Engineering Faculty Document No. 6-20
Updated February 23, 2021

TO: The Faculty of the College of Engineering

FROM: The Faculty of the Weldon School of Biomedical Engineering

RE: New Certificate Program, Graduate Certificate in Regulatory Affairs and Regulatory Science for Medical Devices

The faculty of the Weldon School of Biomedical Engineering have approved the following new certificate program. This action is now submitted to the Engineering Faculty with a recommendation for approval.

Updates:

- Added Regulatory Science to the certificate title
- Created a permanent number for BME 564 (previously BME 595) Ethical Engineering of Medical Technologies
- Added additional course selections for the certificate
- Hired full-time faculty member to teach regulatory courses on a regular (annual) and consistent basis.

Graduate Certificate in Regulatory Affairs and Regulatory Science for Medical Devices

Coursework Required (total 3 = 9 credits):

2 of the following 3 regulatory courses (6 credits)

- BME 56100 Preclinical and Clinical Study Design
- BME 56200 Regulatory Issues Surrounding Approval of Medical Devices
- BME 56300 Quality Systems for Regulatory Compliance

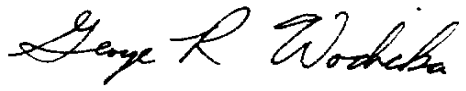
1 of the following other course options (3 credits)

- BME 50100 Multivariate Analyses in Biostatistics
- BME 56400 Ethical Engineering of Medical Technologies
- Remaining Regulatory Course Listed above (BME 56100, 56200 or 56300)

Prerequisite: Enrolled in Engineering Graduate Program or Post-Bac Student

Description: Students enrolled in the certificate program will participate in a sequence of courses designed to educate participants on practical regulatory affairs at both the initial approval and later compliance stages. Students gain valuable in-depth knowledge of regulatory requirements as well as guided practice with effective regulatory document submissions. This advanced education in regulatory quality, science, and compliance will prepare students for rapid integration into regulatory teams in critical areas of medical device and other related industries.

Reason: Regulatory professionals have often been trained on-the-job and under pressure, but in today's world, this approach to addressing regulatory requirements may be impractical as the biomedical technology industry can no longer afford to invest in long-term, internal training efforts to produce managers knowledgeable in both science and regulatory and quality issues. However, only a few university graduates in engineering and the sciences are exposed, as part of their formal university education, to topics such as medical technology product and process development, FDA regulations, quality systems, good clinical, laboratory or manufacturing practices, or management concepts. This certificate program will consist of 3 courses (9 credit hours) total. The certificate will cover topics in Preclinical and Clinical Study Design (BME 561), Regulatory Issues Surrounding Approval of Biomedical Devices (BME 562), Quality Systems for Regulatory Compliance (BME 563), Ethical Engineering of Medical Technologies (BME 564) and Multivariate Analyses in Biostatistics (BME 501). Students will select at least 2 of the regulatory courses (BME 561, 562 or 563) and one additional course (BME 561, BME 562, BME 563, BME 564 or BME 501) of the 5 course options for a total of 3 courses or 9 credit hours.



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