

# HCMG 853 --ADVANCED STUDY PROJECT SEMINAR: MEDICAL DEVICES

Fall 2017

M: 3:00-6:00 pm

Location: CPC Auditorium

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## Faculty

Jeffrey A. Solomon, MD MBA

Lecturer

The Wharton School of Business

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Office Hours: By appointment

Matthew Grennan, PhD

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## Teaching Assistants

Katie Dalldorf ([Katherine.Dalldorf@uphs.upenn.edu](mailto:Katherine.Dalldorf@uphs.upenn.edu))

Anik Saha ([Anik.Saha@uphs.upenn.edu](mailto:Anik.Saha@uphs.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 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

1. Class attendance is mandatory. Students are allowed one unpenalized absence during the semester. Job interviews are not an excused absence. 10%
2. Contribution to class discussion is critical. The class is a discussion among students with a variety of relevant backgrounds, led by the instructors and guests with expertise in the device sector. Students are expected to come prepared and participate. No laptops are permitted in class without express consent of the instructors. 10%
3. A response to each class period's Canvas poll is due by 3pm the day of the class. There is no poll for the 1<sup>st</sup> class or the final student presentation classes. 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 two weeks of class. 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 20<sup>th</sup> at 6pm. 25%
6. Final Case Write-up. Also a group assignment. Due on Friday, Dec 15<sup>th</sup>, at 6pm. 25%

## READINGS

This class will afford students the unique opportunity to have in depth discussions in class and to interact directly with industry leaders. In order 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 and case studies, all readings will be posted on Canvas.

### Required Text

Zenios, S., Makower, J., and Yock, P. (2015) *Biodesign*, 2<sup>nd</sup> 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](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)

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## CLASS SCHEDULE

### Week 1 – September 11

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

**Readings:** *Biodesign*, Ch 1, 2

### Week 2 – September 18

- Intellectual Property – Lou Lieto (Wilson Sonsini Goodrich & Rosati)  
<https://www.linkedin.com/in/loulieto>
- *Heartport, Inc.* Case Study – Matt

**Readings:** *Biodesign*, 4.1, 5.1 ; *Heartport, Inc.* Case Study

### Week 3 – September 25

- Economics of Devices: Regulation, Sales, Pricing – Matt
- Reimbursement – Richard Duszak (Emory)  
<https://www.linkedin.com/in/richard-duszak-md-7702a35>

**Readings:** *Biodesign*, 4.3, 5.6

#### **Week 4 – October 2**

- Innovation – Jennifer Mueller (University of San Diego)  
<https://www.linkedin.com/in/jennifer-mueller-2a7b88129>
- Venture Capital and the Device Sector – Ali Behbahani (NEA)  
<https://www.linkedin.com/in/ali-behbahani-3bb3591>

**Readings:** *Biodesign*, 4.4, 5.9, 6.3

#### **Week 5 – October 9**

- FDA – Pre-/Post- Market – Dina Justice (Terumo)  
<https://www.linkedin.com/in/dina-justice-fleischer-1a45982>

**Readings:** *Biodesign*, 4.2, 5.4

#### **Week 6 – October 16**

- Wall Street Perspective – Misha Lozovik (BlackRock):  
<https://www.linkedin.com/in/misha-lozovik-06a463>
- *Dermacare: Zapping Zits Directly* Case Study – Matt

**Readings:** *Dermacare* Case Study ; *Biodesign*, 5.8 (useful for midterm)

#### **-- MIDTERM EXAMS DUE! 6PM, October 20 --**

#### **Week 7 – October 23**

- Exam Review – Matt / Jeff
- Entrepreneur Panel – Jeff, Lucas Buchanan, Janet Burpee, Adam Dakin, David Lindsay

**Readings:** *Biodesign*, 4.5, 4.6, 5.2, 5.3, 5.7

#### **Week 8 – October 30**

- Consumer Wearables and Analytics – Sean Bruich (Nike)  
<https://www.linkedin.com/in/seanbruich>
- Clinical Wearables and Analytics – Erik Sondergaard Poulsen (Cortrium)  
<https://dk.linkedin.com/in/erikpoulsen>

**Readings:** See Canvas

### **Week 9 – November 3 (\*\*FRIDAY 10am-1pm\*\*)**

- **Future of Device Regulation** – Jeff Shuren, MD (FDA – Director CDRH)  
<https://www.fda.gov/aboutfda/centersoffices/ucm193990.htm> & Jack Lasersohn (Vertical Group) <http://www.vertical-group.com/meet-the-partners.html>

**Readings:** See Canvas

### **Week 10 – November 6**

- Disruptive Innovation (and Clinical Wearables) – Derek Sung (iRhythm)  
<https://www.linkedin.com/in/derrick-sung-a848161>
- Investing in Regulated Markets – David Singer (Maverick Ventures)  
<https://www.linkedin.com/in/david-singer-bbab52>

**Readings:** See Canvas

### **Week 11 – November 13**

- AI and Devices –Dusty Majumdam (IBM Watson):  
<https://www.linkedin.com/in/dmajumdar>
- Device-related Services and Solutions – Pei Ho (Medtronic):  
<https://www.linkedin.com/in/peiho>

**Readings:** See Canvas

### **Week 12 – November 20**

- Design Thinking (+Devices@Penn) - Mohit Prajapati (Penn CHCHI):  
<https://www.linkedin.com/in/mohit-prajapati-387910a>
- *Zimmer: The Gender-specific Knee Case Study* – Matt

**Readings:** *Zimmer Case*; See Canvas

### **Week 13 – December 4** -- Student Presentations!

### **Week 14 – December 11** -- Student Presentations!

**-- FINAL EXAMS DUE! 6PM, December 15 --**