

Biomedical Device Development

The objective of the graduate certificate in Biomedical Device Development is to address the clinical evaluation, regulatory, and commercial aspects of medical device development. It has been widely recognized by our industrial advisors, recent graduates, and industry adjuncts that having knowledge in this area is paramount to building a successful career as a biomedical engineer. The department of biomedical engineering currently offers several online-hybrid courses that address this need as part of our MS program in Biomedical Engineering. Enrollment in these courses and feedback by students has been overwhelmingly positive.

Who would be suited to take this program?

Working professionals in the biomedical engineering and related industries in the New Jersey area. Areas include manufacturing, universities, hospitals, research facilities of companies and educational and medical institutions, and government regulatory agencies.

What will I learn?

- *Systems Management for Medical Devices* - A detailed overview of Project Management techniques and methods applied to medical devices and the integration of medical device Design Controls from 21 CFR820.30. General knowledge from the field of Project Management will be conveyed from the perspective of engineering or science personnel in the industrial medical field, particularly with regard to FDA Quality System Regulations (QSR), ISO 13485 guidelines, and Good Clinical Practices (GCP's) for running clinical trials. Students will also take part in practical problem solving simulations based on real-world examples of medical device project anomalies. The combination of specialized project management knowledge for a heavily regulated area and realistic classroom simulation will provide a basis for those interested in commercial medical device development.
- *Medical Device Development* - A detailed overview of medical device development from a realistic industrial and academic perspective. The processes used in corporations and academic laboratories to conceive and develop devices will be explored from a research, regulatory, clinical, QA/QC, marketing, engineering, and legal perspective under the umbrella of project management techniques. Material will be presented as an aide to students who wish to decide on careers in either industry or academia.
- *Advanced Medical Device Development* - Exploring the primary events that occur from just before "design freeze" of a medical device up through clinical evaluation and commercial launch. Significant emphasis is placed on Quality Systems and Manufacturing, with attention to regulatory and legal compliance as well as design concepts.
- *Orthopedic Medical Devices* - A detailed discussion of biomaterials, biomechanics and medical devices in the Orthopedic therapeutic area. Medical devices discussed include soft and hard tissue fixation and repair devices, tissue engineered constructs and orthobiologics. Current industry and market trends in these areas will be explored and discussed. The regulatory landscape of medical device design and approval will be covered.

Why study Biomedical Device Development at NJIT?

The biomedical device industry is currently on the precipice of becoming more independently operated and developed by smaller entities going forward. There are expectations of industry mergers and acquisitions (<http://www.meddeviceonline.com/doc/healthcare-trends-that-will-transform-medtech-in-0001/>) headed into the near future as the industry fully develops. The current job titles most interested in this field would be:

- Quality Process Engineer
- Systems Engineer
- Production Engineer
- Staff engineer, Manufacturing
- Product Manager
- Project Engineer
- R&D Project Engineer
- Verification Engineer
- Medical Device Engineer
- Medical Device Reporting Supervisor
- Medical Device Sales
- Medical Device Validation Engineer
- Compliance Engineer
- Hardware-Electronics Engineer, Medical Devices

In addition, holders of this graduate certificate may find employment in the following industries: Health Care, Health Sciences, Bio-Medical Engineering, medical device industry, pharmaceutical industry, and other life science related industries

Prerequisites

An undergraduate degree in engineering, with an undergraduate cumulative grade point average (GPA) of at least 3.0 on a 4.0 scale is required. Applicants with a science degree and relevant industrial experience may be considered for conditional admission. Applicants with a GPA below 3.0 but at least 2.8, may also be conditionally admitted to the program. Conditions may involve completion of a bridge program designed on a case-by-case basis.

Related Degree Programs

The certificate program in Biomedical Device Development can convert to an MS in Biomedical Engineering (<http://catalog.njit.edu/graduate/newark-college-engineering/biomedical/ms/>). Students who have completed an undergraduate degree in biomedical engineering may apply all certificate courses with a minimum final grade of B to the MS in BME. All other students may apply up to 2 certificate courses to the MS in BME.

What are the Required Courses?

Code	Title	Credits
Core Courses		
BME 682	System Mgmt for Medical Device	3
BME 684	Medical Device Development	3
BME 698	Selected Topics	3
BME 698	Selected Topics	3