



## Course Information

- BME 56100 – Preclinical and Clinical Study Design
- CRN TBD
- Meeting time: Monday and Wednesday 4:30-5:45 pm Eastern time for in-person section; occasionally, material may be provided asynchronously
- 3.0 Credit Hours
- Course Brightspace page: TBD
- On-campus location: MJIS 1001
- All course sections (on-campus and online) are combined into one section within Brightspace. Students will find lecture resources and recordings, assignments, grades, and other class-related materials in Brightspace.
- Prerequisites: None

## Instructor Contact Information

- Instructor: Aaron Lottes, PhD, MBA, Associate Professor of Engineering Practice, Weldon School of Biomedical Engineering
  - Office Location: MJIS 2029; 765-496-6024
  - Email Address: [lottes@purdue.edu](mailto:lottes@purdue.edu)
- Adjunct Faculty Instructors:
  - TBD
- Office hours – by appointment
- Instructors may be reached via email, office location, phone, or before/after class

This course teaches current industry best practices in the design and testing of medical devices. Guest speakers from industry and FDA will provide insight, expertise, examples, and case studies on the course topics.

## Course Description

Medical devices are developed, manufactured, and distributed in a highly regulated environment. This course concerns the preclinical and clinical study design processes for obtaining FDA marketing approval for biomedical devices. Prior to marketing a medical device, specific governmental approval is required dependent on the type of device and the risk associated with the device. This course is part of a three-course series dealing with various aspect of regulatory science of medical devices. Regulatory science considers the scientific and technical foundations that support the practical testing and regulations that ensure the safety and effectiveness of medical devices.

The practice of Biomedical Engineering concerns itself with the design, development, and testing of medical devices that will be commercialized to improve or sustain life. Medical device companies, and the engineers they employ, have an ethical and legal responsibility to robustly examine the safety and performance of these devices through preclinical and clinical testing. This course covers the responsible conduct of preclinical and clinical study research necessary for obtaining marketing approval, with a focus on US FDA requirements, and using a risk-based approach to ensuring safety and effectiveness of

medical devices. Topics will include non-clinical benchtop testing, evaluation of device-tissue interactions and how they may be studied with pre-clinical animal models to predict safety and performance, statistical considerations for study design, and ethics related to responsible conduct of pre-clinical and clinical research.

## Learning Resources, Technology & Texts

- **Required readings will be assigned throughout the course** (e.g., FDA guidance documents, publications, websites, etc.)
- Optional Textbook: Biodesign: The Process of Innovating Medical Technologies, 2<sup>nd</sup> Edition
- Software/web resources
  - Microsoft Office ([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

By the end of the course, you will be able to:

1. Identify testing strategies for the design and development of a safe and effective medical device.
  - Methods of Evaluation: Homework, Projects, Participation in discussions
2. Demonstrate knowledge of quality, regulatory, marketing, and business considerations/perspectives in designing and implementing a preclinical and clinical study strategy.
  - Methods of Evaluation: Homework, Projects, Quizzes, Participation in discussions
3. Outline the course of medical device development, from feasibility through post-market sustainability, and identify the major milestones throughout the process.
  - Methods of Evaluation: Homework, Projects, Quizzes, Participation in discussions

## Course Schedule

A tentative schedule of topics is attached at the end of this syllabus – some topics and/or their associated dates are likely to change as the schedule is finalized. Guest speakers from industry and FDA will provide insight, expertise, examples, and case studies on many of these topics. While most class sessions are planned in-person, when speakers are remote we may instead meet live via Zoom. In occasional instances, a pre-recorded lecture may be provided in place of a live class session if necessary based on scheduling. Updates to the schedule and meeting format will be provided; please pay attention to associated Brightspace announcements and/or emails.

<b>Weeks</b>	<b>Topic</b>	<b>Overview of Planned Content</b>
1-5	Device Development and Design	Market evaluation, User needs, Disease state, Design input requirements, Acceptance criteria, Failure modes, Verification and validation, In vitro diagnostics
6-11	Bench and Animal Testing	Standards and guidances, Statistics, Test development, Study design, Test protocols and reports, Types of bench tests, Animal studies, Biocompatibility testing,
11-16	Clinical Testing	Clinical study strategy, Clinical study design, Clinical statistics, Clinical study protocols, Real-world evidence, Early feasibility studies, Patient preference, Post-market surveillance, Clinical data strategy

Key dates for Fall 2024-2025 include:

- August 19 – Classes Begin
- September 2 – Labor Day – NO CLASS
- October 7-8 – October Break – NO CLASS
- November 27-30 – Thanksgiving Vacation – NO CLASS
- December 7 – Classes End
- December 9-14 – Final Exams (NO final exam in this course)
- December 15 – Commencement
- December 17 – Grades Due

## Assignments

Your learning will be assessed through a combination of participation/discussion, exams, homework assignments, and a final project spread throughout the academic period. Details on assignments will be posted on Brightspace. Anticipated assignments, exams, and due dates are indicated below and are subject to change. 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. Exams and the group project will not be accepted late.

### Attendance/participation (15 pts)

- Random attendance checks throughout the semester, and/or participation in class discussions (on campus students only)

### Discussion Posts (40 pts)

- **1 Introduction post (5 pts)**
  - Due week 1
- **7 Discussion posts (5 pts x 7 = 35 pts)**
  - Due during any 7 weeks of the semester; i.e., you need to participate in these discussions during at least 7 separate weeks
    - **At least 2 of these must be responses to other students' posts**
  - These will be graded, not just participation points
  - I intend to post at least 1 potential discussion topic in the Discussion Board on Brightspace during most weeks

- You can respond to a question or other post, or develop your own question (with background, etc.); see below for considerations on writing good questions/discussions
- Writing good questions for discussion (for a speaker or in Brightspace discussion board):
  - Ask probing questions that may lead to further discussion
  - Do not ask questions with simple one-word or one-sentence answers
  - Do not ask a question that is already answered in the course material
  - Consider your own professional experiences; e.g., how might you resolve a certain situation or question related to the topic, or do you wonder how someone else might have reacted to a situation you experienced
- Writing good discussion responses to questions or other posts:
  - Provide the basis or rationale for your response
  - Do not just say “I agree”
  - Include supporting information or reference(s) when appropriate
  - Encourage further discussion or comments on the topic (there is rarely a single correct approach or right answer)

### Assignments and project (130 pts)

- Each of six planned assignments will be worth approximately 15 points
- The final project is planned to be worth approximately 40 points
- The first assignment will be completed individually, the remainder are currently planned to be completed in teams of ~3 to 4 students; teams are planned to be randomly assigned and changed for assignments 2-4 and 5-project to provide a greater diversity in working with people from different areas of expertise and backgrounds
- We expect, and are hopeful, that everyone contributes relatively equally to the success of the group assignments. However, we are also aware that is unfortunately not always the case. Mentor and help each other, but if this is not enough then **please let me know as soon as possible if a team member is under-performing**, including lack of participation/contribution, sub-par performance, etc. Constructive peer feedback should improve the overall group performance, but it is not helpful or fair for anyone to ‘cover’ for or ‘fix’ unacceptable work – please make me aware so we can address early. Ideally, all group members will receive the same score on an assignment, but this is at the discretion of the instructor and individual scores may be adjusted as needed.

<b>Assignment</b>	<b>Due (by 11:59 PM Eastern)</b>
Participation / Discussion	<i>Ongoing</i>
Introduction Post	August 27
#1 – Paper review	August 27
#2 – Disease State, Intended Use, Clinical Needs	September 6
#3a – User Needs	September 17
#3b – User Needs, DIR, AC, FMEA	September 24
#4 – Bench	October 15
#5 – Animal	October 29
#6 – Clinical	November 26
Final Project – Study Design Plan	tbd

## Exams (150 pts)

- Three exams of approximately 50 points each (may be a little more or less) are planned for the course; there will not be a Final exam
- Exams will remain open for a specific time frame during which there is one submission allowed; although you can take the exam at any point it is open, once an exam is started you will have a specified time frame to complete the exam (e.g., 90 minutes)
- You are allowed to use external materials (e.g., notes, course content on Brightspace, etc.) during the exam
- **Exams shall be taken individually**, and questions may not be discussed with any student who has not yet completed the exam

Exam		Due (by 11:59 PM Eastern)
Device Development and Design (August 21 – September 20)	Exam Open	September 28
	Exam Close	October 1
Bench and Animal Testing (September 25 – October 30)	Exam Open	November 2
	Exam Close	November 5
Clinical Testing (November 1 – November 29)*	Exam Open	November 30
	Exam Close	December 3

\* the December 4<sup>th</sup> and 6<sup>th</sup> material will not be included in the 3<sup>rd</sup> exam

Late Assignments	Submitted Late	Reduction in Grade
Homework Assignments	≤ 24 hours	20%
	24-48 hours	50%
	>48 hours	May not be accepted
Participation/Discussion	n/a	Not accepted
Exams Project	n/a	Not accepted

## 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%)

## Tentative Grade Composition: Total 365 or 350 Points (subject to change)

Assignments	Points (on-campus)	Points (distance)
Participation/Discussion	55	40
Assignments and Project	130	130
Exams	180	180
<b>TOTAL</b>	<b>365</b>	<b>350</b>

### ***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 includes both on-campus students attending class in-person and remote students participating asynchronously. Accordingly, specific attendance expectations will necessarily vary. For on-campus students, this course will include a mix of in-person sessions whenever possible and remote (live via Zoom) class sessions on days when speakers are remote; if you need a location to join the Zoom meeting from you are welcome to use MJIS 1083. For asynchronous students, all lecture content will be posted on Brightspace shortly after each class session. Students are expected to stay current with the course material and should have viewed all class sessions at the latest by the end of each module.

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 (in-person and via Zoom) for students enrolled on campus unless you have been excused by the instructor or need to be absent for reasons excused by University regulations: grief/bereavement, military service, jury duty, parenting leave or certain medically excused absences (go to the [Office of the Dean of Students \(ODOS\) website](#) for details on how to submit those requests).

### **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](mailto: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 our course Brightspace table of contents, under University Policies.

## 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](mailto: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 [WellTrack](#).** Sign in and find information and tools at your fingertips, available to you at any time.

**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 am- 5 pm.

**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 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.

**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 office on the second floor of the Purdue University

Student Health Center (PUSH) during business hours. The [CAPS website](#) also offers resources specific to situations such as COVID-19.

## **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 instructor via email or phone. You are expected to read your @purdue.edu email on a frequent basis.

## **Emergency Preparedness for Classrooms**

Emergency preparedness is your personal responsibility. Purdue University is actively preparing for natural disasters or human-caused incidents with the ultimate goal of maintaining a safe and secure campus. Please review the following procedures:

- For any emergency text or call 911.
- There are more than 300 Emergency Telephones (aka blue lights) throughout campus that connect directly to the Purdue Police Department (PUPD). If you feel threatened or need help, push the button and you will be connected right away.
- If we hear a fire alarm, we will immediately evacuate the building and proceed to the outside courtyard and main entrance to Hockmeyer; in inclement weather, proceed to the interior main lobby of Hockmeyer.
- If we are notified of a Shelter in Place requirement for a tornado warning we will stop classroom or research activities and shelter in the lowest level of this building away from windows and doors. Our preferred location is the basement hallway via the East stairwell; do not use the elevators.
- If we are notified of a Shelter in Place requirement for a hazardous materials release, we will shelter in our classroom shutting any open doors and windows.
- If we are notified of a Shelter in Place requirement for an active threat such as a shooting, we will shelter in a room that is securable preferably without windows.

For more details, review the MJIS building emergency plan:

[https://www.purdue.edu/ehrs/emergency\\_preparedness/bep/mjis-bep.html](https://www.purdue.edu/ehrs/emergency_preparedness/bep/mjis-bep.html).



## **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.**

**2023 Schedule to be updated for 2024**

**Tentative Schedule (subject to change)**

Week	Date	Topic	Location	
<b>Device Development and Design</b>				
1	Aug 21	Course Introduction; Overview of Device Development Process	MJIS	
	Aug 23	Clinical/User Needs; Clinician Perspective: Disease state, treatment options, device use	MJIS	
2	Aug 28	Design Input Requirements (DIR) and Acceptance Criteria (AC)	Recorded	
	Aug 30	Failure modes, DfMECA, Design Verification and Validation; Design Traceability; Standards and Guidances	Zoom*	
3	Sept 4	LABOR DAY		
	Sept 6	Research translation and Feasibility testing	MJIS	
4	Sep 11	Disease State Fundamentals, Existing Solution Analysis,	MJIS	
	Sept 13	Stakeholder Analysis, Market Analysis	MJIS	
5	Sept 18	In-class working session: Opportunity Summary, Design Inputs and Outputs, AC, Failure Modes	MJIS	
	Sept 20	Developing Diagnostic Devices/IVDs	MJIS	
<b>Bench and Animal Testing</b>				
6	Sept 25	Bench Testing (Overview, Examples, Standards, CAE, etc.)	MJIS	
	Sept 27		MJIS	
7	Oct 2		MJIS	
	Oct 4		MJIS	
8	Oct 9		FALL BREAK	
	Oct 11		Animal Studies (Overview, IACUC, Angiography, QCA, Histopathology, Histomorphometry, GLP, Protocol, Report)	MJIS
Oct 16	MJIS			
Oct 18	MJIS			
Oct 23	MJIS			
10	Oct 25	Digital Health	Zoom*	
11	Oct 30	Biocompatibility	Zoom*	
	Nov 1	Integrating test reports into regulatory submissions	MJIS	
<b>Clinical Testing</b>				
12	Nov 6	Clinical strategy	MJIS	
	Nov 8	Statistics and study design	MJIS	
13	Nov 13	Study design discussion, Clinical test plan	MJIS	
	Nov 15	Clinical operations	MJIS	
14	Nov 20	RWE, patient preference, EFS (tentative)	Zoom* (tbd)	
	Nov 22	THANKSGIVING BREAK		
15	Nov 27	Reimbursement	MJIS	
	Nov 29	Clinical case studies	MJIS	
16	Dec 4	Clinical data needs and strategy (tentative)	MJIS	
	Dec 6	Project Presentations	MJIS	

\* Zoom Link: **tbd**