

HCMG 890
ADVANCED STUDY PROJECT SEMINAR: MEDICAL DEVICES

Spring 2015

TH: 3:00-6:00 pm

Location: JMHH F36

Faculty:

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Teaching Assistants:

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COURSE OVERVIEW

Successful medical devices are an amalgamation of creative and innovative thinking, clinical expertise, and engineering know-how that endures intense regulatory and reimbursement scrutiny. This course will provide a foundation for understanding the nuances of the medical device industry. It will cover topics ranging from device design and discovery, regulatory issues, marketing, reimbursement, management and strategy. Classroom activities will be supplemented with optional tours of hospitals, research and manufacturing facilities, and hands-on demonstrations of devices. Though the course is intended primarily for MBA students, it will be open to medical and engineering students as well as to hospital house staff.

COURSE REQUIREMENTS:

	Percentage of Grade
1. Class attendance is mandatory – Students are allowed one unexcused absence during the semester. Job interviews are not an excused absence.	10%
2. Class participation	10%
3. Weekly online polls on reading. A response to the weekly web poll is due by 3pm the day of the class. There is no poll for the 1 st class on September 9 th , Midterm Case Write-up Week (Oct 24 th), Thanksgiving week and the last day of class on Dec 9 th . Students are allowed to skip one poll during the semester.	20%
4. Short presentation (approx. 15 min) on a device topic. Could be a report/analyses on work experiences, new technologies, strategic issues or important policies. The presentation will be made on the last day of class. Depending on class size this may also be a group assignment but the groups must be different than the Midterm and Final groups. More information will be given out on this during the course.	25%
5. Midterm Case Write-up. This is a group assignment. Due Monday, October 24 th at 4:00pm.	25%
6. Final Case Write-up. Also a group assignment. Due on Friday, Dec 20 th , at 5pm.	

READINGS

This class will afford students the unique opportunity to interact directly with industry leaders. In order for class discussion to optimize the use of discussion time, for many classes there will be readings from the assigned textbook. It is expected that all readings will be done prior to the pertinent class and that students will arrive able to discuss the topic in an informed manner. Additional readings will often be added in advance of particular classes. Except for the textbook readings, all readings will be posted on Canvas -- there is no bulkpack. Certain readings are marked as "required" in the filename. The textbook is available electronically through the UPenn library.

Required Text:

Zenios, S., Makower, J., and Yock, P. (2015) *Biodesign*, 2nd edition, Cambridge University Press.
http://www.amazon.com/gp/product/110708735X/ref=pd_lpo_sbs_dp_ss_3?pf_rd_p=1944579842&pf_rd_s=lpo-top-stripe-1&pf_rd_t=201&pf_rd_i=0521517427&pf_rd_m=ATVPDKIKX0DER&pf_rd_r=18N4PX2FTB560N39PJKG

Class Schedule¹

Week 1 – January 15

- Welcome and Introduction to Medical Devices – Robert Town, PhD, Wharton
- Entrepreneurship and Medical Devices -- Jeff Solomon, MD, Wharton and Infiniti Medical

Readings: *Biodesign*, Chpt. 1

Week 2 – January 22

- Device sector from the Wall Street Perspective – Kurt Kruger (Navigant) and Raj Denhoy (Jefferies)
- Emerging Trends – Adrienne Lovink/Tyler Fletcher – DRG Consulting ([drg-consulting.com](http://drgconsulting.com))

Readings: *Biodesign*, Chpt. 2

Week 3 – January 29

- Pre- and post- market FDA regulations – Dina Justice (Terumo Medical Corp -- <http://www.terumomedical.com>)

Readings: *Biodesign*, Chpt. 4.2, 5.4

Week 4 – February 5

- Cost-effectiveness Analysis – Robert Town, PhD
- Innovation Management -- Forgarty Institute Speaker

Readings: *Biodesign*, Chpt. 4.4, 5.9

¹ The class schedule is tentative and subject to change as speakers schedules can change with little notice.

Week 5 -- February 12

- Intellectual Property and Medical Devices – Jeremy Bond, JD (Sanofi)
- Reimbursement Strategy – Jeff Voigt (Medical Device Consultants)

Readings: *Biodesign*, Chpt. 4.1, 4.3, 5.1, 5.8 (useful for midterm)

Week 6 – February 19

- Clinical Strategy – Mary Russell, MD (Ascent Translational Sciences)

Readings: *Biodesign*, Chpt. 5.3

Week 7 -- February 26

- Distribution Strategies (Jim Rushworth) -- (Terumo
<http://www.terumomedical.com>)
- Devices and Venture Capital – Bill Harrington (Osage Partners --
<http://osagepartners.com>)

Midterm Due

Week 8 – March 5

- Bionics -- Kevin Franch (BiOM -- <http://www.biom.com>)
- Vascular Devices– Ben Jackson, MD, Hospital of the Univ. of Pennsylvania

Readings: *None*

Spring Break!!!! – No Class March 12

Week 9 – March 19

- How to Pitch to VC -- Jordon Halperin (Infiniti Medical)
- Current Trends in Life Science Transactions: Negotiating Deal Terms and Risk Allocation -- Philip Ottinger (Wilson, Saconi, Goodrich and Rosadi)

Readings: *Biodesign*, Chpt. 6.2, 6.3

Week 10 – March 26

- Interventional Cardiology – Howard Hermann, MD, Hospital of the Univ. of Pennsylvania
- Marketing Medical Devices – Todd Canfield, (J&J)

Readings: *Biodesign*, Chpt. 5.7

Week 11 – April 2

- Coverage Strategy – Lindsay Bockstedt, PhD (Medtronic)
- Ardian case study and other med device start-up lessons -- Karun Naga, JD, MBA

Readings: Review Coverage Strategies in *Biodesign*, Chpt. 4.3, 5.6

Week 12 – April 9

- Medical Device Companies - Capital Market Perspective -- Misha Lozovik (Convectro Capital Management)
- Jeff Solomon, MBA, MD, Wharton and Infiniti Medical

Week 13 – April 16

- **Student Presentations!**

Week 14 – April 23

- The Future of Device Regulation -- FDA and Innovation Roundtable -- Jeff Shuren, MD (FDA – Director CDRH -- <http://www.fda.gov/MedicalDevices>) & Jack Lassersohn – (Vertical Group [file://localhost/-- http://www.vertical-group.com](http://localhost/-- http://www.vertical-group.com))

Final Due: May 2th, 5:00pm