

1. Course number and name: BMED 4602 Capstone Design
2. Credits and contact hours: (1-0-6-3)
3. Prepared by: James K. Rains
4. Textbook: Design of Biomedical Devices and Systems, 2nd edition, King and Fries, Marcel-Dekker (2008)
5. Specific course information
 - a. Catalog description: Team-oriented design project in biomedical engineering, incorporating engineering standards and realistic design constraints. Includes introduction to relevant regulatory, intellectual property, and business management topics.
 - b. Prerequisites or co-requisites: BMED 2310 and BMED 3110
 - c. Required
6. Specific goals for the course
 - a. Develop a biomedical engineering design solution for a client (Student Outcomes 1, 2, 3)
 - i. Develop a problem statement and design requirements/constraints for a design problem of interest to a client
 - ii. Use design requirements/constraints to develop a design solution by evaluating a number of alternative designs
 - iii. Build a prototype, model, or related proof of concept of a design
 - b. Understand the non-engineering challenges that must be overcome to develop an effective design solution to a biomedical engineering problem (Student Outcome 4)
 - i. Identify and describe the potential social impact and ethical concerns within the United States associated with a design. For IP students, identify and describe the potential social impact and ethical concerns within the country of the student's international program (IP) experience.
 - ii. Explain the pre- and post-market impact of FDA regulations. For IP students, explain the pre- and post-market impact of the regulatory body in the country of the student's IP experience.
 - c. Understand and communicate a final design and the multiple constraints and considerations that were involved in its creation (Student Outcomes 2 and 3)
 - i. Create and deliver an effective written report that describes a final design and its rationale
 - ii. Conduct and communicate an analysis of critical processes, components or assemblies, CAD drawings, costs of production, material selection and rationale, and manufacturing considerations.
 - d. An ability to function effectively on a team whose members establish goals, plan tasks, and meet objectives
 - e. Acquire and apply new knowledge as needed to meet challenges associated with biomedical engineering design solutions

7. Brief list of topics to be covered:
 - a. FDA Regulatory Guidelines
 - b. Identifying and collecting User Needs
 - c. Development of Design Inputs
 - d. Intellectual Property
 - e. Concept Generation and Selection
 - f. Human Factors Engineering
 - g. Concept Development and Prototyping
 - h. Marketing
 - i. Societal Impact