

Bioengineering MS Capstone Course sequence

The Bioengineering MS Capstone is a three quarter-long course sequence (BIOE 294, 295, 296) where students identify unmet clinical needs, develop and prototype innovative solutions, and work to translate them into market-ready biomedical products. The sequence emphasizes real-world problem solving through user-centered design, regulatory strategy, and commercialization planning. Students conclude the experience by defending their work through a written report and/or an oral presentation, as determined by their advisor. Regardless of format, students are expected to highlight their technical contributions and rigor while demonstrating the application of core bioengineering principles in real-world contexts.

The following sections outline the course descriptions, learning objectives, and key deliverables for each stage of the capstone experience. They also provide guidance to students in the translational track on the expected content and format of their capstone project.

BIOE 294: Needs Identification and Opportunity Framing

The first course of a three-course sequence in which students undertake a year-long project to design and construct a bioengineering device or system. The course focuses on identifying an unmet bioengineering need and developing a clear problem definition. Students conduct a high-level assessment of the clinical landscape, including disease state fundamentals, current treatment options, and opportunities for innovation. Key topics include strategic focus, needs finding through observation, and crafting well-defined demand statements.

Learning Objectives.

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

- Identify and assess unmet clinical needs through observations, literature, and stakeholder input.
- Analyze disease states and treatment landscapes to define biomedical problems and develop a focused demand statement with user needs and design constraints.
- Evaluate the clinical and commercial relevance of biomedical needs and communicate opportunity assessments.

Course Deliverables

- Overview of the clinical need, stakeholder analysis, and disease state.
- Final needs statement with defined user requirements, design criteria, and a preliminary project charter.
- Justification of the selected biomedical need and its clinical and commercial relevance.

BIOE 295: Concept Generation and Prototyping

The second course in a three-quarter sequence focused on the year-long design and development of a bioengineering device or system. Building on the need identified in BIOE 294, this course emphasizes the development and evaluation of conceptual solutions related to

pharmaceutical, biotechnological, drug delivery, or medical device challenges. Students engage in ideation, concept screening, computer-aided design, and prototyping to explore and refine potential solutions. Key focus areas include brainstorming, prototyping, and final concept selection.

Learning Objectives.

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

- Translate identified biomedical needs into actionable design inputs and user-centered criteria.
- Generate, evaluate, and iterate on multiple solution concepts using structured methods and early-stage prototyping.
- Select and refine a final concept based on technical feasibility, user feedback, and alignment with clinical and commercial relevance.

Course Deliverables

- Design documentation, including user needs, design inputs, and concept development.
- Concept evaluation and selection, supported by screening analysis and stakeholder feedback.
- Prototype demonstration, including technical feasibility results and design refinement summary.

BIOE 296: Product Development and Translation

The third course in a three-part sequence focuses on translating a conceptual biomedical design into a product ready for clinical use. Students develop, test, and validate their prototype while addressing real-world constraints such as quality systems, reimbursement, marketing, stakeholder strategy, financial modeling, and business planning. By the end of the course, students will understand how to advance a biomedical innovation from prototype to a market-ready solution.

Learning Objectives.

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

- Translate a conceptual prototype into a functional product through iterative development, testing, and validation.
- Prepare regulatory, quality, and risk assessment aligned with translational and clinical use requirements.
- Develop an integrated commercialization strategy encompassing business models, reimbursement, and a compelling product pitch.

Course Deliverables

- Validated functional prototype, including testing results, regulatory summary, and risk analysis.

- Integrated commercialization plan encompassing market strategy and intellectual property considerations.
- Final capstone report or pitch presentation integrating technical, regulatory, and business components for faculty and stakeholder review.

Please note that the final format of the report (written report or oral presentation) may be influenced by factors such as intellectual property (IP), non-disclosure agreements (NDAs), or the project's scope.