Course Syllabus

Technology Assessment and Regulation of Medical Devices
Stanford University – MS&E 256 – Spring 2012

Meeting time: Fridays 1:15 –3:05 pm; Huang Ctr. 018

Units: 1 (attendance only) – 3 units (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 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.
Office: Huang Engineering Center, Room 352
pietzsch@stanford.edu

Office Hours: Fridays 4:00 – 5:00 pm, Huang 352

Co-Instructor (QSR and Design Controls):
Theresa Brandner-Allen, MS
VP of Quality and Regulatory, Invuity, Inc.
Former VP of Regulatory and Quality, Penumbra, Inc.
theresabrannder@yahoo.com

Course Assistants: Sabina Alistar
Doctoral candidate, MS&E
ssabina@stanford.edu
Office Hours: Mondays 2:00-3:00 pm, Huang 218
Lauren Cipriano  
Doctoral candidate, MS&E  
cipriano@stanford.edu  

Office Hours: Wednesdays 10:00-11:00am (virtual/WebEx office hours – SkypeID: lauren.cipriano; Phone/Webex: to be announced)

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 (June 1). 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 6. 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 6th

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

Assignment DUE: Monday April 9th (by noon)
- Project teams and topic preference submission

Students will be notified about results on Tuesday, April 10th before noon.

Assignment: Thursday April 12th
- First project team meeting with Dr. Pietzsch (10 mins. per team)

Meeting slots from 4:30 – 7:00 pm. Please sign up electronically on or before Wednesday, April 11th (noon).

Lecture 2
Friday, April 13th

- 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): Theresa Brandner-Allen, MS&E 256 Co-Instructor, VP Regulatory and Quality, Invuity Inc.; former VP Regulatory and Quality, Penumbra, Inc.
Lecture 3
Friday, April 20th

- Clinical Trials: Requirements for new technologies
- Clinical Trials: Outcome Measures and Study Design
- Case studies of clinical trials

- Guest speaker (end of class): Greg Bakan, Vice President Sales and Marketing, Nevro Inc.

Lecture 4
Friday, April 27th

- Quality Systems Regulation (QSR)
- Design Controls
- International Regulation of Medical Devices

- Class led by co-instructor Theresa Brander-Allen, MS

Assignment DUE: Tuesday, May 1st
- Midterm documents due at midnight (5 pages max.)

Assignment: Thursday, May 3rd /Tuesday, May 8th
- Midterm meetings with Dr. Pietzsch (10 mins. per team)

Meeting slots from 10:00 – 1:00 pm on Thursday, May 3, and from 2:00 – 4:00 pm on Tuesday, May 8th.
Please sign up electronically on or before May 1 (noon).

Lecture 5:
Friday, May 4th

Guest lecture: The FDA’s Perspective

Elias Mallis
Director, Division of Small Manufacturers, International and Consumer Assistance
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health (CDRH)
U.S. Food and Drug Administration
Lecture 6  
Friday, May 11th  
- Reimbursement: Overview and details  
- Coding, Coverage, and Payment  
- In-patient and out-patient reimbursement for medical devices  
- Health-Economics: Methods of Evaluation  
- Guest speaker (end of class): Garrett Schwab  
  Global Reimbursement Director, Medtronic RDN  
  Former Sr. Global Reimbursement Advisor, Ardian, Inc.

Lecture 7:  
Friday, May 18th  
Guest lecture: Health Economics and Reimbursement – Industry Perspective  
  John Hernandez, Ph.D.  
  Division Vice President, Health Economics and Outcomes Research, Abbott Vascular

Lecture 8  
Friday, May 25th  
- Early Technology Assessment: Decision Support for Industry and Investors  
- Guest speakers (panel):  
  Allan May, CEO, Life Science Angels; Managing Director, Emergent Medical Partners  
  Mir Imran, Chairman, InCube Labs LLC; Chairman, Modulus, Inc.; Managing Director, InCube Ventures LP  
  Adam Seiver, M.D. Ph.D., Senior Director, Clinical Affairs and Chief Medical Officer (CMO), Hospital Respiratory Care, Philips North America; Consulting Associate Professor, Stanford University
Lecture 9
Friday, June 1st

- Course Summary
- Concluding Remarks
- Final Presentations (first part – other presentations between 3:30pm and 6:30pm)

Assignment DUE: Friday, June 1st
- Presentation in class (submit slides by end-of-day Wed. May 30th)
- 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.