

# Medical Device Experience



## Bioengineering 261B/C

**Summary** A two-course sequence providing formal, hands-on training in medical device engineering, with case studies, lectures, and a team prototyping experience driven by actual unmet medical needs and supervised by clinical practitioners and expert engineering faculty. This course set is intended to equip students seeking to work in medical device research and development with the skills they require.

**What to expect** The courses introduce creative and beneficial engineering of medical devices capable of receiving follow-on funding and FDA clearance in the U.S. Case studies from recent device development and regulatory approval efforts will be provided. The process flow required to meet FDA requirements for risk management, engineering, validation, and clinical trials will be discussed. Weekly presentations by guest clinicians will expose students to the latest problems in medicine, alongside lectures on the latest design and prototyping methods to speed your ideas to reality.

**Learning how to design to address the unmet need** The student will be required to identify unmet medical needs that are solvable through engineering available today, and to produce and present design ideas, system engineering solutions, and a detailed plan to prototype a medical device to address this need in the healthcare industry during the first course. To expedite the student's experience, examples of past successes and failures will be provided. To secure a potential commercialization path, standard practices in protecting invention rights and intellectual property will be covered, as will

routes to government, philanthropic, and industry funding to support work towards commercial and clinical use.

**Translation to reality** In the second course, teams of three to five students will produce and present prototypes of their solution, aiming to maintain regular progress and improve the overall outcome via constructive feedback from potential users, clinicians, and engineering experts. The capstone experience is demonstration of the prototype, a presentation "pitched" to potential investors, and a report explaining the details of the clinical benefit, design, system engineering, intellectual property, and prototyping experience.

### Schedule

BENG 261B Winter quarter; BENG 261C Spring quarter

### Prerequisites

MEng MDE Admission, BENG 294A

### Frequently asked questions

I have a topic I would like to work on. Is it acceptable?

Yes, with some conditions: it must fit a team effort, must be reasonably novel, and fit the course requirement of an unmet medical need.

Will I be expected to really produce a working prototype?

Yes. Part of the course experience is to learn how to choose problems that you can solve in such a brief time.

Can I work on software or pharmaceuticals as my medical device technology solution?

Yes, if it can be a team effort and there is reasonable evidence it can be prototyped within two quarters.

Where do I learn more?

Scan the QR code or contact Sandra Marqas at [smarqas@eng.ucsd.edu](mailto:smarqas@eng.ucsd.edu)

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