



## Course Syllabus

### Technology Assessment and Regulation of Medical Devices Stanford University – MS&E 256 – Spring 2011

**Meeting time:** Fridays 1:15 –3:05 pm; Huang Ctr. 18

**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  
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**Course Assistants:** *Mike Francis*  
Masters candidate, MS&E  
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Doctoral candidate, MS&E  
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Office Hours: Monday, 2:00-3:00pm, Location: Huang 019

**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 2 or 3 units are required to perform a class project. The project deliverable is a final report and a final presentation. 2-unit topics are less comprehensive and require less research than 3-unit topics.

Final presentations are scheduled for the day of the last class (May 28). 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 2. 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 projects; 2 students for 2-unit paper/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 2 & 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:**

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**Lecture 1**

**Friday, April 1<sup>st</sup>**

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
- Guest speaker (end of class): [Hank Plain](#), Partner, [Morgenthaler Ventures](#); Vice Chairman, [The Foundry, LLC](#).

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**Assignment DUE: Monday April 4<sup>th</sup> (by noon)**

- **Project teams and topic preference submission**

Students will be notified about results on Tuesday, April 5<sup>th</sup> before noon.

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**Lecture 2**

**Friday, April 8<sup>th</sup>**

- Resources and references for research on medical devices
- Understanding regulatory pathways and FDA classifications
- FDA performance metrics
- FDA's Pre- and Post-market activities in regulating devices
- Guest speaker (end of class): Theresa Brandner-Allen, former VP Regulatory and Quality, [Penumbra, Inc.](#)

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**Assignment: Friday April 8<sup>th</sup>**

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

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

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**Lecture 3**

**Friday, April 15<sup>th</sup>**

- 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, [Medtronic/Ardian, Inc.](#)

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**Lecture 4**

**Friday, April 22<sup>nd</sup>**

- Risk analysis and Total Product Lifecycle
- Quality Systems Regulation (QSR)
- International Regulation of Medical Devices
  
- Guest speaker (end of class): Michelle Paganini, President, [Paganini & Associates](#)

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**Assignment DUE: Tuesday, April 26<sup>th</sup>**

- **Midterm documents due at midnight (5 pages max.)**
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**Lecture 5:**

**Friday, April 29<sup>th</sup>**

Guest lecture: The FDA's Perspective

Elias Mallis

Policy Analyst, FDA Office of Device Evaluation;  
Formerly: Chief, Cardiac Electrophysiology and Monitoring Branch  
Division of Cardiovascular Devices  
Office of Device Evaluation (CDRH/ODE/DCD)  
[U.S. Food and Drug Administration](#)

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**Assignment: Friday, April 29<sup>th</sup>/Monday, May 2<sup>nd</sup>**

- **Midterm meetings with Dr. Pietzsch (10 mins. per team)**

Meeting slots from 4:00 – 6:30 pm on Friday, April 29, and from 5:30 – 7:30 pm on Monday, May 2<sup>nd</sup>.

Please sign up electronically on or before April 27 (noon).

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**Lecture 6**  
**Friday, May 6<sup>th</sup>**

- 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): Dr John O Dwyer, Manager Europe, NSAI (National Standards Association of Ireland) – CE Mark Notified Body

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**Lecture 7:**  
**Friday, May 13<sup>th</sup>**

Guest lecture: Health Economics and Reimbursement – Industry Perspective

John Hernandez, Ph.D.  
Department Vice President, Health Economics and Outcomes Research, [Abbott Vascular](#)

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**Lecture 8**  
**Friday, May 20<sup>th</sup>**

- 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

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**Lecture 9**  
**Friday, May 27<sup>th</sup>**

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

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**Assignment DUE: Friday, May 27<sup>th</sup>**

- **Presentation in class** (submit slides by end-of-day Wed. May 25<sup>th</sup>)
  - **Final papers due at midnight (electronic submission)**
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## **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 2-unit and 3-unit papers. Please keep in mind that high quality content is most important, and is always preferred over quantity with limited insight.

### 2 unit papers:

2-person teams: 20 pages max, plus appendices.

[if only one person working on 2-unit topic: Expected paper length 10 pages max, plus appendices]

### 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 2-unit and 3-unit 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 2 or 3 units are expected to distill their research into a slide presentation. On-campus students will give a brief oral presentation on May 27<sup>th</sup>. 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.