Department of Mechanical Engineering
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Uttyler.edu/engineering

MENG 4350 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.
Prerequisites	MATH 3305 (UG)
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	UG 40 % 30 % 30 %
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	1/26/2026 (Mo): Census Date. 3/30/2026 (Mo): Last day to withdraw from one or more classes. 4/27-30: Final Exam. exact date TBD	
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)	

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)
Tentative Topics / Course Plans	See schedule below
University Policies	https://www.uttyler.edu/offices/academic-affairs/files/syllabus-information-rev122025.pdf

Schedule

Week		UNIT	Assessment
1		Unit 1: Problem Identification	
2			
3		Unit 2: FDA Regulations	Unit 1 Quiz
4			
5		Unit 3: Ideation and Design Process	Unit 2 Quiz

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7		Unit 4: Intellectual Property	Unit 3 Quiz
8		Unit 5: R&D and Prototyping	Unit 4 Quiz
9			
10			
11		Unit 6: Formal Testing	Unit 5 Quiz
12			
13		Unit 7: The Business of Medical Devices	Unit 6 Quiz
14			
15		Final Presentations	Unit 7 Quiz
		FINAL EXAM	