

MECH 4395: Orthopedic Medical Device Design

Fall 2016

Thursday, 3:00-5:40 p.m.

LART: Room 306

INSTRUCTORS: Tom Zink (Director of Engineering, Nvision Biomedical Technologies, email: tomzink@nvisionbiomed.com)
Nick Cordaro (President, Additive Innovations, e-mail: nick.cordaro@additiveinnovations.net)
Mireya Perez (Research Administrator, Keck Center, e-mail: maperez4@utep.edu; office: Keck Center, Engineering Room 108)
Ryan Wicker (Professor, Mechanical Engineering, e-mail: rwicker@utep.edu; office: Keck Center, Engineering Room 108)

OFFICE HRS: by appointment

COURSE DESCRIPTION AND GOALS:

Engineers seeking exposure to medical device design must gain proficiency working within healthcare requirements. Project work will focus on orthopedic designs and include general biomedical principles with broad applicability. The students will be challenged with combining a diverse set of disciplines to achieve a safe and successful medical product development cycle. This course will guide students through a Food and Drug Administration (FDA) compliant Design History File (DHF) as they learn to appreciate the required complex engineering decisions greatly influenced by clinical needs, human factors, hazard analyses, regulatory requirements, verification activities and validation requirements. The course will further incorporate traditional manufacturing methods, including a basic introduction to quality control as well as more advanced manufacturing methods such as additive manufacturing/3D printing.

ORGANIZATION AND METHOD OF INSTRUCTION:

Lectures will be used to introduce the students to the principles required to successfully design orthopedic medical devices and achieve FDA approvals for implantation of those devices. This course will use much project-based instruction to develop a deep understanding of the design process for orthopedic medical devices within healthcare requirements.

TEXT:

The instructors of this course have much experience in the medical device design industry, and as a result, lecture material will be provided in lieu of providing a required textbook. Much relevant information will be conveyed during lectures and the course material will be provided to the students electronically as required. The students will also be encouraged, in some cases, to secure additional references that may benefit understanding of the myriad issues involved in the design and approval of medical devices for human use. The students are also encouraged to access the web to identify additional information on the course topics.

ATTENDANCE AND CLASS PARTICIPATION:

Attendance in class is required because the required information for the course will be delivered during regular class time. No make-up classes will be offered so it is important that you attend every class.

ASSIGNMENT DEADLINES:

All assignments must be submitted on time at the beginning of class the day the assignment is due. Late projects may be accepted with up to a 25% penalty for each day (24 hours) from the assignment due date.

ACADEMIC DISHONESTY:

Scholastic dishonesty is the attempt of any student to present the work of another as his or her own work, any work which he or she has not honestly performed, or attempting to pass any examination by improper means. Scholastic dishonesty is a serious offense and will not be tolerated. Appropriate University policies and procedures will be followed for suspected scholastic dishonesty. You are encouraged to discuss any aspect of the course with classmates, project team members, and the instructors, but do not plagiarize the work of others by copying from the web, other students, articles, or other sources without properly referencing your sources.

CENTER FOR ACCOMMODATIONS AND SUPPORT SERVICES (CASS):

If you have a disability and need classroom accommodations, please contact The Center for Accommodations and Support Services (CASS) at 747-5148, or by email to cass@utep.edu, or visit their office located in UTEP Union East, Room 106. For additional information, please visit the CASS website at www.sa.utep.edu/cass.

METHOD OF EVALUATION:

The final grade will be determined from evaluation of homework, project deliverables (including oral and written deliverables) and a final project/exam. Contributions to your final grade are as follows: homework (20%), two class projects (40%), and one final project/exam (40%).

Grading:

Homework	20%
Project 1	20%
Project 2	20%
Final Project/Exam	40%
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Total	100%