

BMED 4603 Advanced Design (Elective)

Catalog Description: BMED 4603 Advanced Design (1-6-3)
Prerequisite(s): BMED 4602
Continuation of a team-oriented design experience initiated in BMED 4602 Capstone Design. Includes more advanced relevant regulatory such as intellectual property, and business management topics.

Textbook: Design of Biomedical Devices and Systems, 2nd edition, King and Fries, Marcel-Dekker (2008)

Prepared by: James K. Rains

Topics Covered:

1. Design for Manufacturing
2. Prototyping Methods
3. Design Verification
4. Advanced Regulatory Affairs (FDA, CE, and International)
5. Advanced Intellectual Property (U.S. and International)
6. Business Strategies for Medical Products
7. Societal Impact

Course outcomes:

Outcome 1: Develop a biomedical engineering design solution for a client (Student Outcomes c, e, g, and k)

- 1.1 Develop a problem statement and design requirements/constraints for a design problem of interest to a client
- 1.2 Use design requirements/constraints to develop a design solution by evaluating a number of alternative designs
- 1.3 Build a prototype, model, or related proof of concept of a design

Outcome 2: Understand the non-engineering challenges that must be overcome to develop an effective design solution to a biomedical engineering problem (Student Outcomes f and h)

- 2.1 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.
- 2.2 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.

Outcome 3: Understand and communicate a final design and the multiple constraints and considerations that were involved in its creation (Student Outcomes c and g)

- 3.1 Create and deliver an effective written report that describes a final design and its rationale

- 3.2 Conduct and communicate an analysis of critical processes, components or assemblies, CAD drawings, costs of production, material selection and rationale, and manufacturing considerations.

Correlation between course outcomes and student outcomes:

BMED 4603											
	Biomedical Engineering Student Outcomes										
Course outcomes	a	b	c	d	e	f	g	h	i	j	k
1.1			X		X		X		X	X	
1.2			X		X						X
1.3			X								X
2.1						X		X			
2.2							X	X			
3.1							X				
3.2			X				X				X

The Wallace H. Coulter Department of Biomedical Engineering Student Outcomes:

- a. an ability to apply knowledge of mathematics, science, and engineering;
- b. an ability to design and conduct experiments, as well as to analyze and interpret data;
- c. an ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, societal, political, ethical, health and safety, manufacturability, and sustainability;
- d. an ability to function on multidisciplinary teams;
- e. an ability to identify, formulate, and solve engineering problems;
- f. an understanding of professional and ethical responsibility;
- g. an ability to communicate effectively;
- h. the broad education necessary to understand the impact of engineering solutions in a global, economic, environmental, and societal context;
- i. a recognition of the need for, and an ability to engage in lifelong learning;
- j. a knowledge of contemporary issues;
- k. an ability to use the techniques, skills, and modern engineering tools necessary for engineering practice;