Biodesign Innovation  
BIO E 374A/MED 272A/ME 374A/OIT 384, Winter 2005  
Course Outline

**Location:** Clark Center, Room S361 (unless otherwise specified)  
**Time:** 3:30 – 4:30, Monday and Wednesday, Rm S361  
4:30 – 5:30, F100 / Rinedesign Collab

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:**

The class is designed as follows:

On January 12th, students are presented with an array of possible need-areas to choose from. Please submit by email to teresa.robinson@stanford.edu the top 10 areas you are interested in, in order of priority by **7:00 am** the following morning. A lottery will be performed and a single need will be assigned to each individual student. By the end of the week, all students will receive an email indicating their target need. Students are expected to create a “Need Specification” and hand them in by **Wednesday, February 2nd.**

Also on February 2nd, students will be asked to individually present these needs to the class in a one-day poster session. After this event, students should meet with each other and form teams – one need area per team. Team suggestions and top-3 need choices are due **Friday, Feb 4th at 9:00 am.** Here are some notes on acceptable student teams:

- Teams can be no larger than four people and no smaller than two people (*no exceptions*).
- An acceptable 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 need specification chosen and develop at least 5 viable concepts, which represent 5 new and different ways of solving the problem.

Extensive library and online research as well as 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, March 2nd** you will be expected to have discussed your new concepts with the directors of the program and fellows, and should have submitted to the US Patent Office at least one if not more provisional patent applications covering your inventions if your fellows or faculty have suggested you do so.

Your final deliverable, the mid-stage concept development overview, is due on **March 2nd** 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 top 5 concepts
- An explanation of the market, IP, reimbursement, regulatory and development considerations for each of the concepts proposed

Students seeking the extra credit option will be asked to complete an extra project other than the MED 272A final project. Please contact Christine Kurihara [cquinn@stanford.edu](mailto:cquinn@stanford.edu) for further information.

On **March 7th and 9th** your team will present your top three concepts 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.

**GSB students** should submit on **March 14th** a report **summarizing** and **analyzing** the panel feedback for their team. This is an individual report and it should include:

- A **detailed** description of the feedback provided by the panel
- **Specific** recommendations regarding next steps following the panel’s input: these could include a spectrum of options ranging from “abandoning the opportunity” to “pursuing further”
- Three to five key **lessons** learned from the experience

Submit the report electronically to Professor Zenios at [stefzen@stanford.edu](mailto:stefzen@stanford.edu). The title of your email should be “**Final Deliverable for Biodesign Innovation**”.

We would like to encourage the class to also attend MED272B where all these concepts will be further developed and business plans will be created.
January 5  
Wednesday

“Orientation/Class Overview”

In Class:

3:30 - 4:30: Professors Yock, Makower, Zenios, Milroy, and Popp deliver an overview of the course.

4:30 - 5:30: Q & A
Discuss project carts, building access, and website access.
BME Introduction – Christine Kuribara

Note: Course faculty will provide an alternative orientation session starting at 5:30 pm. This session will be for GSB students who may not be able to attend the regular session due to a course conflict because of the first-week schedule. If you are a GSB student and you will need to attend the alternative session starting at 5:30 pm, please send an email to Professor Zenios (stefzen@stanford.edu) prior to class.

All students to register: http://innovation.stanford.edu
Using pass code BIP1020 to view course materials and archived videos.

Handout: Orientation presentation, sample bios, and bio worksheet.

All students will be notified on Thursday or Friday the 7th of their status. If accepted into the course please read below.

Your Assignment:

1. For Jan 10: Read Innovation Primer Chapter 2: Clinical Needs Identification & Screening & Be Prepared To Discuss In Class.

2. Submit your one paragraph bio to teresa.robinson@stanford.edu electronically before Monday, the 10th.

January 10  
Monday

“A Process for Product Design”
David Kelley, IDEO

In Class:

3:30 - 4:30: Professor David Kelley will deliver his classic lecture on the innovation process and describe several IDEO case studies.

4:30 - 5:30: Q&A / Discussion with David Kelley & Faculty

Hand-out: Class People Book; Need Line-Up

All students are requested to have their photo taken for class handout.

Your Assignment:

1. For Jan 12th: Look over the Need Line-Up. Think about these and do some reading/research. Be prepared to ask questions about the ones that seem to interest you the most.
January 12
Wednesday

“Clinical Need Presentations”
Fellows

In-Class:

3:30 - 5:30: Fellows Present Clinical Needs To Pursue For The Class.

Hand-out: Sample Need Specifications, Sample Need Presentations.

Your Assignment:

1. Submit your top 10 need choices by email before 7:00 am tomorrow! List them in order of preference. You will receive your assignment by Wednesday, January 19th. We’ll try our best to give you your top choices.

2. After you receive your need assignment, begin reading and researching your need immediately. There is a lot to do. Your goal is to understand, verify, quantify, organize and expand upon this need so that you can prepare your need specification.

January 17
Monday

Martin Luther King Day
No Class

January 19
Wednesday

“Need Finding Basics”
Greg Lambrecht, Intrinsic Therapeutics

In-Class:

3:30 - 4:30: Greg Lambrecht a successful entrepreneur from Boston will share thoughts on how to think about needs and effectively use them to create innovative solutions.

4:30 - 5:30: Q&A / Discussion with Greg Lambrecht & Faculty

Your Assignment:

1. For Jan 24th: Read Materials on Project Management (to be handed out in class)
January 24 Monday

“Project Management”
Ken Kelley, K2 Bioventures

In-class:

3:30 - 4:30: Ken Kelley lectures on effective team and project management and discusses case examples.

4:30 - 5:30: Stefanos Zenios provides an overview of project management tools and the class engages in a sample project management session.

Your Assignment:

1. Prepare a brief set of questions / problems you are having in your need validation research for discussion during the coaching session on January 26th.

January 26 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:

1. READ PRIMER CHAPTERS 3 & 14 FOR MARKET LECTURE

January 31 Monday

“Market Validation Basics”
Ross Jaffe, MD - Versant Ventures

3:30 - 4:30: Dr. Ross Jaffe provides an overview of market validation basics.

4:30 - 5:30: Q&A / Discussion with Ross Jaffe & Faculty

Your Assignment:

1. Complete & Hand In Need Specifications and prepare a poster to present to the class by **Wednesday, February 2nd**
February 2  
Wednesday

Need Presentation Poster Session

3:30 - 5:30: Each student will be asked to briefly individually present their need in class. Be prepared to explain how significant the needs is from a clinical and market perspective, how the need was (or was not) verified, and if you desire pursuing this in the next phase of the class.

Plan on staying a little later today, we will provide food & beverages after class to allow the everyone to meet and form their teams. Teams can be no less than two and no more than four students.

Handout: Schedule of presentations

Your Assignment:

1. Hand In The Names Of Everyone On Your Team And Your Chosen Topic By Friday, Feb 4th, 9:00 am.

2. You may begin brainstorming solutions and developing your concepts immediately.

3. Read primer Chapter 4, Brainstorming Techniques For Feb 7th Class.

February 7  
Monday

"Brainstorming and Prototyping Basics"
Craig Milroy, Stanford University

3:30 - 4:30: Craig Milroy provides guidelines and ideas for using prototyping as a tool to enhance concept creation and lectures on effective brainstorming techniques and case examples.

4:30 - 5:30: Professors Makower, Yock & Milroy provide an overview of concept mapping and the class engages in a sample brainstorming session.

Minimum Attending Faculty: Yock, Makower, Zenios, Milroy, Lab Head

Your Assignment:

1. Read Handouts provided by Jim Shay

2. Watch previous online lecture about OTL and Stanford IP Guidelines
February 9 Wednesday

“IP Basics + OTL”
Jim Shay, Esq. - Wilson Sonsini Goodrich & Rosati

3:30 - 4:30: Jim Shay reviews the basics of patent law and helpful hints and strategies that will be useful to the new inventor.

4:30 - 5:30: Q&A / Discussion with Jim Shay

Your Assignment:

1. For sharing with faculty on Monday, please prepare a layout of The concept maps from your brainstorming sessions, any Prototypes or models that you may have created and the set of criteria that you plan on using to screen your concepts.

February 14 Monday

“Faculty-Fellow Coaching Sessions”

3:30 - 4:30: Dr. Paul Yock provides guidelines and ideas for using prototyping as a tool to enhance concept creation.

4:30 - 5:30: Teams meet and work with faculty to discuss feedback on need specifications and plan next steps.

Hand in: Team Concept Maps

Your Assignment:

1. READ PRIMER CHAPTER 8 ON REGULATORY PROCESS

February 16 Wednesday

“Regulatory Affairs Basics”
David Feigel, MD, Center for Devices and Radiological Health

3:30 - 4:30: Dr. David Feigel provides an overview of the basics of regulatory affairs and approval pathways in the US and Europe

4:30 - 5:30: Dr. Feigel and faculty meet with the teams and provide advice and suggestions on the regulatory paths for their projects.

Your Assignment:

1. READ PRIMER CHAPTER 9 ON REIMBURSEMENT PROCESS
<table>
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<th>Date</th>
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<tr>
<td>February 21</td>
<td>President’s Day</td>
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<td>No Class</td>
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4:30 - 5:30: Mr. Sugarman and faculty meet with teams and discuss the reimbursement situations and pathways for their projects. |
|            |                                                                        |                                               | Your NEXT & LAST Assignment:                                                                                                                                  |
|            |                                                                        |                                               | 1. By Wednesday, March 2nd: Submit Your Provisional Patent Applications to the USPTO.                                                                 |
|            |                                                                        |                                               | 2. By Monday, March 7th hand in your Final Deliverable: Your Interim Concept Development Overview which includes a detailed description of the clinical problem you are trying to solve, a review of the broader market space, a complete description and rendering (on paper or via prototypes/models) of your top 5 concepts, and an explanation of the market, IP challenges and development considerations you have for each of the concepts proposed. |
|            |                                                                        |                                               | 3. All Students Must Have Their PowerPoint Presentations Submitted By 7:00 am. March 7th |
|            |                                                                        |                                               | 4. For next class: Read Notes on Business Models for Entrepreneurs |
| February 28 | “Business Models”                                                       | Tim Wollaeger, Sanderling Ventures            | 3:30 - 4:30: Tim Wollaeger describes the evolution of the business model for one of the companies he has founded.                                                                                     |
|            |                                                                        |                                               | 4:30 - 5:30: Stefanos Zenios provides a template for reviewing and evaluating different business models.                                                                                          |
|            |                                                                        |                                               |                                                                                                                                                    |
|            |                                                                        |                                               | INNOVATORS WORKBENCH                                                                                                                                         |
|            |                                                                        |                                               | Medical Device CEO’s                                                                                                                                        |
|            |                                                                        |                                               | 5:30 (Arrillaga Alumni Center): Bill Hawkins, Medtronic                                                                                                     |
March 2
Wednesday

“Inventors Panel”
Hanson Gifford, Cliff Alferness, & Fred Khosravi
The Foundry, Seattle Medical Technologies, & Access Closure, Inc.

3:30 – 5:30: The prominent inventors and entrepreneurs share their experiences and insights on the process of medical technology innovation.

Your Assignment:

1. By Wednesday, March 2nd: Submit Your Provisional Patent Applications to the USPTO.

2. By Monday, March 7th hand in your Final Deliverable: Your Interim Concept Development Overview which includes a detailed description of the clinical problem you are trying to solve, a review of the broader market space, a complete description and rendering (on paper or via prototypes/models) of your top 5 concepts, and an explanation of the market, IP challenges and development considerations you have for each of the concepts proposed.

3. All Students Must Have Their PowerPoint Presentations Submitted By 7:00 am, March 7th

March 7
Monday

Student Presentations to Expert Panel

3:30 - 5:30: Students present their need areas and concepts to the expert panel

Expert Panelists:

- Carl Simpson
- Jaime Jacobs
- Mike Carusi
- Erica Rogers

March 9
Wednesday

Student Presentations to Expert Panel

3:30 - 5:30: Students present their need areas and concepts to the expert panel

Expert Panelists:

- Tina Seelig
- Jeff Gold
- Bob Curtis
- Jan Garfinkle
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