**Georgia Institute of Technology**

**Wallace H. Coulter Department of Biomedical Engineering**

*New Course Syllabus*

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| Course Title: **BioID Team Masters Project II** | Instructor: Lewis Franklin Bost, MBA |
| Course Number: **BMED 6509** | Credit Hours: 6 |
| Prerequisites: BMED 6508 |  |

**Course Description:** Master’s Project I and II courses provide graduate student teams with opportunities to work with healthcare professions and industry companies on the creation and development of innovative products to address unmet needs for patient care.

Project Course II focuses on construction of iterative prototypes and performance evaluation for the solution proposed in Course I. Semester deliverables include preparation of a FDA 510(k) regulatory submission package and development of a written project commercialization business plan.

**Catalogue Description:** Teams will construct prototypes for Course I biomedical device project solution, conduct and analyze performance testing, prepare FDA 510(k) submission, and prepare project commercialization plan.

**Course Objectives:**

* Translate, build and evaluate the proposed solution in functioning prototypes.
* Develop written verification protocol for evaluation of functional and performance specifications; perform verification testing, and compose report on verification testing, results with conclusions.
* Develop the “Design Output” document package (FDA) of engineering drawings, specifications, materials, instructions for use, and product claims.
* Develop a commercialization/business plan for team’s masters project.

**Course Format:**

Instructional methods include: weekly lectures, in-class discussions and development lab/studios. Each week there will be a 2-hour class session plus two (2) 4-hour of lab/studio periods for project development activities. Readings will be assigned in the designated textbooks, supplemented with reading from reference materials and contemporary case information on medical device issues in the news. Grading is from a combination of assigned reports, oral progress presentations, and final team-project presentation, project report and business plan.

**Grading**:

* Assignments and reports (30%)
* Design Controls project notebook (15%)
* Team Project (40%)
* Reviews: Peer, Advisor, Instructor/TA (15%)

**Class Materials:**

Required Books/Reference Materials:

* Zenios, Stefanos, Makower, Josh and Yock, Paul. *Biodesign, The Process of Innovating Medical Technologies*, Cambridge University Press 2010. (ISBN: 978-0-521-51742-3)

Recommended Reference Materials:

* To be added…

**Course Topics, Topics and Presentations**

1. Prototyping materials, methods and resources
2. FDA Design Verification Studies
   1. Protocol development and testing/evaluation procedures and processes
3. FDA Design Validation Studies
   1. User experience studies
   2. Required Instructions for use and training
   3. Risk Analysis
   4. Clinical Trials
      1. Medical Institutional Review Boards (IRB)
      2. Documentation; patient consent document
4. Medical device product sterilization methods and requirements
   1. Sterilization method compatibility with product/device materials
5. Packaging design requirements for the “complete” product
   1. Size, protection, shelf life studies
   2. FDA and ISO product and package label information requirements
   3. Sterilization compatibility in materials and package design
   4. User access to product in packaging
   5. Disposal and environmental affects
   6. Package effectiveness studies
6. FDA Design Output requirements
   1. Engineering drawing and specification package
7. Product Costing:
   1. Bill of materials (BOM), approved vendor requirements, and sourcing
   2. Capital investments for molds, tools, and equipment
   3. Assembly, packaging, sterilization (if required), quality control
8. FDA Design History Record (DHR) and Design Master Record (DMR) requirements
9. FDA Design Transfer requirements (to manufacturing) and Design Change controls.
10. Preparation of a Commercialization/business plan for team project

*Attach here - Course General Guidance*