



# HCMG 8530: Management & Strategy in Medical Devices & Technology

Fall 2024, 1.0 CU, Mondays 3:30-6:30 pm, SHDH 107

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## Faculty

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## Teaching Assistant

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## COURSE OVERVIEW

Successful medical devices and technologies 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 and technology 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, tablets, or phones 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 1<sup>st</sup> 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 Sunday, Oct 13, 10pm. 25%

**Final Case Write-up.** This is also a group assignment. Due Sunday, Nov 10, 10pm.

25%

## **COURSE ETIQUETTE**

Many outside speakers work for publicly traded companies or government agencies. To allow them to speak freely in the classroom setting, please do not post any comments on social media, record, or in any way share course content with anyone outside of this class. Any violation of this policy will result in serious repercussions.

## **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.

## **CLASS SCHEDULE**

- **Week 1 – August 26**
  - Welcome and Introduction to Medical Devices – Alon Bergman, PhD (Wharton)
  - Entrepreneurship and Medical Devices - Jeffrey Solomon, MD, MBA (Wharton)
  - Readings: Biodesign, Stages 1, 2
  
- **Labor Day (no class) – September 2**
  
- **Week 2 – September 9**
  - Coding and Reimbursement - Matt Hawkins, MD (Director, Pediatric Interventional Radiology, Children's Healthcare of Atlanta)
    - [www.linkedin.com/in/matt-hawkins-md-93b6b737](http://www.linkedin.com/in/matt-hawkins-md-93b6b737)
  - Scaling an AI Startup: How to go From one Hospital to a Thousand – Elad Walach (Co-founder and CEO, Aidoc)
    - <https://www.linkedin.com/in/elad-walach/>
  - Readings: Biodesign 3.1, 3.2, 4.3, 5.6, 5.7, 5.8

- **Week 3 – September 16**
  - Public Markets Perspective – Chris Pasquale (Partner and Senior Research Analyst, Nephron Research)
    - <https://www.linkedin.com/in/chris-pasquale-b51158245/>
  - TBA – Sheldon Liber (Director, CAPS Medical)
    - <https://www.linkedin.com/in/sheldon-liber-233871/>
  - Readings: Biodesign 4.4, 4.5, 4.6, 6.2, 6.3, 6.4
- **Week 4 – September 23**
  - Hospital Purchasing - Scott Trerotola, MD (Associate Chair and Chief, Interventional Radiology, Penn Medicine)
    - [www.med.upenn.edu/apps/faculty/index.php/q5165284/p15252](http://www.med.upenn.edu/apps/faculty/index.php/q5165284/p15252)
  - Venture Capital and the Device Sector – Ali Behbahani, MD, MBA (Partner, Co-Head of Healthcare, NEA)
    - <https://www.nea.com/team/ali-behbahani-md>
  - Readings: Biodesign 5.2, 5.3
- **Week 5 – September 30**
  - FDA – Pre-/Post- Market Regulation – Dina Justice (VP, Regulatory Affairs, Terumo)
    - <https://www.linkedin.com/in/dina-justice-1a45982/>
  - Readings: Biodesign 4.1, 4.2, 5.1, 5.4, 5.5
- **Week 6 – October 7**
  - Medical Device Reimbursement – Seth Clancy (SVP, Global Health Economics & Reimbursement, Edwards Lifesciences)
    - <https://www.linkedin.com/in/seth-clancy-6973965/>
  - Heartport, Inc. Case Study – Alon
  - Readings: *Heartport, Inc.* case
- **MIDTERM EXAMS DUE! 10PM, October 13**
- **MBA Opportunity Week (no class) – October 14**
- **Week 7 – October 21**
  - Clinical Perspective on Spine/Neuro Devices – Comron Saifi, MD (Associate Professor of Orthopaedic Surgery, Houston Methodist Hospital)

- <https://www.linkedin.com/in/spinesurgeon/>
  - Zimmer: The Gender-specific Knee Case Study – Alon
  - Readings: *Zimmer: The Gender-specific Knee* case
- **Week 8 – October 28**
  - Entrepreneurship and AI in Medical Imaging – Woojin Kim, MD (Co-founder and CMO, Equium Intelligence)
    - <https://www.linkedin.com/in/woojinkim/>
  - Consumer Wearables and Analytics – Sean Bruich (VP, Global Consumer Science & Insights)
    - <https://www.linkedin.com/in/seanbruich>
  - Readings: Biodesign 5.9, 6.1
- **Week 9 – November 4**
  - 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

• **FINAL EXAMS DUE! 10PM, November 10**

- **Week 10 – November 11**
  - Incubate to IPO: The Transition from Survive to Thrive in Medtech - Lucas Buchanan, MBA (CFO/COO, Silk Road Medical)
    - <https://www.linkedin.com/in/lucas-buchanan-34b1995/>
  - Leveraging Intellectual Property for Strategic Advantage – Karun Naga (Partner, the Foundry)
    - <https://www.linkedin.com/in/ali-behbahani-3bb3591/>
  - Readings: See Canvas
- **Week 11 – November 18**
  - Student Presentations!
- **Week 12 – November 25**
  - Student Presentations!