

## Introduction to Medical Device Innovation

University of Cincinnati – MEDS 4030 – Fall 2021

**Credits:** 3

**Course Summary:** This course is concerned with the process of medical device innovation. A framework is presented to introduce students to key areas on how to develop a medical device. In addition to lectures and case studies, guest speakers from industry will share their experiences. Topics covered include:

- Innovation – identify a clinical need, design considerations
- Invention – technology transfer, intellectual properties
- Regulatory affairs – FDA and device classification, standards
- Ethics considerations
- Biocompatibility, sterilization, and testing
- Industry – manufacturing, marketing, quality assurance, and start-ups

**Instructor:** Liran Oren, PhD

**Office Hours:** TBD

**Prerequisites:** This course has no prerequisites. Open to students of 3000 level and above.

**Required Textbook:** No textbook required.

Handouts, case studies, and references will be distributed over the course of the quarter.

**Paper/Project:** Students are required to complete a team-based class project. The project deliverable is a final report and a final presentation. Final presentations are scheduled for the day of the last class. The motivation behind this format is to encourage discussion and learning from your peers about the technologies they have been working on, and the insights they have gained.

Project topics will be presented during the first class. Students are welcome to suggest topics of their choice (approval of topic by instructor is required).

Students are asked to form teams (3 students) and to submit their project preferences after the first class (see below for details).

**Grading:**

Attendance	15%
Midterm	20%
Final Presentation:	20%
Final Paper:	45%