CHE 59700: Chemical Engineering Applications in Medical Devices

A. Instructors: William Clark, M.D. and Michelle Chutka

B. Course Description. This course provides a unique perspective 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 mass transfer, separations, and fluid flow, to devices used for extracorporeal therapies and other treatments. The first part of the course addresses the relevant physiology and pathophysiology serving as a foundation for subsequent clinical material. With the focus on extracorporeal devices, the interactions between blood and biomaterials in a general sense are also explored. The second part of the course assesses the extracorporeal treatment of kidney failure by dialysis, which is highlighted as the only long-term, device-based replacement therapy for terminal organ failure (end-stage renal disease). This analysis will not only consider the evolution of dialysis therapy from a technology perspective (with emphasis on fundamental chemical engineering principles) but also the forces that have shaped its development into a market generating annual revenue of nearly $100 billion on a global basis. The third segment of the course addresses industry-focused concepts pertaining to medical device development, including the role of the chemical engineer in design verification and validation activities, process validations including IQ/OQ/PQ, risk analysis, lean manufacturing concepts, and project management in an increasingly complex regulatory environment. Providing a real-world perspective based on over 15 years of experience in the medical device field, Ms. Michelle Chutka (Director of Product Engineering, Cook Biotech, Inc; Continuing Lecturer, Davidson School of Chemical Engineering, Purdue University) will lead this third part of the course.

C. Instructor Biographical Information: Dr. Clark is a nephrologist (kidney specialist) and chemical engineer by training. He received his M.D. degree along with specialty and sub-specialty training in internal medicine and nephrology, respectively, at Indiana University School of Medicine. In addition, he received both his B.S and M.S. degrees in chemical engineering from Purdue University, at which he is now Professor of Engineering Practice in the Davidson School of Chemical Engineering. Before joining the Purdue faculty, Dr. Clark worked in the medical device (dialysis) industry for more than 20 years in a variety of positions. During this time, he applied engineering principles to gain expertise in two broad areas, namely extracorporeal membrane structure/function and solute kinetics during dialysis. Dr. Clark continues to serve as a consultant in the dialysis industry.

Ms. Chutka is a chemical engineer by training with both B.S and M.S degrees from the University of Michigan. For the past 17 years, she has held roles of increasing responsibility at Cook Biotech, a medical device company based in West Lafayette, IN. In her current position as Director of Product Engineering, Ms. Chutka oversees the product engineering team, responsible for both upstream and discovery work, all aspects of product development through regulatory approval and commercialization, along with sustaining engineering for all aspects of the medical device's product lifecycle. Outside of medical device experience, Ms. Chutka has also worked in the pharmaceutical industry and abroad within the automotive industry.

D. Prerequisites. CHE 37700 (or equivalent) and BIOL 23000 (or BCHM 30700). These are not strict requirements - interested students should contact Dr. Clark with inquiries.

E. Recommended (NOT REQUIRED) Texts.

- *Guyton and Hall Textbook of Medical Physiology*, Edited by John E. Hall, Elsevier, 2016, ISBN: 978-1-4557-7005-2
- *Medical Device Development*, Edited by Jonathan S. Kahan, Barnett International, 2009, ISBN: 1-882615-92-1
- *Biomaterials Science: An Introduction to Materials in Medicine*, Edited by Buddy Ratner, Allan Hoffman, Frederick Schoen, Jack Lemons, Elsevier, 2012, ISBN: 978-0-12-374626-99

F. Course Learning Outcomes

- Assess the mechanisms of blood-surface interactions defining the biocompatibility of an extracorporeal device

- Evaluate the influence of extracorporeal membrane structure and material on transport properties (diffusion, convection, and ultrafiltration) and the overall effect on device performance

- Based on a mass balance approach, analyze device-related and patient-related (physiologic) parameters required for kinetic modeling of different dialysis therapies

- Apply fundamental chemical engineering principles to provide a quantitative basis for treatments of specific clinical disorders, including end-stage renal disease (ESRD), acute kidney injury (AKI), sepsis, cardiac failure, and respiratory failure

- Characterize the major components of a medical device company and the manner in which these different functions interact during the pre-market and post-market phases of product development

- From the perspective of a chemical engineer working in the medical device field, understand how the principles of project management, verification/validation, process validation, risk analysis, and lean manufacturing pertain to product development and the regulatory approval process.

G. Course Meeting Schedule

Lectures: Tues/Thurs 3:00-4:15 PM
Homework 1: due February 6
Homework 2: due February 27
Homework 3: due April 3
Homework 4: due April 24
Presentation 1: March 9 (8-10 PM)
Presentation 2: April 20 (8-10 PM)
Final Report due: May 3

Early in the semester, students will assemble into groups of 3 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.

H. Instructor Contact Information.

Professor William R. Clark – Email: clarkw@purdue.edu, Telephone: (765) 496-8647 (office); (317) 691-1438 (cell); office: FRNY 1055
Professor Michelle Chutka - Email: mchutka@purdue.edu

Office Hours: by appointment

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

Homework (4): 5% each = 20% total
Presentations (2): 20% each = 40% total
Final report: 40%

The grading scale will be as follows.

A: 100 – 85% of the weighted points
B: 84.9 – 75% of the weighted points
C: 74.9 – 65% of the weighted points
D: 64.9 – 55% of the weighted points
F: Less than 55% of the weighted points

Note that students with grades within 3 weighted percentage points of either the upper or lower bounds of a grade range listed above will receive a "plus" or "minus" mark, respectively, after his/her score (*e.g.*, scores between 75% and 78% of the total weighted points would earn an B–). Marks of an A– will not be given.

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.

J. Class Schedule.

- January 10: Introduction
- January 12: Physiology overview (I)
- January 17: Physiology overview (I)
- January 19: Physiology overview (III)
- January 24: Interactions of blood with biomaterials (I)
- January 26: Interactions of blood with biomaterials (II)
- January 31: Kidney structure/function
- February 2: Normal kidney function
- February 7: Chronic kidney disease (CKD) and end-stage renal disease (ESRD)
- February 9: Uremic toxins: Chemical structure and clinical relevance
- February 14: Hemodialysis membrane properties
- February 16: Hemodialysis mass transfer
- February 21: Hemodialysis dose: Mass balance principles
- February 23: Extracorporeal therapy for AKI
- February 28: New device approaches for ESRD and AKI
- March 2: Extracorporeal therapies beyond renal failure
- March 7: Vascular access for dialysis
- March 9: Drug/device combinations
- **March 9 (8-10 PM): Presentation #1**
- March 14: Spring Break
- March 16: Spring Break
- March 21: Medical device regulation and clinical trials (I)
- March 23: Medical device regulation and clinical trials (II)
- March 28: Medical device market dynamics
- March 30: Medical device product development: Design verification/validation (I)
- April 4: Medical device product development: Design verification/validation (II)
- April 6: Medical device product development: Process Validation (I)
- April 11: Medical device product development: Process Validation (II)
- April 13: Applying risk analysis to device design (I)
- April 18: Lean manufacturing in the medical device industry, project management & regulatory strategy
- April 20: Case study
- **April 20 (8-10 PM): Presentation #2**
- April 25: No class
- April 27: No class