PURDUE UNIVERSITY | College of Engineering

Engineering Faculty Document
No.: 64-26
December 4, 2025

TO: The Engineering Faculty

FROM: The Faculty of the Weldon School of Biomedical Engineering

RE: New 500-level course – BME 58500 Clinical Engagement and Translational Biomedical Engineering

The Faculty of the Weldon School of Biomedical Engineering has approved the following new 500-level course. This action is now submitted to the Engineering Faculty with a recommendation for approval.

BME 58500: Clinical Engagement and Translational Biomedical Engineering

Offered Fall Semester
2-credit Lecture
Prerequisites:
Enrollment in BME Professional Master's Program Concentration in "Clinical Engagement and Biomedical Innovation"
or Permission of Instructor

Course description:

This course introduces students to the unique opportunities and challenges in the creation of new medical devices through a combination of didactic instruction and clinical engagement with healthcare professionals. Students will practice identifying unmet clinical needs and apply user-centered design principles tailored to patients and their caregivers. This course will provide opportunities for students to consider how new technologies develop and translate from ideation to finished medical device. Emphasis is placed on translating clinical observations and experiences into actionable design insights within a product discovery context. The benefits, methods, and difficulties encountered when translating ideas into products that are successful in the clinic and in the marketplace will also be discussed. The course is expected to be taken with BME 58501 Clinical Engagement and Translational Biomedical Engineering – Clinic.

RATIONALE:

This Lecture course in combination with the 1-credit Clinic (BME 58501) are the core requirement for the BME PMP concentration in Clinical Engagement and Biomedical Innovation. Clinical experience is essential to prepare students for careers in medical technology, where they will be required to work in a clinical setting, identify and solve clinical problems, manage clinical trials, and, for some, become medical professionals. The lecture course exposes students to key skills for identifying unmet clinical needs and subsequently creating and proposing an engineering solution to a clinical problem using written and verbal communication tools common to medical device development practices

in industry. The course sequence provides a unique opportunity for engineering students to combine theoretical classroom knowledge with practical learning in a real-world clinical environment. Engineering students in this course will gain the industry skills necessary to create advanced medical products and therapies and will be better prepared to pursue career pathways focused on developing products to meet patient, clinician, and market needs.

Signed by:
Kevin Otto
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Kevin Otto, Ph.D.
Dane A. Miller Head and Professor
Weldon School of Biomedical Engineering

Link to Curriculog entry: New Proposal 12/5/2025 12:20 pm | Curriculum

Course Information

- Course number and title: BME 58500 – Clinical Engagement and Translational Biomedical Engineering
- Semester: Fall 2026
- Meeting time: 50 minutes 2x per week
- Credit Hours: 2
- Instructional Modality: In-person in Indianapolis
- Students will find lecture resources and recordings, assignments, grades, and other class-related materials in Brightspace.
- Prerequisites:
    - Enrollment in BME Professional Master's Program Concentration in "Clinical Engagement and Biomedical Innovation" or permission of instructor.

Instructor Contact Information

- Course Director: Matthew Waninger, PhD, Weldon School of Biomedical Engineering
- Clinical Course Director: Steve Conlon, MD, FAAP, Indiana University School of Medicine, Adjunct Faculty, Weldon School of Biomedical Engineering

You can reach the course directors via email to arrange a phone call, a virtual meeting, or an in-person meeting.

Course Description

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Learning Resources, Technology & Texts

- Required readings may be assigned throughout the course (e.g., FDA guidance documents, publications, websites, etc.)
- Optional Textbook: Biodesign: The Process of Innovating Medical Technologies, 2nd Edition
- Software/web resources
    - Word Processor (i.e. MS Word), remember that MS Office is free for all students.
- Brightspace page
    - You can access the course via Brightspace. It is strongly suggested that you explore and become familiar not only with the site navigation, but with content and resources available for this course. See the Help tab for resources.

Learning Outcomes

1. Demonstrate approaches for identifying key unmet clinical needs through observation, engagement, and collaboration with healthcare professionals.
2. Create and propose engineering solutions to clinical problems using written and verbal communication tools common to medical device development practices in industry.

Course Schedule

A tentative schedule of topics is attached at the end of this syllabus.

Assignments

Much of what you get out of this class will reflect what you put into the class.

Your learning will be assessed through a combination of attendance, class participation/discussion, writing assignments, and a final presentation. Details on assignments will be posted on Brightspace. Unless otherwise discussed with and approved by the instructor, late assignments are subject to a reduction in grade or may not be accepted; see table below.

Class Attendance and Active Participation (20 points)

Class attendance and active participation are critical components of learning for all students. These form a substantial part of your grade with the hope that everyone earns all available points.

- Evaluated by random attendance checks and in-class participation throughout the semester.

Product Proposal (25 points) and Presentation (25 points)

To expand your knowledge of and insights into a special topic of interest, you will undertake an exploratory investigation of unmet clinical needs with clinicians and fellow class members. An objective of this exercise is for you to hone your communication skills to convey information both clearly and succinctly. Using the Problem Statement, User Needs, and Clinical Evaluation Summary you created from your clinical experiences (BME58501) you will create:

Product Proposal (25 points):

- You will write a product proposal that outlines the concept, benefits, and development plan for a new product, aimed at persuading stakeholders or investors of its potential value.

Final Presentation (25 points):

- You will present a summary of your clinical engagement experience and product proposal which was derived from it.

Comprehension Quizzes (30 points)

Short quizzes will occur throughout the course to help ensure comprehension of key topics

Grading

Grade Composition

Item	Points
Class attendance and participation	20

Product proposal	25
Final presentation	25
Comprehension Quizzes	**30**
TOTAL	**100**

Tentative Grade Composition (NOTE: these numbers are an estimate only, are subject to change, and may be more or less than indicated in the syllabus)

Attendance/participation

- Attendance and participation in this course is critical for success and learning. Therefore, attendance is mandatory for all clinical and classroom sessions unless excused by the instructor or per University regulations.

Statement on use of Artificial Intelligence

Advancements in Artificial Intelligence (AI) can provide benefits to students. However, over reliance on AI prevents critical thinking and achievement of learning outcomes. The policy on AI use in this course is based on the Weldon School policy for the use of Generative AI in BME Graduate Program exams, theses, and dissertations as well as considerations around the current thinking of AI in supporting education and the role of AI in regulatory research.

Any use of generative AI (e.g., ChatGPT) in assignments (including discussion posts, etc.) must be clearly indicated as supportive and supplemental assistance in the scholarly effort. Appropriate quotation and citation must be documented for use of AI generated text and any lack will be considered as plagiarism and academic dishonesty with repercussions as indicated in the Purdue Academic Code of Conduct and Weldon School documents, which may include grade penalties, course failure, or more severe disciplinary actions.

Acknowledging the potential value and legitimate benefits of AI tools, you are encouraged to consider the use of AI in this course to support research and help generate ideas. In addition to the requirements above regarding AI-generated text, if you use AI on assignments:

1. Be sure to verify or validate the information as there can often be errors or incorrect information generated.
2. Discuss the process you used. For example, if you use AI to help identify appropriate bench testing requirements for a device, describe what you did, how you confirmed the information, and what additional information you included beyond the AI response (i.e., did AI find all the required information and was it correct).

Objectives of this policy include:

- Uphold academic honesty and personal integrity
- Develop skills for critical thinking and independent reasoning
- Use the tools available to you to improve efficiency and results

Guidelines for Responsible Use of AI in this course include:

- Original Work: Students should ensure that assignments submitted are original and based on their understanding. While AI can assist in research or provide general guidance, it should not be the sole source relied upon to produce work on behalf of the student.
- Citation: Any content, ideas, or assistance obtained through AI tools must be appropriately cited, similar to any other reference or source. If citing references, **you** need to find and confirm the relevant information from the primary literature or other source, not cite AI.
- Collaboration: If a student collaborates with AI tools, they must specify the nature and extent of this collaboration in their submission. This includes providing details of the prompts used to generate the AI responses.

Grading Scale

In this class, grades reflect the sum of your achievement throughout the semester. You will accumulate points as described in the assignments portion above, with each assignment graded according to a rubric. At the end of the semester, final grades will be calculated by adding the total points earned and translating those numbers into the following letters.

Grading Scale:
A+ = (≥97.0%)
A = (≥93.0%)
A- = (≥90.0%)
B+ = (≥87.0%)
B = (≥83.0%)
B - = (≥80.0%)
C+ = (≥77.0%)
C = (≥73.0%)
C- = (≥70.0%)
D = (≥60.0%)
F = (below 60.0%)

Policy on academic honesty:

The commitment of the acts of cheating, lying, stealing, and deceit in any of their diverse forms (such as the use of ghostwritten papers, the use of substitutes for taking examinations, the use of illegal cribs, plagiarism, and copying during examinations) is dishonest and not tolerated. Moreover, knowingly to aid and abet, directly or indirectly, other parties in committing dishonest acts is in itself dishonest. Any student committing academic dishonesty will receive a grade of 0 for the assignment, and subsequent offenders will receive a failing grade for the class. In addition, all incidents of academic misconduct will be forwarded to OSRR, where university penalties, including removal from the university, may be considered. Assignments may be checked through Turnitin or comparable software to assess similarity to existing material.

Attendance Policy

This course follows Purdue's academic regulations regarding attendance, which states that students are expected to be present for every meeting of the classes in which they are enrolled. For the purposes of this course, being "present" means attending all class sessions unless you have been excused by the instructor, are ill or need to be absent for reasons excused by university regulations.

Academic Integrity

Purdue's 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."

Academic integrity is one of the highest values that Purdue University holds. Individuals are encouraged to alert university officials to potential breaches of this value by either emailing integrity@purdue.edu or by calling 765-494-8778. While information may be submitted anonymously, the more information is submitted the greater the opportunity for the university to investigate the concern. More details are available on the Academic Resources table on your Brightspace homepage.

Copyright

Online educational environments, like all learning environments, should provide opportunities for students to reflect, explore new ideas, post opinions openly, and have the freedom to change those opinions over time. Students enrolled in and instructors working in online courses are the authors of the works they create in the learning environment. As authors, they own the copyright in their works subject only to the university's right to use those works for educational purposes (Visit Purdue University Copyright Office). Students may not copy, reproduce or post to any other outlet (e.g., YouTube, Facebook, or other open media sources or websites) any work in which they are not the sole or joint author or have not obtained the permission of the author(s).

Nondiscrimination Statement

Purdue University is 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 its goal of academic excellence, the University seeks to develop and nurture diversity. The University believes that diversity among its many members strengthens the institution, stimulates creativity, promotes the exchange of ideas, and enriches campus life. More details are available on our course Brightspace table of contents, under University Policies.

Accessibility

Purdue University strives 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.

Mental Health Statement

If you find yourself beginning to feel some stress, anxiety and/or feeling slightly overwhelmed, try Therapy Assistance Online (TAO), a web and app-based mental health resource available courtesy of Purdue Counseling and Psychological Services (CAPS)**.** TAO is available to all students at any time by creating an account on the TAO Connect website, or downloading the app from the App Store or Google Play. It offers free, confidential well-being resources through a self-guided program informed by psychotherapy research and strategies that may aid in overcoming anxiety, depression and other concerns. It provides accessible and effective resources including short videos, brief exercises, and self-reflection tools.

If you need support and information about options and resources, please contact or see the Office of the Dean of Students. Call 765-494-1747. Hours of operation are M-F, 8 a.m.- 5 p.m.

If you find yourself struggling to find a healthy balance between academics, social life, stress, etc., sign up for free one-on-one virtual or in-person sessions in West Lafayette with a Purdue Wellness Coach at RecWell. Student coaches can help you navigate through barriers and challenges toward your goals throughout the semester. Sign up is free and can be done on BoilerConnect. Students in Indianapolis will find support services curated on the Vice Provost for Student Life website.

If you're struggling and need mental health services: Purdue University is committed to advancing the mental health and well-being of its students. If you or someone you know is feeling overwhelmed, depressed, and/or in need of mental health support, services are available. For help, such individuals should contact Counseling and Psychological Services (CAPS) at 765-494-6995 during and after hours, on weekends and holidays, or by going to the CAPS offices in West Lafayette or Indianapolis.

The Community, Assistance and Resources for Engineering Students (CARES) Hub is open to support the well-being of all engineering students. The CARES Hub, located in ARMS 1261, is a welcoming, inclusive space for students to study, connect, grab a snack, and relax. If you need help handling stress or working through a problem, schedule time with a CARES Hub therapist or drop by ARMS 1251 walk-in hours. Please visit the CARES Hub webpage to learn more. The CARES Hub staff look forward to connecting with you!

Basic Needs Security

Any student who faces challenges securing their food or housing and believes this may affect their performance in the course is urged to contact the Dean of Students for support. There is no appointment needed and Student Support Services is available to serve students 8 a.m.-5 p.m. Monday through Friday. Considering the significant disruptions caused by the current global crisis as it related to COVID-19, students may submit requests for emergency assistance from the Critical Needs Fund

Emergency Preparation

In the event of a major campus emergency, course requirements, deadlines and grading percentages are subject to changes that may be necessitated by a revised semester calendar or other circumstances beyond the instructor's control. Relevant changes to this course will be posted onto the course website or can be obtained by contacting the instructors or TAs via email or phone. You are expected to read your @purdue.edu email on a frequent basis.

See Purdue's Information on Emergency Preparation and Planning. This website covers topics such as Severe Weather Guidance, Emergency Plans, and a place to sign up for the Emergency Warning Notification System. I encourage you to download and review the *Emergency Preparedness for Classrooms document*.

Course Evaluation

During the last two weeks of the semester, you will be provided with an opportunity to give feedback on this course and your instructor. Purdue uses an online course evaluation system. You will receive an official email from evaluation administrators with a link to the online evaluation site. You will have up to 13 days to complete this evaluation. Your participation is an integral part of this course, and your

feedback is vital to improving education at Purdue University. I strongly urge you to participate in the evaluation system.

Additionally, I am open to your feedback at any time during the course. Please let me know what can be improved about this course and what you find most useful.

Disclaimer

This syllabus is subject to change as we progress through the semester.

Tentative Schedule (subject to change)

Week	Content
1	Introduction to course and engagement with medical faculty
2	Schedule/plan for the semester
3	Device design – history and modern processes
4	
5	Fundamental concepts of product discovery and innovation
6	The Fuzzy Front End: Early-Stage Innovation (idea generation, concept development, exploration, creativity, problem identification, risk taking, market discovery, uncertainty, long-term vision, flexibility)
7	
8 (Fall Break)	How to Write a Product Proposal
9	Basics of Intellectual Property Protection
10	The Total Product Lifecycle
11	
12	The Back End of Innovation: Development Planning (execution, implementation, exploitation, process efficiency, solution delivery, risk management, market penetration, predictability, short-term results, structure)
13	
Thanksgiving	
14	Final presentations
15	
16	Finals Week