BIOENGR 233A/MGMT 271A – MedTech Innovation I: Entrepreneurial Opportunities in Medical Technology Winter 2015

Class Hours:	**Monday, Wednesday 4:10-6:00 pm**
Location:	**Gold Hall, B117**
Instructors:	**Dr. Kalyanam Shivkumar, MD, PhD**
	Wentai Liu, PhD
	Jennifer McCaney, PhD
	Roy Doumani, JD
Office Hours:	**By appointment**

Welcome to the Winter Quarter of the MedTech Innovation (MTI) Program. The goal of the 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 hands-on 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 students are presented with a list of unmet clinical needs documented by the MedTech Innovation Fellows during observation and shadowing at UCLA Hospital during the Fall Quarter as well as industry partners. Students select a need of interest and validate whether an opportunity for medical device development exists. Following completion of an individual need assessment, students form interdisciplinary teams around needs of common interest, and the project teams work toward generating concepts to solve each need. Students learn lean startup principles, design thinking ideology, value proposition development, brainstorming techniques, and tools for clinical concept generation. At the end of this quarter – which marks the midpoint of the course – student teams present three final concepts to a panel of clinicians, industry experts, and venture capitalists.

Instructors

Roy Doumani, JD – Executive Director, Business of Science Center and Professor in Molecular and Medical Pharmacology, David Geffen School of Medicine
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Wentai Liu, PhD – Professor in the Department of Bioengineering, Henry Samueli School of Engineering and Applied Science
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Jennifer McCaney, PhD – Lecturer, Anderson School of Management
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Kalyanam Shivkumar, MD, PhD – Professor of Medicine and Radiology and Director of UCLA Cardiac Arrhythmia Center and EP programs, David Geffen School of Medicine
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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

MedTech Innovation Fellows
The MedTech Innovation Fellows are postgraduates with experience in entrepreneurship, engineering and 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 a Medtech Innovation Fellow as a point of contact for the course.

Alex Shen, PhD
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Sascha Hasan, PhD, MBA
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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 ABI 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 or that teams would like to add additional capabilities, enrollment will be re-opened to fill this demand. Enrollment will be strictly at the consent of the instructors.

Class Format

During the Winter Quarter, weekly classes are divided into two sessions. (1) Monday sessions are focused on team-based work and conducted in a "start-up garage" format, where teams are guided through various exercises in venture formation and mentored by faculty and MTI Fellows. During the first four weeks of class, both Monday and Wednesday sessions are devoted to MedTech Bootcamp and will follow a Wednesday format. (2) Wednesday sessions are typically: i) an introduction to the lecture topic by faculty and MTI Fellows (*15-30 min*); ii) a presentation by a guest speaker or instructor (30-*45 min*); iii) Q&A initiated by the MTI Fellows and students (*30 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.

Class Attendance

Attendance is taken at every class and any absences must be approved in advance by the instructors or the MTI Fellows in writing. Please note that FEMBAs, medical, and remote students are only required to attend on Mondays and may attend Wednesday sessions as their schedule permits. Wednesday course content and recordings will be available online.

Textbook (Required)

The required textbook for the course is *Biodesign: The Process of Innovating Medical Technologie*s by Zenios, Makower, and Yock. The book is available at the campus bookstore and is on reserve at the Engineering Library. More information about the book can be found at the Stanford Website ebiodesign.org.

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.

Documentation

Students are encouraged to keep a bound 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.

Class Schedule

Week 1 – Introduction to Innovation & Clinical Needs Finding

Monday January 5th
MedTech Innovation Overview and Review of Unmet Clinical Needs
Speaker: MedTech faculty

Reading

G. Snyder, F. Abdullah and M. Lefferts, "The Three Rules in Medical Technology: The Transformation of an Industry," Deloitte University Press, December 11, 2013

Workshop

Medtech Innovation Fellows, Unmet Clinical Need Overview

Wednesday January 7th
Medtech Industry Overview & Starting a MedTech Company as a UCLA Student
Speaker: Leo Petrossian, PhD, Co-founder & CEO, Neural Analytics

Textbook

1.1 Strategic Focus *(p. 4 - 19)*
1.2 Observation and Problem Identification *(p. 20 - 36)*
1.3 Needs Statement Development *(p. 37 - 50)*
Acclarent Case Study: Needs Finding *(p. 51 - 55)*

Individual student needs preferences DUE by 5 pm on Friday 1/09

Week 2
The Lean Startup Model & FDA Regulation

Monday January 12th
The Lean Startup Methodology in Healthcare
Speaker: MedTech Innovation Faculty

Textbook

2.1 Disease State Fundamentals *(p. 60 - 73)*
2.2 Treatment Options *(p. 74 - 94)*

Reading

S. Blank, "Why the Lean Start-Up Changes Everything," *Harvard Business Review*, May 2013

Workshop

The Business Model Canvas

Individual student need assignments announced IN CLASS

Wednesday January 14th
Regulatory Affairs Overview – FDA Pathways for Medical Devices
Speaker: TBD

Textbook

4.2 Regulatory Basics *(p. 273 - 298)*

Reading

J. Makower, A. Meer and L. Denend, "FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies," November 2010

Workshop

Case Study – Regulatory Pathways for Medical Devices

Week 3
Key Stakeholders & Market Assessment

Wednesday January 21st
Venture Capital Perspective on Stakeholders & Market Opportunities
Speaker: Paul Grand, Managing Director, RCT Ventures

Textbook

2.3 Stakeholder Analysis *(p. 95 - 116)*
2.4 Market Analysis *(p. 117 - 142)*

Reading

"Life Sciences Q3 2014 MoneyTree™ Report," Price Waterhouse Coopers, November 2014

Workshop

Market Research 101

Deliverable 1 DUE

Week 4
Intellectual Property & Reimbursement

Monday January 26th
Intellectual Property Basics – Patents, Filings & University
Speaker: Michael Wise, Partner, Perkins Coie
Brian Shedd, PhD, Technology Transfer Licensing Officer, Office of Intellectual Property and Industry Sponsored Research, UCLA

Textbook

4.1 Intellectual Property Basics *(p. 210 - 272)*

Reading

M. Wise and L. Dueppen, "University Patent Filing Strategy," Perkins Coie LLP

Wednesday January 28th

Reimbursement & Healthcare Reform

Speaker: Charmie Chirgwin, President & CEO, PRO-Spectus, Inc.

Textbook

4.3 Reimbursement Basics *(p. 299 - 318)*

Reading

C. Sorenson, M. Drummond and L. Burns, "Evolving Reimbursement And Pricing Policies For Devices In Europe And The United States Should Encourage Greater Value," *Health Affairs* 32, no. 2 (2013): pp. 788 - 796

Workshop

Reimbursement Rates in the U.S.

Week 5

Clinical Needs Assessment & Innovation at UCLA

Monday February 2nd

Clinical Need Poster Session, CNSI Building Presentation Room

Textbook

2.5 Needs Filtering *(p. 143 - 164)*

Acclarent Case Study: Needs Screening *(p. 165 - 171)*

Deliverable 2 DUE 12 pm

Top 5 needs preferences for project team formation DUE by 7 pm on Wednesday 2/4

Wednesday February 4th

Innovation at UCLA Hospital & The Ecosystem for Entrepreneurship at UCLA

Speaker: Dr. David Feinberg, President and CEO, UCLA Health System

Bill Ouchi, Distinguished Professor of Management and Organizations Professor, UCLA Anderson School of Management

Reading

T. Lee and T. Cosgrove, "Engaging Doctors in the Health Care Revolution," *Harvard Business Review*, June 2014

B. Wright, "Industry-Funded Academic Inventions Boost Innovation," *Nature* 507, (2014): pp. 297 - 299

R. Simon, "Universities Push Harder into Realm of Startups," *The Wall Street Journal*, December 17, 2014

H. Zappe, "Bridging the Market Gap," *Nature* 501, (2013): pp. 483-485

Student teams announced on Friday February 6th

Week 6
Design Thinking in Healthcare – Brainstorming and Concept Development

Monday February 9th
Effective Brainstorming – A Process for Product Design
Speaker: Jeff Higashi, Faculty, Art Center College of Design

Textbook

3.1 Ideation and Brainstorming *(p. 176 - 192)*

Reading

T. Kelley and D. Kelley, "Reclaim Your Creative Confidence," *Harvard Business Review*, December 2012

Workshop

DesignStorm I – Team Brainstorming Session

Wednesday February 11th
Design Thinking in Healthcare
Speaker: Eric Olson, Director of Design, Karten Design
Chris Wu, Senior Designer, Karten Design

Textbook

3.2 Concept Screening *(p. 193 - 204)*
Acclarent Case Study: Concept Generation *(p. 205 - 206)*

Reading

T. Brown, "Design Thinking," *Harvard Business Review*, June 2008

Deliverable 3 DUE 12 pm

Week 7
Industry Perspectives & Medtech Business Models

Wednesday February 18th
Industry Perspectives & Medtech Business Models I - Devices & Drug Delivery
Panelists: Hanson Chang, Director – Product Development, Implantable Electronic Systems Division, St. Jude
Chris Folk, Device Strategy Principle Engineer, Amgen

Textbook

4.4 Business Models *(p. 319 - 339)*

Machine shop training: Friday February 20th 8-9 am & 10-11 am

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Week 8
Concept Map Presentation & Business Model Generation

Monday February 23rd
Concept Map Review

Deliverable 4 DUE 12 pm

Wednesday February 25th
Value Proposition Design
Speaker: MedTech Innovation Faculty

Textbook

5.7 Marketing and Stakeholder Strategy *(p. 536 - 540)*

Reading

M. Porter, "What is Value in Health Care?" *The New England Journal of Medicine* 363, no. 26 (2010): pp. 2477-2481

A. Osterwalder, "The Value Proposition Canvas," http://www.businessmodelgeneration.com/downloads/value_proposition_designer_draft.pdf

A. Osterwalder, "Value Proposition Canvas Explained," https://www.youtube.com/watch?v=aN36EcTE54Q

Workshop

The Value Proposition Canvas – Linking to Business Model Canvas

Machine shop training: Friday February 27th, 8 -9 am & 10-11 am

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Week 9
Concept Development & Refinement

Monday March 2nd
Concept Development & Brainstorming
Speaker: MedTech Innovation Faculty

Textbook

4.6 Final Concept Selection *(p. 367 - 377)*

Workshop

DesignStorm II – Team Brainstorm Session

Machine shop training: Monday March 2nd, 10-11 am

Wednesday March 4th
Understanding your Value Proposition
Speaker: David Nguyen, RF Surgical

Workshop

Presentation Development

Week 10
Final Concept Presentations & Team Evaluations

Monday March 9th
Presentations – Project Team Concept Presentations

Deliverable 5a DUE 12 pm

Wednesday March 11th
Evaluation Meetings with MedTech Innovation Faculty & Fellows

Deliverable 5b DUE 12 pm

Grading
Requirements for letter grading for the Winter Quarter will include four 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 ABI 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." Please note that enrolled medical school students are only required to submit Deliverables 1 and 2 and contribute to team assignment, Deliverables 4a and 4b.

1. Deliverable 1 – Physician Interview Guide 10%
2. Deliverable 2 – Individual Need Assessment & Poster 25%
3. Deliverable 3 – Product Development Timeline 10%
4. Deliverable 4 – Concept Map 10%
5. Deliverable 4 – Team Needs Specification & Concept Presentation 35%
6. Attendance* & Participation** 10%

*More than one unexcused absence will result in a letter grade drop.
**Team-based peer reviews will be considered in determining participation grade.

Deliverables
Deliverable 1 – Physician Interview Guide *(DUE Week 3 – January 21)*
Students will prepare a one-page mock interview guide targeted for a physician or healthcare professional working in an area related to their medical need. The interview guide should seek to understand the true nature of a clinical need and identify relevant information, such as procedure time, target patient population or subgroups, procedure complications, etc.
Length: 1 page

Deliverable 2 – Individual Need Assessment & Poster *(DUE Week 5 – February 2)*
Following the first class, each student will select an unmet clinical need and spend two weeks preparing an individual need assessment. The purpose of the individual need assessment is to validate whether an opportunity for medical device development or innovation exists within the specified need statement. The need may also be restated or refined in order to better articulate the true clinical need. Sources such as current literature, industry/trade publications, the USPTO database, and market research reports are recommended; however, primary research, such as physician interviews and scientific articles are highly encouraged. Two formats will be submitted for this deliverable: a written document and a poster presentation. The poster will be subject to peer review and grading by a panel of judges that will circulate during the poster session.

Deliverable 2a – Individual Need Assessment
This deliverable should provide a brief description of medical need and the relevant clinical context. Students should provide a market assessment that includes estimated market size, market dynamics, existing solutions and competitors, current treatments or products and their limitations, and potential barriers to entry for new products. The need assessment should weigh all the research findings from the process of validating the clinical need and make a final recommendation on the potential opportunity for medical device development.
Length: 3-5 pages

Deliverable 2b – Poster Presentation
Each student will prepare a poster presentation that summarizes the findings of the need assessment and includes a final recommendation for pursuing the medical need. Posters must be emailed on the due date of the deliverable and posted before class in the CNSI main lobby where an easel will be available with the need #.
Length: 24" x 36" poster or a series of PowerPoint slides printed by the student. Maximum poster size is 36" x 48."

Deliverable 3 – Medical Device Product Development Timeline *(DUE Week 6 – February 11)*
Students will individually select a currently marketed medical device, potentially in an area of interest related to the project team clinical need, but not required. For this medical device, a product development timeline will be created that spans the process from initial concept generation to commercialization. Consideration should be given to clinical trials, regulatory pathway, and post-marketing studies if necessary.
Length: 1 page timeline accompanied by 1 page summary

Deliverable 4 – Teams Concept Map *(DUE Week 8 – February 23)*
Student project teams will submit a concept map, which organizes and summarizes the concepts generated from brainstorming sessions. The concept map may be submitted as a hard copy or a digital version.

Deliverable 5 – Teams Needs Specification & Concept Presentation *(DUE Week 10)*
Student project teams will submit a detailed needs specification, which expands on deliverable two and defines key metrics for product development. Three concepts will be presented and discussed in relation to the desired product metrics and the current standard of care. Two formats will be submitted for this deliverable: a written document and a PowerPoint presentation.

Deliverable 5a – Team Needs Specification *(DUE Week 10 – March 9)*
Each student team will submit a detailed needs specification that expands on the detail and level of understanding presented in the individual needs statement. Additional areas to be addressed include detailed market analysis, competitive landscape, intellectual property considerations, and refined ranked needs criteria with a range of design/user specifications. Additionally, at least 3 concepts for product development should be presented and discussed relative to the target needs criteria. Sketches, storybooks, CAD drawings, etc. are encouraged. A final recommendation regarding which concept the team plans to pursue in the Spring Quarter should be indicated and justified at the conclusion of the document. Team member evaluations will also be submitted with this deliverable.
Length: 7-10 pages

Deliverable 5b – Team Concept Presentation *(DUE Week 10 – March 11)*
Each student team will be given 15 minutes to present, followed by 5 minutes of Q&A. Presentations should include a brief description of the medical need and highlights of the findings included in the written needs specification. This presentation should NOT be interpreted as a PowerPoint summary of the team needs specification. The three concepts for device development should be presented clearly and weighted according to the key metrics identified for successful product development.
Length: 12 slides