Syllabus

1. **Course number and name:** BENG 499 (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: 3:00-4:15pm and Wednesdays: 3:00pm-4:15pm, 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: Thursday: 5:00-7:00 pm.

5. **Textbooks**
   - Biodesign, the process of innovating medical technologies, Yock, Zenios, Makower, Brinton, Kumar, Watkins, Makower, Second Edition, Cambridge University Press. (This is the most important book for this course).
   - 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

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. It is mandatory that you attend the visit to Children’s Hospital, FDA and the guest speaker seminars
6. Get to know your classmates since the first class. Your team should be formed at the beginning of October and start brainstorming on the medical condition that will address in your research project. Plan in advance the development of your scientific project according to your academic schedule.
7. Ask questions in class and during the office hours.

10. **Calendar:**

**Class 1 (M). Aug 29.** Overview of translational research and entrepreneurship

**Class 2 (W). Aug 31.** Definition of translation research and key examples (e.g., biomarkers)

**Class 3 (M). Sep 5.** (Memorial day) University closed.

**Class 4 (W). Sep 7.** Case study on Biomarkers

**Class 5 (M). Sep 12.** The art of innovation.

**Class 6 (W). Sep 14.** Fundamentals of nanoparticles, and their application in drug delivery and tissue engineering.

**Class 7 (M). Sep 19.** Case study on drug delivery systems


Class 10 (W). Sep 28. Need statement development (Visit to Children’s Hospital) Assignment #3: Creation of a team based on a well-structured reasoning.

Class 11 (M). Oct 3. Acclarent case study


Class 13 (M). Oct 10. Treatment options

Class 14 (W). Oct 12. Stakeholder Analysis Assignment #4: Development of the treatment option section

Class 15 (T). Oct 17. Continuation on stakeholder analysis

Class 16 (W). Oct 19. Market Analysis and guess speaker Assignment #5: Development of stakeholder analysis

Class 17 (M). Oct 24. Continuation on market analysis


Class 19 (M). Oct 31. Needs filtering and acclarent case study

Class 20 (W). Nov 2. Guest speaker (CEO of startup) Assignment #7: Development of the medical device prototype

Class 21 (M). Nov 7. Brainstorming exercise (use of anatomical props). Assignment #8: Refinement of the medical device prototype

Class 22 (W). Nov 9. Concept screening and acclarent case study Assignment #9: Development of the reimbursement process analysis

Class 23 (M). Nov 14. Intellectual property and guess speaker from the patent office
Class 24 (W). Nov 16. Regulatory basics and introduction to engineering Safety
Assignment # 10: Development of the regulatory process analysis

Class 25 (M). Nov 21. Continuation on regulatory basics (Visit to FDA)

Class 26 (W). Nov 23. Business model
Assignment # 11: Intellectual property analysis

Class 27 (M). Nov 28. Guest speaker (CEO of a startup)

Class 28 (M). Nov 30. Competitive advantage, business strategy, guess speaker

Class 29 (W). Dec 5. Operating plan and financial model and guess speaker

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 an academic research article or a chapter
from the biodesign book. The reading materials have been carefully chosen to help you
familiarize with medical translation and entrepreneurship.

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. 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
15. 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 a team assignment. However, I will make sure that there is accountability in 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.

16. Grading
Activities Percentages
Class participation 10%
Written project report 30%
Prototype (solid works design software) 30%
Oral presentation 30%

17. Written project report
This written report must include the following sections.
• 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

18. Student support resources for literature research
SciFinder Scholar (GMU library)
www.ebiodesign.org/1.1
www.uptodate.com

19. CELL PHONE AND LAPTOP POLICY
The use of cell phone, audio devices and laptop are not allowed during this class.
20. 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/

21. 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.

22. 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.

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/.
23. 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. For assistance during non-office hours, call University Police at 703-993-4357. For 703-527-4077 (CrisisLink) or 1-800-273-8255 (National Suicide Prevention Lifeline) or 1-877-838-2838 (Veterans' Crisis Hotline).

24. 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

25. 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.