



MS MedTech Curriculum 2023-24

Summer

BME 501 MedTech Innovation and Entrepreneurship I – Needs Discovery (4 hrs)

This course utilizes clinical immersion to identify medical device and other healthcare opportunities. Students will be exposed to diverse healthcare environment and learn to quickly triage opportunities based on financial, regulatory and intellectual property landscapes. An integrated seminar series will feature experts in the medical device, pharmaceutical and healthcare industries as well as local entrepreneurs.

Fall

BME 502 MedTech Innovation and Entrepreneurship II – Design & Innovation (4 hrs)

This course teaches iterative innovation processes focused on medical device and pharmaceutical development. Students will walk through a product development process including ideation, prototype creation, experimentation, supporting design and risk documentation, with an eye towards verification and validation testing to support a regulatory submission. Specifically, students will learn how to identify and quantify opportunities based on customer desired outcomes and to translate these outcome statements into user and functional requirements to create criteria against which solutions can be evaluated. Using a framework for identifying uncertainty and risk, students will develop a series of iterative prototypes, each aimed at reducing specific risks or converting uncertainties to facts. Finally, students will develop a minimum “awesome” product and the documentation required to evaluate that product to support submission to a regulatory body for market entry.

BME 504 Medical Device Materials and Manufacturing (3hrs)

This prototyping course will immerse students in state-of-the-art medical device materials and manufacturing methods. Students will explore metals and polymers that are commonly used in medical devices. The course will also introduce common manufacturing methods and design guides for each material. Students will be responsible for the design and manufacture of components and subassemblies to demonstrate an understanding of the techniques.

MBA 576 Technology Evaluation and Commercialization I (3 hrs)

Evaluation of a portfolio of technologies to determine the best alternatives for commercialization through technology based high growth new business startup. Includes technology portfolio analysis, development of technology-product-market linkages and creation of value propositions.

OR MBA 848A: StartUp-UNC I: Feasibility I (1.5 hrs)

Feasibility I covers the initial development of an innovative product or service idea. Students will use Lean Canvas to validate the customer need and assess the product-market fit.

MBA 848B: StartUp-UNC II: Feasibility II (1.5 hrs)

Feasibility II continues to develop and refine the product or service idea explored in Mod 1. Additional students will be added to the teams, bringing complementary skills. Mod II will include continued effort to understand the product and offering that will solve a real customer problem.

BEC 575 Global Regulatory Affairs for Medical Products (3 hrs)

This lecture-based course introduces students to the quality systems used to meet the regulatory requirements for developing, testing, manufacturing, and selling medical products in the global marketplace. It provides a general background for those going into the medical products field, but is especially useful to students preparing for a career in the Regulatory Affairs or Quality Assurance Department within a pharmaceutical, biomanufacturing, or medical device company. BEC 575 students must have graduate standing.

Spring

BME 503 MedTech Innovation and Entrepreneurship III – Product Development (4 hrs)

This course covers project management for new biomedical-related products from accessing various streams of funding to allocation of resources for rapid prototyping and scale-up manufacturing. Students will participate in frequent visits to local biotech companies and prototyping facilities. An integrated seminar series will feature best practices from entrepreneurs and industry practitioners.

MBA 577 Technology Evaluation and Commercialization II (3 hrs)

This course is a continuation of MBA/MSE 576. Topics include refinement of technology-product-market linkages, development of Voice of Customer data and analysis, continued development of a strong business plan suitable for funding opportunities as a new business startup.

OR

MBA 848C: StartUp-UNC III: Strategy (1.5 hrs)

In the Strategy phase, teams will refine their product development plan, establish their business model, develop their marketing and sales strategy, establish their management team priorities and develop their financial projections. It is assumed that teams have mostly completed work on their product, made their segment choices and have interacted with customers during the previous Feasibility phase.

MBA 848D: StartUp-UNC IV: Financing (1.5 hrs)

The objective of this final phase of StartUp-UNC is to develop a refined business plan that is ready to expose to sources of capital and to the market. This course will initially focus on the gaps in your draft business plan that was submitted in March. We will then provide an understanding of how funding sources evaluate startups and expose you to qualified experts in the world of startup funding. The Financing Phase builds cumulatively upon the market content and financial models presented in the Feasibility and Strategy phases. It prepares students for the process of forming the legal structure for their venture and launching their business idea.

BME 650 Internship in Biomedical Engineering or MBA Elective (3hrs)

Students can choose between BME 650, which requires completion of an internship with a medical technology company/consultancy, or 3 credit hours of MBA electives from the 'Elective and Practicum' courses in the Poole College of Management at NC State or from the 'Strategy and Entrepreneurship' track in the Kenan-Flagler Business School at UNC-Chapel Hill.

Technical Elective (select one course: 3hrs)

This elective will allow each student to acquire in-depth knowledge in an area of their choosing. Students will select a minimum of three credit hours of 500-level or 700-level technical coursework from the following course prefixes: BME, CHE, CE, ECE, ISE, MSE, MAE, or NE as approved in conjunction with the program advisor.