



HCMG 853 – MANAGEMENT AND STRATEGY IN MEDICAL DEVICES AND TECHNOLOGY

Fall 2019

M: 3:00-6:00 pm

Location: CPC Auditorium

Faculty

Jeffrey A. Solomon, MD MBA

Lecturer

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Assistant Professor

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Teaching Assistants

Felicity Johnson (feljo@wharton.upenn.edu)

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COURSE OVERVIEW

Successful medical devices involve creative and innovative thinking, clinical expertise, and engineering know-how that endures intense regulatory and reimbursement scrutiny. This course provides a foundation for understanding the nuances of the medical device industry. It covers topics ranging from device design and discovery, regulatory issues, entrepreneurship, marketing, reimbursement, management, and strategy. The course is intended primarily for MBA students, but it will be open to medical and engineering students as well as to hospital house staff. Due to space constraints, we do not permit auditing the class—students must enroll and fully participate.

COURSE REQUIREMENTS

Class **attendance** is mandatory. Students are allowed one unpenalized absence during the semester. Job interviews are not an excused absence. 10%

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%

A response to each class period's **Canvas poll** is due by 3pm the day of the class. There is no poll for the 1st class or the final student presentation classes. Students are allowed to skip one poll during the semester. 10%

Short presentation (approx. 15 min) on a device topic. This 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%

Midterm Case Write-up. This is a group assignment. Due Friday, Oct 18, 6pm. 25%

Final Case Write-up. Also a group assignment. Due on Friday, Dec 13, 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*, 2nd edition, Cambridge University Press.

CLASS SCHEDULE

Week 1 – September 9

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

Readings: *Biodesign*, Chapters 1, 2

Week 2 – September 16

- FDA – Pre-/Post- Market – Dina Justice (Senior Director of Regulatory Affairs, Terumo)
<https://www.linkedin.com/in/dina-justice-1a45982/>

Readings: *Biodesign* 4.2, 5.4

Week 3 – September 23

- *Heartport, Inc.* Case Study – Matt
- Topic - Susan Dentzer (Visiting Fellow, Robert J. Margolis Center for Health Policy, Duke University)
<https://www.linkedin.com/in/susandentzer/>

Readings: *Heartport, Inc.* Case Study; *Biodesign* 5.2, 5.3, 5.5, 5.8 (useful for midterm); *Canvas* for additional

Week 4 – September 30

- Topic - Matt Hawkins , MD (Director, Pediatric Vascular Interventional Radiology, Children's Healthcare of Atlanta)
<https://www.linkedin.com/in/matt-hawkins-md-93b6b737/>
- Value Based Care, The Corporate Perspective - Parashar Patel, MPA (Senior Vice President, Government Affairs and Market Access, ViewRay, Inc.)
<https://www.linkedin.com/in/parashar-patel/>

Readings: *Biodesign* 4.3, 5.6, 5.7; http://vbhcglobassessment.eiu.com/wp-content/uploads/sites/27/2016/09/EIU_Medtronic_Findings-and-Methodology.pdf ; *Canvas* for additional

Week 5 – October 7

- The FDA approved my device – why will no one pay for it?” – Chris Jagmin, MD (Executive Medical Director, Aetna)
<https://www.linkedin.com/in/chris-jagmin-4a5088184/>
- Topic - Anand Veeravagu, MD (Assistant Professor of Neurosurgery, Stanford University School of Medicine)
<https://www.linkedin.com/in/anand-veeravagu-8930736/>

Readings: see *Canvas*

Week 6 – October 14

- Venture Capital and the Device Sector – Ali Behbahani, MD, MBA (Partner, NEA)
<https://www.linkedin.com/in/ali-behbahani-3bb3591>
- Topic – Elizabeth Browning, PhD (Patent Agent, Saul Ewing Arnstein & Lehr LLP) and Paul Liecht, JD (Registered Patent Attorney, Saul Ewing Arnstein & Lehr LLP)
<https://www.linkedin.com/in/elizabeth-browning-30556b3/>
<https://www.linkedin.com/in/paul-leicht-6594744b/>

Readings: *Biodesign* 4.4, 5.9, 6.3; 4.1, 5.1

MIDTERM EXAMS DUE! 6PM, October 18

Week 7 – October 21

- Design Thinking and Prototyping (+Devices@Penn) - Mohit Prajapati, MS, MBA (Director of R&D, Strategy, and Operations, Penn CHCI and Device Accelerator)
<https://www.linkedin.com/in/mohit-prajapati-387910a>
- The Cardiac Catheterization Lab: a Hub for Innovation - Robert H. Li, MD (Co-Director, Transcatheter Aortic Valve Replacement Program, Penn Medicine)
<https://www.linkedin.com/in/li-robert-71a33242/>

Readings: *Biodesign* 3.1, 3.2, 4.5, 4.6;

Week 8 – October 28

- Incubate to IPO: The Transition from Survive to Thrive in Medtech - Lucas Buchanan, MBA (CFO, Silk Road Medical)
<https://www.linkedin.com/in/lucas-buchanan-34b1995/>
- Terumo (midterm)Review - Jeff

Readings: See *Canvas*

Week 9 – November 4

- Medical Devices, The Public Markets Perspective - Mike Kramarz, MD, MBA (Biotechnology Investor, Commodore Capital, LP)
<https://www.linkedin.com/in/michael-kramarz-02922013/>
- Growing a Medical Device Firm - Rami Elghandour, MBA (former CEO, Nevro) Industry Partnership and Implant Innovation in the Field of Spine Surgery – Alexander
<https://www.linkedin.com/in/rami-elghandour-305a153/>

Readings: See *Canvas*

Week 10 – November 11

- Consumer Wearables and Analytics – Sean Bruich (VP, Nike Membership and Consumer Data Science, Analytics, & Insights, Nike)
<https://www.linkedin.com/in/seanbruich>
- Digital Health, Venture Capital Perspective –Gurdane Bhutani (Co-founder and Managing Partner, FundRx)
<https://www.linkedin.com/in/gurdanebhutani/>

Readings: See *Canvas*

Week 11 – November 18

- The Future of Device Regulation – Jeff Shuren, MD (Director CDRH, FDA) and Jack Lasersohn (General Partner, Vertical Group)
<https://www.fda.gov/about-fda/fda-organization/jeffrey-shuren>
<http://www.vertical-group.com/meet-the-partners.html>

Readings: See *Canvas*

Week 12 – November 25

- *Zimmer: The Gender-specific Knee Case Study* – Matt
- Orthopedics - Doug Dirschl (Professor and Chairman, University of Chicago Medicine)
<https://www.linkedin.com/in/douglas-dirschl-036b4a14a/>

Readings: See *Canvas*

Week 13 – December 2 Student Presentations!

Week 14 – December 9 Student Presentations!

FINAL EXAMS DUE! 6PM, December 13