BMEN6331 - Medical Device Regulations and Regulatory Strategy

**BMEN 6331** Medical Device Regulations and Regulatory Strategy (3 semester credit hours) An in-depth review and analysis of biomedical engineering device approval pathways and processes that influence engineering design decisions along these pathways. This course will emphasize the essential skills and tools critical to the introduction of new medical devices, and necessary to the practice of biomedical engineering. Hands-on problem solving of real world biomedical engineering challenges, using critical thinking, data analysis, and interpretation skills. Students will be expected to work in teams to research, evaluate, and present scientifically and legally justifiable strategies for introduction of a biomedical engineering technology, through oral and written communication. Department consent required. (3-0) Y