



Course Syllabus

Technology Assessment and Regulation of Medical Devices Stanford University – MS&E 256/BIOE 256 – Spring 2023

Meeting time: Fridays 9:30 – 11:20 am

Location: Thornton 102

Units:

- 1 - MS&E 256A (attendance only)
- 3 - MS&E 256 (attendance and class project)
- BIOE 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.*
Adjunct Professor, MS&E
Director, Health Economics and Value, Stanford Byers Center for Biodesign; President and CEO, Wing Tech Inc.
pietzsch@stanford.edu

Office Hours: Fridays 8:30-9:15 am Huang 352 and via Zoom
(please reach out by email)

Course Assistant: Anna Lee, M.S. Candidate, MS&E (alee99@stanford.edu)
Office Hours: Wednesdays 2:00-3:00 pm Huang B007 and via Zoom
(please reach out by email).

Prerequisites: This course has no prerequisites. 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 complete a team-based 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 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 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:	<u>CR/NC Option Only</u> (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 considered 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: Product Creation and Innovative Manufacturing; Management Science & Engineering.

Class recorded: Please note that, as a SCPD course, this class is being recorded. See last slide of this syllabus for additional notification detail.

Course Schedule:

Lecture 1

Friday, April 7th

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
- Introductory Case study: Transcatheter vs. surgical heart valve replacement
- Presentation of Project Topics
- Resources and references for research on medical devices
- Guest speaker (end of class): Kavita Patel, M.D., Venture Partner, New Enterprise Associates (NEA), former Policy Director, White House Office of Intergovernmental Affairs and Public Engagement, incoming Director of Policy Program, Stanford Byers Center for Biodesign

Assignment DUE: Monday April 10th (by noon)

- **Project teams and topic preference submission**

Students will be notified about results on Tuesday, April 11th before 2pm.

Lecture 2

Friday, April 14th

- 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): Mahtab Fatemi, Vice President, Regulatory Affairs & Quality Assurance, Pulmonx Corporation (NASDAQ: LUNG)

Assignment: Monday, April 17th & Tuesday, April 18th

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

Meeting slots from 9:00am-12:00pm on Monday 4/17 and from 8:30-12:00pm on Tuesday 4/18. Please sign up electronically by Friday, April 14th at 9am.

Lecture 3

Friday, April 21st

- 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): Greg Bakan, Director of Strategic Initiatives, Fogarty Innovation

Lecture 4

Friday, April 28th

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](https://www.fda.gov/oc)

Assignment DUE: Monday, May 1st

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

Assignment: Wednesday/Thursday, May 3rd/4th

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

Meeting slots from 9:00am-1:00pm on Wed. May 3rd and 8:30-11:00am on Thursday, May 4th. Please sign up electronically by May 1st.

Lecture 5:

Friday, May 5th

- Introduction to healthcare financing, reimbursement, and the increasing focus on Value
 - Initial introduction to health-economic assessment methods

 - Guest speaker (co-teaching this class with Jan Pietzsch): John Hernandez, Ph.D., Clinical Director and Head of Health Impact, Google Health/Alphabet (NASDAQ: GOOGL)
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Lecture 6
Friday, May 12th

- Guest lecture: Health Economics and Reimbursement – Industry Perspective
- U.S. reimbursement: payer, provider, and patient perspectives
 - Shifting healthcare landscape and value-based healthcare
- Sarah Brill, Director, Market Access, Cardiac Rhythm Disease Management, Medtronic, Inc. (NYSE: MDT)

Lecture 7:
Friday, May 19th

- 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
- Karen Nordahl, Vice President, Health Economics & Market Access - Interventional Cardiology / WATCHMAN, Boston Scientific (NYSE: BSX)

Lecture 8
Friday, May 26th

- Case studies of health-economic studies of medical devices
- Approaches to early-stage technology and value assessment during the device development process
- Guest speaker (end of class): Garrett Schwab, President & CEO, XII Medical

Lecture 9
Friday, June 2nd

- Course Summary
- Concluding Remarks
- Final Presentations (first part – other presentations in additional session between 11:30 and 1:00 pm)

Assignment DUE: Friday, June 2nd

- **Presentation in class** (submit slides by end-of-day Wed. May 31st)
 - **Final papers due at end of day (midnight) by 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 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>). In this context, please also be aware of the definition and implications of plagiarism (<https://communitystandards.stanford.edu/student-conduct-process/honor-code-and-fundamental-standard/additional-resources/what-plagiarism>), which constitutes a violation of the Stanford Honor Code. If you have questions related to these topics 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 Canvas. 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 Midterm Deliverable

As outlined, students will schedule midterm meetings with Dr. Pietzsch to discuss their project progress and any questions they might have. A structured five-page midterm report (template to be shared on Canvas at beginning of quarter) will need to be submitted as outlined.

Information about Final Presentation

Students taking the course for 3 units are expected to distill their research into a slide presentation of not more than 8-10 slides total. On-campus students will give a brief oral presentation on June 2nd. The Final Presentation schedule will be published near the end of the quarter. Typically, we set aside 15 minutes of presentation time per team (9 minutes for slide presentation, plus 6 minutes for Q&A).

SCPD students are not required to present in class, although if a SCPD student is local and can present, he or she should contact the teaching team and a suitable time will be assigned. Note that all SCPD students/teams need to submit a slide deck, nevertheless.

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

SCPD notification regarding the video-recording of the course:

Video cameras located in the back of the room will capture the instructor presentations in this course. For your convenience, you can access these recordings by logging into the course Canvas site. These recordings might be reused in other Stanford courses, viewed by other Stanford students, faculty, or staff, or used for other education and research purposes. Note that while the cameras are positioned with the intention of recording only the instructor, occasionally a part of your image or voice might be incidentally captured. If you have questions, please contact a member of the teaching team.
