BMEN6331 - Medical Device Regulations and Regulatory Strategy

BMEN 6331 Medical Device Regulations and Regulatory Strategy (3 semester credit hours) This course will offer students exposure to the core concepts of the global medical device regulatory framework and provide a foundation for the practical application of the "least burdensome approach". The focus of the course is to aid students in the actual application of the regulations so that students are equipped to not only understand the core concepts embedded within the regulations but also apply them in real world biomedical engineering scenarios. The course will include all elements of the total product life-cycle; from initial device design to initial market entry, sustaining activities, post-market activities, and the subsequent obsolescence of the device. Special focus will be placed upon the Medical Device Regulatory landscapes found in the US, Canada, European Union, Brazil, South Korea, Mexico, Australia, and Japan. Department consent required. (3-0) Y