Syllabus

1. **Course number and name**: BENG 451 (undergraduate level) and BENG 590 (Graduate level) – Translation and Entrepreneurship in Bioengineering

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

3. **Class meetings**: Mondays: 1:30pm-2:45pm and Wednesdays: 1:30pm-2:45pm, Nguyen Engineering Building 2608

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

5. **Textbooks**
   - Biodesign, the process of innovating medical technologies, Zenios, Makower, Yock.
   - 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**

   The goal of this course is to teach students the process for inventing and commercializing medical technologies. The course is divided in two modules. The first module is about translational research while the second one focuses on entrepreneurship. The entrepreneurship module will be mainly taught following a biodesign process which 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. These sections focus on medical technologies which are defined as medical devices, diagnostics (including imaging and molecular diagnostics), and drug delivery. There will be a case study 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.

7. **Prerequisites or co-requisites**

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

   This is a high technical level course for both undergraduate and graduates students
8. Course goals

At the end of this course students should have learned:

1. The process of translational research
2. How to innovate in science
3. The process involved in the commercialization of scientific discoveries
4. The process involved in the creation of a start-up

Calendar:

Class 1 (M). Aug 25. Overview of translational research and entrepreneurship

Class 2 (W). Aug 27. Definition of translation research and key examples (e.g., biomarkers)

Class 3 (M). Sep 1. (Memorial day) University closed.

Class 4 (W). Sep 3. Case study on Biomarkers

Class 5 (M). Sep 8. The art of innovation.

Class 6 (W). Sep 10. Fundamentals of nanoparticles, and their application in drug delivery and tissue engineering

Class 7 (M). Sep 15. Case study on drug delivery systems

Class 8 (W). Sep 17. Stage 1. Needs findings: strategy focus and observation

Class 9 (M). Sep 22. Observation and problem identification (Visit to Children’s Hospital)

Class 10 (W). Sep 24. Need statement development (Visit to Children’s Hospital)

Class 11 (M). Sep 29. Acclarent case study


Class 13 (M). Oct 6. Treatment options

Class 14 (W). Oct 8. Stakeholder Analysis

Class 15 (T). Oct 13. Continuation on stakeholder analysis

Class 16 (W). Oct 15. Market Analysis and guess speaker

Class 17 (M). Oct 20. Continuation on market analysis
Class 18 (W). Oct 22. Needs filtering

Class 19 (M). Oct 27. Needs filtering and acclarent case study

Class 20 (W). Oct 29. Guest speaker (CEO of startup)

Class 21 (M). Nov 3. Brainstorming exercise (use of anatomical props)

Class 22 (W). Nov 5. Concept screening and acclarent case study

Class 23 (M). Nov 10. Intellectual property and guess speaker from the patent office

Class 24 (W). Nov 12. Regulatory basics and introduction to engineering Safety

Class 25 (M). Nov 17. Continuation on regulatory basics (Visit to FDA)


Class 27 (M). Nov 24. Guest speaker (CEO of a startup)

Class 28 (M). Dec 1. Competitive advantage and business strategy and guess speaker

Class 29 (W). Dec 3. Operating plan and financial model and guess speaker

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.

Required Readings

The primary reading material for each class is either an academic research article or a chapter from the biodesign book. The reading materials have been carefully chosen to help you familiarize with the translational research and entrepreneurship fields.

Course Requirements and Grading

There are two basic requirements for the course: participation in class discussion and assignments.
**Class Participation**

This course depends heavily on class participation. Participation has three main elements: class attendance, informed involvement in class discussions and exercises. Participation counts for 30% of your grade and will be evaluated on an ongoing basis throughout the semester. Students will be graded on the quality of their comments in class and on the grade of the exercises. You are expected to comment at least 3 times during class. 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

**Final project (individual)**

By September 15, choose a topic of your interest in the medical field, and apply the biodesign process to create your own company. At the end of the semester, in the week of final exams, you will present your company. This assignment will account for 30% of your grade. This is an individual assignment. You will have to come up with 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**

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<thead>
<tr>
<th>Activities</th>
<th>Percentages</th>
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<tbody>
<tr>
<td>Class participation</td>
<td>10%</td>
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<tr>
<td>Written project report</td>
<td>30%</td>
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<tr>
<td>Prototype (solid works design software)</td>
<td>30%</td>
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<tr>
<td>Oral presentation</td>
<td>30%</td>
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**Written project report:**

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

**Student support resources for literature research**

SciFinder Scholar (GMU library)