Syllabus

1. Course number and name: BENG 551 Translational Bioengineering

2. Credits and contact hours: 3 credits; 3 contact hours

3. Class meetings: Mondays and Wednesdays: 4:30 pm - 5:45 pm, Enterprise Hall 77

4. Instructor: Dr. Carolina Salvador-Morales
   Email: csalvado@gmu.edu, Telephone: 703 993 5895, Office: Krasnow Institute, room: 255
   Office hours: Thursday: 5:00- 7:00 pm.

5. Textbooks
   - Biodesign, the process of innovating medical technologies, Zenios, Makower, Yock, second edition. (This is the most important book for this class).
   - Value proposition and design, Alex Osterwalder, Yves Pigneur, Greg Bernarda, Alan Smith, Wiley
   - The Art of Innovation: Lessons in creativity from IDEO, America’s leading design firm, Tom Kelley.
   - Principles of Translational Science in Medicine, from bench to bedside, edited by: Martin Wehling, Cambridge.

6. Course information

7. Pre-requisites or co-requisites

   The goal of this course is to teach students the process of designing, inventing, implementing and commercializing medical technologies such as medical devices. This course is based on the Biodesign process, a process developed by Stanford University several years ago. In this course, the biodesign process will be complemented with key aspects of the customer discovery process, which is a business methodology that has been shown to be a useful tool to develop a successful business model. The biodesign process consists of six main sections: 1) Needs Findings, 2) Needs Screening, 3) Concept Generation, 4) Concept Selection, 5) Development strategy and planning, and 6) Integration. There will be clinical and case studies for each section. Along the course, there will be 2-3 different guest speakers who are Co-founders of successful startups in the life science domain. Furthermore, this course includes a guided visit to the FDA, specifically to the Center for Devices and Radiological Health (CDRH).

   CHEM 251 or CHEM 212, BIOL 213, PHYS 160 or Instructor permission

8. Course goals
At the end of this course students should have learned:

1. The process of translational research
2. How to innovate in Biomedical Engineering
3. The process involves in the design, prototyping and commercialization of medical devices
4. The process involved in the creation of a start-up
5. Learn the fundamentals of the customer discovery process, specifically, students will learn the art of interviewing potential customer.
6. Hands-on learning experience

9. ADVICES FOR SUCCESS

1. Get the Biodesign book, second edition and read the selected chapters indicated in the calendar table before attending the class.
2. Attend the class every time. During the class I will discuss and complement the information that is included in the core and reference books. My class is very dynamic. If you miss the class you will miss important discussion about the class material.
3. Read the reading materials indicated in the syllabus before each class so that you can participate in class.
4. Complete and submit the assignments on time. The assignments are related to the chapters that we will study in class.
5. Conducting the customer interviews outside of GMU is mandatory. Thus, start preparing a list of potential customers that might include physicians, patients, hospital management officers and healthcare providers officers.
6. Get in touch with people who work in hospitals that can give you access to the hospital ecosystem and start cultivating relationships with them.
7. It is mandatory that you attend the FDA visit and guest speaker seminars.
8. Get a Sci-finder account at GMU library
9. Get to know your classmates since the first class. Your team should be formed at the beginning of September and start brainstorming on the medical condition that will address in your research project.
10. Plan in advance the development of your hand on-research project according to your academic schedule.
11. Ask questions in class and during the office hours.

10. Calendar (This calendar might be subject to changes)

Class 1 (M). Aug 28. Overview of translational research and entrepreneurship

Class 2 (W). Aug 30. Definition of translation research and key examples

Class 3 (M). Sep 4. (Memorial day) University closed

Class 5 (M). Sep 11. Customer Discovery Process Part II

Class 6 (W). Sep 13. Getting out of the building to interview potential customers and end users
Interview 5 people (patient, provider (i.e., physician), others in the healthcare system (i.e.,
payers).

Assignment #1: Interview potential customers and document the interview

Class 7 (M). Sep 18. Stage 1. Needs Findings: strategy focus and observation
Assignment # 2: Personal inventory

Class 8 (W). Sep 20. Observation and Problem Identification (i.e., Clinical case in classroom or
visit to Children’s Hospital in DC, Interventional Radiology Department to observe a medical
procedure).
Assignment #3: Clinical observation exercise

Class 9 (M). Sep 25. Need Statement Development
Assignment # 4: Start drafting your need statement, which will become the business thesis of
your medical device company.

Class 10 (W). Sep 27. Acclarent Case Study

Assignments #5: Development of the disease analysis

Class 12 (W). Oct 4. Treatment Options

Class 13 (M). Oct 9. Stakeholder Analysis
Assignment # 6: Development of the treatment option section.

Class 14 (W). Oct 11. Fieldwork on Stakeholder Analysis (i.e., Customer Interviews)
Assignment # 7: Customer interviews to at least three main stakeholders such as patients,
patients and payers.

Assignment #8: Development of stakeholder analysis

Class 16 (W). Oct 18. Midterm exam

Class 17 (M). Oct 23. Guest speaker
Assignment # 9: Development of market analysis

**Class 18 (W). Oct 25.** Needs filtering, Acclarent case study, Value proposition

**Class 19 (M). Oct 30.** Guest speaker (CEO of startup)
Assignment # 10: Development of the medical device prototype

**Class 20 (W). Nov 1.** Brainstorming exercise (use of anatomical props).
Assignment # 11: Refinement of the medical device prototype

**Class 21 (M). Nov 6.** Prototyping session
Assignment # 12: Development of the reimbursement process analysis

**Class 22 (W). Nov 8.** Concept screening and Acclarent Case Study

**Class 23 (M). Nov 13.** Intellectual property and guest speaker from the patent office
Assignment # 13: Development of the regulatory process analysis

**Class 24 (W). Nov 15.** Regulatory basics and introduction to engineering safety

**Class 25 (M). Nov 20.** Continuation on regulatory basics (Visit to FDA)
Assignment # 14: Intellectual property analysis

**Class 26 (W). Nov 22.** Business model canvas

**Class 27 (M). Nov 27.** Clinical strategy
Assignment #15: Develop the suitable business model for your medical device company.

**Class 28 (M). Nov 29.** Guess speaker

**Class 29 (W). Dec 4.** Operating plan

11. **Life in the Classroom**
This is not an entirely lecture-based course. Classroom discussion is an essential part of your learning experience and is important for your grade (see below). You will need to come to class prepared to discuss the homeworks and readings, and to respond to the ideas and comments of others. I will promote and lead a dialogue among the class participants. I expect your interactions to be informative and well-reasoned.

12. **Required Readings**
The primary reading material for each class is either chapter from the biodesign book, clinical or business case study and video on customer discovery process. The reading materials have been carefully chosen to help you familiarize with medical translation, entrepreneurship and customer discovery process.

13. Course Requirements and Grading
There are two basic requirements for the course: participation in class discussion and assignments.

14. Class Participation
This course depends heavily on class participation, specifically on the customer interviews. Participation has three main elements: class attendance, informed involvement in class discussions and exercises. Customer interviews count for 30% of your grade and will be evaluated on an ongoing basis throughout the semester. Students will be graded on the quality of customer interviews, grade of the written and oral assignments as well the midterm and final exam. More than three unexcused absence will rest in zero points for attendance. Quality is judged based on:

1. your rigorous and insightful diagnosis (e.g. sharpening of key issues, depth and relevance of analysis)
2. your ability to draw on course materials and your own experience productively
3. your ability to use logic, precision, and evidence in making arguments

15. Final project (individual)
By September 4th, choose a medical problem and apply the biodesign process to create your company in the medical device field. During this process, you will also use part of the customer discovery process, specifically customer interviews that will help you to identify top customers and customer segments. All the team members perform all the assignments. At the end of the semester, during the week of final exams, you will present your company vision. This assignment will account for 15% of your grade. This is a team assignment. However, I will make sure that there is accountability for each team member. You will have to provide an elevator pitch and a prototype of your medical device or product. Also, you will make a powerpoint presentation showing the following points: 1) Clinical problem, 2) Current limitations, 3) Proposed technology, 4) Team, 5) Customers, 6) Technology development status, 7) Top competitors, 8) Top technology challenges and risks, 9) Commercialization challenges & risks, 10) Conclusions & discussion points.

Grading (This grading system might be subject to changes)

<table>
<thead>
<tr>
<th>Activities</th>
<th>Percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer Interviews</td>
<td>30% Required (Team work: 10%, Individual 10%)</td>
</tr>
<tr>
<td>Final project written report</td>
<td>15% Required (Team work: 10%, Individual work: 10%).</td>
</tr>
</tbody>
</table>
Oral presentation 15% Required (Team work: 10%, Individual work: 10%)

Mid-term exam 20% Required

10/18/2017 from 3:00 pm to 4:15pm
Enterprise Hall 77

Final exam 20% Required

12/13/2017 from 4:30 pm- 5:45pm
Enterprise Hall 77

**Written project report**
This written report must include the following sections.

- Disease State Fundamentals
  - Anatomy and physiology
  - Pathophysiology
  - Epidemiology
- Treatment options
- Design of the proposed medical device
- Stakeholder Analysis
- Market Analysis
- Reimbursement process
- Regulatory process
- Intellectual property analysis
- Lesson learned from the customer interviews
- Business Plan

**Assignment calendar**

<table>
<thead>
<tr>
<th>Assignment #</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deadline</td>
<td>13</td>
<td>18</td>
<td>20</td>
<td>25</td>
<td>2</td>
<td>9</td>
<td>11</td>
<td>16</td>
<td>23</td>
<td>30</td>
<td>1</td>
<td>6</td>
<td>13</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>September</td>
<td>October</td>
<td>November</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**16. Student support resources for the research project**
SciFinder Scholar (GMU library. You need to get an account from the library)
[www.ebiodesign.org/1.1](http://www.ebiodesign.org/1.1)
17. CELL PHONE, LAPTOP, FOOD POLICY

The use of cell phone, audio devices, laptop and eating in class are not allowed during this class.

18. ACADEMIC INTEGRITY CODE DISHONESTY IN EXAMINATION AND HOMEWORK

Dishonesty or cheating in examinations is the use of inappropriate or unauthorized materials, information, or study aids in a test. Unless the instructor directs otherwise, an examination is assumed to be solely a student’s own work. No communication is allowed among students either through voice, written, electronic, or any other form of transmission, nor are students permitted to consult books, papers, study aids or notes without explicit permission. Dishonesty in examination includes but is not confined to copying from another’s paper, giving or receiving unauthorized assistance, failing to hand in the exam at the end of the class period, using electronic devices and/or modified clothing/personal items to obtain unauthorized assistance, obtaining unauthorized advance knowledge of questions on an examination, and using mechanical or marking devices or procedures on scratch paper or machine-graded examinations. Dishonesty or cheating on homework includes but is not confined to plagiarism from another’s paper or from an outside source. Dishonesty or cheating on an examination or homework assignment may result in disciplinary actions including grade reduction and/or a formal complaint with the honor committee.

The complete policy of academic integrity for George Mason University can be found at the Office for Academic Integrity website: http://academicintegrity.gmu.edu/

19. STUDENTS WITH DISABILITIES

If you qualify for accommodations because of a disability, please notify me with a letter from the Office of Disability Services so that I can make arrangements to address your needs.

20. WAVES: WELLNESS, ALCOHOL AND VIOLENCE EDUCATION AND SERVICES

WAVES promotes wellness within the Mason community through health education, alcohol/drug assessment and education, and violence awareness, prevention and sexual assault response. We help students make healthy, safe choices and encourage lifelong, thoughtful healthy decision-making through individualized support, creative programming, and evidence-based education and outreach.
21. WAVES office 703-993-9999
SUB I, Suite 3200
24-Hour Sexual and Intimate Partner Violence Crisis Line 703-380-1434
waves.gmu.edu

- 703-360-7273 (Fairfax County Office for Women and Domestic and Sexual Violence Services 25 hotline)
- 703-228-4848 (Arlington County Domestic Violence Services Hotline) 703-368-4141 (Prince William County Sexual Assault Victims Advocacy Services)
- (SAVAS) hotline 1-800-838-8238 (Virginia Family Violence and Sexual Assault Hotline) o 1-800-656-HOPE (Rape, Abuse and Incest National Network)

https://ohl.rainn.org/online/

22. CAPS: COUNSELING AND PSYCHOLOGICAL SERVICES

Counseling and Psychological Services (CAPS) provides a wide range of free confidential services to students, faculty, and staff. Services are provided by a staff of professional clinical psychologists, social workers, counselors, learning specialists, and psychiatric providers. CAPS individual and group counseling, workshops, and outreach programs are designed to enhance students’ personal experience and academic performance.

Visit us at caps.gmu.edu for additional resources.
For consultation or emergency assistance during office hours call 703-993-2380. o For assistance during non-office hours, call University Police at 703-993-4357. o 703-527-4077 (CrisisLink) o 1-800-273-8255 (National Suicide Prevention Lifeline) o 1-877-838-2838 (Veterans' Crisis Hotline)

23. STUDENT HEALTH SERVICES (SHS)— Provides confidential health care to enrolled students in emergency and non-emergency circumstances on the Fairfax, Arlington and Prince William campuses. If there is a medical emergency and Student Health Services (SHS) is closed, please contact the free after-hours nurse ((703) 993-2831), a hospital emergency room, an urgent care facility, or call 911.

SUB 1, Suite 2300 703-993-2831

24. UNIVERSITY POLICE

Emergency: 911 Non-Emergency: (703) 993-2810
Reporting a Crime (Crime Solvers Anonymous Tip Hot-Line): (703) 993-4111
Mason Police Website: http://police.gmu.edu/
Eric Heath, Chief of Police Phone: (703) 993-3840 E-mail: eheath2@gmu.edu