

HCMG 853 - MANAGEMENT AND STRATEGY IN MEDICAL DEVICES AND TECHNOLOGY

Fall 2018

W: 3:00-6:00 pm

Location: CPC Auditorium

Faculty

Jeffrey A. Solomon, MD MBA Lecturer The Wharton School of Business

Matthew Grennan, PhD Assistant Professor The Wharton School of Business Email: <u>jasolomo@upenn.edu</u> Office Hours: By appointment

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Teaching Assistants

Joe Martinez (josma@wharton.upenn.edu) Campbell Arnold (<u>tcarnold@seas.upenn.edu</u>)

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

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 st 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. 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%
5.	Midterm Case Write-up. This is a group assignment. Due Friday, Oct 12, 6pm.	25%
6.	Final Case Write-up. Also a group assignment. Due on Friday, Dec 14, 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 - August 29

- 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 5

- FDA Pre-/Post- Market Dina Justice (Terumo) https://www.linkedin.com/in/dina-justice-fleischer-1a45982
- Intellectual Property Lou Lieto (Wilson Sonsini Goodrich & Rosati) https://www.linkedin.com/in/loulieto

Readings: Biodesign 4.1, 4.2, 5.1, 5.4

Week 3 - September 12

- *Heartport, Inc.* Case Study Matt
- The Cardiac Catheterization Lab: a Hub for Innovation Robert H. Li, MD (Penn Medicine Cardiology) https://www.pennmedicine.org/providers/profile/robert-li

Readings: Heartport, Inc. Case Study; Biodesign 5.2, 5.3; Canvas for additional

Week 4 – September 19

- Reimbursement Richard Duszak, MD, FACR, FSIR, FRBMA (Professor and Vice Chair for Health Policy and Practice Department of Radiology and Imaging Sciences Emory University School of Medicine) https://www.linkedin.com/in/richard-duszak-md-7702a35/
- Design Thinking and Prototyping (+Devices@Penn) Mohit Prajapati, MS, MBA (Penn CHCHI) https://www.linkedin.com/in/mohit-prajapati-387910a

Readings: Biodesign 4.3, 5.6; 3.1, 3.2, 4.5, 4.6, 5.5

<u>Week 5 – September 26</u>

- Venture Capital and the Device Sector Ali Behbahani, MD, MBA (NEA) <u>https://www.linkedin.com/in/ali-behbahani-3bb3591</u>
- Device-related Services and Solutions Pei Ho, MBA (Medtronic) <u>https://www.linkedin.com/in/peiho</u>

Readings: Biodesign 4.4, 5.9, 6.3

Week 6 - October 3

- Consumer Wearables and Analytics Sean Bruich (Nike) https://www.linkedin.com/in/seanbruich
- Data and the Endurance Athlete Joe Friel, MS (Co-founder Training Peaks, author, and professional cycling coach) <u>http://joefriel.typepad.com/blog/bio.html</u>

Readings: *Biodesign* 5.7, 5.8 (useful for midterm); https://www.trainingpeaks.com/blog/an-introduction-to-trainingpeaks-metrics/ https://www.trainingpeaks.com/blog/an-introduction-to-more-trainingpeaks-metricspart-two/

Week 7 - October 10

- Disruptive Innovation (and Clinical Wearables) Derek Sung, PhD, MBA (EVP Strategy and Corporate Development, iRhythmTechnologies, Inc.) <u>https://www.linkedin.com/in/derrick-sung-a848161</u>
- Value Based Care, The Corporate Perspective Parashar Patel, MPA (Vice President, Global Health Policy, Boston Scientific) <u>https://www.linkedin.com/in/parashar-patel-aa76574b/</u>

Readings: <u>http://vbhcglobalassessment.eiu.com/wp-</u> <u>content/uploads/sites/27/2016/09/EIU_Medtronic_Findings-and-Methodology.pdf</u>; *Canvas* for additional

-- MIDTERM EXAMS DUE! 6PM, October 12 --

Week 8 - October 17

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

Readings: See Canvas

Week 9 - October 24

- Zimmer: The Gender-specific Knee Case Study Matt
- Industry Partnership and Implant Innovation in the Field of Spine Surgery Alexander Vaccaro, MD, PhD, MBA (President, The Rothman Institute) https://www.rothmaninstitute.com/physicians/alexander-r-vaccaro-md-phd

Readings: See Canvas

<u>Week 10 - October 31</u>

- Digital Health, Venture Capital Perspective Adam Goulburn, PhD (General Partner, Lux Capital) and Gurdane Bhutani (Managing Partner, FundRx) <u>https://www.luxcapital.com/team/adam-goulburn/</u> <u>https://www.linkedin.com/in/gurdanebhutani/</u>
- "The FDA approved my device why will no one pay for it?" Chris Jagmin, MD (Senior Medical Director, Head of Medical Policy, Clinical Services, Aetna) <u>https://exlevents.com/speakers/chris-l-jagmin/</u>

Readings: See Canvas

<u>Week 11 – November 7</u>

- Pre-clinical Regulatory Strategies –Victoria (Tory) Hampshire, (CEO, Capital Preclinical Scientific Consulting, LLC) <u>https://www.linkedin.com/in/victoria-tory-hampshire-266130b3/</u>
- Medical Devices, The Public Markets Perspective Mike Kramarz, MD, MBA (Samlyn Capital, LLC) <u>https://www.linkedin.com/in/michael-kramarz-02922013/</u>

Readings: See Canvas

Week 12 - November 14

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

Week 13 - November 28 -- Student Presentations!

Week 14 – December 5 -- Student Presentations!

-- FINAL EXAMS DUE! 6PM, December 14 --