

**MENG 5340 Introduction to Medical Device Design
Course Syllabus**

Semester / Year	Spring 2025
Catalog Description	This course provides an introduction to the design of medical devices and other medical technologies. It overviews the entire process of producing a commercial medical device from concept to commerce. Topics include problem identification, solution ideation, the FDA and design in a regulated environment, the design process and prototyping, intellectual property, preclinical and clinical testing, and regulatory paths to market. Students will evaluate existing medical technologies. Students will produce a comprehensive technical and commercial feasibility analysis for a new medical device that will consider the intellectual property and regulatory landscapes.
Prerequisites	Graduate Classification (Grad)
Section Number	050 (Tyler) 051 (HEC)
Instructor Name	Dr. Andrew Robbins
Contact Information	Office: RBN 3006 Email: arobbins@uttyler.edu
Lecture Class Type / Instruction Mode / Location	Section 050 Type: Face-to-Face Instruction Mode: Lecture Location: RBN 1031 Section 051 Type: Hybrid Instruction Mode: Lecture Location: HEC 0C204, ZOOM
Lecture Class Time	W 2:00 PM - 4:45 PM
Office Hours	T 9:00-11:00 am TR 9:00-11:00 am In-person or ZOOM, additional times available by request
No. of Credits	3
Required Textbook	None

Optional References	<p>Zenios, S., Makower, J., & Yock, P. (2015). <i>Biodesign: The Process of innovating medical technologies</i>. Cambridge University Press.</p> <p>Will Durfee, Paul Iaizzo, <i>Medical Device Innovation Handbook</i>, University of Minnesota, MN. Book is available free online.</p>	
Additional Rules and Requirements	<p>AI is permitted only for specific assignments or situations, and appropriate acknowledgment is required. Any assignment for which the use of AI is permitted will have instructions in the assignment instructions detailing the expectations regarding the use of AI on that assignment.</p>	
Evaluation Method	<p>Quizzes Exams HW Project Commercialization Assessment and plan</p>	<p>GRAD 24 % 16 % 16 % 24 % 20 %</p>
Grading Policy / Scale	<p>Letter grades, scale: A: 90 – 100; B: 80 – 89; C: 70 – 79; D: 60 – 69; F: < 60</p>	
Important Events / Dates	<p>Census: 1-27-2025 Last to withdraw from 15-week courses: 3-31-2024 Final Date: 4-28-2025</p>	
Attendance / Makeup policy / other rules	<p>Attendance is required. Only excused absences in accordance with university policy as written in the current catalog will be accepted.</p> <p>It is expected that you will coordinate anticipated excused absences 2 weeks in advance with your instructor, including a plan for makeup work. For unexpected excused absences, students are expected to provide documentation and coordinate makeup work within 2 business days of the end of the excused absence period.</p> <p>For more information refer to the university policy University of Texas at Tyler - Class Attendance/Excused Absences (smartcatalogiq.com)</p>	

Course Learning Objectives / ABET & PEOs Relation	<p>At the completion of this course, students should be able to:</p> <ol style="list-style-type: none"> 1. Identify and assess the commercial potential of clinical need statements (SO1) 2. Identify the risk based classification and regulatory pathway for a medical technology (SO2) 3. Apply design process methods to explore the design solution space and generate viable and novel solutions to problems (SO1, SO2) 4. Develop plans for prototyping and testing medical devices (SO2) 5. Navigate and apply Good Laboratory Practice (21 CFR 58), Good Clinical Practice, and Design Controls (21 CFR 820.30) (SO2, SO4) 6. Generate a technical and commercial feasibility analysis of a new medical technology (SO2)
Tentative Topics / Course Plans	See schedule below
University Policies	https://www.uttlyer.edu/offices/academic-affairs/files/syllabus-information.pdf

Schedule

Week	Date	UNIT	Assessment
1	01-15-25	Unit 1: Problem Identification	
2	01-22-25		
3	01-29-25	Unit 2: FDA Regulations	Unit 1 Quiz
4	02-05-25		
5	02-12-25	Unit 3: Ideation and Design Process	Unit 2 Quiz
6	02-19-25		

7	02-26-25	Unit 4: Intellectual Property	Unit 3 Quiz
8	03-05-25	Unit 5: R&D and Prototyping	Unit 4 Quiz
9	03-12-25		
10	03-19-25		
11	03-26-25	Unit 6: Formal Testing	Unit 5 Quiz
12	04-02-25		
13	04-09-25	Unit 7: The Business of Medical Devices	Unit 6 Quiz
14	04-16-25		
15	04-23-25	Final Presentations	Unit 7 Quiz
	4-28 to 5-02	FINAL EXAM	