BIOEN 4801, Biomedical Engineering Design II (3 credits)

Department: Bioengineering

Designation: Required for BME Majors in their Senior Year

Catalog Description: Continuation of BIOEN 3801. Initial designs will be prototyped before going through a design review. Design verification issues and improvements will then be solved in a redesign phase following a design process based on FDA-QSR. Projects will be team oriented and lead to increased project management skills. In addition, discussions on design considerations will continue. A final written design document and an oral presentation of the working prototype will culminate the class. Lecture: 1 hour and Lab: 3 hours + 3 hours arranged.

Prerequisite: BME Major Status or Instructor Permission

Instructors: Kelly W. Broadhead, Ph.D. (KWB) and Robert Hitchcock, Ph.D. (RH)

Office hours: During lab time on Wednesday in MEB 2560 or by appointment.

KW Broadhead email: kelly.broadhead@utah.edu    phone: 585-7605
B Hitchcock email: R.Hitchcock@utah.edu         phone: 585-7741

Class T.A.S: Monir Parikh

Office hours: During lab time on Wednesday in MEB 2560 or by appointment.

Monir Parikh     email: monir.parikh@utah.edu

Lecture: Wednesday 10:45-11:35 Room 1208 MEB
Lab: Lab 1: Wednesday 2:00-5:00 in MEB 2405   Lab 2: Thursday 2:00-5:00 in MEB 2405

Web Site: All class material will be available through WEBCT


Learning Objectives:
1) Students will design and prototype a medical device using FDA requirements for Design Control.
   a) Students will be to explain and describe Design Control within the overall structure of FDA-QSR
      (Quality System Requirements) and other international regulatory requirements.
   b) Students will apply FDA-QSR Design Control in their projects.

2) All projects will be planned, managed, documented and executed using FDA Design Control
   Requirements.
   a) Students will create a project plan and implement their design project based on this plan.
   b) Students will develop and implement a hazard management plan within the scope of the overall
      project plan.
   c) Students will be able to explain tools and concepts of design management including how to deal
      with people of different backgrounds (engineers, physicians, and patients).
d) Students will **assemble** a Design History File that will include appropriate version controlled
documentation.

e) Students will **apply** the QSR design process including appropriate written documentation and oral
presentations.

f) Students will be able to **explain** the design control process beyond prototype verification testing
including design validation and experimental design including human studies.

3) The medical device design projects will require customer driven inputs, product specifications,
prototype fabrication, testing & evaluation.

   a) Students will **formulate** project ideas by interacting with potential customers (clinicians and
   patients).
   
   b) Design requirements will be **determined** and documented based on customer interactions.

   c) Design specifications will be **derived** based on design requirements.

   d) Students will **determine** unambiguous acceptance criteria to verify prototype designs.

   e) Various design tools including CAD and modeling software will be **applied** to determine
   potential design solutions.

   f) Students will **evaluate** various aspects of their designs by **modeling** electronics, hardware and
   software.

   g) Students will **develop** a prototype device based on specifications, models and other input criteria.

   h) The prototype designs will be **tested** and **verified** to determine if they meet the design
   specifications.

4) All projects will be implemented using a planned, multidisciplinary, ethics-based team approach.

   a) Students will be able to **identify** the elements of QSR project planning and implementation that
   are important to all design projects (medical and non-medical).

   b) Students will **assemble** into “multidisciplinary” teams and **report** on team management and
dynamics.

   c) Students will **present** their design work in written form by means of team reports and the Design
   History File.

   d) Students will **present** their design work in oral form by means of Design Reviews.

   e) Students will be able to **identify** engineering constraints and considerations including economic,
environmental, sustainability, manufacturability, health, safety, social, and political.

   f) Students will **explore** and **analyze** projects for ethical issues and potential solutions will be
   proposed.

5) Students will choose whether they will use their design project or an outside project for their senior
project class.

   a) The design projects will be developed and implemented in such a way that the students may
desire to use them for their senior project.

   b) Students will determine (formally indicate) by (insert date here) if they will use their Biomedical
   Device Design project as their senior project.

   c) Students will provide a written and oral project proposal for their senior project.
### Tentative Class Schedule:

<table>
<thead>
<tr>
<th>Week</th>
<th>Day</th>
<th>Date</th>
<th>Topic</th>
<th>Lect.</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Wed</td>
<td>8/26/2009</td>
<td>Course introduction and prototyping</td>
<td>Kelly</td>
</tr>
<tr>
<td>2</td>
<td>Wed</td>
<td>9/2/2009</td>
<td>Packaging and Labeling</td>
<td>Bob</td>
</tr>
<tr>
<td>3</td>
<td>Wed</td>
<td>9/9/2009</td>
<td>Mechanical modeling techniques</td>
<td>Bob</td>
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<tr>
<td>4</td>
<td>Wed</td>
<td>9/16/2009</td>
<td>Verification test policy, plans and procedures</td>
<td>Kelly</td>
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<tr>
<td>5</td>
<td>Wed</td>
<td>9/23/2009</td>
<td>Modeling and simulation</td>
<td>Kelly</td>
</tr>
<tr>
<td>6</td>
<td>Wed</td>
<td>9/30/2009</td>
<td>Ethics I</td>
<td>Kelly</td>
</tr>
<tr>
<td>7</td>
<td>Wed</td>
<td>10/7/2009</td>
<td>Ethics II</td>
<td>Kelly</td>
</tr>
<tr>
<td>8</td>
<td>Wed</td>
<td>10/14/2009</td>
<td>Fall Break</td>
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<tr>
<td>9</td>
<td>Wed</td>
<td>10/21/2009</td>
<td>Mechanical systems</td>
<td>Bob</td>
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<tr>
<td>10</td>
<td>Wed</td>
<td>10/28/2009</td>
<td>Optics</td>
<td>Kelly</td>
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<tr>
<td>11</td>
<td>Wed</td>
<td>11/4/2009</td>
<td>Labview and hardware</td>
<td>Kelly</td>
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<tr>
<td>12</td>
<td>Wed</td>
<td>11/11/2009</td>
<td>Design validation, other tests and clinical trials</td>
<td>Bob</td>
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<tr>
<td>13</td>
<td>Wed</td>
<td>11/18/2009</td>
<td>Electronics</td>
<td>Bob</td>
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<tr>
<td>14</td>
<td>Wed</td>
<td>11/25/2009</td>
<td>Thanksgiving Break</td>
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<tr>
<td>15</td>
<td>Wed</td>
<td>12/2/2009</td>
<td>Design for manufacture and assembly</td>
<td>Monir</td>
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<tr>
<td>16</td>
<td>Wed</td>
<td>12/9/2009</td>
<td>Design Thinking</td>
<td>Bob</td>
</tr>
<tr>
<td>17</td>
<td>Mon</td>
<td>12/14/2009</td>
<td>Final Exam 10:30 - 12:30</td>
<td>Monir</td>
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### Grade Breakout and Tentative Due Dates:

<table>
<thead>
<tr>
<th>Assign.</th>
<th>Title</th>
<th>Due Date</th>
<th>Ind. Comp.</th>
<th>Team Comp.</th>
<th>Grade Value</th>
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</thead>
<tbody>
<tr>
<td>Prog. Report</td>
<td>Progress Reports (9/4 to 11/20 except fall break)</td>
<td>Each Fri. at 5:00 p.m.</td>
<td>2%</td>
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</tr>
<tr>
<td>Prsnt. 1</td>
<td>Team Meeting Minutes: Prototype Elements</td>
<td>9/4 by 5:00 p.m.</td>
<td>1%</td>
<td>2%</td>
<td>3%</td>
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<tr>
<td>Review 1</td>
<td>Project Review of Prototype Elements</td>
<td>10/7 &amp; 10/8</td>
<td>2%</td>
<td>3%</td>
<td>5%</td>
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<tr>
<td>Homework</td>
<td>Ethics Assignment</td>
<td>10/30 at 5:00 p.m.</td>
<td>10%</td>
<td>10%</td>
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</tr>
<tr>
<td>Test Plan</td>
<td>Testing plan document with updated docs</td>
<td>11/6 at 5:00 p.m.</td>
<td>2%</td>
<td>3%</td>
<td>5%</td>
</tr>
<tr>
<td>Prototypes</td>
<td>Documented Prototypes and other docs</td>
<td>12/7 at 5:00 p.m.</td>
<td>10%</td>
<td>15%</td>
<td>25%</td>
</tr>
<tr>
<td>Testing</td>
<td>Documented Testing Results</td>
<td>12/7 at 5:00 p.m.</td>
<td>7%</td>
<td>13%</td>
<td>20%</td>
</tr>
<tr>
<td>Review 2</td>
<td>Testing Results and Final Design Demonstration</td>
<td>12/9 &amp; 12/10</td>
<td>2%</td>
<td>3%</td>
<td>5%</td>
</tr>
<tr>
<td>Final</td>
<td>Final Exam During Final Week</td>
<td>12/14 at 10:30</td>
<td>10%</td>
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</tr>
<tr>
<td>DHF Binder</td>
<td>Final Design History File</td>
<td>12/18 at 5:00 p.m.</td>
<td>6%</td>
<td>9%</td>
<td>15%</td>
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<td>Total</td>
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### Design Project Requirements:

**Minimum Requirements**

**QSR-DHF documentation (spring binder + the following items)**

- Minimum of a Prototype Elements per person (TBD in Proposal Meeting)

  One of these elements must include a portion of the design that humans interact with (human factors and ergonomics)

  Appropriate documentation (written description, images, video, engineering drawings, mechanical analysis, etc.)

**Verification studies and results**

**Other Items:**

- U of Utah Content Disclaimer: [http://www.utah.edu/disclaimer/index.html](http://www.utah.edu/disclaimer/index.html)
- ADA Policy: [http://www.hr.utah.edu/oeo/ada/guide/faculty](http://www.hr.utah.edu/oeo/ada/guide/faculty)
- Faculty Responsibilities: [http://www.admin.utah.edu/ppmanual/8/8-12-4.html](http://www.admin.utah.edu/ppmanual/8/8-12-4.html)