**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 device and process innovation and improvement. Students rotate through multiple clinical rotations and work as 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 faculty mentorship. Throughout the course students vet their findings with interprofessional teams to ultimately uncover unmet healthcare device, process, and 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 & Specifications – Clinical Rotations II (3 credits, 7.5 weeks)**

This course builds upon MENG 6310 (Identification of Medical Engineering Opportunities – Clinical Rotations I). The student selects an unmet healthcare device, process, or delivery need, and scrutinizes factors such as clinical impact, technical feasibility, and commercial viability to determine an opportunity on which to focus. During the course students are required to define technical specifications that engineering solutions would have to meet for a viable solution, which is confirmed by all stakeholders (ie, patients, doctors, nurses, hospital administration). Once the needs and specifications are understood, the student has an opportunity to continue the product development cycle by developing models and prototypes.

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

This is a hands-on course that highlights keys to product and process innovation. Topics 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 & Testing (3 credits, 15 weeks)**

This course provides students with 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 analysis, 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 & Management (3 credits, 15 weeks)**

This course introduces students to intellectual property issues. Topics covered include: confidentiality, nondisclosures, non-compete agreements, founders’ agreements, patents, copyrights, trademarks, trade secrets, licensing, funding, and commercialization.

**MEDE 7310 Specialty Track Classes (3 credits each, 15 weeks each)**

Specialty track courses strengthen the student’s understanding of a specific engineering topic area. Students may select from one of three specialty tracks: 1) Biomechanics and Biomaterials; 2) Biological Signal Processing, Sensors, and Instrumentation; or 3) Healthcare Systems Engineering.

**Biomechanics and Biomaterials**

The biomechanics and biomaterials track introduces the fundamental concepts in ergonomics, musculoskeletal mechanics, and tissues. It also applies novel uses of materials in medicine, dentistry, and other healthcare fields. Students may design, assess, and evaluate medical devices. This track also provides opportunities for modeling, simulation, and experimentation.

**Biological Signal Processing, Sensors, and Instrumentation**

Students study topics critical in medical engineering applications ranging from sensing, device design and fabrication, and processing of biological signals to molecular interactions and transport processes. Application areas include medical imaging and pattern recognition, medical instrumentation, diagnostics, drug delivery, and biosystems.

**Healthcare Systems Engineering**

Students learn how to apply relevant systems engineering tools in healthcare settings. This includes tools for systems analysis and design, planning and implementation, performance monitoring, and continuous improvement. Students build competencies in health systems modeling and analysis, human factors, patient safety, quality improvement, and advanced cost analysis.

**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-reviewed journal.

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

This course provides the student the opportunity 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.