BE467: Product Design and Innovation in Biomedical Engineering

Fall 2016

1. Logistics
   a. Instructor
      
      Gregory Martin, Ph.D.
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      ERB 406
      44 Cummington Mall
      gtmartin@bu.edu
   
   b. Meeting time and location
      i. Mondays and Wednesdays Section A1, 4-5 PM; Section A2, 5-6 PM
      ii. Room PHO 203

2. Motivation
   a. The Boston area alone contains a significant percentage of the nation’s medical device and diagnostics companies and employs many people. It is very likely that students will find themselves at some point in their career employed in or working with this industry. Central to maintaining a viable medical device industry is the introduction of new technologies and products that expand the capabilities of clinical practice, improve the lives of patients, improve the efficiency and lower the cost of healthcare delivery. A basic understanding of concepts and processes that govern medical device product development and innovation is part of the knowledge foundation that will aid the student throughout their career whether the work directly or indirectly in this field.

3. Course Goals and description
   a. The goal of this course is to introduce the student to the many aspects, constraints, regulations, standards, and practices that are necessary to create a commercial medical product. While most undergraduate biomedical engineering coursework forms a strong foundation of engineering analysis, such topics represent a small percentage of the activity of a practicing engineer. In addition to the limitations of physics and physiology, medical device development is equally, if not more significantly shaped by considerations of economics, regulation, clinical practice, and the ability to deliver a product at scale. To bring such products to market, 95% of the engineering effort takes place after a fully working prototype is produced.
   b. In this course, special emphasis is placed on the design constraints that come in to play not from the physics of the device operation, but rather from all of the other considerations that can have a greater impact device design: the product development process, design for manufacturability, demonstrating clinical safety and efficacy, obtaining regulatory approval, managing patient risk, and deploying a product acceptable to your customers. In this course, students will be grouped into teams and each team will develop a “virtual medical device” that they will take through a simulated product development process.
4. Course Operations
   a. The course content is designed to present many of the topics necessary to develop a medical device and
      the course operation is designed to simulate, as much as possible, working in a company developing
      medical devices. Thus all assignments will be done in teams. After the first class meeting, students will
      self-assemble into teams of 5 and will remain as part of this team throughout the semester. All team
      assignments will be done as a group and all members of the same team will received the same grade for
      a group assignment. As in real life, there will be no quizzes or exams. However, students will be graded
      individually, additionally considering class participation and team-peer assessments.

5. Project Selection
   a. Each team will select a single project that it will work on for the entire semester. Projects can be
      selected from a team member’s senior project, a project from BE 428, or from a list provided. All
      projects must be to develop a regulated medical device or diagnostic product. Combination products
      (device-drug, device-biologic, and device-drug-biologic) are permitted.
   b. No team may select the same project as any other team. The instructor must approve all projects for
      each team.

6. Assignments (40% of grade)
   a. There will be 10 team assignments throughout the semester. Combined, these assignments will account
      for 40% of a team’s semester grade. The deliverable for each assignment will become a critical
      component of the final project presentation at the end of the term. These assignments will give each
      team the opportunity to explore aspects of their project before final presentation. It is strongly advised
      that teams learn from their assignment evaluations and incorporate these into their final project.
      Otherwise, teams are at risk for being down-graded twice for the same mistake.
   b. Late assignments (as defined by the timestamp on Blackboard or via email to the instructor), will be
      downgraded 20% and an additional 20% for each 24 hours late thereafter. All assignments will be due at
      11:59 PM on the due date unless otherwise noted.

7. Final Presentation (40% of grade)
   a. The final presentation will be a professional quality, oral presentation with slides that details the design
      concept, requirements & specifications, development, test plan, risk management, regulatory strategy,
      and intellectual property. Each presentation will be limited to 10 minutes with an additional 5 minutes
      for Q&A from the audience. All team members are expected to be present during the presentation and
      all team members are expected to have an equal speaking role.

8. Individual Assessment (20% of grade)
   a. The individual assessment of a student will include class attendance, class participation and peer review
      from the other team members. Class attendance will not be taken every day, but will be randomly taken
      at least twice throughout the semester. Individual performance of each student will be evaluated by
      their other team members. Results from these peer-reviews will be factored into the individual
      assessment grade.

9. Target Skills to be developed
   a. Team work
   b. Oral communication
   c. Written communication
10. Processes to be highlighted in course
   a. Product development
   b. Design Verification and Validation
   c. Intellectual property creation
   d. Risk Management
   e. Regulatory assessment

11. Required Materials
   a. There is no required text, but students are encouraged to review the supplemental material.

12. Supplemental Materials

13. Expectations and Requirements
   a. Team Participation
      i. Each individual is expected to be an active and contributing member of their team. It is understood that each person may contribute something different to the team, however, each person is expected to exert a similar level of effort on the project. Conflicts within each team should be resolved by the team. However, if teams are unable to come to some sort of accommodation, the instructor may be called upon for arbitration.
   b. Class Attendance
      i. Each student is required to attend every class. Excused absences may be requested by email to the instructor at least 24 hours in advance of class.
      ii. Excused absences will NOT be granted for working a shift at your job or attending your cousin’s wedding in Ohio.
   c. Class Behavior
      i. The use of laptops and tablets are permitted during class, but only for class-related activities. Also, please silence these devices and your phone.
   d. Blackboard
      i. Course assignments, announcements and resources will be available on Blackboard. Electronic submissions of assignments should be to the site. It is your responsibility to ensure that submissions are completed and accepted by Blackboard.
   e. Academic Honesty
      i. Any form of plagiarism or cheating will not be tolerated and will be dealt with according to the university’s policies. For more information, see: http://www.bu.edu/academics/policies/academic-conduct-code/
   f. Disability Accommodation
      i. Disability Accommodation: Reasonable accommodations for eligible individuals will be provided in accordance with Boston University policies as described: http://www.bu.edu/academics/policies/disability-accommodation/
# 14. Class Schedule

<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Class</th>
<th>Topic</th>
<th>Suggested Reading / Review</th>
<th>Deliverable</th>
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<tr>
<td>1</td>
<td>9/7/2016</td>
<td>1</td>
<td>Course Introduction, Logistics and Objectives, Project Team Project Selection</td>
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<tr>
<td>2</td>
<td>9/12/2016</td>
<td>2</td>
<td>Problem Identification, Needs Finding &amp; Value Proposition</td>
<td>What makes good teams</td>
<td>Assignment #0: Form groups, sign on to BlackBoard</td>
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<td></td>
<td>9/14/2016</td>
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<td><em>Case Studies on needs finding and value proposition</em></td>
<td>The Value Proposition Lecture Video</td>
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<td>3</td>
<td>9/19/2016</td>
<td>4</td>
<td>Design and the Product Development Process</td>
<td>Biodesign, 3.1, 3.2</td>
<td>Assignment #1: Problem to be addressed</td>
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<td>9/21/2016</td>
<td>5</td>
<td>Design Case Studies</td>
<td>Biodesign, 4.5 Concept Exploring and Testing</td>
<td>Assignment #2: Design concepts to address problem</td>
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<td>4</td>
<td>9/26/2016</td>
<td>6</td>
<td>The Product Development Process</td>
<td>Biodesign, 4.6 Final Concept Selection</td>
<td>Assignment #3: The most promising design concept</td>
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<td>9/28/2016</td>
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<td>Clinical Requirements, Device Requirements &amp; Device Specifications</td>
<td>Biodesign, 4.6 Final Concept Selection</td>
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<td>5</td>
<td>10/3/2016</td>
<td>8</td>
<td>Design &amp; Manufacturability</td>
<td>Assignment #4: Clinical requirements, device requirements and significant design specifications</td>
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<td>10/5/2016</td>
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<td>Design Verification &amp; Validation</td>
<td>Assignment #5: Identify processes to make device at scale &gt; 1000 units per year</td>
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<td>10/10/2016</td>
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<td><em>Columbus Day - no class</em></td>
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<td>10/11/2016</td>
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<td>Design Case Study - Hemedex (Monday Schedule)</td>
<td>Biodesign, 5.5 Quality Management</td>
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<td>Quality Systems</td>
<td>Biodesign, 5.5 Quality Management</td>
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<td>10/17/2016</td>
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<td>IP Lecture 1</td>
<td>Biodesign, 4.1 IP Basics</td>
<td>Assignment #6: Verification &amp; Validation Plan</td>
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<td>10/19/2016</td>
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<td>IP Lecture 2</td>
<td>Biodesign, 5.1 IP Strategy</td>
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<td>10/24/2016</td>
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<td>Risk Management, Hazards &amp; Harms</td>
<td>Assignment #7: Prior art and claims for your patent</td>
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<td>IsoCool Case Study</td>
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<td>National and International Standards</td>
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<td>11/7/2016</td>
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<td>FDA Regulatory Requirements</td>
<td>Biodesign, 4.2 Regulatory Basics</td>
<td>Assignment #9: FMEA</td>
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<td>11/9/2016</td>
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<td>510k, PMA &amp; De Novo Process</td>
<td>Biodesign 5.4 Regulatory Strategy</td>
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<td>11/14/2016</td>
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<td>Regulatory Case Study</td>
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<td>Clinical Studies</td>
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<td>11/21/2016</td>
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<td><em>Case Study Silk Road Medical</em></td>
<td>Silk Road Medical Video</td>
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<td>11/23/2016</td>
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<td>Thanksgiving break</td>
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<td>13</td>
<td>11/28/2016</td>
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<td>Project Presentations</td>
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<td>11/30/2016</td>
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<td>12/5/2016</td>
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