## BE 468 Clinical Applications of Biomedical Design Fall 2022 Boston University, College of Engineering, Department of Biomedical Engineering

| Hours           | Tuesdays/Thursdays 1:30-3:15 pm                                      |
|-----------------|--|
| Location        | LSEB B03   |
| Course Director | Dr. Catherine Klapperich, Professor, BME                             |
| email           | catherin@bu.edu  |
| Office          | 44 Cummington Mall, Room 725   |
| Office Hours    | Wednesdays, 10:00-11:30 am, 44 Cummington Mall, Room 705 (conf room) |

\*\***Special Covid requirements**\*\*: All students are expected to follow University guidelines regarding COVID-19. If you are sick, please let me know ASAP and **do not** come to class. Please mask as appropriate after a positive COVID test.

## **COURSE DESCRIPTION AND APPROACH**

BE 468 is a case-based course that provides clinical examples of how technology is integrated into the care and treatment of patients. This course is designed for BME undergraduates and is part of the engineering design sequence that includes the Senior Design Capstone. The course will include at least five clinical Grand Rounds, conducted by senior clinicians, Guest Lectures from biomedical research and industry leaders, and student-led discussions. Students will also present novel cases to the class either as oral presentations or in written reports.

Students will be assigned materials to prepare for cases in advance. Students will preview the relevant anatomy, physiology, pathology, and technology of the case. Training videos of surgical procedures and medical technology animations will be viewed, and responses to potential questions about specific aspects of the case will be prepared by students in advance. Each Grand Rounds presentation will follow a generally accepted format, but timing and topics may vary based on the specific details of the case, the physician's own experience, and the learning objectives set out for each session. A typical "Grand Rounds" will include:

- 5 min Introduction of the presenting physician
- 10 min Introduction and general discussion of the underlying medical disorder, disease, or condition
- 15 min Presentation of the specific clinical problem including (de-identified) medical history, diagnosis, and treatment options
- 15 min Discussion about specific medical technologies used and options
- 10 min Medical outcomes, clinical challenges, and technology innovation opportunities
- 10 min Summary, questions, assignments

# **COURSE OUTCOMES**

- 1. Recall key anatomy, physiology, and pathology concepts
- 2. Identify clinical challenges where biomedical innovation can advance the standard of care
- 3. Develop and revise clinical requirements
- 4. Utilize key principles of biomedical design elements
- 5. Critique the selection, use, and outcomes of specific medical technologies
- 6. Evaluate options for improving care for future patients
- 7. Work effectively as a team member and contributor to achieving the learning objectives

#### **REQUIRED MATERIALS**

**There are no required books for the course.** Clinical papers, patents, regulatory, and product literature will be assigned for cases. I will do my best to choose open access and/or library available readings.

# **EXPECTATIONS AND REQUIREMENTS**

1. Attendance: You must let me know in advance (via email – <u>catherin@bu.edu</u>) if you plan to miss a class.

We will work together to find appropriate and accessible ways to help you make up any missed work.

- 2. **Study Groups and Teams:** Students will form self-selected Study Groups of between 4-6 students to collect, share, and analyze the materials provided and acquired during the course. Arrange to sit with your Group in class so you can collectively discuss answers to discussion topics in class. You will complete your final presentation/paper with this team.
- 3. Blackboard Learn Site: All course documents, assignments, and announcements will be available on the Blackboard Learn course site. Submit all assignments to the Blackboard site unless otherwise instructed.
- Academic Honesty: All students should read and understand the provisions of the BU Academic Conduct Code, which is available at <u>https://www.bu.edu/academics/policies/academic-conduct-code/</u>. Cases of suspected misconduct will be dealt with according to University guidelines and may be referred to the Dean.
- 5. **Disability Accommodation:** Reasonable accommodations for eligible individuals will be provided in accordance with Boston University policies as described: <u>http://www.bu.edu/academics/policies/disability-accommodation/</u>

# ASSESSMENT

Your final grade will be determined by a combination of individual and group assignments:

- 1. Individual Assignments (50%): All individual assignments are to be performed separately.
- 2. <u>Class Participation</u> (**10%**): This portion of final grades includes attendance, active participation during class and both live and online discussions. You are also expected to participate fully in providing feedback to other teams during their presentations.
- 3. <u>Final Paper/Presentation of Novel Case</u> (40%): Each Team will prepare a Final Paper or Presentation that will incorporate the learning objectives of the class through the design and analysis of an independently developed case based on an actual medical technology success or failure as reported in the literature. Which teams will present a paper vs. an oral case will be determined later in the semester.

*Note:* There is not enough class time for all teams to do an oral presentation. If more teams request presentations than we have slots, I will choose by lottery which teams will present and which teams will do papers.

Papers will be 12 pages maximum (1" margins, 12 pt. Times New Roman, double spaced) including figures. References are expected and are not included in the page count. **Papers are due on or before December 8**, **2022**.

4. <u>There is no final exam, and all Novel Case assignments (paper or presentation) are due by the last day</u> <u>of class</u>.

| Week | Date      | Class |   |
|------|-----------|-------|---|
|      |           |       | Intro to Course   |
|      |           | 1     | Case 0: Dalkon Shield Anatomy, Physiology, Case Prep, Dr.             |
| 1    | 9/6/22    |       | Klapperich (How to do Prep for a Case)                                |
|      |           | 2     | Case 1: The Del Em Device and other medical devices in a post         |
| 2    | 9/8/22    | 2     | Roe World, Dr. Klapperich (How to do Q&A effectively)                 |
|      | 9/13/22   | 3     | Case 2: Case Prep – Student Led                                       |
|      |           | 4     | Case 2: Artificial Elbow, Dr. Andrew Stein, Boston University         |
| 3    | 9/15/22   | •     | School of Medicine, Presentation and Q&A                              |
|      | 0 /00 /00 | 5     | Case 1 Legal Analysis: Carrie Baker, J.D., Ph.D. Smith College –      |
|      | 9/20/22   |       | "Post Roe Medical Devices and the Law"                                |
|      |           | c     | Steven Saunders, J.D., Partner, Nutter McClennen & Fish LLC           |
| Л    | 9/22/22   | 0     | Business and Strategy"  |
|      | 5/22/22   |       |   |
|      | 0/27/22   | 7     | Case 3: Injectables Prep Legal and Illegal, Student Led               |
|      | 9/2//22   |       | Case 2: Dr. Neelam A. Vashi MD. Associate Professor of                |
|      |           | 8     | Case S. Dr. Neelan A. Vasin, WD, Associate Professor Of               |
| 5    | 9/29/22   | 0     | Boston University School of Medicine. "Trends in Injectables"         |
|      | 10/4/22   | 9     | Cases 0.0.5.1. and 2: Follow Un Activity. Dr. Klapperich              |
| 6    | 10/6/22   | 10    | Cases 0, 0.5, 1, and 2: Follow Up Activity, Dr. Klapperich            |
| 0    | 10/0/22   | 10    | No class Monday Schedule  |
|      | 10/11/22  |       | Prof. Notelia Redriguez, Durdus University, Llear Contered            |
| _    | 10/10/00  | 11    | Prof. Natalia Rodriguez, Purdue University, Oser Centered             |
| /    | 10/13/22  | 12    |   |
|      | 10/18/22  | 12    | FDA Regulations Dr. Klapperich  |
| 8    | 10/20/22  | 13    | Risk Management Lecture, Dr. Klapperich                               |
|      | 10/25/22  | 14    | Case 4: Prep: Student Led   |
| 9    | 10/27/22  | 15    | Case 4: Jasmine Kwasa, Ph.D.  |
|      | 11/1/22   | 16    | Case 4: Follow up Activity  |
|      |           |       |   |
| 10   |           | 17    | Case 5: Morcellators, Anatomy Physiology, Case Prep. Student          |
|      | 11/8/22   | 17    | Led   |
|      | 10        | 18    | Case 5: Fibroid Morcellation Presentation and Q&A, Dr.                |
|      | 11/10/22  | 10    | Suzanne George, DFCI  |
| 11   | 11/15/22  | 19    | Case 6: Prep: Student Led   |
|      |           | 20    | Case 6: Dialysis Presentation and Q & A, Dr. Sushrut S. Waikar        |
|      | 11/17/22  | 20    | and Dr. Vipul Chitalia, Nephrology, BUSM, BMC                         |
|      |           | 21    | <b>Dr. Klapperich</b> : COVID Testing at BU – how the heck did we set |
| 12   | 11/22/22  |       | this thing up in 12 weeks?  |
|      | 11/24/22  |       | No class/Thanksgiving   |

| 13 | 11/29/22 | 22 | Student Cases TBA |
|----|----------|----|-------------------|
|    | 12/1/22  | 23 | Student Cases TBA |
| 14 | 12/6/22  | 24 | Student Cases TBA |
|    | 12/8/22  | 25 | Student Cases TBA |