**Georgia Institute of Technology**

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

*New Course Syllabus*

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| Course Title: **BioID Team Masters Project I** | Instructor: Lewis Franklin Bost |
| Course Number: BMED 6508 | Credit Hours: 3 |
| Perquisites: Enrollment in BioID masters program |  |

**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 I provides hands-on experience with industry-focused design and commercial development processes including: needs definition, solution alternative generation and analysis, project planning, concept and prototype development, design verification testing, FDA Quality Systems Regulations, design controls and regulatory pathways for commercialization of medical devices. Additionally, requirements of business functions such as marketing, sales, manufacturing, finance, intellectual property and their affects on the product development process are integrated into the master’s projects and reports.

**Catalogue Description:** Team project to address an unmet medical need and develop an innovative solution including the engineering design document package and proof-of-concept prototype.

**Course Objectives:**

* Apply the biomedical innovation and development process in a team project to address a specific unmet medical/clinical need; mentored by healthcare professionals or medical industry advisors.
* Investigate, analyze, and define the “problem/opportunity”, its users and stakeholders, establish solution goals; define Design Input requirements (FDA) for a desired solution.
* Generate and evaluate solution directions, methods, and alternatives.
* Synthesize and propose a project solution including: proof-of-concept prototype, engineering drawings, cost and manufacturing analysis, vendor/source identification.

**Course Format:**

Instructional methods include: weekly lectures, in-class discussions and development lab/studios. Each week there will be a 1-hour class session plus two (2) 3-hour of lab/studio periods for project development activities. Readings will be assigned in the designated textbooks, supplemented with reading from reference material 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.

**Grading**:

* Class Activities and Discussion Leadership (30%)
* Reports, Assignments, and Projects (70%)

**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. Master’s team and Project Assignment/Matching
   1. As applied to a specific project
2. Project Proposal
3. Needs assessment
4. Definition of stakeholders
5. Design Research
   1. “User” assessment
   2. Investigation of current technology and methods
   3. “Competitive” landscape – existing companies and product analysis
6. Compose and submit Design Brief
   1. Definition of target design, function and performance parameters
   2. Definition of Constraints (from users, client, …
   3. Project Work Plan: schedule, assignments, milestones
7. Compose and submit Team Project Engineering Design Specifications (EDS)
   1. Investigative research and to establish metrics on functional, performance requirements, cost and target market price objectives and constraints on any of these factors.
   2. Process analysis on current methods and target product use
   3. Human Factors Requirements
   4. Potential Regulatory (FDA) Pathway for commercialization
8. Ideation and Development of Alternatives
9. Intellectual property analysis
10. Proposed Project Solution
    1. Engineering description, justification and drawings
    2. Bill of Materials
    3. Study model, proof-of concept
    4. Report and presentation of results
11. Initial Business Plan

*Attach here - Course General Guidance*