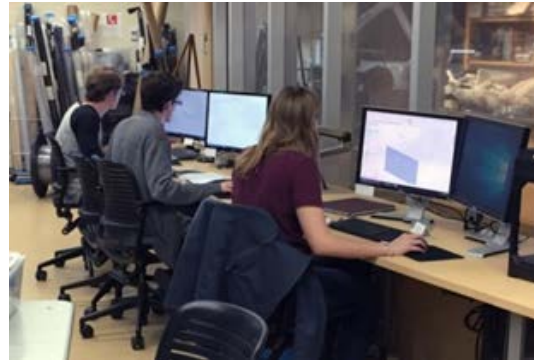


## **BME 3xxx “Medical Device Practicum”**

Department of Biomedical Engineering, University of Minnesota

### **Syllabus – May Session 2018**

Instructor: Prof. Steven Saliterman  
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Location: Medical Devices Center  
TA: TBD  
Office Hours: TBD  
Location: TBD  
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**Overview:** This course allows students to use the skills they learned in BMEN 2151 “Introductory Medical Device Prototyping” for making an actual medical device prototype. Weekly seminars introduce advanced medical device topics that will be fundamental to senior design. The class size will be 21 students.

**Schedule:** Seminars are in the Earl Bakken Medical Devices Center’s “Brainstorming Room.” The Anderson Student Innovation Labs and ME Student Machine Shop will also be used for independent projects. “May Session” runs from 5/21 to 6/8/2018.

Mondays	9:30 – 10:30 a.m.
Wednesdays	9:30 – 11:30 a.m.
Fridays	9:30 – 11:30 a.m.

**Credits:** 1

**Prerequisites:** BMEN 2151 “Introductory Medical Device Prototyping”

#### **Course Goals and Objectives**

Students will become acquainted with the following topics:

- Design opportunities in medicine
- Conceiving and vetting a medical device
- FDA regulations & guidance

- Intellectual property
- Commercialization – licensing and entrepreneurship
- Building a medical device prototype

**Required Books:**

None

**Required Software**

Arduino (free download)

SolidWorks (free from the University – download as soon as you register for the class)

Multisim and Ultiboard (free student evaluation period, then \$39.95 to purchase)

**Reference Books:** *(Most are available on reserve from Prof. Saliterman in the EBMDC)*

***Design, Quality, Testing & Validation:***

Gad, S. *Biomaterials, Medical Devices, and Combination Products*, CRC Press (2015)

Geckler, V. *Design Controls, Risk Management & Process Validation for Medical Device Professionals*, Wasatch Consulting Resources LLC; 1st edition (2017)

King, P.H., *Design of Biomedical Devices and Systems*, Third Edition (2014)

Kucklick, T.R., *The Medical Device R&D Handbook*, Second Edition (2012)

Rodriguez-Perez, J. *Quality Risk Management in the FDA-Regulated Industry*, Quality Press; 2nd ed. (2017)

Yock, P., *Biodesign*, 2nd ed. (2015)

***Intellectual Property & Law:***

Kane, S.D., *Trademark Law – A Practitioner’s Guide*, Practicing law Institute (2005).

Mehta, S.S., *Commercializing Successful Biomedical Technologies*, Cambridge University Press, New York (2008).

Poltorak, A. and P. J. Lerner, *Essentials of Intellectual Property*, Wiley, New York, (2002).

Razgaitus, R., *Valuation and Pricing of Technology-Based Intellectual Property*, Wiley, New Jersey (2003).

Stim, R., *Patent, Copyright & Trademark*, 8<sup>th</sup> ed., Nolo (2006).

Wellons, H.B. and E.S. Ewing, *Biotechnology and the Law*, ABA Publishing, (2007).

**Examinations:** None

**Homework:** Additional time and activities may be required depending on the nature and complexity of the project chosen.

**Class Time:** About 20% lecture, 20% discussion and 60% independent project time.

**Grading**

Participation	20%
Presentation	20%
Project	60%

If you are having difficulties with the material please let Prof. Saliterman or the TA know. We will meet with you and set up whatever is necessary for you to improve.

**Course Conflicts:** Please notify Prof. Saliterman if you have a course or final examination conflict.



## **University Policies**

### **Administrative Policy for Legitimate Absences**

Students may be absent during the semester due to unavoidable or legitimate circumstances. Such circumstances include illness of the student or his or her dependent, participation in intercollegiate athletic events. For other University of Minnesota policies regarding absences and makeup work, please see:

<http://policy.umn.edu/Policies/Education/Education/MAKEUPWORK.html>

### **Board of Regents Policy on Academic Freedom**

Please read this important information on the University of Minnesota's Board of Regents Policy on Academic Freedom and Responsibility

[http://regents.umn.edu/sites/default/files/policies/Academic\\_Freedom.pdf](http://regents.umn.edu/sites/default/files/policies/Academic_Freedom.pdf)

### **Board of Regents and Administrative Policy on Conduct, Teaching, and Learning**

Please familiarize yourself with the Student Conduct Code and Administrative Policy on Teaching and Learning:

<http://policy.umn.edu/Policies/Education/Education/STUDENTRESP.html>

[http://regents.umn.edu/sites/default/files/policies/Student\\_Conduct\\_Code.pdf](http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf)

### **Board of Regents Policy on Equity, Diversity, Equal Employment Opportunity, and Affirmative Action**

Please see this important information on the University of Minnesota's Board of Regents Policy on Equity, Diversity, Equal Employment Opportunity, and Affirmative Action:

[http://regents.umn.edu/sites/default/files/policies/Equity\\_Diversity\\_EO\\_AA.pdf](http://regents.umn.edu/sites/default/files/policies/Equity_Diversity_EO_AA.pdf)

### **Board of Regents Policy on Sexual Harassment**

Please see this important information on the University of Minnesota's Policy on Sexual Harassment:

<http://regents.umn.edu/sites/default/files/policies/SexHarassment.pdf>

### **Disability**

The University of Minnesota is committed to providing equitable access to learning opportunities for all students. Disability Services (DS) is the campus office that collaborates with students who have disabilities to provide and/or arrange reasonable accommodations.

If you have, or think you may have, a disability (e.g., mental health, attentional, learning, chronic health, sensory, or physical), please contact DS at 612-626-1333 to arrange a confidential discussion regarding equitable access and reasonable accommodations. If you are registered with DS and have a current letter requesting reasonable accommodations, I encourage you to contact me early in the semester to review how the accommodations will be applied in the course.

### **Grade Definitions**

The University of Minnesota's "Grading and Transcripts" policy can be reviewed here:

<http://policy.umn.edu/Policies/Education/Education/GRADINGTRANSCRIPTS.html>

### **Mental Health and Stress Management Services**

As a student you may experience a range of issues that can cause barriers to learning, such as strained relationships, increased anxiety, alcohol/drug problems, feeling down, difficulty concentrating, and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance or reduce your ability to participate in daily activities. University of Minnesota services are available to assist you with addressing these and other concerns you may be experiencing. You can learn more about the broad range of confidential mental health services available on campus via [www.mentalhealth.umn.edu](http://www.mentalhealth.umn.edu). Please visit

<http://mentalhealth.umn.edu/> for several resources for students, their parents, faculty, and staff.

### **Student Conduct Code**

The University of Minnesota's Student Conduct Code: can be reviewed here:

[http://regents.umn.edu/sites/default/files/policies/Student\\_Conduct\\_Code.pdf](http://regents.umn.edu/sites/default/files/policies/Student_Conduct_Code.pdf)