1. BMEN 4312 - FDA Regulations and Quality Control of Biomedical Systems

2. 3 Credits, and 2:40 Contact Hours

3. Instructor: Mr. Peter Chen, Adjunct Faculty, Industry


5. Specific course information
   a. Course catalog description: Introduction to regulations and best practices recommended by the US Food and Drug Administration (FDA) that pertain to testing and marketing of biomedical devices and systems. Discussion on implementation of best practices for pre-clinical and clinical studies. Introduction to total quality engineering and total quality management as related to medical devices and systems. Building quality into design of products and systems in biomedical engineering.
   b. Prerequisites or co-requisites: Prerequisite(s): BMEN 3311, BMEN 3321; and senior classification.
   c. Required

6. Specific goals for the course:
   a. Specific outcomes of instruction: Upon successful completion of this course, students will understand: FDA regulations for the medical device industry; EU MDR; an overview on medical device design in industry; the product lifecycle of medical device; risk analysis methodology for medical device; and application of quality engineering tools into design processes.

   b. ABET Outcome 1: an ability to identify, formulate, and solve complex engineering problems by applying principles of engineering, science, and mathematics;

7. Brief list of topics to be covered:
   • FDA regulations for the medical device industry;
   • Overview on medical device design and product lifecycle;
   • Application of quality engineering tools into design processes