

HCMG 853
ADVANCED STUDY PROJECT SEMINAR: MEDICAL DEVICES

Fall 2015

W: 3:00-6:00 pm

Location: CPC Auditorium

Faculty:

Jeffrey A. Solomon, MD MBA
Instructor

University of Pennsylvania School of Veterinary Medicine
The Wharton School of Business

Office: 1 Silverstein Pavilion, HUP
Email: solomon@infinitemedical.com

Office Hours: By appointment

Robert Town, PhD
Professor
The Wharton School of Business

Office: 305 Colonial Penn Center
Email: rtown@wharton.penn.edu

Office Hours: By appointment
Phone: 215-746-3171

Teaching Assistants:

David Lindsay -- <mailto:lindsay@mail.med.upenn.edu>
Yan Yan -- <mailto:yan1@wharton.upenn.edu>

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 finance 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. 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.	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 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.	20%
5. Midterm Case Write-up. This is a group assignment. Due Wednesday, October 21 th at 4:00pm.	25%
6. Final Case Write-up. Also a group assignment. Due on Friday, Dec 11 th , at 5pm.	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 26

- 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

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

Week 2 – September 2

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

Readings: *Biodesign*, 4.3, 5.1, (optional chpt 2)

Week 3 – September 9

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

Readings: *Biodesign*, 4.2, 5.4

Week 4 – September 16

- Intellectual Property – Lou Lieto, JD, PhD (Wilson Sonsini Goodrich & Rosati)
- Coverage of Medical Devices – Robert Town, PhD

Readings: *Biodesign*, 4.1, 5.1

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

Week 5 – September 23

- Angels and Device Sector -- Bob Knorr
- Venture Capital and the Device Sector – Bill Harrington, Osage University Partners

Readings: *Biodesign*, 5.9, 6.3, 5.8 (useful for midterm)

Week 6 – September 30

- Disruptive Innovation -- David Roman & Derrick Sung

Readings: See Canvas

Week 7 – October 7

- No Class –Meetings on Class Project

Readings: *None*

Week 8 – October 14

- Wall Street and Med Device Sector – Misha Lovovik (Convactor Capital Management) & Laurence McGraff

Readings: See Canvas

Week 9 – October 21

- Med Device Life Cycle -- Owen Hughes
- Investment Banking and Med Devices -- Doretta Mistras

Readings: See Canvas

Midterm Due!

Week 10 – October 28

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

Readings: See Canvas

Week 11 – November 4

- Distribution Strategies (Jim Rushworth) -- (Terumo <http://www.terumomedical.com>)
- Marketing Medical Devices – Todd Canfield (Mentor/J&J)

Readings: *Biodesign*, Chpt. 5.2, 5.7

Week 12 – November 11

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

Readings: *Biodesign*, Chpt. 5.3

Week 13 – November 18

- 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>)

Readings: See Canvas

Week 14 – December 2

- **Student Presentations!**

Final Due: December 11th.