MARYLAND APPLIED GRADUATE ENGINEERING

INDUSTRY PRACTICES IN MEDICAL ROBOTICS (ENPM809A)
Sections 0101 and RO01

Term: *Fall/2026*
Professor: Anindo Roy, Ph.D.
Office Phone: (410) 200-0894
Credits: 3
Course Dates: From September 4, 2026 - December 14, 2026
Course Times: Friday, 2:00pm – 4:40pm
Classroom: ###

Teaching Assistant: N/A
Email: anindo.roy@nextsteprobo.com
Office Hours: Fridays, 12pm – 2pm

Canvas/ELMS: Course Canvas Site Link

Section 1: Course Overview & Learning Outcomes

1.1 Course Description

Medical robotics is rewriting the rules of patient care, blending advanced engineering with biological interface to restore human mobility. As lifestyle diseases and increased longevity expand the global healthcare landscape, the demand for specialized engineers who understand both technical design and regulatory frameworks is surging.

ENPM809A provides a rigorous, design-oriented introduction to standard engineering and regulatory practices deployed across the medical robotics industry. While the structural principles taught here apply universally to all medical devices, this course grounds its concepts in a high-impact clinical target: **lower limb dysfunction (e.g., gait disorders due to neurologic injury)**. Throughout the semester, we will pull back the curtain on the commercial **AMBLE robotic exoskeleton system**, using it as a living case study to trace the entire product development lifecycle.

The course curriculum systematically mirrors an authentic medical device product realization pipeline, guiding students through a structured logical sequence: **high-level regulatory strategy → electromechanical system architecture and component specification → physical interaction control loop design → risk management and usability compliance → clinical trial validation**.

Unlike generalized robotics tracks, this curriculum bridges the gap between theoretical engineering and commercial reality. Students will master the complete Design Controls process—transforming qualitative user needs into precise design inputs/outputs, developing kinematic models, navigating physical interaction control, managing risk matrices (ISO 14971), and structuring clinical trial validations.

Course Capstone Focus: The course culminates in a simulated product development project. Working in collaborative teams, students will apply design, development, and verification & validation (V&V) principles to author a simulated Design History File (DHF) for either a **hip or knee exoskeleton** tailored for neurorehabilitation.

1.2 Prerequisites

- Familiarity with basic linear control systems.
- *Note:* This is an introductory course. Prior medical or anatomical background is not required; the essential clinical concepts will be taught from the ground up.

1.3 Learning Outcomes

By the conclusion of this course, you will be able to:

- **Classify** therapeutic and assistive robotic devices within FDA and international regulatory frameworks, identifying specific special controls and market pathways (510(k), De Novo, PMA).
- **Translate** qualitative clinical user needs into quantitative engineering design inputs and hardware outputs for lower-limb wearable systems.
- **Synthesize** kinematics, motor/actuator selection criteria, and physical interaction control architectures (impedance/admittance) to optimize safety and performance during human-in-the-loop operation
- **Construct** compliant Risk Management Matrices (ISO 14971) and Usability Engineering specifications (IEC 62366-1) that mitigate mechanical, electrical, and physical interaction hazards.
- **Design and Evaluate** rigorous bench verification protocols and clinical validation trial strategies to prove the safety and efficacy of a simulated rehabilitation robotic device.

Course Materials

Required Resources

- None.

Supplemental Resources (no purchase required)

- Readings: As assigned by Instructor.
- Hardware/Software: MATLAB/Simulink, CAD etc. for capstone project only (freely available from UMD).

Section 2: Course Structure, Communication Guidelines & Announcements

2.1 Course Structure

This course includes both on-campus and online sections, structured to support collaborative and flexible learning.

- **Synchronous Attendance:** To attend synchronously online, log into ELMS-Canvas at the time of the Section 0101 class (Friday, 2pm – 4:40pm) and select "Video Conference" from the left side menu. This will open a Zoom link to the live classroom.
- **Asynchronous Attendance:** For asynchronous online students, all lectures will be recorded and made available on ELMS-Canvas under "Panopto Recordings/Video Lectures" within 24 hours of the class time. Asynchronous students are expected to review these recordings promptly to keep pace with course deliverables.
- **Participation:** On-campus students come to class prepared to engage with the lecture and materials. Online students, be sure to log into Canvas regularly and participate in discussions and activities. Regardless of the section you are enrolled in, active participation is expected.
- **Please note** that F1 students enrolled in the on-campus section are required to attend in person. If you have a conflict on a particular day, please reach out to me in advance to discuss.

2.2 Communicating with the Instructor

My goal is to be readily available to you throughout the semester. I can be reached by email at anindo.roy@nextsteprobo.com. Please DO NOT email me with questions that are easily found in the syllabus or on ELMS-Canvas (e.g., When is this assignment due? How much is it worth? etc.), but please DO reach out about personal, academic, and intellectual concerns/questions.

While I will do my best to respond to emails within 24 hours, you will more likely receive email responses from me on Thursdays and Fridays from 9am to 11am EST. When constructing an email to me please put "ENPM809A (Section XXXX): Your Topic" in the subject line. This will draw my attention to your email and enable me to respond to you more quickly.
Additionally, please review These tips for 'How to email a Professor'. By following these guidelines, you will be ensured to receive a timely and courteous response.

Finally, if you need to discuss issues not appropriate for the classroom and/or an email, we can arrange to talk by phone, over Zoom, or in person. Send me an email asking for a meeting and we can set something up.

2.3 Announcements

I will send IMPORTANT messages, announcements, and updates through ELMS-Canvas. To ensure you receive this information in a timely fashion, make sure your email and announcement notifications (including changes in assignments and/or due dates) are enabled in ELMS-Canvas (How to change notification settings in CANVAS).

Log into our ELMs-Canvas course site at least once every 24-hour period to check your inbox and the Announcements page.

2.4 Names/Pronouns and Self-Identifications

The University of Maryland recognizes the importance of a diverse student body, and we are committed to fostering inclusive and equitable classroom environments. I invite you, if you wish, to tell us how you want to be referred to in this class, both in terms of your name and your pronouns (he/him, she/her, they/them, etc.). Keep in mind that the pronouns someone uses are not necessarily indicative of their gender identity. Visit trans.umd.edu to learn more.

Additionally, it is your choice whether to disclose how you identify in terms of your gender, race, class, sexuality, religion, and dis/ability, among all aspects of your identity (e.g., should it come up in classroom conversation about our experiences and perspectives) and should be self-identified, not presumed or imposed. I will do my best to address and refer to all students accordingly, and I ask you to do the same for all your fellow Terps.

2.5 Communicating with your Peers

With a diversity of perspectives and experience, we may find ourselves in disagreement and/or debate with one another. As such, it is important that we agree to conduct ourselves in a professional manner and that we work together to foster and preserve a virtual classroom environment in which we can respectfully discuss and deliberate controversial questions. I encourage you to confidently exercise your right to free speech—bearing in mind, of course, that you will be expected to craft and defend arguments that support your position. Keep in mind, that free speech has its limit and this course is NOT the space for hate speech, harassment, and derogatory language. I will make every reasonable attempt to create an atmosphere in which each student feels comfortable voicing their argument without fear of being personally attacked, mocked, demeaned, or devalued.

Any behavior (including harassment, sexual harassment, and racially and/or culturally derogatory language) that threatens this atmosphere will not be tolerated. Please alert me immediately if you feel threatened, dismissed, or silenced at any point during our semester together and/or if your engagement in discussion has been in some way hindered by the learning environment.

2.6 Netiquette Policy

Netiquette is the social code of online classes. Students share a responsibility for the course's learning environment. Creating a cohesive online learning community requires learners to support and assist each other. To

craft an open and interactive online learning environment, communication has to be conducted in a professional and courteous manner at all times, guided by common sense, collegiality and basic rules of etiquette.

Section 3: Grade Breakdown, Grading Policy, & Assignment Breakdown

3.1 Grade Breakdown

Assignment	Percentage Weight	Description
Homework Assignments	**30%**	**Core technical engineering and analytical problem sets.**
Capstone Project (DHF)	**35%**	**Collaborative development of a rehabilitation exoskeleton.**
Final Exam	**35%**	**Comprehensive in-class assessment covering all thematic tracks**
Total	**100%**	

3.2 Course Assignments Defined

Homework Assignments (30%)

- Three (3) comprehensive homework packages distributed throughout the semester.
- Assignments require students to mathematically model, select hardware components, analyze physical interaction controls, and construct technical risk and usability controls using real-world clinical baselines.

Capstone Project: Simulated Product Realization (35%)

- A collaborative group project requiring teams to act as **medical device engineering firms**.
- Teams will select either a **hip or knee exoskeleton** optimized for neurorehabilitation following a neurologic injury (e.g., stroke or spinal cord injury).
- Deliverables culminate in a simulated **Design History File (DHF)** containing: User Needs, Design Inputs/Outputs, an ISO 14971 Risk Matrix, an IEC 62366 Usability Specification, and rigorous Bench Verification protocols modeled after the industry practices of the AMBLE system.
- During the final lecture, teams will present their completed projects using a **shared slide deck**. Each member must **individually present a specific technical component** of the DHF (e.g., design, control, risk, V&V, usability). Total presentation time will be determined based on the number of groups.
- **Simulated Corporate Design Review:** To elevate the final presentations beyond a passive academic exercise, the course utilizes a novel anonymous peer-grading framework in Week 14. Students will actively evaluate peer performance using key industry benchmarks—*Significance, Innovation, Technical Soundness, Results,* and *Applicability for Future Product Development*—transforming presentation day into a rigorous, simulated corporate design review.

Final Exam (35%)

- A comprehensive, in-class engineering examination during the finals week.
- Access to all course materials shall be allowed during the examination.

3.3 Grading of Assignments

All assignments will be graded according to a predetermined set of criteria (i.e., rubric) which will be communicated to students before the assignment is submitted.

To progress satisfactorily in this class, students need to receive timely feedback. To that end, it is my intention to grade all assignments within **1 week** of their due date. If an assignment is taking longer than expected to grade, students will be informed of when they can expect to see their grade.

3.4 Grade Computation

All assessment scores will be posted on ELMS/Canvas page. If you would like to review any of your grades (including the exams), or have questions about how something was scored, please email me to schedule a time for us to meet and discuss.

It is expected that you will submit work by the deadline listed in the syllabus and/or on ELMS-Canvas. Late work will be penalized according to the late work policy described in the **Course Policies and Procedures** section below.

Grade Disputes: I am happy to discuss any of your grades with you, and if I have made a mistake, I will immediately correct it. Any formal grade disputes must be submitted in writing and within one week of receiving the grade.

3.5 Final Grade Cutoffs

Final letter grades are assigned based on the percentage of total assessment points earned. To be fair to everyone I have to establish clear standards and apply them consistently, so please understand that being close to a cutoff is not the same as making the cut (89.99 ≠ 90.00). It would be unethical to make exceptions for some and not others.

Letter Grade	Cutoff
A+	97%
A	94%
A-	90%
B+	87%
B	84%
B-	80%
C+	77%
C	74%
C-	70%
D+	67%
D	64%
D-	60%
F	<60%

Section 4: Course Schedule & Topics

4.1 Lecture Topics

Week/ Lecture	Topic	Deliverable
Week 1/ Lecture 1	***Introduction to Medical Robotics & Regulatory Frameworks*** • Definition and regulatory scope of medical devices under the FDA and FD&C Act. • FDA risk-based classification paradigm (Class I, II, III) and commercial market implications. • Regulatory pathways to market: 510(k), Premarket Approval (PMA), De Novo, and Humanitarian Device Exemption (HDE). • Introduction to international consensus standards (IEC 60601, ISO 13485, ISO 14971) and regulatory requirements for Physiologic Closed-Loop Controllers (PCLCs). • Overview of the medical robotics industry, lower limb neurorehabilitation targets, and the AMBLE exemplar exoskeleton system.	**Homework 1 Assigned (Regulatory & Design Controls)**
Week 2/ Lecture 2	***Design & Development (D&D) Framework: Quality Systems & Core Components*** • Quality Management Systems (QMS) in medical device manufacturing: Harmonization between FDA 21 CFR Part 820 and ISO 13485. • The D&D process: Formulating User Needs (UNs) from clinical needs, translating qualitative UNs into quantitative, verifiable Design Inputs (Dis) and Outputs (DOs), Verification & Validation (V&V) for lower-limb wearable systems. • Mapping between UNs-Dis-DOs-V&V; concept of "orphan" Dis (e.g., IEC testing standard based). • Intended Use vs. Indications for Use with real-world examples. • Hardware sub-system architectures: Introduction to actuators, sensors, power supplies, and structural peripheral attachments.	**Capstone Group Formation & Device Selection**
Week 3/ Lecture 3	***Hardware Design & Modeling: Sizing, Kinematics, & Applied Parts*** • Actuator selection criteria: Torque, thrust, lead length, back-drivability, and gearless architectures (e.g., Roh'lix). • Motor selection: Evaluation of torque, RPM, inertia, and direct matching to human gait biomechanics. • Sensor selection: Integrating linear encoders based on resolution, read speed, and count frequency. • Kinematic modeling: Defining nominal actuator length based on range of motion (ROM), anthropometry, and linear displacement-to-angle estimation models. • Applied parts and structural peripherals: Materials, fastening methods, load distribution, and managing alignment/slippage for patient-specific conditions (e.g., stroke hemiplegia, SCI-related osteoporosis).	**Homework 1 Due** **Homework 2 Assigned *(Hardware Sizing)*** **Sub-System AMBLE Hardware Demo**

Week/ Lecture	Topic	Deliverable
	• *Case Study:* Establishing/performing hardware verification strategies/rig-based tests using AMBLE technical benchmarks (e.g., lead length, transmission ratio, and max thrust for threadless lead screw rigs).	
Week 4/ Lecture 4	***Physiologic Closed-Loop Control Systems (PCLCS) & Bench Verification*** • Fundamentals of Physiologic Closed-Loop Control Systems (PCLCS) under IEC 60601-1-10. • PCLC architecture: Mapping command, reference, controller output, manipulated, feedback, and physiologic variables. • Analysis of physical interaction, contact instability, coupled vs. isolated stability, and impedance/admittance control in human-robot loops. • Dynamic performance attributes: Response time, settling time, relative overshoot, steady-state deviation, tracking error, fallback mode architectures. • *Case Study:* AMBLE PCLCS bench verification: Hardware testbed setup (wooden shank-ankle-foot mockup), instrumentation (load cells, LA11 linear encoders, DAQ), and protocol execution across walking speeds, body mass variations, gait synchronization latency, disturbance rejection, and single-fault conditions (0 Nm torque drop, free-fall arc, PEMS watchdog).	*None (Work on HW2 & Capstone Proposal)*
Week5/ Lecture 5	***Interactive Design: Sizing, Plant Modeling, & Control Loop Tuning*** • Interactive design process for lower-limb wearable robots: Translating qualitative stroke patient and therapist needs into quantitative Design Inputs (DIs) and Design Outputs (DOs). • Hardware component selection and design calculations: Actuator sizing (Roh'Lix #5901 linear thrust and lead length), motor selection (Kollmorgen TBM-7631 continuous stall torque and current draw), magnetic linear encoders (Renishaw LA10B resolution and edge separation), stroke length, energetics, and 48V Li-ion battery pack capacity calculations. • Formulating the patient transfer element ("plant") using anthropometric mass moment of inertia, stiffness, and damping characteristics for hip and knee joints. • Closed-loop transfer functions and PD controller tuning (K_p, K_d) to achieve dynamic response attributes and disturbance rejection. • Drafting substantial equivalence tables for 510(k) submissions (ReWalk predicate comparison) and integrating design outputs into the ISO 14971 risk register.	**Homework 2 Due**
Week 6/ Lecture 6	***Risk Management Processes & Technical Safety Execution*** • Core principles of ISO 14971 Risk Management, ISO/TR 24971 for medical devices. • Key definitions: Mapping hazards, hazardous situations, harms, severity levels, and probabilities of occurrence (P_1, P_2).	**Homework 3 Assigned *(Risk Management & Usability)***

Week/ Lecture	Topic	Deliverable
	• Risk Management Plan (RMP) scope boundaries and populating 5×5 Risk Acceptability Matrices using the Intuitive da Vinci surgical robot exemplar. • Applying a risk-based approach across Quality Management System (QMS) processes under ISO 13485. • *Case Study:* Technical execution of risk controls in lower-limb robotics using the AMBLE Class II: Type B Applied Parts vs. Accessible Parts (IEC 60601-1 Cl. 4.6), Essential Performance limits under Normal and Single Fault Conditions (SFC), Inherent Safety by Design (rolling helix friction slip fuse at 20 Nm, kinematic stroke hard stops at $\leq 28^{\circ}$, emergency doffing < 30 s), insulation coordination (2x MOOP), 4-stage battery BMS safety, PEMS software watchdogs (IEC 62304), EMC essential vs. intended performance (IEC 60601-1-2), and E-Stop non-applicability rationales.	
Week 7/ Lecture 7	***Risk Matrix Quantification & IFU Boundary Stress-Testing*** • Quantifying the AMBLE 5×5 Risk Acceptability Matrix under ISO 14971: Decomposing probability ($P_O = P_1 \times P_2$), causal chain mapping, pre- vs. post-mitigation scoring, and deterministic risk placement. • Verifying AMBLE risk controls through V&V testing and compiling formal Benefit-Risk Analyses (BRA) for residual risks. • *Case Study* 1 — Expanding IFU from Clinic to Home: Rebuilding the risk matrix for unmonitored home environments, loss of clinician backup, mechanical entrapment hazards, ischemic tissue necrosis, and engineering controls (quick-release pull tabs, default-safe spring returns, IMU/cellular alerts). • *Case Study 2* — Expanding IFU from Stroke to Spinal Cord Injury (SCI): Analyzing T4–T12 paraplegia impairments (sensory anesthesia, Autonomic Dysreflexia) and implementing clinic design controls (capacitive pressure cuffs, load-limiting actuators, biometric vital sync). • *Case Study 3* — Global Demographics & Anthropometric Re-Sizing: Adapting hardware for East Asian markets (tibial length shift, short-stroke actuators, concentrated lever-arm torque, post-stroke osteopenia risks) and implementing adjustable mechanical hard-stops and dynamic mass/length firmware calibration.	**Capstone Project Proposal Due**
Week 8/ Lecture 8	***Usability Engineering: Process Frameworks & HFTF Exemplar Execution*** • Regulatory Standards: Frameworks governing usability engineering: FDA 21 CFR 820.30, IEC 62366-1:2015/AMD1:2020, ANSI/AAMI HE75, and FDA 2016 Human Factors Guidance. • Robotics HMI & Error Taxonomies: HMI challenges medical robotics (teleoperation mapping, 3D horizon drift, haptic loss, mode switching) and cognitive error classification (Slips, Lapses, Mistakes, Mode Confusion). • Task Analysis & Risk Control Hierarchy: Workflow deconstruction via Hierarchical Task Analysis (HTA) to isolate Critical Tasks and the FDA 3-	**Homework 3 Due**

Week/ Lecture	Topic	Deliverable
	Tier Usability Risk Control Hierarchy (Priority 1 Design → Priority 2 Interlocks → Priority 3 Training/IFU). • *Case Study:* AMBLE HFTF Exemplar — Use & UI Specs: Authoring an audit-ready Human Factors Technical File (HFTF): Use Specifications (Cl. 5.1), physical UI specs (Cl. 5.2: BOA dials, 3-tier crampons, 11-pad footswitches, 20 Nm slip clutch, 3-inch drive rod, 5-bar fuel gauge), and connector keying (Cl. 15.4.4). • Software GUI Architecture & Use-FMEA: App design controls (14 pt text, heartbeat icon, Low Power Mode lockout, pseudo-anonymous IDs), dynamic parameter guardrails (0–20° target angle, steep descent slope limits), and Use-FMEA risk mapping (Cl. 5.3: HUS-01–04). • Workflows, Checkports & Validation: Idealized 4-phase clinical workflows, the 23-Checkport Verification Matrix (V-01–V-23), 3-round formative records (Cl. 5.6), Summative Validation Protocol (Cl. 5.7/5.9: n=15 PT cohort, 24-hr washout, <30 s emergency egress TC-17, root-cause analysis).	
Week 9/ Lecture 9	***Validation Testing: Clinical Trial Design & Comparative Effectiveness*** • Fundamentals of Clinical Trial Design: Formulating clinical hypotheses, defining measurable/reproducible endpoints, and establishing intervention parameters (dosing schedule, duration, and intensity). • Causal Inference & Methodological Rigor: Counterfactual reasoning, substitute control populations, randomization mechanics, allocation concealment, and multi-tier blinding (single, double, triple-blind) to eliminate confounding biases. • Observational vs. Interventional Study Paradigms: *Observational (Cross-Sectional):* Measuring natural population characteristics (*Case Study 1*: Passive ankle stiffness in chronic stroke vs. age-matched controls). *Single-Arm Interventional:* Evaluating treatment efficacy over time (*Case Study 2*: Seated videogame-based Anklebot therapy for ankle motor control and over-ground walking speed). • Comparative Effectiveness & Multi-Arm Design: Matching baseline population variables (age, gender, deficit severity) and designing comparative trials to prove superiority or non-inferiority over standard care. • Deconstructing Landmark Rehabilitation Robotics Case Studies: *Case Study 3 (2-Arm Robot vs. Manual):* Anklebot therapy vs. dose-matched manual stretching in sub-acute stroke. *Case Study 4 (2-Arm Paradigm Comparison):* Treadmill-Integrated Robotic Training (TMR) vs. Seated Robotic Training (SRT) for foot drop, evaluating over-ground velocity, AP propulsion impulse, and AFO brace self-discard rates. *Case Study 5 (2-Arm Multi-Center RCTs):* Lokomat vs. conventional physical therapy and ankle robot ("Anklebot" plus treadmill) vs. treadmill-only. *Case Study 6 (3-Arm Multi-Site VA Trial):* MIT-Manus upper-limb robot vs. Intensive Comparison Therapy vs. Usual Care. *Case Study 7 (Dose-*	*None (Focus on Capstone DHF Development)*

Week/ Lecture	Topic	Deliverable
	Ranging Study): MIME robotic therapy across low-dose (15h), high-dose (30h), and conventional control arms. • Healthcare Economics & The "Gold Standard" Hierarchy: Conducting cost-effectiveness analyses (evaluating healthcare utilization and total cost offsets) to satisfy the 3-tier clinical evidence hierarchy (Efficacy → Comparative Effectiveness → Economic Cost-Benefit Approval).	
Week 10/ Lecture 10	***Design Validation & AMBLE Clinical Validation Study Execution*** • Principles of design validation under 21 CFR 820.30(g) and ISO 13485 for wearable medical robotics. • Structuring clinical validation trials for lower-limb exoskeletons: Defining primary and secondary clinical efficacy endpoints (10-meter walk test speed, 6-minute walk distance, cadence, step symmetry, Functional Ambulation Categories) and safety endpoints (Adverse Events, skin integrity, fall incidence). • *Case Study:* Execution of the AMBLE Class II clinical validation protocol: Patient inclusion/exclusion criteria, therapist-assisted over-ground gait retraining paradigms, session dosing, real-time telemetry data logging, and statistical hypothesis testing. • Compiling the formal Clinical Validation Report for 510(k) pre-market submissions and bridging clinical data into post-market surveillance plans.	*None (Focus on Capstone DHF Development)*
Week 11/ Lecture 11	***Capstone Project Technical Workshop & Peer-Instructor Review*** • Interactive Capstone Project Workshop and structured design review session. • Student-driven Q&A: Each student brings two specific technical or regulatory questions related to their team's capstone exoskeleton project (e.g., refining User Needs, calculating actuator/motor sizing, tuning PCLCS control laws, populating ISO 14971 Risk Matrices, or structuring IEC 62366 Usability Protocols). • Collaborative peer critique and direct instructor feedback to troubleshoot design bottlenecks, resolve technical ambiguities, and ensure full DHF alignment with FDA submission standards. • Formative review of draft Design History Files (DHFs) to prepare teams for upcoming draft submissions; final simulated corporate design review presentations.	**Capstone DHF Formative Technical Check-in**
Week 12/ Lecture 12	***The Future of Neurorehabilitation Robotics: A Physical Therapist's View*** • Clinical realities of the clinic floor: Adoption barriers, clinician skepticism, and patient engagement factors. • Application of neuroplasticity principles within robotic design: Facilitating task-specific practice, motor priming, and physiological augmentation. • Practical evaluation of how commercial device constraints impact long-term therapy outcomes.	**Capstone Project: Draft DHF Deliverable Due *(Peer Review)***

Week/ Lecture	Topic	Deliverable
Week 13/ Lecture 13	***Special Topic: Cybersecurity in Medical Robotics / Spillover Buffer*** • Guest lecture or specialized module addressing software security, data connectivity, and privacy risks in active medical devices. • Analyzing FDA pre-market cybersecurity guidelines.	**Capstone Project: Final DHF & Slide Deck Due**
Week 14/ Lecture 14	***Capstone Project Presentations & Course Wrap-up*** • Final Technical Presentation Session: Group presentations utilizing a unified slide deck. Every team member will individually present a distinct, technical aspect of their DHF (e.g., design, control laws, risk matrix, usability, or V&V strategy). Presentation times (roughly 30-45 min per group) will be allocated based on the final group count. During presentations, to encourage participation, members of other groups will anonymously grade each presenting group's performance on Significance, Innovation, Technical Soundness of Methods, Results, Applicability for Future Product Development.	**Capstone Final Presentations & Peer Evaluations**

Note: This is a tentative schedule, and subject to change as necessary. Monitor ELMS-Canvas for current deadlines. In the unlikely event of a prolonged university closing, or an extended absence from the university, adjustments to the course schedule, deadlines, and assignments will be made based on the duration of the closing and the specific dates missed.

4.2 Industry Alignment & Career Pathways

The 14-week technical sequence is deliberately structured to mirror modern, cross-functional engineering sprints found in the medical device industry. The engineering competencies, computational models, and regulatory documentation (DHF) authored in this class are explicitly designed to scale into standard commercial career tracks. Students looking to enter the medical device or robotics sectors will find that specific thematic blocks map directly onto distinct engineering functions:

- **Weeks 2–3 (Quality Systems & Mechanical Architecture):** Aligns with the core competencies required for **Electromechanical Design & Hardware Engineering** roles
- **Weeks 4–5 (Physical Interaction Control Loops):** Establishes the analytical foundations essential for **Robotics Controls & Systems Engineering** positions.
- **Weeks 6–9 (Risk Matrix & Usability Protocols):** Provides the specific compliance toolsets demanded in **Quality Assurance (QA), Regulatory Affairs (RA), and Human Factors Engineering**.
- **Weeks 11–13 (Clinical Trial Strategies & Validation):** Develops the strategic framework necessary for **Verification & Validation (V&V) and Clinical Evaluation Engineering** tracks.

Section 5: Course Policies and Procedures

The University of Maryland's conduct policy indicates that course syllabi should refer to a webpage of course-related policies and procedures. For a complete list of graduate course related policies, visit the Graduate School website. Below are course-specific policies and procedures which explain how these Graduate School policies will be implemented in this class.

5.1 Satisfactory Performance

The Graduate School expects students to take full responsibility for their academic work and academic progress. The student, to progress satisfactorily, must meet all the academic requirements of this course. Additionally, each student is expected to complete all readings and any preparatory work before each class session, come to class prepared to make substantive contributions to the learning experience, and to proactively communicate with the instructor when challenges or issues arise.

5.2 Questions about Assignments

Please ask all questions you may have about an assignment by 5PM the day before the assignment is due. Any questions asked after that time may not be answered in time for you to make changes to your work.

5.3 Late Work Policy

Assignments should be completed by the due date and time listed with the assignment, on the syllabus, and/or in the course calendar. If you are unable to complete an assignment by the stated due date, it is your responsibility to contact your instructor to discuss an extension, at least 24 hours BEFORE the assignment is due. Extensions are not guaranteed but may be granted at the instructor's discretion.

Assignments submitted late will receive a 10% deduction in total grade per each calendar day late up to a maximum of three days late (i.e., there is a maximum of a 30% grade reduction for assignments submitted late). Work submitted more than three days late will not receive feedback and will automatically earn a grade of zero.

5.4 Responsible Use of Generative AI

It is University of Maryland Policy and the expectation of MAGE that instructors clearly communicate with their students regarding AI usage in their course. Please use this space to clearly specify your policy on AI use in your class. What (if any) Generative AI use is permitted, and what is not? University policy also dictates that you include mention of university approved tools and provide your students with a link to those tools. Below is a sample AI policy that you can edit for your needs. Consider also, specifying appropriate AI use for each of your assignments in the Academic Integrity Chart located in the Academic Integrity section below.

SAMPLE GENERATIVE AI POLICY: Generative AI tools (e.g., ChatGPT, GitHub Copilot, etc.) are becoming increasingly common in engineering education and in the workplace. In this course, students are expected to use AI technologies ethically and in ways that support learning, uphold academic integrity, and align with course objectives.

Permitted Uses of AI Tools in This Course

Students may use generative AI tools for the following purposes:

- *Brainstorming initial ideas or outlining for assignments*
- *Getting help understanding difficult engineering concepts (e.g., asking for explanations or examples)*
- *Writing assistance at the sentence level (e.g., grammar or clarity improvements)*
- *Debugging support in coding assignments, provided students still understand & can explain their code*

Prohibited Uses of AI Tools in This Course

Students may not use generative AI tools for:

- *Completing graded assignments, problem sets, or projects unless explicitly permitted*
- *Generating solutions to coding or engineering problems without understanding and verifying the output*

- *Writing full sections of reports, papers, or lab assignments*
- *Submitting AI-generated work as their own without proper citation or instructor approval*

It is the student's responsibility to make sure any use of AI aligns with the expectations outlined above. Misuse of AI tools may constitute academic dishonesty and will be addressed accordingly (see section on academic integrity, below). Lastly, please become familiar with the University-approved AI tools and university guidelines on responsible AI use. If you are unsure whether a particular use of AI is appropriate, please ask before proceeding.

5.4 Religious Observance

It is the student's responsibility to inform the instructor of any intended absences for religious observances in advance. Notice should be provided as soon as possible but no later than the end of the schedule adjustment period.

5.5 Academic Integrity

For this course, some of your assignments will be collected via Turnitin on ELMS/Canvas. I have chosen to use this tool because it can help you improve your scholarly writing and help me verify the integrity of student work. For information about Turnitin, how it works, and the feedback reports you may have access to, visit Turnitin Originality Checker for Students

The University's Code of Academic Integrity is designed to ensure that the principles of academic honesty and integrity are upheld. In accordance with this code, the University of Maryland does not tolerate academic dishonesty. Please ensure that you fully understand this code and its implications because all acts of academic dishonesty will be dealt with in accordance with the provisions of this code. All students are expected to adhere to this Code. It is your responsibility to read it and know what it says, so you can start your professional life on the right path. **As future professionals, your commitment to high ethical standards and honesty begins with your time at the University of Maryland.**

It is important to note that course assistance websites, such as CourseHero, or AI generated content are not permitted sources, unless the instructor explicitly gives permission. Material taken or copied from these sites can be deemed unauthorized material and a violation of academic integrity. These sites offer information that might be inaccurate or biased and most importantly, relying on restricted sources will hamper your learning process, particularly the critical thinking steps necessary for college-level assignments.

Additionally, students may naturally choose to use online forums for course-wide discussions (e.g., Group lists or chats) to discuss concepts in the course. However**, collaboration on graded assignments is strictly prohibited unless otherwise stated**. Examples of prohibited collaboration include asking classmates for answers on quizzes or exams, asking for access codes to clicker polls, etc. Please visit the **Office of Graduate Studies' full list of campus-wide policies** and reach out if you have questions.

Finally, on each exam or assignment you must write out and sign the following pledge: ***"I pledge on my honor that I have not given or received any unauthorized assistance on this exam/assignment."***

If you ever feel pressured to comply with someone else's academic integrity violation, please reach out to me straight away. Also, ***if you are ever unclear*** about acceptable levels of collaboration, ***please ask***!

To help you avoid unintentional violations, ***the following table*** lists levels of collaboration that are acceptable for each graded exercise. Each assignment will contain more specific information regarding acceptable levels of collaboration.

Assessment	 OPEN NOTES	 READ BOOK	 LEARN ONLINE	 GATHER CONTENT WITH AI	 ASK FRIENDS	 WORK IN GROUPS
Homework Assignments	✔		✔	X	X	X
Capstone Project	✔		✔	✔	✔	✔
Final Exam	✔		X	X	X	X

5.6 Course Evaluation

Please submit a course evaluation through Student Feedback on Course Experiences in order to help faculty and administrators improve teaching and learning at Maryland. All information submitted to Course Experiences is confidential. Campus will notify you when Student Feedback on Course Experiences is open for you to complete your evaluations at the end of the semester. Please go directly to the **Student Feedback on Course Experiences** to complete your evaluations. By completing all of your evaluations each semester, you will have the privilege of accessing through Testudo the evaluation reports for the thousands of courses for which 70% or more students submitted their evaluations.

5.7 Copyright Notice

Course materials are copyrighted and may not be reproduced for anything other than personal use without written permission.

6. Tips for Succeeding in this Course

1. **Participate.** I invite you to engage deeply, ask questions, and talk about the course content with your classmates. You can learn a great deal from discussing ideas and perspectives with your peers and professor. Participation can also help you articulate your thoughts and develop critical thinking skills.
2. **Manage your time.** Students are often very busy, and I understand that you have obligations outside of this class. However, students do best when they plan adequate time that is devoted to course work. Block your schedule and set aside plenty of time to complete assignments including extra time to handle any technology related problems.
3. **Login regularly.** I recommend that you log in to ELMS-Canvas several times a week to view announcements, discussion posts and replies to your posts. You may need to log in multiple times a day when group submissions are due.
4. **Do not fall behind.** This class moves at a quick pace and each week builds on the previous content. If you feel you are starting to fall behind, check in with the instructor as soon as possible so we can troubleshoot together. It will be hard to keep up with the course content if you fall behind in the pre-work or post-work.
5. **Use ELMS-Canvas notification settings.** Pro tip! Canvas ELMS-Canvas can ensure you receive timely notifications in your email or via text. Be sure to enable announcements to be sent instantly or daily.
6. **Ask for help if needed.** If you need help with ELMS-Canvas or other technology, IT Support. If you are struggling with a course concept, reach out to me and your classmates for support.

7. Student Resources and Services

Taking personal responsibility for your learning means acknowledging when your performance does not match your goals and doing something about it. I hope you will come talk to me so that I can help you find the right approach to success in this course, and I encourage you to visit the Counseling Center's Academic Resources to learn more about the wide range of resources available to you. Below are some additional resources and services commonly used by graduate students. For a more comprehensive list, please visit the Graduate School's Campus Resources Page.

7.1 Accessibility and Disability Services

The University of Maryland is committed to creating and maintaining a welcoming and inclusive educational, working, and living environment for people of all abilities. The University of Maryland is also committed to the principle that no qualified individual with a disability shall, on the basis of disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of the University, or be subjected to discrimination. The Accessibility & Disability Service (ADS) provides reasonable accommodations to qualified individuals to provide equal access to services, programs and activities. ADS cannot assist retroactively, so it is generally best to request accommodations several weeks before the semester begins or as soon as a disability becomes known. Any student who needs accommodations should contact me as soon as possible so that I have sufficient time to make arrangements.

For assistance in obtaining an accommodation, contact Accessibility and Disability Service at 301-314-7682, or email them at adsfrontdesk@umd.edu. Information about sharing your accommodations with instructors, note taking assistance and more is available from the Counseling Center.

7.2 Writing Center

Everyone can use some help sharpening their communication skills (and improving their grade) by visiting The Graduate School's Writing Center and schedule an appointment with them. Additionally, international graduate students may want to take advantage of the Graduate School's free English Editing for International Graduate Students (EEIGS) program.

7.3 Health Services

The University offers a variety of physical and mental health services to students. If you are feeling ill or need non-emergency medical attention, please visit the University Health Center.

If you feel it would be helpful to have someone to talk to, visit UMD's Counseling Center or one of the many other mental health resources on campus.

7.4 Notice of Mandatory Reporting

Notice of mandatory reporting of sexual assault, sexual harassment, interpersonal violence, and stalking: As a faculty member, I am designated as a "Responsible University Employee," and I must report all disclosures of sexual assault, sexual harassment, interpersonal violence, and stalking to UMD's Title IX Coordinator per University Policy on Sexual Harassment and Other Sexual Misconduct.

If you wish to speak with someone confidentially, please contact one of UMD's confidential resources, such as CARE to Stop Violence (located on the Ground Floor of the Health Center) at 301-741-3442 or the Counseling Center (located at the Shoemaker Building) at 301-314-7651.

You may also seek assistance or supportive measures from UMD's Title IX Coordinator, Angela Nastase, by calling 301-405-1142, or emailing titleIXcoordinator@umd.edu.
To view further information on the above, please visit the Office of Civil Rights and Sexual Misconduct's website at ocrsm.umd.edu.

7.5 Basic Needs Security

If you have difficulty affording groceries or accessing sufficient food to eat every day, or lack a safe and stable place to live, please visit UMD's Division of Student Affairs website for information about resources the campus offers you and let me know if I can help in any way.

7.6 Veteran Resources

UMD provides some additional supports to our student veterans. You can access those resources at the office of Veteran Student life and the Counseling Center. Veterans and active duty military personnel with special circumstances (e.g., upcoming deployments, drill requirements, disabilities) are welcome and encouraged to communicate these, in advance if possible, to the instructor.