

TO: The Engineering Faculty

FROM: The Faculty of the Weldon School of Biomedical Engineering

RE: Revision to Course Selections for the graduate certificate in Regulatory Affairs

The Faculty of the Weldon School of Biomedical Engineering has approved the addition of the following course to the course selections to satisfy the Regulatory Certificate. This action is now submitted to the Engineering Faculty with a recommendation for Fast-Track approval.

PROPOSED COURSE SELECTION (NEW ADDITION UNDERLINED):

- BME 50100 Multivariate Analyses in Biostatistics (currently approved)
- BME 56100 Regulatory Issues and Clinical Design (currently approved)
- BME 56200 Regulatory Issues Surrounding Approval of Biomedical Devices (currently approved)
- BME 56300 Quality Systems for Regulatory Compliance (currently approved)
- BME 56400 Ethical Engineering of Medical Technologies (currently approved)
- BME 59500 Digital Healthcare and AI (new)

RATIONALE:

In order to remain relevant in the current biomedical industry, we need to continue to create and offer courses relevant to emerging technologies and the regulation of those technologies (or discussions on how they will be regulated) in order to offer our students relevant information for today's industry. This new course in Digital Healthcare and AI will tackle one of the key trending areas for our field. This course will also add a more robust course offering giving our students more flexibility in coursework as well as increase the number of courses we add to our summer offering. This course will help both our online and on campus students enrolled in the regulatory certificate program.



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Link to Curriculog entry:

<https://purdue.curriculog.com/proposal:22258/form>