

HCMG 890
ADVANCED STUDY PROJECT SEMINAR: MEDICAL DEVICES

Fall 2012

Weds. 4:30-7:30 pm

Location: SH-DH 109

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. 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 12 th	10%
4. Short presentation (10- 15 min) or paper (3-5 pages) on a device topic. Could be a report/analyses on work experiences, new technologies, strategic issues or important policies. The presentation will be made in class between the two speakers	20%
5. Midterm Case Write-up. This is a group assignment. Due Wed. October 24 th at 4:00pm.	20%
6. Final Case Write-up. Also a group assignment. Due on Friday, Dec 14 th , at 5pm.	30%

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 may 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.

Required Text:

Zenios, S., Makower, J., and Yock, P. (2011) *Biodesign*, Cambridge University Press.

<http://www.amazon.com/Biodesign-Process-Innovating-Medical-Technologies/dp/0521517427>

Class Schedule¹

Week 1 – September 5 -- No Class

Week 2 – September 12

- Welcome and Introduction to Course – Robert Town
- Device sector from the Wall Street Perspective – Kurt Kruger (Cyberkinetics) and Raj Denhoy (Jefferies)

Week 3 – September 19

- Starting a Start-up -- Jeff Solomon, MD (UPenn and Infiniti Medical)
- Stent Wars -- Sean Salomon (Medtronic)

Readings: *Biodesign*, Chpt. 5.9

Week 4 -- September 26

- Devices, Venture Capital and Exits – Lucas Buchanan (Silk Road Medical)
- Devices and Angel Investing -- Alan May (Life Science Angels)

Readings: *Biodesign*, Chpt. 2.3-2.4

Week 5 -- October 3

- Pre- and Post- market FDA regulations – Dina Justice (Terumo Medical Corp)

Readings: *Biodesign*, Chpt. 4.2, 5.4

Week 6 -- October 10

- Coverage and Device Policy -- Lindsay Bockstedt, Ph.D (Medtronic)
- Payment and Coding -- Jeff Voigt (Medical Device Consultants)

Readings: *Biodesign*, Chpt. 4.3, 5.6

Week 7 -- October 17

- Clinical Trials – Melissa Russell, MD

Readings: *Biodesign*, Chpt. 5.3

¹ The class schedule is tentative.

Week 8 -- October 24

- Distribution strategies – Jim Rushworth (Terumo Medical Corp.)
- Intellectual Property and medical devices -- TBA

Readings: *Biodesign*, Chpt. 4.1, 5.1, 5.8

Midterm Due

Week 9 – October 31

- Cardiology Overview – Ken McLearron (Millennium Research Group)
- Overview – TBA

Week 10 – November 7

- Ardian Case Study – Karun Naga (formerly of Ardian/Medtronic)
- Corporate Ventures – Karun Naga

Week 11 – November 14

- Product Launch – Eric Stone
- Robotic Surgery – Dr. Heidi Harvey (UPenn)

Week 12 -- No Class -- Thanksgiving

Week 13 – November 28

- Device Regulation and Innovation -- Jeff Shuren, MD (FDA – Director CDRH) & Jack Lassersohn – (Vertical Group)

Week 14 – December 5

- Marketing Devices -- Todd Canfield (Johnson & Johnson)
- Economics of Devices -- Robert Town (UPenn)

Readings: *Biodesign*, Chpt. 5.7

Final Due: December 14th, 5:00pm