MECH 4395: Orthopedic Medical Device Design

Fall 2017
Time: R 3:00-5:50
Room: BUSN 302

INSTRUCTORS:
Tom Zink (Director of Engineering, Nvision Biomedical Technologies, email: TomZink@nvisionbiomed.com)
Nick Cordaro (CEO, Watershed Idea Foundry, e-mail: NickCordaro@watershedideas.com)
Jim Steele (Executive Quality Director, Watershed Idea Foundry, email: JimSteele@watershedideas.com)
Cesar Terrazas (Research Assistant Professor, Keck Center, e-mail: caterrazas2@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.

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:

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<tr>
<th>Component</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Homework</td>
<td>20%</td>
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<td>Project 1</td>
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<td>Project 2</td>
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<td>Final Project/Exam</td>
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* See addendum for other class policies.