

MEDICAL DEVICE DEVELOPMENT (MDD)

College of Engineering

MDD 401 – Introduction to Product Development (3 units)

Course Description: Product development process and design controls embedded within. Clinical/customer needs finding and screening using principles of the Biodesign process and clinical exposure. Establishing a business case through market analysis, intellectual property, and reimbursement considerations. Case studies of medical devices and drug/device combination products illustrate the product life cycle.

Learning Activities: Lecture 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 402 – Advanced Product Development (3 units)

Course Description: Concept selection, design, prototype manufacturing, initial testing, iteration, and product and process verification and validation activities. Reducing risk throughout the product development stages. US and OUS regulatory options and the design of clinical trials including treatment groups, control groups, and sample sizes.

Prerequisite(s): MDD 401.

Learning Activities: Lecture 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 403 – Manufacturing Readiness, Optimization & Post Market Support (3 units)

Course Description: Manufacturing readiness strategies employed in the medical device and life science industries, including contract manufacturing. Tools to reduce manufacturing waste and variation, including Lean Six Sigma. Regulatory requirements for quality assurance through quality management systems. Post-market activities including complaint investigation and reporting, FMEA impacts, clinical trial support and closure, and product obsolescence.

Learning Activities: Lecture 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 411 – Business Leadership for Engineers I (3 units)

Course Description: Latest technologies and practices in the medical devices industry. Business context within which companies operate in the medical devices industry. Basic psychological and social psychological processes shaping human behavior and application of these processes to the following organizational problems: motivation, job design, commitment, socialization, culture, individual and group decision-making, and team building.

Learning Activities: Lecture 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 412 – Business Leadership for Engineers II (3 units)

Course Description: Managing innovative enterprise in changing and uncertain environments. Technology forecasting and assessment, program selection and control, financial management, regulation, and ethics. Strategic management of organizations, including analysis of industries, firm resources and capabilities and corporate strategy. Strategy formulation, implementation and strategic decision-making. Firm and industry life cycles and change.

Learning Activities: Lecture 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 413 – Business Leadership for Engineers III (3 units)

Course Description: Corporate financial policy and investment management. Capital budgeting and cost-of-capital determination. Valuation principles for investments with long-lived and risky cash-flows. Theory of negotiation; application of theory to process of building teams to achieve business purposes. Integrative and distributive strategies of claiming value, recognizing bargaining tricks, uncovering hidden agendas, and brainstorming to extend Pareto frontier.

Learning Activities: Lecture 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 421 – Engineering Skills I: Computer Aided Design & Simulation (3 units)

Course Description: Essential engineering skills driven by modern computing including computer aided design (CAD), numerical simulation, and coding in Python. Advanced CAD skills focused on design intent and manufacturability, implementation and testing of engineering design concepts using finite element methods. Application of simulation and optimization techniques integrated in CAD software to analyze physical phenomena such as fluid and solid mechanics in medical devices.

Prerequisite(s): Introductory CAD course or prior equivalent industry experience required (SolidWorks preferred); engineering math recommended; one or more of the following recommended: transport phenomena, fluid dynamics, mechanics.

Learning Activities: Lecture/Discussion 2 hour(s), Laboratory 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 422 – Engineering Skills II: Electronics, Microcontrollers, & Coding (3 units)

Course Description: Electronic circuit design, analysis, and prototyping. Programming of commonly used microcontrollers or single board computers (SBCs) for use in medical device applications. Artificial intelligence and machine learning in the medical device and healthcare industries. CAD tools and PCB prototyping to realize simple designs.

Prerequisite(s): MDD 421; introductory course on engineering circuits or electronics required; introduction to coding recommended (Python preferred)

Learning Activities: Lecture/Discussion 2 hour(s), Laboratory 3 hour(s).

Grade Mode: Letter.

MDD 423 – Engineering Skills III: Prototyping (3 units)

Course Description: Essential skills required for prototyping medical devices. Rapid prototyping techniques including 3D printing, soft lithography, laser cutting and etching, 3D scanning, medical modeling from imaging data. Leveraging CAD and simulation skills to design for fabrication by rapid prototyping. Projects include enclosure design and assembly for electronic assembly.

Prerequisite(s): MDD 421; MDD 422.

Learning Activities: Lecture/Discussion 2 hour(s), Laboratory 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 431 – Capstone Project I: Introduction to Clinical Needs & Operations (3 units)

Course Description: Principles of medical device innovation, with exposure to hospital and clinical operations. Needs finding and needs screening based on real-world unmet needs. Identification of potential solutions based on needs refinement and operational constraints to secure topics for capstone projects.

Learning Activities: Lecture/Discussion 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 432 – Capstone Project II: Product Concept Development (3 units)

Course Description: Teams apply product development, business leadership and engineering content to propose, implement, and verify a concept solution for their capstone project. Application of business and engineering principles and design theory to deliver initial prototypes that could meet client needs under operational constraints.

Prerequisite(s): MDD 431.

Learning Activities: Lecture/Discussion 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.

MDD 433 – Capstone Project III: Commercialization & Development Strategy (3 units)

Course Description: Develop a commercialization plan for their capstone product concept. Regulatory strategy, reimbursement options, and intellectual property protection integrated with technical feasibility assessment around focused clinical needs. Written and oral communication, and relevant professional and ethical responsibilities.

Prerequisite(s): MDD 432.

Learning Activities: Lecture/Discussion 3 hour(s).

Enrollment Restriction(s): Open to Medical Device Development majors only.

Grade Mode: Letter.