

MEDE 6310 Identification of Medical Engineering Opportunities – Clinical Rotations I (3 credits, 7.5 weeks)

This course immerses students in the clinical environment to identify opportunities for innovation and improvement. Students rotate through multiple clinical rotations and become part of a team consisting of senior clinicians, surgeons, residents, nurses and medical technologists. Students learn to identify unmet health care delivery needs through direct observations, interviews, literature surveys, and more. Throughout the semester students will vet their findings to differential teams to ultimately uncover unmet healthcare device/delivery needs for future work. Concurrently, students learn the process of assessing market size, intellectual property regulatory framework, and competitor dynamics.

MEDE 6320 Identification of Medical Engineering Needs and Specifications – Clinical Rotations II (3 credits, 7.5 weeks)

This course builds upon MEDE 6310 (Identification of Medical Engineering Opportunities – Clinical Rotations I) by having the student select an unmet healthcare device/delivery needs and then scrutinize factors such as clinical impact, commercial viability and technical feasibility to determine an opportunity on which to focus. During the course of the semester students are required to define technical specifications that engineering solutions would have to meet for a viable solution to be confirmed by all stakeholders (patients, doctors, nurses, hospital administration, etc). Once the needs and specifications are understood, the student will have an opportunity to continue the product development cycle by developing models.

MEDE 6330 Medical Engineering Innovation and Concept Generation (3 credits, 15 weeks)

This course is designed to highlight keys to product/process innovation. Topics in this hands-on course include: creativity methods, visualization techniques, anthropological research, SWOT analysis, market research, product concept development and design, risk analysis for product innovation, product development strategies for new designs, and distribution alternatives.

MEDE 6340 Medical Engineering Modeling and Testing (3 credits, 15 weeks)

In this course, students will use an integrated interdisciplinary approach to engineering design, concurrent engineering, design for manufacturing, and industrial design for new product development. Topics include design methods, philosophy and practice, the role of modeling and prototyping, decision making, risk, cost, materials, manufacturing process selection, platform and modular design, quality, planning and scheduling, and creativity and innovation.

MEDE 6350 Regulation of Medical Devices (3 credits, 15 weeks)

This course introduces students to the regulatory framework as it pertains to bringing a medical device from concept to market. Topics include: FDA design controls, regulatory approval mechanisms (including the 510k and PMA process), investigational device

exemption, planning clinical trials, clinical trial ethics, and post market surveillance. Students learn through a series of invited lectures from professionals in the medical device industry, clinical trialists, and ethicists

MEDE 6360 Intellectual Property Creation and Management (3 credits, 15 weeks)

This course introduces students to intellectual property issues. Topics covered include: confidentiality, nondisclosures, agreements not to compete, founders' agreements, patents, copyrights, trademarks, and trade secrets.

MEDE 7320 Medical Engineering Design Project (3 credits)

This course provides the student opportunities to research and develop a product or process under the direction of a faculty advisor. The design project is a scholarly process that addresses a clinically relevant problem in medical engineering. The project examines the most current evidence and applies it to a clinical situation. The project is written as a manuscript, which is expected to be submitted for publication in a peer-review journal.

MEDE 7330 Medical Engineering Design Thesis (1-6 credits, 6 credits total)

This course provides the student opportunities to research and develop a product or process under the direction of a faculty advisor. The design thesis is an independent research work that includes designing a study and performing the aspects of the research process in the development of a medical engineering device or process. The thesis addresses a knowledge gap and results in clearly defined new knowledge through the concurrent development of a product or process.

Specialty Track Courses

Students in the MedE program will have to take 3 specialty track courses during their program. The courses a student will take will be determined by their technical advisor and Program Chief or his/her designee. The specialty courses are taken at College of Engineering and Applied Sciences at Western Michigan University.