Purdue University CHE 59700: Medical Devices: Development and Clinical Application (Fall 2019)

A. Instructor. William R. Clark, M.D.

B. Course Description. This course is an introduction to the medical device field, with emphasis on the ways in which chemical engineering processes provide the foundation for many device-related therapies. The course involves the application of several fundamental chemical engineering principles, including those related to transport phenomena, separations, and fluid flow, to devices used for extracorporeal therapies and other treatments. Several clinical conditions in which these considerations are relevant are discussed, using the treatment of renal failure by dialysis as a large, representative medical device sector. Finally, the vital roles that chemical engineers may play in the various functions comprising a medical device company are highlighted. New topics for the course this semester include the principles of verification/validation, lean manufacturing, and project management as they relate to medical device development from the chemical engineering perspective. (Ms. Michelle Chutka, Director of Product Engineering at Cook Biotech, will provide these lectures.) An additional new topic is drug/device combinations, with focus on drug delivery systems for biologic pharmaceutical products.

C. Prerequisites. CHE 37700 and BIOL 23000 (or BCHM 30700); or permission from the instructor.

D. Recommended (NOT REQUIRED) Texts.


E. Course Learning Objectives. The overall objective of this course is to provide students a detailed foundation regarding the medical device industry from a chemical engineer’s perspective. After an initial overview of relevant physiologic principles, this learning is achieved by structuring the course in three parts, the first two of which focus heavily on extracorporeal therapeutic devices.

- **Chemical Engineering Processes for Medical Devices.** Identify the mechanisms of blood-surface interactions defining the biocompatibility of an extracorporeal device; describe the influence of extracorporeal membrane structure and material on transport properties (diffusion, convection, and ultrafiltration) and the overall effect on device performance; characterize and quantify the role of adsorption in extracorporeal therapies designed to extract molecules of specific size or chemical nature; explain the implications of different blood flow regimes (laminar versus turbulent) on both the removal properties of membrane-based devices and the function of different vascular access devices; define device-related and patient-related (physiologic) parameters required for kinetic modeling of different therapies.

- **Quantitative Characterization of Extracorporeal Therapies.** Apply general learnings from the first part of the course to treatments used for specific clinical disorders, including end-stage renal disease (ESRD), acute kidney injury (AKI), sepsis, cardiac failure and respiratory failure; describe the major technical factors influencing delivery of therapy in each of these categories and the manner in which treatment success is measured, both from a patient and device perspective; describe the engineering challenges associated with the development of novel devices for the treatment of renal failure.

- **The Chemical Engineer and Medical Device Industry.** Delineate the components of a medical device company and the manner in which these different functions interact during the pre-market and post-market phases of a product; describe in particular those functions for which chemical engineers play an important role over the entire life-cycle of a product, including research and development, manufacturing, regulatory affairs, sustaining engineering, intellectual property, and business development; understand the application of medical device principles in the development of drug/device combinations.
F. Course Meeting Schedule.

Lectures: Tuesday and Thursday 10:30-11:45 AM HAMP 2108
Presentation 1: 11/05 (Tuesday) 10:30-11:45 AM HAMP 2108
Presentation 2: 12/03 (Tuesday) 10:30-11:45 AM HAMP 2108
Final Report due: 12/06 (Friday) 5:00 PM FRNY 2158

At the approximate mid-point of the semester, students will assemble into groups of four and choose a medical device-based clinical therapy to study. Each group will provide two progress updates (Presentations 1 and 2) during the course of the semester in lieu of formal examinations. A complete written summary of each group’s assessment (Final Report) will be due at semester’s end in lieu of a final examination.

Class Drop Deadline with a Withdrawal (W): Tuesday, October 22

No Class: 10/08 (Tuesday) October Break
11/21 (Thursday) Thanksgiving Vacation

G. Instructor Contact Information.

Professor William R. Clark – Email: clarkw@purdue.edu, Telephone: (765) 496-8647 (office); (317) 691-1438 (cell); office: FRNY 2158

Office Hours: TTh 9:00 – 10:00 AM (or by appointment)

H. Assessment of Course Outcomes. A weighted average grade will be calculated as follows.

Homework (2): 10% each = 20% total
Presentations: 20% each = 40% total
Final report: 40%

Group projects

Student groups may assess a medical device-based therapy from a suggested list prepared by Professor Clark or choose one on their own. In either case, each group should plan to meet with Professor Clark before beginning work on the project to set expectations. The assessment will include the disease state(s) for which the technology is used, its historical development and evolution, the engineering principles underlying its use, the clinical challenges associated with the device, and potentially improved designs for the future. Requirements for the presentations during the semester and the final written summary will be provided early in the semester.