1. Course number and name: BMED 4602 Capstone Design
2. Credits and contact hours: (1-0-6-3)
3. Prepared by: James K. Rains
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