BMEN 6335 - Design for Human Use

BMEN 6335 Design for Human Use (3 semester credit hours) Medical device design must be controlled in a way that ensures its safety and fulfillment of its intended use. This course provides the engineering value of relevant regulation and guidance throughout the product life cycle and how that relates to product quality and ultimately, customer satisfaction. Students will learn how to evaluate and understand human needs as a basis for designing and engineering new technologies and the practical implementation of design controls, risk management, requirements engineering, transfer planning, configuration control, and records. Department consent required. Prerequisite: BMEN 6331. (3-0) Y