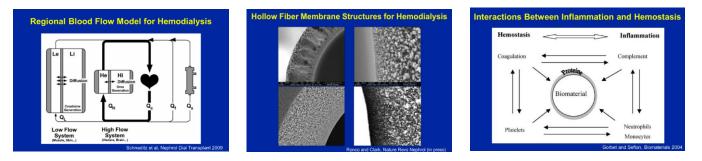
## CHE 59700: MEDICAL DEVICES: DEVELOPMENT AND CLINICAL APPLICATION



**Course Description:** This course is an introduction to the medical device field, with emphasis on the ways in which engineering processes provide the foundation for many device-related therapies. The course involves the application of several fundamental engineering principles, including those related to transport phenomena, separations, and fluid flow, to devices used for extracorporeal therapies. Several clinical conditions in which these considerations are relevant are discussed, with a focus on the treatment of renal failure by dialysis. Finally, the vital roles that engineers may play in the various functions comprising a medical device company are highlighted.

**Course Objectives:** The overall objective of this course is to provide students a foundation regarding the medical device industry from an 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.

- Engineering Processes for Medical Devices. Identify the mechanisms of blood-surface interactions; describe the influence of extracorporeal membrane structure and material on transport properties (diffusion, convection, and ultrafiltration); 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.
- The Engineer in the 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, including research and development, manufacturing, regulatory affairs, sustaining engineering, intellectual property, and business development.

**Team projects:** Students will form groups of four people and be tasked with performing an assessment of a medical device-based therapy currently prescribed in clinical medicine. 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 potential improved designs for the future. Each group will provide two progress updates during the second half of the semester in lieu of formal examinations. A written report summarizing each group's assessment will be due at semester's end in lieu of a final examination.

Course Information: Instructor: William R. Clark, M.D. Course Hours (FRNY 1043): TTh 10:30 - 11:45 AM

**Course Requirements:** Transport phenomena course (CHE 37700 or equivalent) and BIOL 23000 (or BCHM 30700); or permission from the instructor.

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