Biodesign Innovation
BIOE 374B/MED 272B/ME 374B/OIT 385, Spring 2005
Course Outline

Location: Clark Center, Room S361 (unless otherwise specified)
Time: 3:30 – 5:30 pm, Monday and Wednesday, Rm S361

Room S361 is located on the third floor of the Clark Center. Enter through Peet’s coffee and go through the double doors.

Faculty will take attendance at the beginning of each class. Only students present before 3:45 pm will be signed in. We consider attendance essential. Only one unexcused absence will be permitted. Additional unexcused absences will permanently limit the maximum grade possible for the course.

Your grade will be based on:

- The quality of your independent and team written assignments.
- Your individual participation in class and attendance.
- A separate evaluation by your teaching faculty, assigned team mentors, and the Innovation Fellow assigned to your team.
- A final review by the other members of your team.
- Your final team presentation and deliverable.

Course Work Flow:

On April 4th, Fellows and Team Representatives from last quarter will present concepts targeted at several of the needs that were defined. Please submit by email to biodesign4@lists.stanford.edu indicating the top 5 concepts you are interested in, in order of priority by 7am the following morning. A lottery will be performed and a single concept will be assigned to each individual student. By the end of the week, all students will receive an email indicating their target concept. Students are expected to re-investigate the need, and further develop the concept with the goal of creating a better prototype and poster presentation which will be delivered on April 27th.

On that date students will be asked to individually present their prototypes and posters to the class. This event is followed by a mixer during which the students will have time to interact with each other and form teams – one concept per team.

Some notes on acceptable student teams:

- Teams can be no larger that four people and no smaller than two people (no exceptions).
- An ideal team is composed of students from different programs with different experiences (i.e. Business, Medical, Engineering, Design, etc.).
- The goal of the team is to take the concept chosen and develop a full business plan.

Extensive library and online research and interaction with Physicians, the Biodesign Fellows, the Mentors you’ve been assigned and other Faculty will be important in your success.

Before the end of the day on Wednesday, May 25th you will be expected to have discussed your concepts with the Directors of the program and Fellows. You should have submitted to the US Patent Office at least one provisional patent application covering your inventions if any new matter has been created, and if your Fellows or Faculty have suggested you do so.
For each invention, the team should also complete a Technology Disclosure Form and submit it to the Office of Technology Licensing (OTL). Note: Guidelines for patent application reimbursement and OTL disclosures will be distributed during the course.

Your final deliverable, the business plan, is due on May 25th as well and should include:

- A detailed description of the clinical problem you are trying to solve.
- A review of the broader market space and competition.
- A complete description and rendering (on paper or via prototypes/models) of your product concept.
- An explanation of the market, IP, reimbursement, regulatory and development considerations for the concept.
- Financial projections with key milestones and assumptions clearly highlighted.

Students seeking extra credit will be asked to complete an extra project other than the MED 272B final project:

Please contact Christine Kurihara at cquinn@stanford.edu for further information.

On **May 25th and June 1st** your team will present your business plan to a panel of experts consisting of some of the most successful venture capitalists, entrepreneurs and business leaders in the medical device field. You will receive real-time feedback.
March 30
Wednesday

Orientation/Class Overview

In Class:

3:30 - 4:30: Professors Dr. Paul Yock, Dr. Josh Makower, Craig Milroy and Dr. Richard Popp deliver an overview of the course.

4:30 - 5:30: Q & A
Discuss project carts and building access; website access.
BME Source – Christine Kurihara

All students to register http://innovation.stanford.edu using passcode BIP1020 to view course materials and archived videos.

Handout: Orientation presentation; sample bios.

All students will be notified on Thursday or Friday April 1 of their status. If accepted into the course please read below.

Your Assignment:

1. Students who did not take the class last quarter are encouraged to watch the final presentations on-line.

2. Submit your one paragraph bio to aleonio@stanford.edu electronically before Monday, April 4th.

April 4
Monday

New Concepts Presentations

In Class:

3:30 - 5:30: Fellows / Representatives from last quarter present concepts and discuss the needs they focused on.

All students to send a photo in jpg format to aleonio@stanford.edu.

Your Assignment:

1. Choose the best concept or propose a better one.

2. Your top 5 choices are due to Biodesign4lists@stanford.edu by 7am tomorrow.

3. Read Chapters 1 and 5 in The Definitive Business Plan.

INNOVATORS WORKBENCH
Medical Device CEO’s

5:30 (Arrillaga Alumni Center)
Guy LeBeau, Cordis Cardiology J & J
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Speaker</th>
<th>Time</th>
<th>Details</th>
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<tbody>
<tr>
<td>April 6</td>
<td>Concept Screening &amp; Evaluation: Market Analysis</td>
<td>Leslie Bottorf, (Onset Ventures)</td>
<td>3:30 – 4:30</td>
<td>Leslie Bottorf, a venture capitalist with Onset Ventures, will provide her perspective on market analysis for ideas and technologies that are still at an early stage. 4:30 – 5:30: Interactive Session- Students, Speaker and Faculty discuss market issues and concerns about their ideas. Your Assignment: 1. Prepare for the workshop session on Monday: You’ve got the faculty as free consultants on your project and you can get some key guidance! 2. Read Chapters 3 and 4 in <em>The Definitive Business Plan</em>.</td>
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<td>April 11</td>
<td>Patent Strategy &amp; Execution</td>
<td>Tom Kohler, (Morgan Lewis)</td>
<td>3:30 - 4:30</td>
<td>Tom Kohler will share his perspectives on patent strategy and execution giving real-world case examples. 4:30 – 5:00: Q&amp;A with the Speaker. Your Assignment: 1. Review Section 6 of the Primer: Intellectual Property</td>
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<tr>
<td>April 13</td>
<td>Faculty Support Workshop</td>
<td></td>
<td>3:30 - 5:30</td>
<td>Students meet and work with faculty to discuss progress and plan next steps. Your Assignment: 1. Read Section 8 of The Primer: Clinical Development / Regulatory Process.</td>
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April 18
Monday

**Quality Systems Basics**
Michelle Paganini, (Michelle Paganini Associates)

3:30 - 4:30: Michelle Paganini will share her perspectives on quality systems basics and execution giving real-world case examples.

4:30 – 5:00: Q&A with the Speaker.

**Your Assignment:**

1. Move toward finalizing your poster and prototypes.

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April 20
Wednesday

**Clinical Trial Strategy & Outcome Research**
John Morton, MD (Stanford University Medical Center)

3:30 - 4:30: Dr. Morton will present his views and several cases on the topic.

4:30 - 5:30: Interactive Session- The Faculty, Speaker and students discuss possible regulatory approaches on their projects.

**Prepare to bring your poster and prototype to class on Monday. Your poster must be mountable. Please make them no larger than 4 ft high by 5 ft wide.**

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April 25
Monday

**Concept Poster Presentations:**

3:30 - 5:30: Students will present their posters to the class with the goal of forming teams and selecting the most compelling projects. Students will be able to wander and scan concepts of interest, and spend more time on the ones that they find most interesting.

**Plan on staying a little later today, we will provide food & beverages after class to allow everyone to meet and form their teams. Teams can be no less than two and no more than four students. An ideal team consists of a diverse group of people with different backgrounds and expertise.**

**Handout:**

**Your Assignment:**

1. Hand in your Project and Team Selections by 7am tomorrow.

2. Read Chapter 6 in *The Definitive Business Plan*. 
April 27
Wednesday

The Business Plan
Ellen Koskinas, (Interwest Partners)

3:30 - 4:30: Ellen Koskinas will provide a framework for you to build your business plan around.

4:30 - 5:30: Q&A with the Speaker.

Handout:

Your Assignment:

1. Read Chapter 11 in The Definitive Business Plan.

2. Read Section 12 in the Primer: The Start-Up Team & Board.

May 2
Monday

Business Planning & Financial Modeling
Larry Tannenbaum, (Iridex Medical)

3:30 - 4:30: Larry Tannenbaum, CFO of Iridex Medical and former CFO of several successful medical companies presents an array of practical approaches towards building and analyzing financial models in the med-tech space.

4:30 - 5:30: Biodesign Co-lab- Teams bring their projects and work with Mr. Tannenbaum on modeling.

May 4
Wednesday

Financial Modeling
Stefanos Zenios, (Stanford University GSB)

3:30 - 4:30: Professor Zenios will review several financial models.

4:30 - 5:30: Professor Zenios will walk the class through the development of some of these models.

Your Assignment:

Read Chapter 2 in The Definitive Business Plan.

Read Section 14 of the Primer: Marketing Strategies.
May 9
Monday

**Ethics**

Richard Popp, MD (Stanford University)

3:30 - 4:30: Richard Popp will share his perspectives on Ethics giving real-world case examples.

4:30 - 5:30: Q&A with the Speaker.

**Your Assignment:**


Richard L. Popp, Co-Chair

Popp, RL. Conflict of interest for the physician-inventor using a device in human subjects. Am Heart J 2005;149:1-3

“Ethics Case Studies” on the URL:
http://www.stanford.edu/group/biodesign/index_cases.html

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INNOVATORS WORKBENCH

Medical Device CEO’s

5:30 (Arrillaga Alumni Center)

William Hawkins, Medtronic

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May 11
Wednesday

**Venture & Angel Financing**

Chris Shen, MD (New Enterprise Associates)

3:30 - 4:30: Chris Shen will share his perspectives on venture & angel financing giving real-world case examples.

4:30 - 5:30: Q&A with the Speaker.

**Your Assignment:**

1. Read Section 15 of the Primer: Financing Strategies.
May 16
Monday

**Corporate Financing Workshop**
Sami Hamade, VP (Guidant Corp.)

3:30 - 4:30: Sami Hamade will discuss various aspects of corporate partnering and venture capital.

4:30 - 5:30: Interactive Session- Q&A with the Speaker and Faculty.

**Your Assignment:**

1. Read Chapter 10 in *The Definitive Business Plan*.

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May 18
Wednesday

**Faculty-Fellow Coaching Sessions**

3:30 - 5:30: Teams meet and work with Faculty to discuss progress on need specifications and plan next steps.

**Your Assignment:**


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May 23
Monday

**Entrepreneurial Workshop**
Richard Ferrari, (Denovo Ventures)

3:30 - 4:30: Rich Ferrari will draw from his extensive start-up experience to share several cases and pearls.

4:30 - 5:30: Interactive Session- Q&A with the Speaker.
May 25
Wednesday

Final Presentations

3:30 - 5:30pm
5:30 - 7:30pm (reception)

Expert Panelists:

1. Mike Raab - New Enterprise Associates
2. Scott Wolf, MD - Frazier Healthcare
3. Annette Bianchi - Vantage Point Venture Partners
4. Paul Auerbach, MD - Delphi Ventures

All students must have their PowerPoint Presentations and all business plans submitted By 7am today!

May 31st
Monday

Memorial Day
No Class

June 1
Wednesday

Final Presentations

3:30 - 5:30pm
5:30 - 7:30pm (reception)

Expert Panelists:

1. Jeani Delgardelle - Spout Group
2. Sigrid Van Bladel - New Enterprise Associates
3. Doug Roeder – Delphi Ventures
4. Wilf Jaeger – Three Arch Partners

All students must have their PowerPoint Presentations and all business plans submitted By 7am today!
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