

**BIOENGR 233B/MGMT 271B – MedTech Innovation II:
Entrepreneurial Opportunities in Medical Device Development
Spring 2015**

Class Hours:	Wednesday 4:00-6:50 pm
Location:	Entrepreneurs Hall, C301
Instructors:	Dr. Kalyanam Shivkumar, MD, PhD Wentai Liu, PhD Jennifer McCaney, PhD Roy Doumani, JD
Office Hours:	By appointment

Welcome to the Spring Quarter of the MedTech Innovation (MTI) program. The goal of the MTI program is to teach students a framework for developing medical device innovations that address unmet clinical needs and to prepare students for careers in healthcare, product development, and entrepreneurship. The two-quarter course consists of a series of weekly lectures and interactive workshops, which are intended to complement practical experience that students gain through an interdisciplinary team-based project. During the Winter Quarter, project teams select an unmet clinical need identified within the UCLA Health System or by industry partners, and the teams are tasked with brainstorming and developing concepts to solve these medical needs. The Spring Quarter of the course focuses on concept refinement, rapid prototyping, provisional patent submission, and building a business plan. Lectures include invited guest speakers and panels composed of industry representatives from venture capital, medical device, design and law, as well as UCLA and Art Center College of Design faculty.

This quarter focuses on concept refinement, prototyping, provisional patent submission, and building a business plan. Additionally, this quarter each project team is assigned an industry and a clinical mentor to provide guidance on the product development process and entrepreneurship as it relates to medical devices. The culmination of the two-quarter course is the completion of a business plan and pitch by each team, which will be presented to a panel of angel investors and venture capitalists at the end of quarter.

Instructors

Roy Doumani, JD – Executive Director of Business of Science Center and Professor in Molecular and Medical Pharmacology, David Geffen School of Medicine

Wentai Liu, PhD - Professor in the Department of Bioengineering, Henry Samueli School of Engineering and Applied Science

Jennifer McCaney, PhD – Lecturer, Anderson School of Management
Email: jennifer.mccaney@anderson.ucla.edu

Kalyanam Shivkumar, MD, PhD - Professor of Medicine and Radiology, Director of UCLA Cardiac Arrhythmia Center and EP programs, David Geffen School of Medicine

Visiting Scholars

Paul Grand – Managing Director of Pacific Coast Office, Research Corporation Technologies

Jeff Higashi – Faculty, Art Center College of Design

Jason Jolly – Chief Operating Officer, Brain Biomarker Analytics

MTI Program Fellows

The MTI Fellows are postgraduates with experience in medical device entrepreneurship, engineering design, and product development. The role of the MTI Fellows is to provide mentorship and instruction to student project teams. Each student is also individually assigned an MTI Fellow as a point of contact for the course.

Alex Shen, PhD

Email: shenibo@gmail.com

Sascha Hasan, PhD, MBA

Email: sascha.hasan@gmail.com

MedTech Program Administration

Samantha Le – Administrative Director, UCLA Business of Science Center

Email: samanthale@mednet.ucla.edu

Clinical Leadership

Clinical leadership will provide advice and mentorship to the teams, participate in classes, and help guide the overall MTI program development.

Jean deKernion, MD – Professor of Urology and Senior Associate Dean of the David Geffen School of Medicine

Aman Mahajan, MD, PhD – Chair of the Department of Anesthesiology, David Geffen School of Medicine

Ben Wu, DDS, PhD – Chair of the Department of Bioengineering, Henry Samueli School of Engineering and Applied Science

Criteria for Acceptance into Course

UCLA graduate or professional students are permitted to enroll in this course. In order to qualify for course enrollment, students are required to submit a resume and short statement explaining their interest in the course. Enrollment in Spring Quarter is contingent upon participation and satisfactory performance in the Winter Quarter course. In the event that there is attrition following Winter Quarter, enrollment will be re-opened to fill any openings or to meet team needs. Enrollment will be strictly at the consent of the instructors.

Class Format

Weekly classes are separated into 3 parts: i) introduction to the lecture topic by faculty and fellows (15 min); ii) presentation by a guest speaker (45 min) followed by Q&A initiated by the MTI Fellows and students (30 min) and a break (15 min); iii) individual and project team-based workshops with guidance provided by the MTI Fellows, industry experts, and course instructors (75 min).

Class Recordings

Sessions will be recorded and available on the class website. Portions of sessions containing student-derived material will only be shared with the student(s) that own the material.

Textbook (Required)

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 Biodesign website: ebiodesign.org.

Students are encouraged to keep a lab notebook to document the product design process and to keep records for their intellectual property submissions, which will be prepared in the Spring Quarter.

Assigned Readings

Required readings will be assigned for every session and should be completed prior to the class. Readings consist of textbook chapters, and current articles from key stakeholders, policy-makers and manufacturers. Readings are the responsibility of the student, and each session one to two students will be asked to give a short introduction to the class based on the readings.

Course Outline

Week 1

Prototyping & Team Dynamics

Wednesday, April 1st 2015

Rapid Prototyping and the Iterative Design Process

Guest Speaker: Jeff Higashi, Art Center College of Design

Textbook

4.5 Prototyping (*p. 340 - 362*)

Handouts

MTI UCLA Prototyping Resources

Funding Resources – UCLA & National Start-up Competitions

Workshop

Team Building

Week 2

Design for Manufacturing

Monday April 6th

MTI Team Faculty & Mentor Meetings

Anderson School of Management, Cornell Hall, D210, 4-7pm

Wednesday April 8th

Design for Manufacturing

Guest Speaker: Pradnya Parulekar, Key Accounts Manager, NuSil Technology

Textbook

5.5 Quality & Process Management (*p. 473 - 500*)

Reading

S. Chilukuri, "Design to Value in Medical Devices," McKinsey & Company 2010

Handout

MTI Prototyping Kit

Workshop

Rapid Prototyping

Deliverable 1 Concept Refinement & Budget Plan DUE 12 pm

Week 3

Intellectual Property Strategy & Provisional Patents

Wednesday, April 15th

Intellectual Property Strategy

Guest Speaker: Dr. Samir Elamrani, Partner, Wilson Sonsini Goodrich & Rosati

Textbook

5.1 IP Strategy (*p. 388 - 405*)

Reading

D. Portnow, "How to Expedite Examination of a Patent Application," Wilson Sonsini Goodrich & Rosati, The Life Sciences Report, Fall 2013

K. Johnson and D. Melwani, "5 Things a Medical Device Company Can Do to Maximize its Competitive Patent Position," *MedicalDeviceSummit.com*, epub. March 15, 2013

D. Dykeman and M.Cohen, "Patent Trolls Invade MedTech," *Medical Device and Diagnostic Industry*, epub. February 21, 2014

Handouts

MTI Prior Art Search Guidelines

MTI Prior Art Team Inventory Report

Sample MTI Prior Art Team Inventory Report

UCLA OIP Related Art Report

Workshop

Provisional Patent Application Preparation – Technology Transfer Officers, UCLA Office of Intellectual Property

Week 4

MedTech Start-up Founder's Perspective: Diagnostics & Prototyping Review

Wednesday April 22nd

MedTech Start-up Founder's Perspective: Diagnostics & Diabetes

Guest Speaker: Craig Misrach, CEO & Co-founder, Freedom Meditech

Textbook

5.2 Early R&D Strategy (p. 407 - 424)

Reading

A Cure for Health Care Costs - Where the Health Dollars Go," *MIT Technology Review*, Business Report, September 2013, page 7

T. Bodenheimer, "Confronting The Growing Burden Of Chronic Disease: Can The U.S. Health Care Workforce Do The Job?" *Health Affairs*, 28 no. 1, 2009: 64-74

A. Schwartz, "This Six-Second Eye Scan Can Tell You If You're Going To Get Diabetes," *Fast Company*, epub. January 28, 2014

Handout

MTI Prototyping Peer Review Worksheet

Workshop

Prototyping Review

Deliverable 2 Prototyping Review DUE 12 pm

Week 5

MedTech Market Strategy

Wednesday April 29th

MedTech Market Strategy

Guest Speaker: David Nyugen, RF Surgical

Textbook

5.6 Reimbursement Strategy (p. 503 - 533)

5.7 Marketing & Stakeholder Strategy (p. 536 - 554)

Workshop

Business Model Canvas Workshop

Week 6

Monday May 4th

MTI Team Faculty & Mentor Meetings

Anderson School of Management, Cornell Hall, D210, 4-7pm

Wednesday May 6th

Regulatory Strategy & Clinical Trial Design

Guest Speaker: Evelyn De La Vega, MSRS, RAC, Global Regulatory Affairs Manager, Bausch & Lomb

Textbook

5.3 Clinical Strategy (p. 425 - 455)

5.4 Regulatory Strategy (p. 458 - 571)

Reading

T. Kampfrath and S. Cotton, "The new collaborative path in medical device development: The medical device innovation consortium," *Clinical Biochemistry*, 46 (2013): 1320-1322

K. Fargen et al., "The FDA approval process for medical devices: an inherently flawed system or a valuable pathway for innovation?" *Journal Neurointerventional Surgery*, 5 no. 4 (2013): 269-275

M. Thibault, "FDA Approving Devices Faster," *Medical Device and Diagnostic Industry*, epub. March 26, 2015

Handouts

MTI FDA Regulatory Approval Case Studies

Workshop

FDA Regulatory Approval Case Studies

Deliverable 3 Preliminary Invention Report & Provisional Patent Application DUE 12 pm

Week 7

MedTech Start-up Founder's Perspectives

Wednesday May 13th

Start-up Founder's Perspectives: Software in MedTech

Guest Speakers: Guri Stark, CEO, CorTech Labs

Textbook

5.8 Sales & Distribution Strategy (*p. 556 - 578*)

5.9 Competitive Advantage & Business Strategy (*p. 580 - 595*)

Workshop

Value Proposition Development

Week 8

MedTech Start-up Founder's Perspectives & Financial Modeling

Wednesday May 20th

MedTech Start-up Founder's Perspectives: Medical Devices

Guest Speaker: TBD

Textbook

6.1 Operating Plan and Financial Model (*p. 612 - 655*)

6.4 Licensing and Alternate Pathways (*p. 708 - 725*)

Handout

Sample MedTech Business Plan

MTI Business Plan Checklist

MTI Start-up Financials Spreadsheet Template

Workshop

Start-up Financials – Jason Jolly, COO, Brain Biomarker Analytics

Week 9

Start-up Funding & Business Plan Development

Wednesday May 27th

Venture Capital, Corporate, and Angel Financing – Panel Discussion

Panelists: TBD

Textbook

6.2 Business Plan Development (*p. 657 - 675*)

6.3 Funding Sources (*p. 676 - 706*)

Reading

J. Fleming, "The Decline Of Venture Capital Investment In Early-Stage Life

Sciences Poses A Challenge To Continued Innovation," *Health Affairs*, 34 no.2 (2015): 271-276

D. Malhotra, "How to Negotiate with VCs," *Harvard Business Review*, May 2013

T. David, "Your Elevator Pitch Needs an Elevator Pitch," *Harvard Business Review*, December 30, 2014

Handouts

Sample Term Sheet

MTI Investor Pitch Guidelines

Workshop

The Pitch Deck

Deliverable 4 Business Model Canvas & Value Proposition Design Worksheets DUE 12 pm

Week 10

Final Meetings & Business Pitches

Monday June 1st

MTI Team Faculty & Mentor Meetings

Anderson School of Management, Cornell Hall, D210, 4-7pm

Wednesday June 3rd

Final Presentations – Project Team Group Presentations to Judges Panel

Handout

MTI Final Pitch Peer Review Worksheet

Deliverable 5a Business Pitch DUE 12 pm

Friday June 5rd

Deliverable 5b Business Plan DUE 12 pm

Grading

Requirements for letter grading in Spring Quarter will include 4 deliverables. A hard copy of all deliverables is due in class, and each student or student team must email a copy by 12 pm on the DUE DATE of the deliverable to the MTI Fellow assigned to the individual or team in the following format: "Student Last Name_Student First Name_Deliverable X" or "Student Team Name_Deliverable X."

1. Deliverable 1 – Concept Refinement & Budget Plan	10%
2. Deliverable 2 – Prototyping Review	15%
3. Deliverable 3 – Preliminary Invention Report & Provisional Patent Application	15%
4. Deliverable 4 – Business Model Canvas & Value Proposition	15%
5. Business Plan & Pitch	35%
6. Attendance and Participation	10%

Deliverables

Deliverable 1 – Concept Refinement & Budget Plan (*DUE Week 2 - April 8th*)

Project teams will submit a detailed description(s) of a refined concept presented in the Winter Quarter final deliverable in parallel with a budget plan for Spring Quarter. This deliverable should expand on the preliminary concept description and discuss how the concept has been refined to better meet the clinical need. Key sub-modules of the device design should be identified, along with required prototyping needs to test and validate critical modules should be outlined in the budget. Drawings of the concept and its deployment and/or interactions with the patient and the end user are recommended.

Length: 2 page description & 1 page budget

Deliverable 2 – Prototyping Review (*DUE Week 4 - April 22nd*)

Project teams will present device and/or sub-module prototypes. Presentation format will be live demonstration of prototypes. Slides are not required for this presentation, but if desired, slides may include drawings of prototypes, CAD files, program architecture for software, video of prototypes in action, etc. Teams are encouraged to present the evolution of their prototypes with an emphasis on iterative prototyping, ranging from drawings to 3D models.

Length: 7 minute presentation (3 min Q & A)

Deliverable 3 – Preliminary Invention Report & Provisional Patent Application (*DUE Week 6 - May 6th*)

In preparation for this deliverable, project teams will meet with representatives from the Office of Intellectual Property and complete a draft of the UCLA Invention Report Form. This deliverable will outline key intellectual property or drawings that may potentially form the basis for a provisional patent application. Student teams are expected to submit their finalized Invention Report Form to OIP one week prior to the final presentation and communicate their intention to file a provisional patent. Student teams intending to file a Provisional Patent Application should also include an accompanying OIP Related Art report with the most relevant Art listed first.

Length: 5 page form found on the OIP website (<http://oip.ucla.edu/submit-invention-report>)

Deliverable 4 – Business Model Canvas & Value Proposition Design Worksheets (*DUE Week 8 - May 20th*)

Student project teams will complete the Business Model Generation and Value Proposition Worksheets and a one page discussion on the assumptions and evolution of their canvas as well as any key outstanding risks that have been addressed or remain to be addressed.

Length: 2 page template and 1 page discussion

Deliverable 5 – Business Plan & Pitch (*DUE Week 10 - June 3rd, June 5th*)

Project teams will submit a business plan and prepare a pitch that effectively communicates the value proposition for their technology to potential investors. A detailed outline of the grading criteria for the business plan will be discussed in class.

Length: 15-20 page business plan & 10 slide presentation (10 minute presentation & 5 minute Q & A)