properties of Solutions and Disperse Systems
  - Surface and Interfacial Phenomena
- Biopharmaceutical Principles of Drug Delivery
  - Drug Delivery
  - Pharmacodynamics
  - Pharmacokinetics
  - Biopharmaceutics
- Active Pharmaceutical Ingredient (API) Unit Operations
  - Crystallization (Ch. 13)
  - Membrane Separation Operations (Ch. 16)
  - Filtration and Drying (Ch. 17)
  - Chromatographic and Fixed Bed Separations (Ch. 18)
  - Distillation and Extraction (Ch.12)
  - Mixing (Ch. 14, 15)
- Drug Product and Dosage Form Unit Operations
  - Design of Solid Dosage Formulations (Ch. 36)
  - Granulation (Ch. 38, 39)
  - Milling (Ch. 19)
  - Coating (Ch. 40)
  - Freeze-Drying (Ch. 41)

- Special Topics
  - Drug Solubility and Thermodynamics (Ch. 24, 25, 27)
  - Quality by Design (Ch. 5, 29, 34, 35)
  - Sterilization
  - Pharmaceutical Manufacturing (Ch. 43)
  - Pharmaceutical Plant Design

The contents and order of the course are tentative and subject to revision. The amount of time devoted to each topic will vary as the semester progresses.

Important Dates

Midterm Exam – October 2011
Final Exam – December 15 or 20, 2011
Project/Presentation – December 2011
AIChE Conference – October 16-21, 2011

References

The following textbooks are on reserve in the library:

1. *Chemical Engineering in the Pharmaceutical Industry: R&D to Manufacturing*, Edited by David J. am Ende. Wiley (2010)
2. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems* by Allen, et al. Lippincott Williams & Wilkins (2011)
3. *Aulton's Pharmaceutics* Edited by Aulton. Churchill Livingstone (2007)
4. *Martin's Physical Pharmacy* by Sinko. Lippincott Williams & Wilkins (2011)
5. *Separation Process Principles* by Seader and Henley. Prentice-Hall (2006)