About the **SCHOOL OF ENGINEERING AND APPLIED SCIENCE**

http://go.gwu.edu/seasgradprograms

The School of Engineering and Applied Science is one of the leading research institutions in the United States, boasting more than 90 tenured and tenure-track faculty members, and housing 11 research centers and institutes. We also house 55 research facilities and laboratories in 30 research fields. The school offers a breadth of expertise in 10 major engineering and computer science disciplines with an array of focus areas in each.

**REGULATORY BIOMEDICAL ENGINEERING (M.Eng.)**

The Department of Biomedical Engineering (BME) at the George Washington University’s School of Engineering and Applied Science (SEAS) is pleased to offer the Master of Engineering in Regulatory Biomedical Engineering (rBME).

**Why rBME?**

There is a strong need for today’s biomedical engineers to know the fundamentals of regulatory science in order to advance medical devices, imaging diagnostics, and therapy. Translation of biomedical discoveries to lifesaving therapies requires sophisticated human resources and infrastructure in academic and business institutions to match the rapidly evolving landscape.

Students with training in engineering, physics, and/or relevant industry and government experience study the fundamentals of biomedical engineering global regulatory affairs, regulatory strategy in the development of devices and diagnostics, regulatory compliance, engineering patent law, medical measurements, and instrument design.

**Program Overview**

This program seeks to meet the national and international need for engineers trained in biomedical innovation, entrepreneurship, and regulatory science. In addition to coursework in regulatory law, compliance, and global regulatory affairs, students gain experience in SBIR/STTR grant applications and/or FDA Premarket Notification (510(k)) submissions for medical devices. Consequently, students who complete this program acquire the skill sets of professional engineers with 5–7 years of experience, making them competitive in the job market for medical devices or imaging industries.

Graduates will be prepared to create new startup companies, provide in-house regulatory expertise to device companies, or join government regulatory and compliance institutions.

**Curriculum**

This program requires 30 credits for completion. Full-time students will require 12–24 months to complete the program, including the summer semester. Students may also complete the program part-time.

The 30 credits are distributed into four areas:

- Biomedical engineering coursework and practicum (12 credits)
- Regulatory issues (9 credits)
- Regulatory law for engineers (3 credits)
- Targeted electives from various disciplines (6 credits), including: computer science, patent law, engineering management, telecommunications, and mechanical and aerospace engineering.
Sample of Courses Offered

- Regulatory Law: Medical Devices
- Biomaterials
- Clinical Medicine for Engineers
- Computer Security
- Data Analysis for Engineers and Scientists
- Decision Making with Uncertainty
- Information Policy
- Introduction to Global Regulatory Affairs
- Introduction to Medical Imaging Methods
- Medical Instrument Design
- Medical Measurements
- Patent Law for Engineers
- Regulatory Compliance
- Regulatory Strategy in the Development of Devices and Diagnostics
- Rehabilitation Medicine Engineering
- Techniques of Risk Analysis and Management
- Telecommunication Security
- Tissue Engineering

Faculty Composition

Faculty for the rBME program come from various disciplines not only within SEAS, but also the GW School of Medicine and Health Sciences. Instruction is augmented by officers from the Food and Drug Administration, National Institutes of Health, and other government regulatory and compliance offices, as well as lawyers who specialize in FDA compliance and regulatory issues.

Admissions Requirements

In addition to a background in engineering, physics, and/or relevant industry or government experience, the ideal candidate for this program should demonstrate interest in accelerating their career in companies that produce medical or imaging devices; starting a new company in this field; or joining a government regulatory agency.

A completed online application form requires the following documents:

- GRE exam scores*
- Transcripts from previously attended universities
- Statement of purpose
- Two letters of recommendation
- For international students: TOEFL or IELTS scores

* The GRE may be waived for prospective students with significant and relevant work experience.