TO: The Engineering Faculty

FROM: The Davidson School of Chemical Engineering

RE: New graduate course – CHE 50100 **Chemical Engineering Applications of Medical Devices**

The faculty of the Davidson School of Chemical Engineering have approved the following new course. This action is now submitted to the Engineering Faculty with a recommendation for approval.

COURSE:
CHE 50100 Chemical Engineering Applications of Medical Devices Fall/Summer/Spring, Lecture, Cr. 3
Restrictions:
May not be enrolled as the following Classifications:

Freshman: 0 - 14 hours
Freshman: 15 - 29 hours
Sophomore: 30 - 44 hours
Sophomore: 45 - 59 hours
Junior: 60 - 74 hours
Junior: 75 - 89 hours

Prerequisites:
Prior biology, physics (mechanics) and calculus classes (or permission from the instructor)

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 mass transfer, separations, and fluid flow, to devices used for extracorporeal therapies and other treatments.

Reason: This course has been taught successfully as a temporary course and it is now being submitted for a permanent course number.

Residential course enrollment history:

- Fall 2017: 12
- Fall 2018: 12
- Fall 2019: 18
- Spring 2021: 9
- Spring 2022: 22

Online course enrollment history: 5 (Summer 2021)

CHE 59700-048/CHE 59700-OL4: Chemical Engineering Applications of Medical Devices

A. Instructors: Dr. William Clark 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 performing design verification and validation activities, process validations including IQ/OQ/PQ, risk analysis, lean manufacturing concepts, and project management skills in an increasingly complex regulatory environment**. Providing a real-world perspective based on 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 15 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

- 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, and lean manufacturing **pertain** to **product** development **and the regulatory approval process.**

G. Course Meeting Schedule

Lectures:	Tuesday/Thursday, 3:00-4:15 PM (AMS 1103)
Homework 1	Due February 8
Homework 2:	Due March 1
Homework 3:	Due March 29
Homework 4:	Due April 26
Presentation 1:	March 18 (8:00 PM by Zoom)
Presentation 2:	April 29 (8:00 PM by Zoom)
Final Report due:	April 30 (5:00 PM)

Early in the semester, students will assemble into groups of 2 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 2158
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: 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.

- Class #1 (Jan 19): Introduction
- Class #2 (Jan 21): Overview of the medical device industry
- Class #3 (Jan 26): Physiology overview (I)
- Class #4 (Jan 28): Physiology overview (II)
- Class #5 (Feb 2): Physiology overview (III)
- Class #6 (Feb 4): Interactions of blood with biomaterials (I)
- Class #7 (Feb 9): Interactions of blood with biomaterials (II)
- Class #8 (Feb 11): Normal kidney function
- Class #9 (Feb 16): Chronic kidney disease (CKD) and end-stage renal disease (ESRD)
- Class #10 (Feb 18): Hemodialysis and related therapies (I)
- Class #11 (Feb 23): Hemodialysis and related therapies (II)
- Class #12 (Feb 25): Physiologic models for determining hemodialysis dose
- Class #13 (Mar 2): Acute kidney injury (AKI)/sepsis
- Class #14 (Mar 4): New device approaches for ESRD and AKI
- Class #15 (Mar 9): Extracorporeal therapies beyond renal failure
- Class #16 (Mar 11): Vascular access for dialysis
- Class #17 (Mar 16): Evolution of a medical device market: chronic dialysis case study
- Mar 18: Reading Day
- Class #18 (Mar 23): Medical device clinical trials
- Class #19 (Mar 25): Regulation of medical devices (I)
- Class #20 (Mar 30): Regulation of medical devices (II)
- Class #21 (Apr 1): Drug/device combinations
- Class #22 (Apr 6): Medical device product development: Design verification/validation (I)
- Class #23 (Apr 8): Medical device product development: Design verification/validation (II)
- Apr 13: Reading Day
- Class #24 (Apr 15): Medical device product development: Project management (I)
- Class #25 (Apr 20): Medical device product development: Project management (II)
- Class #26 (Apr 22): Lean manufacturing in the medical device industry (I)
- Class #27 (Apr 27): Lean manufacturing in the medical device industry (II)
- Class #28 (Apr 29): Challenges/opportunities in the medical device industry; wrap-up

K. Academic Guidance in the Event a Student is Quarantined/Isolated. If you become quarantined or isolated at any point in time during the semester, in addition to support from the Protect Purdue Health Center, you will also have access to an Academic Case Manager who can provide you academic support during this time. Your Academic Case Manager can be reached at acmq@purdue.edu and will provide you with general guidelines/resources around communicating with your instructors, be available for academic support, and offer suggestions for how to be successful when learning remotely. Importantly, if you find yourself too sick to progress in the course, notify your academic case manager and notify me via email or Brightspace. We will make arrangements based on your

particular situation. The Office of the Dean of Students (odos@purdue.edu) is also available to support you should this situation occur.

L. Attendance Policy during COVID-19. Students should stay home and contact the Protect Purdue Health Center (496-INFO) if they feel ill, have any symptoms associated with COVID-19, or suspect they have been exposed to the virus. In the current context of COVID-19, in-person attendance will not be a factor in the final grades, but the student still needs to inform the instructor of any conflict that can be anticipated and will affect the submission of an assignment or the ability to take an exam. Only the instructor can excuse a student from a course requirement or responsibility. When conflicts can be anticipated, such as for many University-sponsored activities and religious observations, the student should inform the instructor of the situation as far in advance as possible. For unanticipated or emergency conflict, when advance notification to an instructor is not possible, the student should contact the instructor as soon as possible by email, through Brightspace, or by phone. When the student is unable to make direct contact with the instructor and is unable to leave word with the instructor's department because of circumstances beyond the student's control, and in cases of bereavement, quarantine, or isolation, the student or the student's representative should contact the Office of the Dean of Students via email or phone at 765-494-1747. Our course Brightspace includes a link on Attendance and Grief Absence policies under the University Policies menu.

M. Classroom Guidance Regarding Protect Purdue. The Protect Purdue Plan, which includes the Protect Purdue Pledge, is campus policy and as such all members of the Purdue community must comply with the required health and safety guidelines. Required behaviors in this class include: staying home and contacting the Protect Purdue Health Center (496-INFO) if you feel ill or know you have been exposed to the virus, properly wearing a mask in classrooms and campus building, at all times (e.g., mask covers nose and mouth, no eating/drinking in the classroom), disinfecting desk/workspace prior to and after use, maintaining appropriate social distancing with peers and instructors (including when entering/exiting classrooms), refraining from moving furniture, avoiding shared use of personal items, maintaining robust hygiene (e.g., handwashing, disposal of tissues) prior to, during and after class, and following all safety directions from the instructor.
Students who are not engaging in these behaviors (e.g., wearing a mask) will be offered the opportunity to comply. If non-compliance continues, possible results include instructors asking the student to leave class and instructors dismissing the whole class. Students who do not comply with the required health behaviors are violating the University Code of Conduct and will be reported to the Dean of Students Office with sanctions ranging from educational requirements to dismissal from the university.

Any student who has substantial reason to believe that another person in a campus room (e.g., classroom) is threatening the safety of others by not complying (e.g., not wearing a mask) may leave the room without consequence. The student is encouraged to report the behavior to and discuss next steps with their instructor. Students also have the option of reporting the behavior to the Office of the Student Rights and Responsibilities. See also Purdue University Bill of Student Rights.

N. Instructor's Commitment. Your instructor will: 1) be courteous, punctual, well-organized, and prepared for lecture and other class activities; 2) answer questions clearly in class or arrange for detailed discussions out of class if in-class answers are not suitably clear; 3) be available during office hours or notify you beforehand if I am unable to keep them; 4) provide a suitable guest lecturer when I am traveling; and 5) grade uniformly and consistently to the posted guidelines.

O. Consulting with the Instructor. I encourage you to discuss academic or personal questions with me during my office hours or via email. These discussions need not be limited to CHE 59700 content.

P. Academic Dishonesty. Academic dishonesty ***will not be tolerated*** in any form in this course. Specifically, Purdue prohibits "dishonesty in connection with any University activity. Cheating, plagiarism, or knowingly furnishing false information to the University are examples of dishonesty." [Section B-2-a, Code of Student Conduct] Furthermore, the University Senate has stipulated that "the commitment of acts of cheating, lying, and deceit in any of their diverse forms (such as the use of substitutes for taking examinations, the use of illegal cribs, plagiarism, and copying during examinations) is dishonest and must not be tolerated. Moreover, knowingly to aid and abet, directly or indirectly, other parties in committing dishonest acts is in itself dishonest." [University Senate Document 72-18, December 15, 1972] All incidents of academic dishonesty will be reported to the Dean of Students. **Such incidents include: i) possessing or accessing, in hardcopy or electronic form, the solution manual to the course**

text, or to the exams, ii) claiming credit for work that is not your own original work, and iii) enabling other students to create work that is not their original work. The punishment for the first offense is a grade of zero for the entire work (exam or homework), and the punishment for a second offense is an F mark for the class.

Q. Conduct. University policy states that it is the responsibility of all students to attend all class sessions (http://www.purdue.edu/studentregulations/regulations_procedures/classes.html). Each student is expected to come to class on time and not disrupt the class. Each student is also expected to follow Purdue's codes of student conduct (http://www.purdue.edu/studentregulations/student_conduct/regulations.html) and behave in a professional manner. The rights of students in violation of the code of conduct are outlined. Each student is expected to exhibit consideration and respect towards the other students, the graders, the teaching assistants (TAs), and the faculty member. Each student is expected to exhibit a positive attitude. Your conduct will be a factor in awarding grades to students between two letter grades. Purdue University's student conduct policy specifically addresses academic dishonesty.

R. Violent Behavior Policy. Purdue University is committed to providing a safe and secure campus environment for members of the University community. Purdue strives to create an educational environment for students and a work environment for employees that promote educational and career goals. Violent behavior impedes such goals. Therefore, violent behavior is prohibited in or on any University Facility or while participating in any University activity.

S. Nondiscrimination. Purdue University is committed to maintaining a community which recognizes and values the inherent worth and dignity of every person; fosters tolerance, sensitivity, understanding, and mutual respect among its members; and encourages each individual to strive to reach his or her own potential. In pursuit of its goal of academic excellence, the University seeks to develop and nurture diversity. The University believes that diversity among its many members strengthens the institution, stimulates creativity, promotes the exchange of ideas, and enriches campus life. Purdue University prohibits discrimination against any member of the University community on the basis of race, religion, color, sex, age, national origin or ancestry, genetic information, marital status, parental status, sexual orientation, gender identity and expression, disability, or status as a veteran. The University will conduct its programs, services and activities consistent with applicable federal, state and local laws, regulations and orders and in conformance with the procedures and limitations as set forth in Executive Memorandum No. D-1, which provides specific contractual rights and remedies. Any student who believes they have been discriminated against may visit www.purdue.edu/report-hate to submit a complaint to the Office of Institutional Equity. Information may be reported anonymously.

T. Bereavement Policy. Purdue recognizes that a time of bereavement is very difficult for a student. The University therefore provides rights to students facing the loss of a family member through the Grief Absence Policy for Students (GAPS): http://www.purdue.edu/odos/services/griefabsencepolicyforstudents.php. Students who find themselves in need of assistance in a time of bereavement should contact Professor Clark privately to discuss specific needs.

U. Individual Learning and Testing Needs. Any student who feels he/she may need an accommodation with any aspect of the course based on a personal circumstance should contact Professor Clark privately to discuss his/her specific needs. If you are a student with any form of individual learning needs, please speak with the faculty instructors whether or not you seek an accommodation so that we are aware of your circumstance and can deliver course content in a manner that is most compatible with your situation.

V. Emergency Preparedness. Purdue University is a very safe campus and there is a low probability that a serious incident will occur here at Purdue. However, it is important to emphasize the emergency procedures for evacuation and shelter-in-place incidents. Preparedness will be critical if an unexpected event is to occur. Emergency preparedness is your personal responsibility. Purdue University is actively preparing for natural disasters or human-caused incidents with the ultimate goal of maintaining a safe and secure campus.

The following is a review of the emergency procedures at Purdue University. The evacuation and shelter-in-place procedures for Forney are posted at the entrances to all Forney classrooms and detailed in the Building Emergency Plan https://www.purdue.edu/ehps/emergency_preparedness/bep/FRNY-bep.html. Students are responsible for

understanding and adhering to these procedures in the event of an emergency. Please see additional information on Brightspace.

1. For any emergency call 911.
2. There are nearly 300 Emergency Telephone Systems throughout campus that connect directly to the Purdue Police Department (PUPD). If you feel threatened or need help, push the button and you will be connected to the PUPD.
3. If there is a fire alarm, we will immediately evacuate the building and proceed to in front of Forney Hall (FRNY). Do not use the elevator.
4. If there is a Shelter-in-Place requirement for a tornado warning, we will shelter in the lowest level of this building away from windows and doors.
5. If there is a Shelter-in-Place requirement for a hazardous materials release, we will shelter in the classroom shutting any open doors and windows.
6. If there is a Shelter-in-Place requirement for a civil disturbance, we will shelter in a room that is securable preferably without windows.

W. Campus Emergencies. In the event of a major campus emergency, course requirements, deadlines and grading percentages are subject to changes that may be necessitated by a revised semester calendar or other circumstances beyond the instructors' control. ***You are expected to check your @purdue.edu email address frequently.***

X. Use of Copyrighted Material. Among the materials that may be protected by copyright law are the lectures, notes, and other material presented in class or as part of the course. Always assume the materials presented by an instructor are protected by copyright unless the instructor has stated otherwise. Students enrolled in, and authorized visitors to, Purdue University courses are permitted to take notes, which they may use for individual/group study or for other non-commercial purposes reasonably arising from enrollment in the course or the University generally.

Notes taken in class are, however, generally considered to be "derivative works" of the instructor's presentations and materials, and they are thus subject to the instructor's copyright in such presentations and materials. No individual is permitted to sell or otherwise barter notes, either to other students or to any commercial concern, for a course without the express written permission of the course instructor. To obtain permission to sell or barter notes, the individual wishing to sell or barter the notes must be registered in the course or must be an approved visitor to the class. Course instructors may choose to grant or not grant such permission at their own discretion and may require a review of the notes prior to their being sold or bartered. If they do grant such permission, they may revoke it at any time, if they so choose.