BMEN6336 - Regulatory Strategy and Submission

BMEN 6336 Regulatory Strategy and Submission (3 semester credit hours) Through interactive lectures and facilitated group projects, students gain an understanding of the regulatory pathways and how to develop and use a regulatory strategy to overcome barriers to entry in the medical device market. This course provides hands-on experience working with the regulations, guidance documents, and tools needed to develop an effective regulatory submission, including how to integrate regulatory strategy with product development and design control activities. This course will include U.S. regulatory pathways and a comparison to OUS pathways and evaluate the benefits of using a STED submission for global registrations. Prerequisite: BMEN 6331. (3-0) Y