Course Syllabus

Technology Assessment and Regulation of Medical Devices
Stanford University – MS&E 256 – Spring 2016

Meeting time: Fridays 1:30 –3:20 pm; Thornton 102

Units:
1 - MS&E 256A (attendance only)
3 - MS&E 256 (attendance and class project)

Course Summary: Regulatory approval and reimbursement for new medical technologies are key components of successful product commercialization. This class discusses the regulatory and payer environment in the U.S. and abroad, and common methods of health technology assessment. A framework is presented to identify factors relevant to the value proposition and adoption of new medical devices and the management of those factors in the design and development phases. In addition to lectures and case studies, guest speakers from government (FDA) and industry share their experiences. Students investigate real-world diagnostic and therapeutic technologies in course projects.

Instructor:
Jan B. Pietzsch, Ph.D.
Consulting Associate Professor, MS&E
Core Faculty Member, Stanford Biodesign Program
President and CEO, Wing Tech Inc.
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Office Hours: Fridays 3:45 – 4:30 pm, Huang 352

Co-Instructors:
John Hernandez, Ph.D.
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Course Assistants: Claire Margolis, claiream@stanford.edu

Office Hours: Mondays, 1:00-2:00pm, Location TBA
Office hours will be Skype-accessible for remote students.

Prerequisites: No prerequisites are required. Open to students of all levels and majors that are interested in medical technology and its commercialization. Limited enrollment.

Course Website: http://www.stanford.edu/class/msande256

Required Textbook: No textbook required.

Handouts, case studies, and references will be distributed over the course of the quarter.

Paper/Project: Students taking the class for 3 units are required to perform a class project. The project deliverable is a final report and a final presentation.

In cases where team formation is not possible, an exception may be granted to accommodate a 2-student project or individual project. This exception may only be granted for specific, justifiable reasons (e.g., out-of-region SCPD student).

Final presentations are scheduled for the day of the last class (May 27). The motivation behind this format is to encourage discussion and learning from your peers about the technologies they have been working on, and the insights they have gained.

Project topics will be presented during the first class on April 1. Students are welcome to suggest topics of their choice (approval of topic by instructor is required).

Students are asked to form teams (3 students for 3-unit project) and to submit their project preferences after the first class (see below for details).

Grading:

For 1 Unit:	CR/NC Option Only (based on attendance)	
For 3 Units:	Letter or CR/NC	
	Midterm Outline & Meeting:	10%
	Final Presentation:	20%
	Final Paper:	70%

Participation and contributions to class discussion are a factor in grading, and will be taken into account in final grade determination. Attendance is required in all classes.
Additional information on specific grading criteria for the paper and presentation are listed further below in this document.

Certificates: This course is an SCPD course and is a core course of the following Graduate Certificate Programs: Biodesign; Cardiovascular Bioengineering; Product Creation and Innovative Manufacturing; Management Science & Engineering.

Course Schedule:

Lecture 1
Friday, April 1st

Topics:

- Course Overview & Introduction
- Organizational Details
- Definitions of Medical Devices and of Health Technology Assessment
- Discussion of Regulation and Reimbursement Hurdles
- Role & Mission of FDA in Medical Device Regulation
- Presentation of Project Topics
- Resources and references for research on medical devices

- Guest speaker (end of class): Gary Burbach, Medtech executive and former CEO, Thoratec, Inc. (now part of St. Jude Medical)

Assignment DUE: Monday April 4th (by noon)

- **Project teams and topic preference submission**

Students will be notified about results on Tuesday, April 5th before noon.

Assignment: Thursday April 7th

- **First project team meeting with Dr. Pietzsch (10 mins. per team)**

Meeting slots from 4:00 – 7:00 pm. Please sign up electronically on or before Wednesday, April 6th (noon).

Lecture 2
Friday, April 8th

- Regulatory pathways and FDA classifications
- Risk analysis
- FDA's Pre- and Post-market activities in regulating devices (Total Product Lifecycle)
- FDA performance metrics

- Guest speaker (end of class): Colin Cahill, Vice President, Venrock

Lecture 3
Friday, April 15th

- Clinical Trials: Requirements for new technologies
- Clinical Trials: Outcome Measures and Study Design
- Case studies of clinical trials
- Quality Systems Regulation (QSR)

- Guest speaker (end of class): Chris Pfaff, VP of Marketing and Clinical Research, Ceterix Orthopaedics, Inc.

Lecture 4
Friday, April 22nd

Guest lecture: The FDA's Perspective

Elias Mallis
Director, Division of Industry and Consumer Education
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration

Assignment DUE: Monday, April 25th

- **Midterm documents due at noon (5 pages max.)**

Assignment: Thursday, April 28th

- **Midterm meetings with Dr. Pietzsch (15 mins. per team)**

Meeting slots from 3:30-7:00 pm Thursday, April 28th. Please sign up electronically by April 26th.

Lecture 5:
Friday, April 29th

- International Regulation of Medical Devices
- Regulation of mobile health technologies

- Initial overview of health-economics and reimbursement

- Guest speaker (end of class): Marta G. Zanchi, Ph.D., Lecturer, Stanford University Department of Surgery; Course Co-Director, Biodesign for Mobile Health

Lecture 6
Friday, May 6th

Guest lecture: Health Economics and Reimbursement – Industry Perspective

Sheri Dodd, Vice President & General Manager, Medtronic Care Management Services, Medtronic, Inc.

Lecture 7:
Friday, May 13th

- Health economics methods and case studies:
  - Cost analysis
  - Outcomes analysis
  - Cost-effectiveness and budget impact analysis

Guest lecture (2nd half of class):
Medicare Decision Making Process for National Coverage Decisions – Boston Scientific Watchman® case study
Wendy Chan, Manager, Global Health Economics & Reimbursement, Boston Scientific [TBC]

Lecture 8
Friday, May 20th

- Case studies of health-economic studies of medical devices
- Approaches to early-stage technology and value assessment during the device development process

Garrett Schwab, President and CEO, Ziva Medical, Inc.

Lecture 9
Friday, May 27th

- Course Summary
- Concluding Remarks
- Final Presentations (first part – other presentations between 3:30 and 4:30 pm)

Assignment DUE: Friday, May 27th

- **Presentation in class (submit slides by end-of-day Wed. May 25th)**
- **Final papers due at midnight (electronic submission)**

Additional Information about Project and Evaluation:

Grading Criteria for Final Papers:

The key criteria we are looking for in the papers are substance and form: These involve content, clarity and conciseness, analysis and insight, quality of references, structure of the paper, appropriate use of citations, and overall appearance (layout and editing). You will be able to get additional bonus points for compelling use of tables and figures.

Below is some guidance for the 3-unit papers. Please keep in mind that high quality content is most important, and is always preferred over quantity with limited insight.

3 unit papers:
3-person teams: max 30 pages plus appendices.

> [if only two persons working on 3-unit topic: max. 23 pages plus appendices; if only one person: max. 15 pages plus appendices]

Among the important evaluation criteria, please put sufficient emphasis on the "appropriate use of citations" criterion. By definition, many of your papers need to rely heavily on a review of existing data and material, which requires significant inclusion of original contributions by others. Please make sure that you cite these sources appropriately, and that you follow the appropriate academic protocols for doing so (the following websites contain some useful information on how to avoid insufficient referencing of the work of others: http://www.northwestern.edu/uacc/plagiar.html , http://www.stanford.edu/dept/vpsa/judicialaffairs/students/plagiarism.htm). If you have questions about citations that are not answered to your satisfaction by these websites, please raise the question with one of us in the teaching team.

To give you some guidance of what we expect in the papers, we will post a couple of high-quality projects from previous years in CourseWork. You may find review of these documents helpful as you are getting started with your papers.

Structure of the Final Papers:

Be sure that your paper includes the following:

- Brief abstract or executive summary at the beginning of the paper, summarizing the objective of your paper, how you approached the topic from a methodological point of view, and what are the main findings and conclusions of your work (this can be brief and should certainly not be more than one page overall; if necessary, the abstract can be counted as an additional page outside the page requirements outlined earlier)

- Introduction section to your paper in which you, again, briefly outline the objective/ motivation of your work, and introduce the field of your study (what is the disease that's treated with your device, etc.)

- Summary/conclusion section in the end, in which you clearly identify the main findings of your work, and share/ reiterate the major insights you have gained. Remember that analysis and insight gained should be one of the pivotal elements of your paper, and this is where you can reflect on it.

Information about Final Presentation

Students taking the course for 3 units are expected to distill their research into a slide presentation. On-campus students will give a brief oral presentation on June 1st. The Final Presentation schedule will be published near the end of the quarter.

SCPD students are not required to present in class, although if a SPCD student is local and can present, he or she should contact the teaching team and a suitable time will be assigned.

Additional information on the final presentations and a slide template will be distributed in early May.