FIU
FLORIDA INTERNATIONAL UNIVERSITY
Department of Biomedical Engineering

BME 4800			
Course Title: Design of Biomedical Systems & Devices		**Instructors:** Michael Christie/ Hamid Shahrestani	
Required Course	Term :Spring 2017	Date: 6/13/2017	Page 1 of 5

Abbreviated Course Title (19 spaces or less):
Design of Biomedical Systems and Devices

Catalog Description (200 spaces or less):
Design of various biomedical systems and devices such as cardiovascular assist devices, orthopaedic devices, pulmonary assist devices, neurological devices, and diagnostic systems.

Course Objectives:
This course is designed to provide the student with an introduction to systems and devices used in the biomedical industry and the basic principles of their design. It is meant to offer the students an application in the biomedical area to the basic theory developed in the lower level course work as well as an opportunity to learn basic steps and processes involved in engineering design as it specifically applies to biomedical problems. Global Learning principles will be integrated into the course work through the use of international standards, multicultural marketing and design considerations, societal and environmental considerations, as well as ethics and sustainability. Assessments will be done by Senior Design Faculty Evaluation committee at the end of the semester in two separate evaluation forms: (1) Senior Design Report Evaluation Form and (2) Senior Design Proposal Presentation Faculty Evaluation Form. Hence, this is a global learning course that will satisfy the global learning upper division requirement.

Contribution to Professional Component: Engineering Topics

Major Topics:
The student works on a team formed during BM 4090 Design Project Organization, mentored by a faculty member. The students must complete the project, with prototype designed, built and tested, and submit a final report and presentation at the annual BME Spring Projects Conference.

Co-requisites:
BME4090
Prerequisites:
BME 3632, BME 3721, BME 3404

Contact Hours per Week: Lecture: _3_, Lab: _0_, Field Work: _0_

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Course Outcome:

1. Ability to apply the principles of engineering design from recognition of need to a fully-tested product.
2. Ability to organize and manage a design project and work effectively in a team to complete the project.
3. Ability to recognize the existence, similarities and differences of various regulatory processes for assessment and approval for commercialization of biomedical devices and systems in national and the global markets.
4. Ability to apply knowledge of natural physiological systems to the design of their replacements and to devise means to overcome constraints in doing so.
5. Ability to design and conduct tests to verify design input and validate the final product to meet user needs.
6. Ability to Communicate items 1 through 5 in written, oral and graphical form.
7. Students will learn the process to formulate and present an engineered solution which will directly or indirectly enable or enhance the diagnosis or treatment of a current unresolved issue of global biomedical significance.
8. Ability to implement the design tools (i.e. QFD, FMECA, budget analysis, cost analysis, simulations, prototyping and verification testing) effectively toward assessment, development and verification of a Biomedical system, Device or manufacturing process which will address global clinical needs diagnostically or therapeutically

Global Learning Course Learning Outcomes:

1. Students will be able to identify, analyze and integrate ethics, similarities and differences in multiple markets and cultures.
2. Students will be able to conduct an analysis of an engineering problem and its global impact by identifying different factors such as technology, economics and society, and their contributions to the problem and/or solution.
3. Students will be willing to work in teams to develop solutions, actions, and action plans to address local, global and /or international engineering problems.

Textbook(s):

Reliable Design of Biomedical Devices, Second Edition (Richard Fries) by Taylor & Francis Group (ISBN 0-8247-2375-9) or (978082472370)

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Reference Material

- Does Cultures Matter for Product Design, By Don Norman
- The Influence of Designers' own Culture on the Design Aspects of products, By Mohammad Tazzaghi and Mariano Ramirez J
- Medical Device Developments
  www.medicaldevice-developments.com
- Beyond Compliance: Medical Device Product Development
  https://ww2.frost.com/files/3914/2200/7195/Beyond_Compliance.pdf
- International Medical Device Regulators Forum (IMDRF)
  https://www.fda.gov/MedicalDevices/InternationalPrograms/IMDRF/...
- WHO | Medical devices
  www.who.int › Medical devices

Major Topics:

1. Recognition of Need/Opportunity
2. Problem Formulation: Design Input
   a. Design in a Regulated Environment: Introduction to QSR and Design Controls
   b. Primary Biomedical Design Input: Biocompatibility
3. Solution Formulation: Creativity and Innovation
4. Feasibility Assessment
5. Project Management
6. Engineering Analysis and Decision Making
7. Detailed Design: Design Output
   Construction: Prototype design concepts
9. Testing: Simulations and Design Concept Evaluation
10. Financial Evaluation

Course Learning Outcomes:

No.	Course Learning Outcome	Corresponding BSBME Program Learning Outcome and Metric
1	See outcome number 1 below in BSBME Program Learning Outcomes	1, Faculty Senior Design Project Evaluation Form

2	See outcome number 2 below in BSBME Program Learning Outcomes	2, Faculty Senior Design Project Evaluation Form
3	See outcome number 3 below in BSBME Program Learning Outcomes	3, Faculty Senior Design Project Evaluation Form
4	See outcome number 4 below in BSBME Program Learning Outcomes	4, Faculty Senior Design Project Evaluation Form
5	See outcome number 5 below in BSBME Program Learning Outcomes	5, Faculty Senior Design Project Evaluation Form
6	See outcome number 6 below in BSBME Program Learning Outcomes	6, Faculty Senior Design Project Evaluation Form
7	See outcome number 7 below in BSBME Program Learning Outcomes	7, Faculty Senior Design Project Evaluation Form
8	See outcome number 8 below in BSBME Program Learning Outcomes	8, Faculty Senior Design Project Evaluation Form

BSBME Program Learning Outcomes:

1. Ability to apply knowledge of mathematics (including differential equations and statistics), physical and life sciences, and engineering to carry out analysis and design to solve problems at the interface of engineering and biology;
2. Ability to design and conduct experiments, as well as to measure, analyze and interpret data from living systems;
3. Ability to design a system, component, or process to meet desired needs, including systems that involve the interaction between living and non-living materials, within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability;
4. Ability to identify, formulate, and adapt engineering solutions to unmet biological needs;
5. Ability to use the techniques, skills, and modern engineering tools necessary for engineering practice, including the ability to model and analyze biological systems as engineering systems;
6. Ability to function on multi-disciplinary teams;
7. Ability to communicate effectively;
8. Awareness of the characteristics of responsible professional engineering practice, including ethical conduct, consideration of the impact of engineering solutions on society in a global and contemporary context, and the value of life-long learning.

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SPRING 2017 COURSE OUTLINE

Week #	Subject	Related Assignment(s)	Global Awareness/ Perspective/ Engagement
1	Introduction & Review Course Syllabus Team Definition, Characteristics & Success Factors. Introduction of the Waterfall Model	Resume, Strength/Weaknesses Statement, & Completed Survey	
2	Idea Generation Methods	In Class sub-team exercise	
3	Determination of Need (Clinical Need) - Review techniques and sources to identify needs (Domestic)	Research Paper- (Individual Assignment) Research FDA Recalls for past 180 days.	Global Awareness
4	Determination of Need (Clinical Need)	Research Paper- (Individual Assignment) Research global regulatory processes for receiving approval to market Medical Devices FDA recalls for past 180 days.	Global Awareness
5	Determination of Need (Business Need)	Ladder of Abstraction - Technique to organize and communicate information	Global Engagement
6	Developing Product Definition & Market Requirements	Create Market Requirements for Specific Medical Device and Submit results. (Team Assignment)	Global Engagement
7	Developing Product Definition & Market Requirements	(Individual Assignment) Clinical Research Devices related to drug delivery systems, Strengths, Weaknesses, Opportunities (Clinical Need)	Global Engagement
8	Developing Product Definition & Market Requirements	(Team Assignment) Market Research Global Devices related to Drug Delivery Systems (Diagnostics and Treatment) (Global Business Need)	
9	Developing Design Inputs (Characteristics, Methodology)	Establish Design Inputs for Available Market Requirements. Investigate the impact of global demographics on the Design Inputs Considering Environment, Economic conditions, Race, Religion and Regulatory Requirement in various regions of the world.	
10	Regulatory Assessment (Design, Test & Safety Standards). Hazard Analysis	Applicable Design, Test and Safety Standard for drug delivery System, related Domestic & International Regulatory Bodies and their functions.	Global Engagement
11	Developing Design Inputs (Bio-Mechanical Devices). Cost Assessment and Budgeting, Hazard Analysis and Technology Assessment	Convert Market Requirements to Design Inputs (Drug Delivery System). Develop Design Concepts and perform cost assessment	

12	Design Methodology (Mechanical, Electrical, Software). Design (Mechanical, Electro-Mechanical, Interfaces and Systems).		
13	Simulations & Prototyping.	Second Interim Presentation of Senior Design Project to the class. (Complete proposal)	Global Perspective
14	Design Control (Documentation Control). Intro to Intellectual Property (Patents)		Global Perspective
15	Design Verification & Validation		
16	Design (Reliability Assessment). Design (Human Factors). Commercialization Process	Team Presentation of the Senior Design Project in class covering Market Research, Scope, and Feasibility Assessments	Global Perspective

BME 4800 – Senior Design Proposal Presentation Evaluation Form

Category	SCORE				
	1	2	3	4	5
Meets the requirements of the Senior Design Project					
Detail determination of the Clinical need					
Detail determination of the Business impact					
Team has identified the project challenges and demonstrated an effective mitigation plan					
Project Risk and a mitigation plan have been identified					
Meets the requirements of the Senior Design Project					
Detail determination of the Clinical need					
"Project at a Glance" provided a clear overview of the project					
Determination of Need (Clinical & Business) was clearly articulated					
Discussion of current modalities including the pros and cons					
Scope of the Project is SMART (Specific, Measureable, Attainable, Relevant & Time-bound)					
Applied sciences were clearly articulated and rationalized					
All Inclusions & Exclusions were communicated					
Project success factors including challenges, risks and mitigations					
Design Inputs were appropriate and complete					
Hazard Analysis appropriately identified the product risks and Preventive Methods of Control					
Viable and creative design concepts were presented					
Technology Assessment/Clearance demonstrated					
Product and project budget were feasible					
Regulatory assessment outlined the appropriate regulatory path					
Determination of Domestic and International Design, Test & Safety Standards					

At least three Design Verification tests were presented					
The project plan was clearly discussed including Critical Milestones					
Usage of Handouts & Visual Aid					
Clarity of slides, size of fonts, wordiness					
Clear & Visible Graphs, diagrams, and charts					

Taxonomy for BME Senior Design Proposal Presentation Evaluation

Scale	Performance	Description
1	Not Demonstrated	Is unable to demonstrate competency
2	Weak	Demonstrates superficial competency
3	Marginal	Demonstrates minimal competency
4	Acceptable	Demonstrates sufficient level of competency
5	Well Done	Demonstrates strong competency

Category (GL Learning Outcomes)	SCORE				
	1	2	3	4	
Students will be able to identify, analyze, and integrate ethics similarities and differences in multiple markets and cultures.					
Students will be able to plan to conduct an analysis of an engineering problem and its global impact by identifying different factors such as technology, economics and society, regional regulatory requirements, and their contributions to the problem and or solution.					
Students will be willing to work in teams to develop solutions and actions and action-plans to address local, global and/or international engineering problems.					