**Biomedical Engineering 460: Introduction to Biomedical Device Design (3 Credits)**

**Fall 2022**

**Time: Tuesday & Thursday 9:30 – 10:45 am, Location: SECC 209**

# Instructor Information:

Professor: Dr. Nicole Ramo

Email: [nramo@wcupa.edu](mailto:nramo@wcupa.edu) (include “BME460” in the subject line of any emails)

Office Phone: 610-436-2492

Office: SECC 353

Office Hours: Tuesdays 2 – 4 pm; Wednesdays 11 am – 12 pm; Thursday 1 – 3 pm; or by appointment  
O*ffice hours may be attended in person or* [*via Zoom*](https://wcupa.zoom.us/my/office.hours.nramo?pwd=WDNvOS9EdVl1ZTRBamVQT2p0elJjQT09)

# Course Description:

BME 460 is an elective, project-based learning course for Biomedical Engineering (BME) majors. It introduces the engineering design process and related concepts, tools, and methodologies in the context of biomedical device design. Students will work in teams to redesign, modify, fabricate, and validate a current medical device. Topics include the engineering design process, rapid prototyping using 3D printing, finite-element analysis (FEA), and the use of standards in design evaluation (e.g., ASTM testing standards).

# Course Pre-requisites:

BME 460 requires prerequisites of BME 120: Intro to Computer-Aided Engineering and Design and BME 365: Biomechanics for Engineers.

# **Required Materials:**

There are **no required materials for the course**, but the following may serve as good references for different parts of the course as well as future work in biomedical device research & development:

* Biodesign: The Process of Innovating Medical Technologies by Yock et al.; 2nd edition; 2015
  + [The Student Guide to Biodesign](https://biodesignguide.stanford.edu/) by the Stanford Byers Center for Biodesign
  + [eBiodesign](http://ebiodesign.org/) (Textbook companion website)
* Design of Biomedical Devices and Systems by King, Fries, and Johnson; 4th edition; 2018

# **D2L Usage:**

All course materials including homework assignments, feedback files, and important communications will be posted on WCU’s D2L website for the course. ***You are strongly encouraged to set D2L to notify you when new content is posted and when an announcement is made.***

# **Course Student Learning Objectives:**

After successfully completing the BME 460 course, you will be able to:

1. Locate standards relevant to biomedical device design and evaluation (assessed by: Homework Assignments)
2. Describe the value of 3D models and FEA simulation in biomedical device design and evaluation (assessed by: Homework Assignments)
3. Create 3D models of a biomedical product using modern prototyping tools (assessed by: Design Updates, Design Report, Design Presentation)
4. Perform an FEA simulation to evaluate a biomedical product (assessed by: Design Updates, Design Report, Design Presentation)
5. Contribute to the development of a collaborative team environment (assessed by: Peer Evaluation, Self-Reflections)

# Meeting & Assessing Student Learning Objectives:

Your individual achievement of the course learning objectives will be assessed by homework assignments/tutorials, self-reflections, and your team members’ evaluations of you; your team’s achievement of the course learning objectives will be assessed by your team’s design updates, design report, and design presentation. Rubrics will be provided for each of the team-based assessments. To succeed in this course, you should strive to communicate effectively with team members, contribute to a positive team dynamic, follow through on individual and group work, take initiative to find external resources, provide and adjust to constructive feedback.

# Evaluation & Grading:

* Team Assignments
  + Design Updates (5% each) = 20%
  + Design Presentation = 20%
  + Design Report = 20%
* Individual Assignments
  + Homework Assignments/Tutorials (5% each) = 15%
  + Team Members’ Evaluation = 10%
  + Evaluation of Team Members = 5%
  + Self-reflections = 10%

# ****Team Assignments and Teamwork:****

As shown above, team-based work comprises 60% of your overall grade. Design updates are regularly spaced opportunities for your team to document and get feedback on your progress. Design updates allow your team to build toward the design presentation and design report due at the end of the semester. You are encouraged to set clear expectations for work-sharing and effort at the start of the semester. Any significant disparity in efforts that cannot be resolved as a team, should be brought to the attention of the instructor.

# Individual Assignments:

Your final course grade will be differentiated from those of your team members by your performance on individual assignments (40% of your overall course grade). Homework assignments or tutorials ensure that you have mastered the concepts and skills introduced in the course. At the mid-point and at the end of the semester, you will get the opportunity to evaluate each of your team members. Your completion of thoughtful and constructive evaluations is worth 5% of your course grade. Your team members’ evaluation of your contributions will compose 10% of your final grade. Rubrics and guidelines will be provided to help you complete and learn from peer evaluations. Self-reflections provide opportunities for you to reflect on your contribution to team dynamics and the course project.

# Communication Expectations:

Emails, with BME460 in the subject line, are the preferred way to contact the instructor in this course. Your instructor intends to respond to all student emails within one business day. If you are still waiting on a response after this time frame, please send a follow-up message. **Please note that if you email a question within 24 hours of an assignment deadline, you are not guaranteed a response before your assignment is due; plan accordingly.** You are also expected to maintain regular and respectful communication with your team members.

# Attendance Policy:

If your absence is unavoidable (for excused or unexcused reasons), please email the instructor as soon as possible. Excused absences are limited to those due to participation in university-sanctioned events (see policy in the WCU undergraduate catalog) or those accompanied by written confirmation from a doctor, the Dean of Students, etc. If you are sick, you must obtain a doctor’s note. Whether your absence is excused or unexcused (or if you are late to class), you will be responsible for any material covered and any announcements that were made. **You should also extend these courtesies to your team members; if you are unable to attend a scheduled team meeting, you should let your team members know as soon as possible.**

# Grading Scheme:

A letter grade will be assigned based on performance in the course according to the following scale (Refer to the Undergraduate Catalog for a description of NG (No Grade), W, Z, and other grades):

|  |  |  |  |
| --- | --- | --- | --- |
| **Grade** | **Quality Points** | **Percentage Equivalents** | **Interpretation** |
| A | 4.00 | 93-100 | Excellent |
| A- | 3.67 | 90-92 |  |
| B+ | 3.33 | 87-89 | Superior |
| B | 3.00 | 83-86 |  |
| B- | 2.67 | 80-82 |  |
| C+ | 2.33 | 77-79 | Average |
| C | 2.00 | 73-76 |  |
| C- | 1.67 | 70-72 |  |
| D+ | 1.33 | 67-69 | Below Average |
| D | 1.00 | 63-66 |  |
| D- | 0.67 | 60-62 |  |
| F | 0 | < 60% | Failure |

# Tentative Course Outline: The following schedule is subject to change at the discretion of the instructor. Every effort will be made to announce changes in advance, but you as a student are responsible for changes.

|  |  |  |  |
| --- | --- | --- | --- |
| **Week** | **Dates** | **Topics** | **Deliverables** |
| **1** | 8/30; 9/1 | Course Introduction;  Intentional Teamwork and Project Management | Team Formation Survey |
| **2** | 9/6; 9/8 | The Engineering Design Process;  Problem Definition & Needs Statements |  |
| **3** | 9/16;  9/15 | Design Requirements for Biomedical Devices;  Role of Standards in Biomedical Device Design & Evaluation;  Finding Relevant Standards and Regulations (e.g., ASTM, FDA, etc.) | Design Update #1 |
| **4** | 9/20; 9/22 | Documenting the Design Process;  Concept Generation, Screening, and Down-selection |  |
| **5** | 9/27; 9/29 | Tools of Virtual Prototyping (e.g., advanced features of CAD); Review of SolidWorks Assemblies | Homework #1 |
| **6** | 10/4; 10/6 | CAD Modeling of Biomedical Devices | Design Update #2 |
| **7** | 10/11; 10/13 | Tools of Physical Prototyping (e.g., 3D printing and other manufacturing techniques) |  |
| **8** | 10/18; 10/20 | ***Fall Break (no class Tuesday, October 18th);*** 3D Printing of Biomedical Devices |  |
| **9** | 10/25; 10/27 | 3D Printing of Biomedical Devices | Design Update #3; Peer Evaluation #1;  Self-Reflection #1 |
| **10** | 11/1;  11/3 | Tools of Virtual Prototype Evaluation: Finite Element Analysis (Introductory Principles and Theory) |  |
| **11** | 11/8;  11/10 | Tools of Virtual Prototype Evaluation: Finite Element Analysis (Implementation in SolidWorks) |  |
| **12** | 11/15;  11/17 | Tools of Virtual Prototype Evaluation: Finite Element Analysis (Sensitivity Analysis & Parametric Sweeps) | Homework #2 |
| **13** | 11/22;  11/24 | FEA Simulations of Biomedical Devices;  ***Thanksgiving Break (no class Thursday, November 24th)*** | Design Update #4 |
| **14** | 11/29;  12/1 | Design Evaluation;  Importance of Iteration |  |
| **15** | 12/6;  12/8 | Research & Development Careers; Guest Lecture(s) | Homework #3 |
| **16** | 12/15 | ***Design Presentations: Thursday, December 15th 8 – 10 am*** | Design Report;  Peer Evaluation #2;  Self-Reflection #2 |

# Bibliography: Some components of this course are based on observation of the following courses and/or collaboration with the following instructors:

* BME 3401A: Introduction to Biomedical Engineering Design and Rapid Prototyping (Shantou University)
  + Dr. Christian Poblete Rivera
* BIOMEDE 350: Introduction to Biomedical Engineering Design (University of Michigan)
  + Dr. Xueding Wang, Dr. C. Alberto Figueroa, Dr. Sriram Chandrasekaren

# Statements Common to All WCU Undergraduate Syllabi:

## Academic & Personal Integrity

It is the responsibility of each student to adhere to the university’s standards for academic integrity. Violations of academic integrity include any act that violates the rights of another student in academic work, that involves misrepresentation of your own work, or that disrupts the instruction of the course. Other violations include (but are not limited to): cheating on assignments or examinations; plagiarizing, which means copying any part of another’s work and/or using ideas of another and presenting them as one’s own without giving proper credit to the source; selling, purchasing, or exchanging of term papers; falsifying of information; and using your own work from one class to fulfill the assignment for another class without significant modification. Proof of academic misconduct can result in the automatic failure and removal from this course. For questions regarding Academic Integrity, the No-Grade Policy, Sexual Harassment, or the Student Code of Conduct, students are encouraged to refer to the Department Undergraduate Handbook, the Undergraduate Catalog, the Ram’s Eye View, the [University website](http://www.wcupa.edu), and [Undergraduate Student Academic Integrity Policy](https://catalog.wcupa.edu/undergraduate/academic-policies-procedures/academic-integrity/)

## Students With Disabilities

If you have a disability that requires accommodations under the Americans with Disabilities Act (ADA), please present your letter of accommodations and meet with your instructor as soon as possible so that they can support your success in an informed manner. Accommodations cannot be granted retroactively. If you would like to know more about [West Chester University’s Services for Students with Disabilities (OSSD), please visit their website](https://www.wcupa.edu/universityCollege/ossd/) or visit them in-person at 223 Lawrence Center. Their phone number is 610-436-2564, their fax number is 610-436-2600, their email address is [ossd@wcupa.edu](mailto:ossd@wcupa.edu). In an effort to assist students who either receive or may believe they are entitled to receive accommodations under the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973, the University has appointed a student advocate to be a contact for students who have questions regarding the provision of their accommodations or their right to accommodations. The advocate will assist any student who may have questions regarding these rights. The Director for Equity and Compliance/Title IX Coordinator has been designated in this role. Students who need assistance with their rights to accommodations should contact them at 610-436-2433.

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## Excused Absences Policy

Students are advised to carefully read and comply with the excused absences policy, including absences for university-sanctioned events, contained in the WCU Undergraduate Catalog. In particular, please note that the “responsibility for meeting academic requirements rests with the student,” that this policy does not excuse students from completing required academic work, and that professors can require a “fair alternative” to attendance on those days that students must be absent from class in order to participate in a University-Sanctioned Event.

## Inclusive Learning Environment and Anti-Racist Statement

Diversity, equity, and inclusion are central to West Chester University’s mission as reflected in our [Mission Statement](https://protect-us.mimecast.com/s/Kh8QCrk6x5SDqM24CQRU_b?domain=wcupa.edu),[Values Statement](https://protect-us.mimecast.com/s/XD1FCv2kB5Ty91Arswntb5?domain=wcupa.edu),[Vision Statement](https://protect-us.mimecast.com/s/XD1FCv2kB5Ty91Arswntb5?domain=wcupa.edu) and[Strategic Plan: Pathways to Student Success](https://protect-us.mimecast.com/s/ovVXCwplD5TRj6yghld0bL?domain=wcupa.edu). We disavow racism and all actions that silence, threaten, or degrade historically marginalized groups in the U.S. We acknowledge that all members of this learning community may experience harm stemming from forms of oppression including but not limited to classism, ableism, heterosexism, sexism, Islamophobia, anti-Semitism, and xenophobia, and recognize that these forms of oppression are compounded by racism.

Our core commitment as an institution of higher education shapes our expectation for behavior within this learning community, which represents diverse individual beliefs, backgrounds, and experiences. Courteous and respectful behavior, interactions, and responses are expected from all members of the University. We must work together to make this a safe and productive learning environment for everyone. Part of this work is recognizing how race and other aspects of who we are shape our beliefs and our experiences as individuals. It is not enough to condemn acts of racism. For real, sustainable change, we must stand together as a diverse coalition against racism and oppression of any form, anywhere, at any time.

Resources for education and action are available through WCU’s [Office for Diversity, Equity, and Inclusion](https://www.wcupa.edu/_admin/diversityEquityInclusion/changeBeginsHere.aspx) (ODEI), DEI committees within departments or colleges, the student [ombudsperson](https://www.wcupa.edu/_services/STU/studentOmbuds/), and centers on campus committed to doing this work (e.g., [Dowdy Multicultural Center](https://www.wcupa.edu/_services/multicultural/), [Center for Women and Gender Equity](https://www.wcupa.edu/_services/stu.wce/), and the [Center for Trans and Queer Advocacy](https://www.wcupa.edu/_services/transAndQueer/)).

Guidance on how to report incidents of discrimination and harassment is available at the University’s [Office of Diversity, Equity, and Inclusion](https://www.wcupa.edu/_admin/diversityEquityInclusion/).

## Emergency Preparedness

All students are encouraged to sign up for the University’s free [WCU ALERT service](http://www.wcupa.edu/wcualert), which delivers official WCU emergency text messages directly to your cell phone. To report an emergency, call the Department of Public Safety at 610-436-3311.

## Reporting Incidents of Sexual Violence

West Chester University and its faculty are committed to assuring a safe and productive educational environment for all students. In order to comply with the requirements of Title IX of the Education Amendments of 1972 and the University’s commitment to offering supportive measures in accordance with the new regulations issued under Title IX, the University requires faculty members to report incidents of sexual violence shared by students to the University's Title IX Coordinator. The only exceptions to the faculty member's reporting obligation are when incidents of sexual violence are communicated by a student during a classroom discussion, in a writing assignment for a class, or as part of a university-approved research project. **Faculty members are obligated to report sexual violence or any other abuse of a student who was, or is, a child (a person under 18 years of age) when the abuse allegedly occurred to the person designated in the University Protection of Minors Policy.** Information regarding the reporting of sexual violence and the resources that are available to victims of sexual violence is found on the [Sexual Misconduct page of the Office for Diversity, Equity, and Inclusion](https://www.wcupa.edu/_admin/diversityEquityInclusion/sexualMisconduct/default.aspx).

## Electronic Mail Policy

It is expected that faculty, staff, and students activate and maintain regular access to University provided e-mail accounts. Official university communications, including those from your instructor, will be sent through your university e-mail account. You are responsible for accessing that mail to be sure to obtain official University communications. Failure to access will not exempt individuals from the responsibilities associated with this course.

## Basic Needs Statement

WCU is committed to ensuring that all students are able to reach their full academic potential. We know that basic needs are essential for effective learning, and we are working to address economic insecurity among our students in a number of ways. In particular, the WCU Resource Pantry is open to all students who lack access to food and supplies. Resources are also available for students facing housing insecurity. Please contact the Office of Service-Learning & Volunteer Programs for more information. As these factors directly affect academics, students who are comfortable doing so should contact faculty for further support.