Introduction to Biomedical Innovation – Course Description

Course Directors:
Ann Majewicz Fey, PhD
Andra Blomkalns, MD

Student Facilitators:
Kayla Maaraoui
Alexander Bass
Diana Hoang
Kevin Ma

Requirements:
Minimum of 15 students
Maximum of 60 students

Mission:
Through the Biomedical Innovation Program, students will acquire the skills and mindset required to accurately assess clinical needs and develop feasible solutions in a team-based environment. Using these skills and the aid of course facilitators, students will tackle real world deficiencies in healthcare through device design and implementation.

Course Objectives:
- Think holistically about the current standard of care and how that standard could be improved
- Identify unmet clinical needs via effective communication with members of the healthcare team and keen understanding of the context of care delivery
- Use a structured process to evaluate the practical impact of a problem, adverse contributing factors, stakeholders, competing solutions, and economic implications
- Understand the lifecycle of products in the healthcare industry, including the strategic and operational events from conception through commercialization
- Lead multidisciplinary teams that bridge the gap between the clinic, research, and business to deliver high quality patient care

Course Text:
All required reading will be provided to students in class. The following text may be useful as a supplement to course material.

Biodesign: The Process of Innovating Medical Technologies.
Free Website: ebiodesign.com
Schedule and Specific Objectives

Session 1: Customer Validation for Healthcare Solutions
Thursday, January 18 2018: 12:00-1:00 PM; ROOM E6.200

Learning Objectives
- Know the PDSA and DMAIC models for healthcare quality improvement initiatives
- Understand user studies, as well as cohort, case-control and randomized controlled trials
- Be able to determine appropriate variables and methods to measure them for your specific project

Speakers
- Andra Blomkalns, MD (Emergency Physician and Course Administrator)

Session 2: Mini-Grants and Project Funding
Thursday, January 25 2018: 12:00-1:00 PM; ROOM E6.200

Learning Objectives
- Understand common sources of grant funding for device research
- Be able to calculate the direct and indirect costs of a device research project
- Know the best practices for grant writing, including useful campus resources

Speaker
- Ann Majewicz Fey, PhD (Program Director, UTD/UTSW Engineering)

Session 3: Market Analysis and Licensing
Thursday, February 1 2018: 12:00-1:00 PM; ROOM E6.200

Learning Objectives
- Learn the benefits of anticipating the potential market and target markets
- Identify sources of market data and trends in the medical space
- Be able to determine the target market for your own specific project and approximate its size
- Understand the basics of an intellectual property license
- Identify appropriate potential licensees for your specific project

Speakers
- Frank Grassler, JD (Director, UTSW Office of Technology Development)
**Session 4: Think Tank Day**  
*Thursday, February 15 2018: 12:00-1:00 PM; ROOM K2.228*

Learning Activities
- Work with your teammate to anticipate possible customer validation studies that will be required to validate your device
- Conduct a short review of market data for medical devices similar to your own
- Continue prototyping work-up

Speaker
- Student Facilitators

**Session 5: Generating University Support for Advanced Device Development**  
*Thursday, February 22 2018: 12:00-1:00 PM; ROOM E6.200*

Learning Objectives
- Know the campus resources and personnel that are available to assist prototyping, validation, IP securities and regulatory guidance
- Identify the specific contacts that relate to your specific project and hedge them to develop a support network for the project

Speaker
- Andra Blomkalns, MD (Emergency Physician and Course Administrator)

**Session 6: Start-Up Preparations and Financing**  
*Thursday, March 1 2018: 12:00-1:00 PM; ROOM E6.200*

Learning Objectives
- Understand the characteristics of a market offering that create an opportunity for start-up success
- Know the components of a medical start-up team and expectations for the IP license
- Understand the sources of commercial research funding, including angel investors, venture capital and loans

Speaker
- Lucas Richardson (CEO of Cersei Therapeutics)
**Session 7: Think Tank Day**  
*Thursday, March 8 2018: 12:00-1:00 PM; ROOM K2.228*

Learning Activities  
- Contact the support personnel from Session 5 who may be useful to the forward momentum of your project  
- Continue prototyping work-up

Speaker  
- Student Facilitators

**Session 8: Regulatory Considerations for Medical Devices**  
*Thursday, March 15 2018: 12:00-1:00 PM; ROOM E6.200*

Learning Objectives  
- Understand the various FDA device classifications and anticipate the appropriate classification for your own device  
- Develop the skill to estimate useful equivalents at the FDA  
- Appreciate the cost and timeline for FDA trials of a medical device

Speaker  
- Darold Tippey (Director of TMAC)

**Session 9: Solutions: From Concept to Reality**  
*Thursday, April 5 2018: 12:00-1:00 PM; ROOM E6.200*

Learning Objectives  
- Understand the pipeline to take a clinical need past prototype phase to generate commercial interest and engage FDA trials  
- Know the general activities and best practices for testing a medical device in the clinical setting

Speakers  
- Malcolm MacConmara (UTSW Transplant Surgery)

**Session 10: Think Tank Day**  
*Thursday, April 12 2018: 12:00-1:00 PM; ROOM K2.228*

Learning Objectives  
- Develop your team’s slide deck for the Final Symposium  
- Finish designing and assembling a demonstration model for the Final Symposium

Speaker
• Student Facilitators

**Session 11: Final Symposium**  
*Thursday, April 19 2018: 5:00-8:30 PM; ROOM E6.200*

Symposium Activities
- Each team will have 12 minutes to present their clinical need and prototyped solution
- Each presentation is allotted a 4 minute Q&A follow-up
- Judges will provide feedback on the need, solution, prototype, delivery and professionalism

Speakers
- You!