The Advancing Bioengineering Innovations (ABI) program is a two-quarter long course designed to teach students about the medical device design process through lectures, guest speakers, and a hands-on project. Multi-disciplinary teams of graduate students will evaluate actual unmet medical needs identified in the UCLA Hospital System and invent and develop practical solutions that address these needs. The team-based project component of the course will be complemented by lectures and panels from UCLA faculty and industry experts to provide additional teaching and guidance on the product development process and entrepreneurship as it relates to medical devices. The goals of the ABI program are to develop medical device solutions that improve patient care and prepare students for careers in healthcare, product development, and entrepreneurship. The Winter and Spring series is open to students enrolled in all graduate programs across campus (medicine, management, engineering, life sciences, law, dentistry, design, etc.) although final course enrollment is at the discretion of the faculty.

**Criteria for Acceptance into Course**

You must be a UCLA graduate or professional student to enroll on this course. Interested students should send their resume and a completed survey describing their background interest in the course to the ABI fellows prior to January 2\textsuperscript{nd}, 2013. We will be assessing student interest and potential to work in multidisciplinary teams and prior experience in the invention and commercialization of novel medical products. Enrollment will be strictly at the consent of the instructors.
**Faculty & Course Advisors**

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Course Description
BE 233A is the first quarter of a two-part series and will focus on understanding how to identify unmet clinical needs, properly filter through these needs by defining acceptance criteria, and select a promising need for which potential medical device systems will be explored. We will also be presenting an introduction to intellectual property basics and effective medtech business models. Enrolled students will be from the subject areas of medicine, management, engineering, life sciences, law, dentistry, and design. They will then form interdisciplinary groups to work on solutions for unmet clinical needs. These unmet clinical needs will originate from fellows’ rotation through the UCLA Health System.

The ABI class lecture will be one day/week on Wednesdays from 4:00-6:50PM in Engineering V, Room 4101. The Wednesday lecture is separated into 3 parts:
   a) an introduction to the day’s topic by the course professors,
   b) a presentation/case study delivered by a guest speaker from industry, and
   c) Q&A and time to work in teams on the medtech projects.
Hands on project guidance will be provided by the ABI fellows, industry experts, and course advisors.

There is also a Thursday discussion section from 4:00pm-5:30pm led by the ABI fellows to provide an additional knowledge base for students while they work on their class projects. The room will be available until 6:50pm for students to continue working as a team on their projects.

Course Objectives and Goals
ABI Part I (BE 233A, Winter 2013) will predominantly focus on the nuts and bolts of invention. Students will be given a list of unmet medical needs previously identified by the ABI fellows. Needs will be chosen during the discussion section on January 17th. Multiple students on a single need will not be allowed—one student per need.

Students will be paired in “Collaboration” groups during the first weeks for their individual projects. The purpose of the collaboration groups is to allow students to work with each other, learn from different backgrounds, and consider their projects from different perspectives. These collaboration groups may or may not be their final project groups.
Although we will promote group work for these initial needs, each student is still responsible for presenting an individual assessment of their selected need. Individual PowerPoint presentations will be given by each student during Week 5. Presentations will be judged by an expert panel familiar with the medical field. The expert panel will select the top projects, and teams will then be assigned to further develop selected needs for the second half of the quarter.

Once teams have been assigned to a particular need, groups will begin to develop solutions/concepts for their need. The final deliverables for the course will include a comprehensive PowerPoint presentation and written report on a chosen solution for a particular need (details on the deliverables are embedded within respective lectures when they are due).

The overall goal of the ABI Program is to create novel biomedical solutions for unmet clinical needs via prototyping of new inventions. The outcomes of the Winter quarter will flow into the Spring quarter, during which students will draft provisional patents, create business plans to commercialize those inventions, and advance the solution towards licensing the IP to an existing company or a start-up.

Grading
Requirements for letter grading for the Winter quarter will include 5 deliverables:

1) An individual write-up and presentation on a selected unmet medical need 30%
2) A group write-up and presentation on concepts that address a specific medical need 40%
3) A group project plan for spring quarter 10%
4) Team evaluation 10%
5) Attendance and participation 10%

*More than one unexcused absence will result in a letter grade drop*

Deliverable 1 – Medical Need Assessment
Students will be allowed to choose a specific medical need provided by the Fellows. Individual students will provide an assessment of their medical need to determine whether to pursue (Go) or abandon the need (No-Go). Each student

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will be asked to provide a short 5 minute PowerPoint presentation as well as a “Medical Need Assessment” document. The students’ PowerPoint and Medical Need Assessment document will be reviewed by an expert panel to confirm the students’ assessment for Go/No-Go.

**Deliverable 1a – Medical Need Assessment Paper (Individual)**
- Written assignment should be 3-5 pages, single spaced
- Contents
  - Background information and description of medical need
  - Brief market assessment that includes existing solutions and competitors, barriers to entry for new products, limitations of current products, market size, and market dynamics
  - Potential impact and value of a successful solution, who realizes this value
  - Recommendation & justification for Go/No-Go

**Deliverable 1b – Medical Need Assessment Presentation (Individual)**
- 5 minute presentation, 3-5 slides in length

**Deliverable 2 & 3 – Group Medical Needs Specification**
Students will form groups of 4-6 people - one student from each discipline – to generate preliminary concepts, perform thorough market analysis, define key requirements for a successful product, and effective business proposals for a specific clinical need.

**Deliverable 2a – Group Medical Need Specification**
- Written assignment should be 5-10 pages, single spaced
- Contents:
  - Summary of Deliverable 1
  - Market requirements/needs specification
  - 2-5 concept solutions and comparison to market specification and potential risks
  - Recommendation for which concept to advance through Spring quarter

**Deliverable 2b – Group Power Point Presentation**
- 20 minute presentation, 12-15 slides in length
Deliverable 3 – Group Project Plan for next quarter

- Written assignment should be 1-2 pages, single spaced
- For selected concept, describe major technical & business risks and milestones to address those risks
- List of expected and desired prototyping requirements (software, hardware, resources, etc.)
- Schedule of group’s activities during spring quarter

Textbook (and handouts)

The required textbook for the course is “Biodesign: The Process of Innovating Medical Technologies” by Zenios, Makower, and Yock. More information about the book can be found at the Stanford Website ebodesign.org. We will also be recommending and distributing periodicals that relate to particular class discussions.

A lab notebook will also be required

Course Outline

- **Lecture 1 - Wednesday, January 9, 2013**
  Introduction to Innovation & Needs Finding
  Reading
  1.1 Strategic Focus
  1.2 Observation and Problem Identification
  1.3 Needs Statement Development

- **Lecture 2 - Wednesday, January 16, 2013**
  Understanding Medical Problems & Existing Treatments
  Guest Speaker: Dr. David T. Feinberg, CEO of UCLA Hospital System
  Reading
  2.1 Disease State Fundamentals
  2.2 Treatment Options

- **Lecture 3 - Wednesday, January 23, 2013**
  Healthcare Stakeholder Analysis and Assessing New Markets
  Guest Speaker: Dr. Reza Zadno, Venture Partner at Interwest Partners
  Reading
  2.3 Stakeholder Analysis
  2.4 Market Analysis
2.5 Needs Filtering

- **Lecture 4 - Wednesday, January 30, 2013**
  Intellectual Property Basics
  Guest Speaker: Miles Gerson, Managing Officer of Business Development at UCLA OIP
  **Reading**
  4.1 Intellectual Property Basics

- **Lecture 5 - Wednesday, February 6, 2013**
  Presentations – Individual Medical Need Assessment
  **Deliverable 1a Due Monday 11:59pm, Feb 4**
  **Deliverable 1b Due Wednesday 12:00pm, Feb 6**

- **Lecture 6 - Wednesday, February 13, 2013**
  Product Design - Medical Needs Specification & Final Concept Selection
  Guest Speaker: David Nguyen, Marketing Manager at Abbott Medical Optics
  **Reading**
  1.3 Need Statement Development (needs criteria)
  2.5 Needs Filtering (needs specification)
  4.6 Final Concept Selection

- **Lecture 7 - Wednesday, February 20, 2013**
  Effective Brainstorming – A Process for Product Design
  **Reading**
  3.1 Ideation and Brainstorming
  3.2 Concept Screening

- **Lecture 8 - Wednesday, February 27, 2013**
  Reimbursement Basics & Medical Technology Business Models
  Guest Speaker: George Ayoub, Cofounder and former President/CEO at One Lambda, Inc
  **Reading**
  4.3 Reimbursement Basics
  4.4 Business Models
Lecture 9 - Wednesday, March 6, 2013
Regulatory Affairs Basics
Guest Speaker: Dr. Warren Grundfest, Professor at UCLA

Reading
4.2 Regulatory Basics

Lecture 10 - Wednesday, March 13, 2013
Presentations – Group Medical Needs Specification
Deliverable 2a Due Monday 11:59pm, Mar 11
Deliverable 2b Due Wednesday 12:00pm, Mar 13
Deliverable 3 Due Friday 5:00pm, Mar 22