

**HCMG 890**  
**ADVANCED STUDY PROJECT SEMINAR: MEDICAL DEVICES**

Fall 2013

Mondays: 4:30-7:30 pm

Location: SHDH 209

---

**Faculty:**

Jeffrey A. Solomon, MD MBA  
Assistant Professor  
University of Pennsylvania School of Medicine  
University of Pennsylvania School of Veterinary Medicine  
The Wharton School of Business

Office: 1 Silverstein Pavilion, HUP  
Email: [solomon@infinitemedical.com](mailto:solomon@infinitemedical.com)  
Office Hours: By appointment

Robert Town, PhD  
Associate Professor  
The Wharton School of Business

Office: 305 Colonial Penn Center  
Email: [rtown@wharton.penn.edu](mailto: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@mail.med.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, 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 <sup>st</sup> class on September 9 <sup>th</sup> , Midterm Case Write-up Week (Oct 24 <sup>th</sup> ), Thanksgiving week and the last day of class on Dec 9 <sup>th</sup> . 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 <sup>th</sup> at 4:00pm.	25%
6. Final Case Write-up. Also a group assignment. Due on Friday, Dec 20 <sup>th</sup> , 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 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. The textbook is available electronically through the UPenn library.

### 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 Schedule<sup>1</sup>**

### **Week 1 – September 9**

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

**Readings:** *Biodesign*, Chpt. 1

### **Week 2 – September 16**

- Device sector from the Wall Street Perspective – Kurt Kruger (Cyberkinetics) and Raj Denhoy (Jefferies)
- TBA

**Readings:** *Biodesign*, Chpt. 2

### **Week 3 – September 23**

- Stent Wars -- Sean Salmon (Medtronic -- <http://www.medtronic.com/>)
- Emerging Markets -- Geoff Martha (Medtronic -- <http://www.medtronic.com/>)

**Readings:** *Biodesign*, Chpt. 4.4, 5.9

### **Week 4 -- September 30**

- Clinical Strategy – Mary Russell, MD

**Readings:** *Biodesign*, Chpt. 5.3

### **Week 5 -- October 7**

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

**Readings:** *Biodesign*, Chpt. 4.2, 5.4

---

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

### **Week 6 -- October 14**

- Intellectual Property and medical devices – Jeremy Bond, JD (Finnegan -- <http://www.finnegan.com>)
- Reimbursement Strategy – Jeff Voigt (Medical Device Consultants)

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

### **Week 7 -- October 21**

- Distribution Strategies (Jim Rushworth) -- (Terumo <http://www.terumomedical.com>)
- Keys to Successful Device Startups -- Amir Belson, MD

**Midterm Due**

### **Week 8 -- October 28**

- Bionics -- Kevin Franch (BiOM -- <http://www.biom.com>)
- Cost Effectiveness – Robert Town, UPenn

**Readings:** *Biodesign*, Chpt. 4.3, 5.6

### **Week 9 -- November 4**

- Devices and Venture Capital – Bill Harrington (Osage Partners -- <http://osagepartners.com>)
- Devices and Angel Investing -- Alan May (Life Science Angels)

**Readings:** *Biodesign*, Chpt. 2.3-2.4

### **Week 10 -- November 11**

- Vascular Devices -- Ben Jackson, MD, UPenn
- Marketing Medical Devices – Todd Canfield, (J&J)

**Readings:** *Biodesign*, Chpt. 5.7

### **Week 11 – November 18**

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

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

### **Week 12 – November 25**

**Thanksgiving Week – No Class – Meetings on Presentations**

### **Week 13 – December 2**

- 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))

### **Week 14 – December 9**

- **Course Wrap-up**
- **Student Presentations!**

**Final Due: December 20<sup>th</sup>, 5:00pm**