Instructor:
Peter Chen
pwgchen@yahoo.com
(817) 637-8962 – cell
Office: TBD
Office Hours: 8:30 – 9:30 PM TR or by appointment

Class Schedule:
7:00 – 8:20 PM TR, Room: NTDP D201

Required Textbook:

Reference Book:

Catalog Course 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.

Prerequisite(s): BMEN 3311, BMEN 3321; and senior classification.

Course Objectives:
1. Understand FDA regulations for the medical device industry
2. Provide an overview on medical device design in industry
3. Understand the product lifecycle of medical device
4. Application of following quality engineering tools into design processes:
   a. House of Quality
   b. ANOVA (analysis of variance)
   c. Statistical test and inference
   d. MSA (measurement system analysis)
   e. Reliability concept
   f. DOE (design of experiment)
   g. Risk analysis
   h. Capability study
5. Gain experience working in teams
6. Apply learned knowledge through a team-based project

**ABET Criteria:**

BMEN 4312 addresses the following ABET program outcomes:

- c) Function in multi-disciplinary teams
- d) Identify, formulate, and solve engineering problems
- e) Have an understanding of professional and ethical responsibility
- f) Communicate effectively
- g) Achieve broad education necessary to understand the impact of Biomedical Engineering solutions in a global and societal context
- j) Achieve knowledge of contemporary issues

**Homework:**

Homework assignments will be given using UNT’s Blackboard Learn online program.

**Grade Evaluation:**

- Homework/Quizzes: 20%
- Upto 3 Exams: 60%
- Final Project: 20%

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**Disability Policy:**

All reasonable accommodation will be made to facilitate special needs. If special accommodations are required, the student must first meet with the staff of the Office of Disability Accommodation (ODA), Union Suite 322, (940) 565-4323. After meeting with that office, please contact me to discuss what accommodations will be necessary. For more information, see [http://www.unt.edu/oda](http://www.unt.edu/oda).