BIOE 435
Senior Design

Dr Amos
Run > Hide > Fight

Emergencies can happen anywhere and at any time. It is important that we take a minute to prepare for a situation in which our safety or even our lives could depend on our ability to react quickly. When we’re faced with any kind of emergency – like fire, severe weather or if someone is trying to hurt you – we have three options: Run, hide or fight.

**Run**
Leaving the area quickly is the best option if it is safe to do so.

- Take time now to learn the different ways to leave your building.
- Leave personal items behind.
- Assist those who need help, but consider whether doing so puts yourself at risk.
- Alert authorities of the emergency when it is safe to do so.

**Hide**
When you can’t or don’t want to run, take shelter indoors.

- Take time now to learn different ways to seek shelter in your building.
- If severe weather is imminent, go to the nearest indoor storm refuge area. If someone is trying to hurt you and you can’t evacuate, get to a place where you can’t be seen, lock or barricade your area, silence your phone, don’t make any noise and don’t come out until you receive an Illini-Alert indicating it is safe to do so.

**Fight**
As a last resort, you may need to fight to increase your chances of survival.

- Think about what kind of common items are in your area which you can use to defend yourself.
- Team up with others to fight if the situation allows.
- Mentally prepare yourself – you may be in a fight for your life.

http://police.illinois.edu/emergency-preparedness/run-hide-fight/
What Did You Do This Summer?

• Lets go around the room and get updates!
My Background

- BS Chemical Engineering and Computer Science
- PhD Chemical Engineering area focused in Tissue Engineering (Conc. in Developmental Biology) 
  “A Mechanotransduction Study of Chondrogenesis Using a Novel Tubular Scaffold”

- Areas of research/experience
  - Developmental biology
  - Histology
  - Tissue engineering (scaffold & bioreactor design)
  - Hydrogels/Shape memory polymers
  - AFM
  - Six Sigma
  - Tribology
  - Gene arrays
  - Fluid dynamics
  - Rheology
  - Computer programming (C++, Perl, VB, Java)
My Philosophy for This Course

Attendance is not mandatory, but you will be applying concepts to your design projects in your teams, so please come!

Mostly group work – make sure you still have a voice! Peer review at end of each semester.
My Philosophy for This Course

You are all seniors in BIOE, congrats – you made it!

It’s okay to eat in class but keep it small, simple, and quiet

It’s going to be hard to fail this course so please don’t try ;)

☑️

❌
My Philosophy for This Course

We will follow the “life’s a journey, not a destination” philosophy...

You are expected to go above and beyond, not just meet the minimum needs

See the Senior Design Manual on the website

https://courses.engr.illinois.edu/bioe435/fa2016/SrDesignManual.html
When, where

Lectures and Client presentations
- MWF 12:00-12:50
- MW 253 MEB
- F 106B1 Eng Hall

Planning meetings (Fall) and Status meetings (Spring)
- Half hour per team, biweekly
  • Additional time available, on request
- To be scheduled at a fixed time each week once groups are formed
- L425 DCL (design lab)
Reference texts (first two on hold at library reserves)

- *Biodesign the Process of Innovating Medical Technologies*. Paul Yock, Josh Makower, Stefanos Zenios
- *Design of Biomedical Devices and Systems*. Paul H. King and Richard C. Fries

[http://courses.engr.illinois.edu/bioe435/](http://courses.engr.illinois.edu/bioe435/)
### Keep up with the schedule on the website

<table>
<thead>
<tr>
<th>Week</th>
<th>Module</th>
<th>Mon</th>
<th>Wed</th>
<th>Fri</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Needs Finding</td>
<td>8/28 Challenges of Design for Healthcare</td>
<td>8/30 Client Presentations</td>
<td>9/1 Client Presentations</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>9/4 Labor Day, no class</td>
<td>9/6 Client Presentations</td>
<td>9/8 Client Presentations</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>9/11 Team Assigned</td>
<td>9/13 Design Problems</td>
<td>9/15 Work Day</td>
</tr>
<tr>
<td>5</td>
<td>Screening</td>
<td>9/25 Verification and Validation</td>
<td>9/27 Pretotyping</td>
<td>9/29 Work Day</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>QFD/Inputs to Outputs/Product Specifications</td>
<td>10/4 Parametric Design &amp; Modeling</td>
<td>10/6 Work Day</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>10/9 FDA &amp; Regulatory</td>
<td>10/11 BMES - AMOS OUT</td>
<td>10/13 BMES - AMOS OUT</td>
</tr>
<tr>
<td>8</td>
<td>Concept Generation</td>
<td>10/16 FDA Regulatory Pharm</td>
<td>10/18 Project management + Budgetting</td>
<td>10/20 Work Day</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>10/23 AMOS OUT, possible Guest</td>
<td>10/25 Six Sigma I</td>
<td>10/27 Work Day</td>
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<tr>
<td>10</td>
<td></td>
<td>10/30 Six Sigma II</td>
<td>11/1 Six Sigma III</td>
<td>11/3 Work Day</td>
</tr>
<tr>
<td>11</td>
<td></td>
<td>11/6 Other Six Sigma Models</td>
<td>11/8 FMEA/Safety and Failure</td>
<td>11/10 Work Day</td>
</tr>
<tr>
<td>12</td>
<td>Design Development</td>
<td>11/13 FMEA Case Study</td>
<td>11/15 TBD Guest</td>
<td>11/17 Work Day</td>
</tr>
<tr>
<td>13</td>
<td></td>
<td>11/20 Thanksgiving, no class</td>
<td>11/22 Thanksgiving, no class</td>
<td>11/24 Thanksgiving, no class</td>
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<tr>
<td>14</td>
<td></td>
<td>11/27 Guest Lecture- Product Development</td>
<td>11/29 Six Sigma Certification Exam</td>
<td>12/1 Work Day</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td>12/4 Guest Lecture - Simulation Service, IRB</td>
<td>12/6 Senior Exam</td>
<td>12/8 Work Day</td>
</tr>
<tr>
<td>16</td>
<td></td>
<td>12/11 Wrap up, what to expect in spring</td>
<td>12/13 Poster showcase</td>
<td>12/17 Final Exam Period</td>
</tr>
</tbody>
</table>
This is about professionalism, consider design like a full-time job

<table>
<thead>
<tr>
<th>Week</th>
<th>Module</th>
<th>Comments - Assignments due Sunday @ midnight</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Needs Finding</td>
<td>HW 1 Due 9/6</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Submit Group rankings Due 9/8</td>
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<tr>
<td>3</td>
<td></td>
<td>Set up meeting with client to interview</td>
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<tr>
<td>4</td>
<td></td>
<td>HW 2 &amp; Client Needs Assessment Due 9/25</td>
</tr>
<tr>
<td>5</td>
<td>Screening</td>
<td>9-22 Autodesk I workshop</td>
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<tr>
<td>6</td>
<td></td>
<td>inputs/outputs Due 10/9</td>
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<tr>
<td>7</td>
<td></td>
<td>1st prototype plan and testing plan submitted for review Due 10/10</td>
</tr>
<tr>
<td>8</td>
<td>Concept Generation</td>
<td>Product Design Specs Due 10/16</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>10-20 Autodesk II workshop</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>Modeling parametric design Due 10/30</td>
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<tr>
<td>11</td>
<td>Design Development</td>
<td>First Prototype due with revised testing plan Due 11/13</td>
</tr>
<tr>
<td>12</td>
<td></td>
<td>MOU Drafts, FMEA analysis Due 11/20</td>
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<tr>
<td>13</td>
<td></td>
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<tr>
<td>14</td>
<td></td>
<td>Final fall prototype due with testing, posters due for printing 12/5</td>
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<tr>
<td>15</td>
<td></td>
<td>Final (signed) MOU Due 12/10, Version 1.0 Due 12/17</td>
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<tr>
<td>16</td>
<td></td>
<td>HW 1 Due 9/6</td>
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<td></td>
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<td>Submit Group rankings Due 9/8</td>
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<td></td>
<td>Set up meeting with client to interview</td>
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<tr>
<td></td>
<td></td>
<td>HW 2 &amp; Client Needs Assessment Due 9/25</td>
</tr>
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</table>
Looking ahead to spring, you’ll be doing a lot of industry related work

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<th>Week</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Design Development</td>
<td>Submit Schedules to Amos</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Revisions from fall feedback</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Preparation for 2nd prototype testing</td>
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<tr>
<td>4</td>
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</tr>
<tr>
<td>5</td>
<td>Prepare for Testing</td>
<td>2nd prototype testing, prepare for FDA clinical trials at Jump</td>
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<td>6</td>
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<tr>
<td>7</td>
<td></td>
<td>Complete the patent process</td>
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<td>8</td>
<td></td>
<td>FORMAL DESIGN REVIEW I</td>
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<tr>
<td>9</td>
<td></td>
<td>Perform trials at Jump this month</td>
</tr>
<tr>
<td>10</td>
<td>Break</td>
<td>Establish corporate identity, brand names, trademarks</td>
</tr>
<tr>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Testing and Refinement</td>
<td>Testing of final product</td>
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<td>13</td>
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<tr>
<td>14</td>
<td></td>
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</tr>
<tr>
<td>15</td>
<td>Reporting</td>
<td>FORMAL DESIGN REVIEW II</td>
</tr>
<tr>
<td>16</td>
<td></td>
<td>Vendor Fair and Public Presentations</td>
</tr>
</tbody>
</table>
Here’s a sneak peek for 2017-2018 projects!

- Illinois Child and Developmental Services Wheelchair sensors for ulcer prevention
- Beckman Novel therapeutic for use in cancer research
- OSF Bilirubin removal system
- Beckman Ultrasound probe tracking system
- Carle Fall prevention device for in-patient care
- Carle PT tracking device for therapy compliance
- Carle Rapid strep test
- Siemens catheter lab equipment optimization
- Siemens physical simulator for vital signs
- Jump pill extractor to create liquid medications from pills
- Jump Fracture reduction simulator
- Jump Capillary refill simulator
- OSF ALS Neurology Exam training and tracking device
- Carle Gelfoam for use in embolism treatment
- Innsight Biosensing of albumin in tear fluid
Contact Information

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  – Phone: 217-244-2938

• TA
  – Ian Berg
  – ianberg1@illinois.edu
  – Former BIOE 415 and 435-436 TA
  – Worked at Abbvie for 4 years doing commercial product design
  – CAD experience
There are more than 500,000 distinct forms of medical technologies that make up health care products.

Source: Eucomed, Google Images
Bioengineering design is a complex process, further complicated by FDA requirements and expensive trials.
The biggest breakthrough in medicine doesn’t mean profits

Human Genome Sciences Inc.

Largest Biotech companies with catastrophic price declines, 2000-02: Millennium, Celera, Abgenix, Protein Design Labs, Medarex, Maxisyn, Curagen, Enzon, Cell Therapeutics

FDA approval is only the first hurdle, the customer demand has to follow as well...

You actually want your competitors to succeed
What Design is Not...

- Design is not research
- Design is not invention
- Design is not marketing
- Design is not just creativity
- Design is not fulfilling a utopian vision
Then what is research?

- Scholarly, scientific activity or inquiry
- Exploratory
- May not result in a product or service
- Motto: “If we knew what it was we were doing, it would not be called research, would it?” – Albert Einstein

Motto for research

Steps:
- Observation or prediction of phenomena
- Hypothesis concerning said observation
- Determine truthiness or falsiness of hypothesis through
  - Testing
  - Statistics
  - Reasoning
  - Luck

Clarity / Focus

Uncertainty / patterns / insights
Then what is inventing?

- Creating a new machine or process for doing things
- Must be novel or “not obvious” to others skilled in the same field
- Is part of the design process

Side bar: Innovation
- Having the vision to go beyond what the inventor of the device could have ever imagined (i.e. iPhone versus cell phone)

Motto for inventing...
- “It's really hard to design products by focus groups. A lot of times, people don't know they want it until you show it to them” – Steve Jobs
What Design is

- Design is finding the solution to an open-ended problem, usually ill-posed and ill-conditioned.
- “The systematic, intelligent generation and evaluation of specifications for artifacts whose form and function achieve stated objectives and satisfy specified constraints.” – Dym and Little, Engineering Design

Motto for design
- “Design, in its broadest sense, is the enabler of the digital era – it’s a process that creates order out of chaos, that renders technology usable in business. Design means being good, not just looking good.” - Clement Mok
The ‘Central Dogma of Design’
Function > Design > Form
What Is the Design Process for BIOE?

- Obtain client statement
- Needs analysis and define the problem
- Specifications/requirements for design
  - Electrical, mechanical and environmental
  - Functional needs
- Brainstorming
- Paper concept
- Flowchart
- Modeling/analysis
- Define a problem
- Identify what’s needed to solve the problem
- Improve the solution
- Make and test the best solution
- Brainstorm solutions
- Evaluate results
- Share results
- Prototype
- Benchtop Test
- Sim Center Test
- Patient Testing

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We follow and document all decisions because one change can have a huge impact on the outcome.
You will learn many Six Sigma techniques in this class

- Brainstorming approaches
- Design of Experiments
- Control Charts, Cause & Effect
- Failure Mode Effects Analysis (FMEA)
- Pareto Plot
- Pugh Matrix
- Quality Function Deployment (QFD)
- Voice of Customer
1. Take notes
2. Ask questions
3. Come on time
4. Be flexible to stay a few minutes after 12:50 if we run behind