

BME 59500 Ethical Engineering of Medical Devices

Spring 2019 Instructors: **Dr. Andrew Brightman**, Assistant Head, Associate Professor of Engineering Practice, Weldon School of Biomedical Engineering, aob@purdue.edu ph. 496-3537 **Dr. Michael Hiles**, Senior Vice President & Chief Scientific Officer, Cook Biotech, Inc., Adjunct Professor, Basic Medical Sciences and Biomedical Engineering hiles@purdue.edu Credit Hours: **3** or **1*** Days and Times: **MWF 4:30 pm – 5:20 pm** Room: **1083 MJIS** [Martin Jischke Hall of Biomedical Engineering] **Description:** The medical device industry may be on the brink of a crisis. While innovations in lifesaving new technologies are transforming medical practice, the rapid pace at which these developments are emerging and the intense pressures of the competitive industry is challenging the ethical training of the engineers involved. In addition, the regulatory environment for medical device development has been changing dramatically, leaving companies with more questions than answers on how to best practice safe and effective medical device development. These changes are creating opportunities for ethical problems to arise-- and they have. Recent documentaries, such as *The Bleeding Edge* and *Bleed Out* highlights some of the concerns over the state of the industry. In this course we will examine many of these ethical and regulatory concerns from multiple frameworks and perspectives including industry, government, and society. We will practice ethical analysis and develop empathic and decision-making skills designed to prepare engineers to deal productively and ethically with these issues in their professional practice. Guest speakers will include thought leaders from clinical medicine, engineering innovation, and the healthcare products industry who will offer their professional insights. The final project of the course will be a paper analyzing the ethical development of an emerging medical product. This course is designed for graduate students and upper-level students in all engineering disciplines. **NOTE:** For biomedical engineers, this 3-credit course satisfies the ethics and policy in healthcare requirement for undergraduates and counts toward the ethical, regulatory, and medical device development requirement for professional MS and other graduate course for thesis MS degrees. *However, to encourage broader participation in analyzing engineering ethical issues this course is being **offered also in 3 modules (1 credit each)**. **The first two of these are open to all students** from outside engineering and at all undergraduate levels. Please see additional descriptions. **BME 39500 - Ethical Issues Surrounding Development of Medical Technologies, Mon. 4:30-5:20 PM BME 49500 - Engineering Empathy in Medical Device Design, Wed. 4:30-5:20 PM BME 59500 - Ethical Reasoning in Medical Device Design and Development, Fri. 4:30-5:20 PM ABET Student Outcome and Performance Indicators:** This course maps directly to *Student Educational Outcome 4* and the related performance indicators (**4a-4e**).

4. An ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts;
 - a. Recognize and describe professional and ethical codes of conduct, and ethical dilemmas which pertain to a practicing biomedical engineer.

- b. Explain ethical considerations relevant to experimentation with animal and human subjects.
- c. Justify selection of a biomedical engineering process in research or product development based on an economic analysis.
- d. Identify and/or describe how biomedical engineering solutions affect society.
- e. Recognize contemporary issues impacting biomedical engineering.

Student Learning Objectives: Students who successfully complete this course will be able to:

- 1 Easily recognize and analyze personal and systemic ethical issues and challenges to ethical reasoning and social responsibility (**4a, 4b, 4d, 4e**)...
- 2 Independently engage in empathy building activities to enhance their abilities to understand and value the perspectives of other stakeholders (**4d**)
- 3 Effectively use a structured, iterative, and collaborative decision-making process that considers the perspectives of multiple stakeholders in optimizing a design decision (**4a, 4b, 4c**)...

...when facing an engineering problem in design and development of medical devices or assistive technologies that are ethical and socially responsible.

Learning Strategies: In as much as possible the course will focus on active and experiential learning strategies. Students will be engaged in discussions and debates about ethical issues of real engineering cases involving medical devices and assistive technologies. Students will engage in dialogue with content experts and thought leaders from clinical, academic, and industry perspectives. Students will also engage with non-technical expert users of medical and assistive technologies to gain perspectives differing from their own. They will also learn techniques for empathic perspective-taking and tools for ethical reasoning. Students will be challenged with three team-based, experiential learning projects for the semester.

Experiential Learning Projects:

Each of the three projects will be addressing a real case involving the design and development of an emerging medical device technology. Details of the projects will be forthcoming in a handout.

- 1 A **reflection paper** based on a team analysis of the ethical issues
- 2 A **stakeholder report** based on a team analysis of the varying stakeholder perspectives
- 3 A **journal article** based on full ethical analysis of the emerging medical technology

How to succeed in this course:

- Ask questions if anything is unclear and be willing to “speak up” if problems arise
- Accept challenging content, critical thinking, and collaborative discussions and decision-making as part of the learning process
- Actively build trusting relationships with classmates and
- Be curious about the material and also about what you can learn as well as contribute to the course
- Be thoughtful, clear, and well supported in your written responses
- Be willing to engage with the activities in class and outside even if they are unfamiliar
- Communicate as clearly as you can and be respectful at all times both in class and online with classmates, instructors, and guest presenters
- Commit the time necessary to do readings ahead of class and prepare to discuss in class
- Complete all assignments on time and to the best of your ability

Engaging with the Instructors:

For most questions, we will be available via email and will respond as soon as available (generally within 24-48) hours. When emailing us, please place in the subject line: **BME Ethics Course** and the topic of the email (i.e. Assignment 2 Question) and include your full name at the end of the text. This will help us tremendously in locating your emails quicker when we scan the hundreds of emails that seem to make it into our inboxes each day. If you need to speak with an instructor in person, Dr. Brightman will have open office hours on Monday and Wednesdays from 3-4 pm and you can make an appointment for other meeting times by email. When there are online discussions, we will check in at least 3 times per week. Keep in mind that it is not possible for me to respond to every single posting every week (nor is it pedagogically appropriate), but I will be sure to respond to a variety of postings and students each week and attempt to assure equality in terms of responses to students. If you feel you are being neglected in any way, please alert one of us immediately before or after class.

Attendance and participation:

This course is heavily participation dependent. Twenty percent of the grade is based on participation in discussions in class and online as well as weekly written responses submitted online. You will start the semester with full credit for participation and will lose points based on unexcused absences, lack of participation in discussions, or disrespectful communication or behaviors of any type. The class will not meet on several dates (announced in advance) and there will be activities assigned outside of class for those sessions for which full participation is expected just as if you are in class. Students participating at a distance will also have out of class activities, e.g. online discussions or postings or email contributions to compensate for not being in the classroom. Only the instructor can excuse a student from a course requirement or responsibility. When conflicts or absences can be anticipated, such as for many University sponsored activities and religious observations, the student should inform the instructor of the situation as far in advance as possible. For unanticipated or emergency absences when advance notification to an instructor is not possible, the student should contact the instructor as soon as possible by email, or by contacting the main office that offers the course. When the student is unable to make direct contact with the instructor and

is unable to leave word with the instructor's department because of circumstances beyond the student's control, and in cases of bereavement, the student or the student's representative should contact the Office of the Dean of Students. The link to the complete policy and implications can be found at: http://www.purdue.edu/studentregulations/regulations_procedures/classes.html

Accessibility and Accommodations:

As educators of Purdue University, we strive to make learning experiences as accessible as possible. If you anticipate or experience physical or academic barriers based on disability, you are welcome to let me know so that we can discuss options. You are also encouraged to contact the Disability Resource Center at: drc@purdue.edu or by phone: 765-494-1247.

Nondiscrimination statement:

As educators of Purdue University, we are committed to maintaining a community which recognizes and values the inherent worth and dignity of every person; fosters tolerance, sensitivity, understanding, and mutual respect among its members; and encourages each individual to strive to reach his or her own potential. In pursuit of a goal of academic excellence we, along with the University, seek to develop and nurture diversity. We believe that diversity among its many members strengthens the institution, stimulates creativity, promotes the exchange of ideas, and enriches campus life. We, along with the University, attempt to view, evaluate, and treat all persons in any University related activity or circumstance in which they may be involved, solely as individuals on the basis of their own personal abilities, qualifications, and other relevant characteristics.

Purdue University prohibits discrimination against any member of the University community on the basis of race, religion, color, sex, age, national origin or ancestry, genetic information, marital status, parental status, sexual orientation, gender identity and expression, disability, or status as a veteran. The University will conduct its programs, services and activities consistent with applicable federal, state and local laws, regulations and orders and in conformance with the procedures and limitations as set forth in Purdue's Equal Opportunity, Equal Access and Affirmative Action policy which provides specific contractual rights and remedies. Additionally, the University promotes the full realization of equal employment opportunity for women, minorities, persons with disabilities and veterans through its affirmative action program. For further information, please read Purdue's nondiscrimination statement: http://www.purdue.edu/purdue/ea_eou_statement.html

Academic Dishonesty:

This class on ethical engineering aspires to prepare students for ethical professional practice. Any acts of dishonesty will not be tolerated and subject to failing the assignment, failing the class, or reporting to the Dean of Students for potential expulsion from the University. Purdue prohibits "dishonesty in connection with any University activity. Cheating, plagiarism, or knowingly furnishing false information to the University are examples of dishonesty." [Part 5, Section III-B-2-a, University Regulations] Furthermore, the University Senate has stipulated that "the commitment of acts of cheating, lying, and deceit in any of their diverse forms (such as the use of substitutes for taking examinations, the use of illegal cribs, plagiarism, and copying during examinations) is dishonest and must not be tolerated. Moreover, knowingly to aid and abet, directly or indirectly, other parties in committing dishonest acts is in itself dishonest." [University Senate Document 72-18, December 15, 1972]

Please review the following resource page on plagiarism: http://www.education.purdue.edu/discovery/research_integrity.html.

You may also want to refer students to Purdue's student guide for academic integrity:
<https://www.purdue.edu/odos/academic-integrity>

The Purdue Honor Pledge: "As a boilermaker pursuing academic excellence, I pledge to be honest and true in all that I do. Accountable together -we are Purdue"

Text Books: This course has no text books. Students will engage with scholarly literature, recent news articles, and relevant videos. (see updated Scholarly Reference List)

Grading: Each module of the 3-credit course will be assessed separately based on satisfactory completion of assignments and experiential learning projects listed below. The grade assignment will follow be based on percentage of points earned: A+ $\geq 97\%$ A $\geq 93\%$ A- $\geq 90\%$ B+ $> 87\%$ B $> 83\%$ B - $> 80\%$ C+ $> 77\%$ C $> 73\%$ C- $> 70\%$ D $> 60\%$ F = below 59%

Everyone: Weekly class participation and documentation (see participation policy above)	Points 20
BME 395001 -Assignments for completion:	
Find and Analyze an Engineering Code of Ethics	10
Interview a medical device developer	10
News Review Report	10
Ethical Issues Analysis Case 1	10
Ethical Issues Analysis -Case 2	10
Ethical Issues Analysis -Case 3	10
Project: Team written reflection paper analyzing ethical issues of an emerging medical product	20
BME 495001 -Assignments for completion:	Points
Concept map of engineering ethics	10
Interview a medical or assistive device user (long-term)	10
Empathic Awareness Activity Reflection 1	10
Empathic Awareness Activity Reflection 2	10
Empathic Awareness Activity Reflection 3	10
Empathic Awareness Activity Reflection 4	10
Project: Team written stakeholder report of emerging medical product	20
BME 595001 -Assignments for completion:	Points
Ethical reasoning diagram	10
Case study report 1: team-based decision / justification	10
Case study report 2: team-based decision / justification	10
Case study report 3: team-based decision / justification	10
Case study report 4: team-based decision / justification	10
Project: Team written journal article on ethical analysis of emerging medical product	30