BIOE 435
Senior Design

Dr Amos
Prof Bashir
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
Meet at Engineering Quad area, south of Grainger or inside Eng Hall if raining
Area of refuge = stairwell landings on each floor

HIDE
Storm refuge area = ground floor basement

FIGHT

http://police.illinois.edu/emergency-preparedness/run-hide-fight/
Get to know your awesome course staff

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TA: Tanmay Ghonge
– ghorge2@illinois.edu
– Electronics experience
– CAD experience
– Project management experience
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
  – Tuesdays 8-9:20 am

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
  – 1306 Everitt (Design Lab)
http://courses.engr.illinois.edu/bioe435/

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


# Keep up with the schedule on the website

<table>
<thead>
<tr>
<th>Week</th>
<th>Module</th>
<th>Tuesday</th>
<th>TOPIC</th>
<th>Comments - Assignments due Sunday @ midnight</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>8/27 Challenges of Design for Healthcare</td>
<td></td>
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<tr>
<td>2</td>
<td></td>
<td></td>
<td>9/3 Pitches</td>
<td></td>
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<tr>
<td>3</td>
<td>Needs Finding</td>
<td></td>
<td>9/10 Pitches part II</td>
<td>Submit Group rankings Friday @ 11:59pm</td>
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<tr>
<td>4</td>
<td></td>
<td></td>
<td>9/17 Teams assigned, Needs Statements</td>
<td>Set up meeting with client to interview</td>
</tr>
<tr>
<td>5</td>
<td>Screening</td>
<td>9/24</td>
<td>Inputs to Outputs/Product Specifications</td>
<td>Client Needs Assessment Bring to Class</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>10/1</td>
<td>Patents/lit review</td>
<td>Component I: Elements A-C</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>10/8</td>
<td>FDA &amp; Regulatory</td>
<td>MOU Draft Due</td>
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<tr>
<td>8</td>
<td>Concept Generation</td>
<td>10/15</td>
<td>Prototyping/Mold Making</td>
<td>Midpoint CATME</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>10/22</td>
<td>Rapid Prototyping</td>
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<tr>
<td>10</td>
<td></td>
<td>10/29</td>
<td>Modeling - Parametric design, Six Sigma</td>
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</tr>
<tr>
<td>11</td>
<td>Design Development</td>
<td>11/5</td>
<td>Project management</td>
<td>Component II: Elements D-F</td>
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<tr>
<td>12</td>
<td></td>
<td>11/12</td>
<td>Verification and Validation</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td></td>
<td>11/19</td>
<td>Thanksgiving, no class</td>
<td>Eat, drink and be merry</td>
</tr>
<tr>
<td>14</td>
<td></td>
<td>11/26</td>
<td>FMEA</td>
<td>Component III: Elements G-I</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td>12/3</td>
<td>Competitions, IP and start-up resources</td>
<td>Posters due for printing 12/5</td>
</tr>
<tr>
<td>16</td>
<td></td>
<td>12/10</td>
<td>Wrap up, what to expect in spring</td>
<td>Final (signed) MOU Due, Components I-III due Due, Final CATME</td>
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<tr>
<td></td>
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<td>Design Expo</td>
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</tbody>
</table>
Looking ahead to spring, you’ll be doing a lot of industry related work

<table>
<thead>
<tr>
<th>Week</th>
<th>Module</th>
<th>Comments</th>
</tr>
</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>
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<tr>
<td>3</td>
<td></td>
<td>Preparation for 2nd prototype testing</td>
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<td>4</td>
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<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>
</tr>
<tr>
<td>8</td>
<td></td>
<td>FORMAL DESIGN REVIEW I</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>Perform trials at Jump this month</td>
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<tr>
<td>10</td>
<td>Break</td>
<td>Establish corporate identity, brand names, trademarks</td>
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<tr>
<td>11</td>
<td></td>
<td></td>
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<tr>
<td>12</td>
<td>Testing and Refinement</td>
<td>Testing of final product</td>
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<tr>
<td>13</td>
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<tr>
<td>14</td>
<td></td>
<td></td>
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<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 2018-2019 projects!

- Trauma Monitoring Notification System
- Robotic neuro-surgery tool
- CP Head Pointer
- Bedside Nerve Detection
- Robotic Arm for Cath Lab
- Radio-Opaque catheter marker sleeve
- IV pump for anesthetist
- CPR trainer
- Ascites draining
- Pleurx app
- Digital Health initiatives project
- Umbilical catheterization trainer
- Bacterial detection and diagnosis for developing countries
There are more than 500,000 distinct forms of medical technologies that make up health care products.
Bioengineering design is a complex process, further complicated by FDA requirements and expensive trials.
Global population is expected to reach 9 billion people by 2050.

Healthcare is changing dramatically due to technology advances.

Convergence of medicine, biology, and engineering is the next frontier.

Can we do for medicine what we did for electronics and computing.
Costs of Health Care Are Unsustainable!

Expenditures on health care as percentage of GDP

- United States
- Other developed countries

Can we provide higher quality healthcare, for more people, at lower cost?

We need a Moore’s Law for Healthcare!
Healthcare Productivity Lags Other Economic Sectors

Source: BLS

2002 – 2012 Industry Output Change

High

Mining

Healthcare

Information & Technology

Agriculture

Manufacturing

Low

Education

Start

End

Less efficient

Labor

More efficient

2002 – 2012 Employment Efficiency Change

With permission from Greg Sorenson, Past CEO, Siemens Healthcare, NA
The World is Getting Older!

- Globally, the number of persons aged 60 years or over is expected to increase from 841 million in 2013, to more than 2 billion in 2050.

- Older persons are projected to exceed the number of children for the first time in 2047.
The inclusion of engineering ideas and approaches makes medicine a quantitative discipline that facilitates precision diagnostics and therapeutics improving healthcare delivery for all......Achieving this vision of higher-quality healthcare globally while containing or reducing its rising costs presents conflicting demands and is a challenge for engineering and medicine ..... We posit that the integration of engineering into medicine, and medicine into engineering—until boundaries vanish—will play a critical role in achieving these broad and specific goals.
Industry Trend for POC Devices - Funding to Regulatory approval

Industry Trend for POC Devices: Funding vs time to approval

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, Maxygen, Curagen, Enzon, Cell Therapeutics

Raise 2B in 1999-2000

Company acquired by GSK for $3.6B

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

Source: Bloomberg, July 2014.

http://topforeignstocks.com
You actually want your competitors to succeed!

Neurocrine Biosciences, Inc.

FDA denies approval for larger dose Indiplon insomnia drug
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 for research – “If we knew what it was we were doing, it would not be called research, would it?” — Albert Einstein

Steps:
- Observation or prediction of phenomena
- Hypothesis concerning said observation
- Should be quantitative but is often not...
- Determine truthiness or falsiness of hypothesis through
  - Testing
  - Statistics
  - Reasoning
  - Luck

Uncertainty / patterns / insights

Clarity / Focus

Research

Concept

Design
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 what they want 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

• "Design, in its broadest sense, is the enablement of the digital era – it’s a process that creates order out of chaos, it renders technology usable, it renders 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
Voice of Customer
Specifications/requirements for design
Electrical, mechanical and environmental Functional needs

Define a problem
Identify what’s needed to solve the problem
Improve the solution
Make and test the best solution
Evaluate results
Share results

Brainstorming
Paper concept
Flowchart
Quality Function Diagrams

Modeling/analysis
Prototype
Six Sigma testing

Design Review
Expo
Panel Presentations

Failure Modes Effects Analysis
Benchtop Test
Sim Center Test
Patient Testing
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 9:20 if we run behind