

## **Biomedical Engineering for Medical Devices**

**Dept:** Biomedical Engineering

**Designator:** BMEN 3xxx

**Credits:** 1

**Day and Time:** Monday, 2:30-3:20 PM

**Instructor:** Mark Kroll [kroll051@umn.edu](mailto:kroll051@umn.edu)

**Prerequisites:** Biomedical Engineering Junior

### **Goals and Objectives:**

To learn how to prepare for a career in life science technology or the medical device industry. Learn positions available and for which BME graduates are best suited. Understand the role of a quality engineer, verification/validation engineer, design engineer, process development engineer, test engineer, product development engineer, and manufacturing engineer.

General quality and regulatory standards for medical device design. Which standards require what type of test. How to write a test protocol to verify compliance with required standards. Design principles (i.e. material choice, specification and tolerance setting, and concept justification). Introduction to LEAN manufacturing practices

Medical device and life science companies, their products, and locations. How the companies rank and what jobs they offer vs. your aspirations. Start-up vs. larger company pros and cons. Career progression — how to keep that first job and move ahead.

### **Textbook:**

Principles of Design controls for Medical Device: A handbook for Professionals in the Medical Device Industry (Volume 1) by Muchemu

### **Required Work:**

Write a test protocol. Interview a medical device engineer and write report on the engineers duties. The grade will be based on these 2 writing projects. There will be no exams.

### **Guest Lecturers:**

There will be a broad sampling of guest lecturers from industry.