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<b>BME 4908</b>			
<b>Course Title:</b> Senior Design Project		<b>Instructors:</b> Michael Christie	
Required Course	Term :Spring 2017	Date: 6/14/2017	Page 1 of 6

**Abbreviated Course Title (19 spaces or less):**  
**Senior Design Project**

**Catalog Description (200 spaces or less):**

Customer needs; design requirements, biocompatibility, regulatory, ethical, societal, economic, and environmental considerations. Demonstrated global awareness, perspective, and engagement. Creativity, project management, prototype construction and testing, final report and presentation.

**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. This course is a continuation of BME 4800, Design of Biomedical Systems and Devices. 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 attributes developed in BME 4800 will be integrated into senior design projects and they will be assessed by Biomedical Engineering faculty, and the BME Industrial Advisory Board at the end of the semester in two separate evaluation forms: (1) Senior Design Report Evaluation Form and (2) Senior Design Presentation Evaluation Form. Hence, this is a global learning course that towards the upper division global learning requirement.

**Contribution to Professional Component:** Engineering Topics

**Major Topics:**

The student works on a team formed during BME 4800 Design of Biomedical Systems and Devices, and 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 Senior Design Expo.

**Co-requisites:**

**Prerequisites:**

BME 4800

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**Contact Hours per Week: Lecture:   1  , Lab:   0  , Field Work:   2**

**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):**

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**Required:** None

**Reference course materials (Engineering testing & Standards):**

United States Pharmacopeia  
International Standardization Organization  
American Society for Testing Materials  
American National Standards Institute  
International Electrochemical Commission  
National Institute of Standards & Testing

**Required Reading as assigned:**

World health Organization

- [http://www.who.int/medical\\_devices/publications/en/MD\\_Regulations.pdf](http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf)

National Academy of Engineering: \_ Engineering Challenges for the Developing World

- <http://www.engineeringchallenges.org/cms/7126/7356.aspx>

United States Patent and Trademark Office

- <https://www.uspto.gov/sites/default/files/patents/process/file/efs/guidance/indexing-pct-new-appl.pdf>

Global Engineering Project Management\_by M. Kamal Atesman ISBN-10: 1420073931

**Assignments:**

Students will provide a Design History File and Device Master Record and a detailed report. Students will present their projects in front of a panel of industry experts that will evaluate the projects to ensure that they have met all eight course and program learning outcomes. Final report and presentation must address 1) Determination of Need/Opportunity, 2) Formulation of the Problem, 3) Determination of Design Inputs (Solution Formulation), 4) Feasibility Analysis (Technical, Operational, Schedule, Risk, Budget), 5) Project Management (Feasible Project Plan), 6) Engineering Analysis and Decision Making, 7) Determination of Design Outputs (Product Specifications), 8) Detailed Design (Engineering Drawings, Procedures, Material Specifications), 9) Construction of the End Product, 10) Design Verification and 11) Impact on society in a global and contemporary context.

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Groups must meet weekly with their faculty advisor and project sponsors (which may be the same).

**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.

**Major Topics:**

The student works on a team formed during BME 4880 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. Course requires attendance of weekly lectures:

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1. Required Components of the Senior Design Project (Report, evaluations, DHF, DMR etc.)
2. Industry-Ready Biomedical Engineering: What does Industry Expect
3. Principles of DFX – Considerations before the design begins
4. The Role of Prototyping in Product Development
5. Regulatory Standards including US and International (ISO, ASTM etc)
6. The laboratory Notebook (Assign Responsible Conduct of Research on-line training)
7. Impact of Engineering Solutions on Society in a Global Context
8. Engineering Challenges for the Developing World
9. Good Manufacturing Practice/Good Documentation Practice/Compliance
10. The Essentials of Six Sigma
11. Intellectual Property and Patents – US and International

**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
	See outcome number 8 below in BSBME Program Learning Outcomes	8, Faculty Senior Design Project Evaluation Form

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**Department of Biomedical Engineering**

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**COURSE OUTLINE**

Week	Topic	Date	Global Awareness/ Perspective/ ment
1	<p><b>Course Overview: Required components of the senior design project (Interim Report, Evaluations, DHF, DMR, Final Presentations, Final Report, Development Plan) –</b> Dr. Michael Christie</p> <p>Discussion on Engineering Challenges in the Developing World</p> <p>Reading Assignment: <a href="http://www.engineeringchallenges.org/cms/7126/7356.aspx">http://www.engineeringchallenges.org/cms/7126/7356.aspx</a></p> <p>In-Class Discussion of health challenges in the developing world</p>	1/11/17	Global Awareness
2	<p><b>Design, Product Development &amp; Manufacturing Resources at FIU –</b> Dr. Yun Qian (FIU) and Mr. Richard Zicarelli (FIU)</p>	1/18/17	
3	<p><b>Design for Excellence –</b> Hamid Shahrestani (FIU) Prof.</p>	1/25/17	
4	<p><b>Design of Experiments –</b> Hamid Shahrestani (FIU) Prof.</p> <p>Class discussion of DOE</p> <p>Quiz I: Design for Excellence</p>	2/1/17	
5	<p><b>Essentials of Six Sigma and Lean Manufacturing –</b> Alfredo Moran Hassan &amp; Johnny Rojas Eng'g Management</p> <p>Class Discussion of Six Sigma &amp; Lean and their importance in global manufacturing</p>	2/8/17	Global Awareness

	<p><b>Engineering –</b> Dr. Michael Christie</p> <p>Reading Assignment:</p> <p><a href="http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf">http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf</a></p> <p>Discussion of Engineering standards and developing devices for the national and International markets.</p> <p>Quiz II: Quiz on Design of Experiments and Six Sigma</p>	2/15/17	Global Engagement
7	<p><b>FDA and Regulatory Compliance, and GMP –</b> Ms. Ebony Daniels, Director of Regulatory Affairs, Biotechnica, Inc, formerly of the Food and Drug Administration</p> <p>Required reading: ISO 13485/ Worldwide Quality Management System <a href="http://www.iso.org/iso/home/standards.htm">www.iso.org/iso/home/standards.htm</a></p> <p>Discussion on the FDA and worldwide medical device regulations</p>	2/22/17	Global Engagement
8	<p><b>Career Development: Bullet Proof Cover letters &amp; Resumes –</b> Ms. Stanislaus &amp; Ms. Vickers –Career Services_FIU</p> <p><b>Undergraduate Research Day</b> Dr. Jonathan Vande Geest, Univ of Pittsburgh : 4:00 PM -5:30PM – EC 2300 “Open Forum on Medical Device Development and FDA Approval”</p>	3/1/17  3/3/17	
9	<p><b>Career Development: Interviewing Skills, Negotiation, and the new Job –</b> Ms. Emmanuela Stanislaus &amp; Ms. Leandra Vickers –Career Services FIU</p>	3/8/17	
10	<b>Spring Break – No class</b>	3/15/17	
11	<p><b>Engineering Practice: Research &amp; Development –</b> Dr. Shabnam Namin, Vice President of Research &amp; Development, Miami Tissue Bank</p> <p>Discussion: Research and Development and the multinational company, and maintaining a global competitive edge</p> <p>Quiz III: FDA and Worldwide Standards and Compliance</p>	3/22/17	Global Perspective
12	<p><b>Engineering practice: Manufacturing and Quality Assurance –</b> Ms. Joanna Naranjo, Quality Engineer, MedTronic Inc Mr. William Williamson, manufacturing Engineer, Medtronic Inc Mr. Josue Servalis, Principal manufacturing Engineer, Medtronic Inc</p>	3/29/17	



13	<b>Intellectual Property and Patents –</b> “Peter” Hernandez Dr. Pedro Required Reading: How to file an international Patent <a href="https://www.uspto.gov/sites/default/files/patents/process/file/efs/guidance/indexing-pct-new-appl.pdf">https://www.uspto.gov/sites/default/files/patents/process/file/efs/guidance/indexing-pct-new-appl.pdf</a>	4/5/17	Global Perspective
14	<b>Entrepreneurship –</b> Resource Group, Inc Mr. Chris Ross , Engineering Discussion on Entrepreneurship and Global Manufacturing and Logistics Quiz IV: Intellectual Property and Patents, Quality Assurance and Manufacturing	4/12/17	Global Perspective
15	<b>No Class</b> Final Written Report, Peer Evaluations, Sponsor Evaluations, DHF and DMR and development plan due.	4/19/17	
16	<b>Senior Design Expo</b>	4/21/17	

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**BME 4908 – Senior Design Final Evaluation Form**

Team #	Classwork, Quizzes & Compliance	Senior Design Expo Judges' Evaluation	Sponsor's Final Assessment	Self and Peer Evaluations	Faculty Advisor's Assessment of Reports, DHF, DMR, Development Plan and Team Dynamics	Final Grade
	20%	20%	20%	5%	35%	100%

**THE GRADING/EVALUATION AND RUBRIC FOR BME 4908 IS INCLUDED AS A SEPARATE EXCEL FILE.**

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