Department of Mechanical Engineering
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Uttyler.edu/engineering

MENG 5340 Introduction to Medical Device Design
Course Syllabus

Semester / Year	**Spring 2026**
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 and produce a comprehensive technical and commercial feasibility analysis for a medical device.
Prerequisites	Graduate Classification (Grad)
Section Number	001 (Tyler) 051 (HEC)
Instructor Name	Dr. Andrew Robbins
Contact Information	Office: RBN 3006 Email: arobbins@uttyler.edu
Lecture Class Type / Instruction Mode / Location	Section 001 Type: Face-to-Face Instruction Mode: Lecture Location: RBN 3040 Section 051 Type: Hybrid Instruction Mode: Lecture Location: 0B210, ZOOM
Lecture Class Time	MW 3:30PM - 4:50PM
Office Hours	TR 9:00-11:00 am In-person or ZOOM, additional times available by request
No. of Credits	3
Required Textbook	None
Optional References	Zenios, S., Makower, J., & Yock, P. (2015). *Biodesign: The Process of*

	innovating medical technologies. Cambridge University Press. Will Durfee, Paul Iaizzo, *Medical Device Innovation Handbook*, University of Minnesota, MN. Book is available free online.	
Additional Rules and Requirements	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. Since the mechanical engineering program is designed to prepare students for professional practice, all submitted work (e.g., homework, lab reports, projects, presentations) is expected to meet professional standards. Work that does not reflect professional quality may be subject to grade reductions, even if professionalism is not explicitly listed in the grading rubric.	
Evaluation Method	Quizzes Exam HW Project	GRAD 35 % 20 % 20 % 25 %
Grading Policy / Scale	Letter grades, scale: A: 90 – 100; B: 80 – 89.9; C: 70 – 79.9; D: 60 – 69.9; F: < 60	
Important Events / Dates	Census: 1-27-2025 Last to withdraw from 15-week courses: 3-31-2024 Final Date: 4-28-2025	
Attendance / Makeup policy / other rules	Attendance is required. Only excused absences in accordance with university policy as written in the current catalog will be accepted. 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. For more information refer to the university policy University of Texas at Tyler - Class Attendance/Excused Absences (smartcatalogiq.com)	

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Course Learning Objectives / ABET & PEOs Relation	At the completion of this course, students should be able to: 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 medical technology (SO2)
Tentative Topics / Course Plans	See schedule below
University Policies	https://www.uttyler.edu/offices/academic-affairs/files/syllabus-information-rev122025.pdf

Schedule (Updated)

UNIT	Date	Week	Topic	Assessment
Unit 0: Introduction	1-12-26	1	Course Intro, Learning, Syllabus	
	1-14-26	1	Medical Terminology MTS: Total Knee Replacement	
	1-19-26			
Unit 1: Problem Definition	1-21-26	2	Defining the Problem: Clinical Need Statements	Unit 0 Quiz
	1-26-26	3	Basic Research In Class Exercise, Existing solutions, Literature searching, Patent searching	
Unit 2: FDA Regulations	1-28-26	3	History and Justification of the FDA	Unit 1 Quiz
	2-2-26	4	Regulatory Pathway and 510(k)	
	2-4-26	4	De Novo, Class III and Pre Market Approval	
	2-9-26	5	MTS: Intro to Neural Engineering	
Unit 3: Ideation and Design Process	2-11-26	5	Ideation Exercise	Unit 2 Quiz
	2-16-26	6	Design in a Regulated Environment (Design Controls)	
	2-18-26	6	Universal Principles of Design Design Tools for Medical Devices	
	2-23-26	7	MTS: Tomographic Imaging	

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Unit 4: Intellectual Property	2-25-26	7	Intellectual Property	Unit 3 Quiz
Unit 5: R&D and Prototyping	3-2-26	8	Prototyping and Testing (plus R&D strat)	Unit 4 Quiz
	3-4-26	8	Biomaterials	
	3-9-26			
	3-11-26			
	3-16-26	9	Bonus Prototyping Topic	
	3-18-26	9	MTS: Deep Brain Stimulation	
Unit 6: Compliance	3-23-26	10	Biosafety, IACUC and Animals	Unit 5 Quiz
	3-25-26	10	Good Laboratory Practices	
	3-30-26	11	Human Subject Protection	
	4-1-26	11	Good Clinical Practices	
	4-6-26	12	MTS: Elastography	
Unit 7: The Business of Medical Devices	4-8-26	12	Entrepreneurship, Business Models, Cap tables	Unit 6 Quiz
	4-13-26	13	Entrepreneurship, Business Models, Cap tables	
	4-15-26	13	In Class Activity	
	4-20-26	14	MTS: ???	
	4-22-26	14	Exam Review	Unit 7 Quiz
	4-27 to 4-30		**Final Exam**	