

HCMG 853
ADVANCED STUDY PROJECT SEMINAR: MEDICAL DEVICES

Fall 2016

W: 3:00-6:00 pm

Location: CPC Auditorium

Faculty:

Jeffrey A. Solomon, MD MBA
Instructor

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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, entrepreneurship, marketing, reimbursement, management and strategy. This year we will emphasize the role of digital and diagnostics in the dynamics of the device sector. 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:

	<u>Percentage of Grade</u>
1. Class attendance is mandatory – Students are allowed one un-penalized, unexcused absence during the semester. Job interviews are not an excused absence.	10%
2. Contribution to class discussion	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, Midterm Case Write-up Week (Oct 12 th), Thanksgiving week and the presentation weeks Dec 7 and 12. Students are allowed to skip one poll during the semester.	10%
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 days of class Dec 7 and 12. More information will be given out on this during the course. This can be an individual or group assignment, but groups must be different than midterm and final groups.	20%
5. Midterm Case Write-up. This is a group assignment. Due Friday, October 14 th at 6pm.	25%
6. Final Case Write-up. Also a group assignment. Due on Friday, Dec 16 th , at 6pm.	25%

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 to 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. (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 – August 31

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

Readings: *Biodesign*, Chpt. 1

Kruger, K. and Kruger, M. “Medical Device Sector” (Chapter 6) in *Business of Innovation*, Lawton R. Burns, ed., 2nd edition.

Week 2 – September 7

- Innovation, Entrepreneurship and Med Devices – Jeff
- Reimbursement Strategy – Jeff Voigt (Medical Device Consultants)

Readings: *Biodesign*, 4.3, 5.6, (optional Ch 2)

Week 3 – September 14

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

Readings: *Biodesign*, 4.2, 5.4

Week 4 – September 21

- Coverage / Competitive Strategy – Matt
- Venture Capital and the Device Sector – Ali Behbahani (NEA)

Readings: *Biodesign*, 5.9, 6.3

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

Week 5 – September 28

- Cost Effectiveness / Competitive Strategy – Matt
- Intellectual Property – Lou Lieto, JD, PhD (Wilson Sonsini Goodrich & Rosati)

Readings: *Biodesign*, 4.1, 5.1

Week 6 – October 5

- Design Thinking – Matt Van Der Tuyn and Caroline Garzon Mrad (Penn)
- Heartport, Inc. Case Study – Matt

Readings: *Biodesign*, 5.8 (useful for midterm)

Heartport, Inc (Harvard Case Study)

Week 7 – October 12 No Class, Fall Break

-- MIDTERMS DUE! 6PM, October 14 --

Week 8 – October 19

- Distribution Strategies – Jim Rushworth (Terumo)
- Devices and Digital – Bob Boland (J&J) and Ken Fernandez (DePuy)

Readings: *Biodesign*, Chpt. 5.2, 5.7

Week 9 – October 26

- Clinical Trials Basics and Strategy – Tracy Ziolk (Penn) and Dan Schultz, MD (Greenleaf Health)

Readings: *Biodesign*, Chpt. 5.3

Week 10 – November 2

- Devices, Data, and Diagnostics – David Giannino (Medtronic)
- Wearable Devices – Erik Poulsen, MD, MSc (Cortrium)

Readings: See Canvas

Week 11 - November 9

- Start-up Panel on Medical Devices – Solomon, Buchanan, Devgon, Port

Readings: See Canvas

Week 12 - November 16

- Disruptive Innovation -- Derrick Sung (iRhythm)
- Wall Street and Med Device Sector – Misha Lozovik, (Convactor Capital Management)

Readings: See Canvas

Week 13 - November 23 No Class, Thanksgiving

Week 14 - November 30

- 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>)
- Wrap up – Jeff and Matt

Readings: See Canvas

Week 15 - December 7

- Student Presentations!

Week 16 - December 12

- Student Presentations!

-- FINALS DUE! 6PM, December 16 --