Introduction to Medical Device Development and Regulation

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Office Hour: By appointment

Course description: This course introduces the design and application of medical devices, and include the relevant laws and regulations. Therefore, students can understand the requirement to comply with these norms, and they can design products to meet the regulatory requirements in the future. The lectures in this course includes the basic concepts of medical instrumentation, principles of basic sensors, amplifiers and signal processing, origin of biopotential and so on. After learning this course, the students should obtain the foundations necessary to build a strong understanding of the development of medical devices.

Pre-requisite:
Students are expected to have basic knowledge in physics, electronics and electrical engineering. This course also welcome the undergraduate student of fourth grader.

Required Textbook:
[1] John G. Webster, "Medical Instrumentation: Application and Design", Wiley, 2009. (Optional)

Required Equipment: A laptop computer (with wireless internet capability)

Topics and Schedules:

Week	Topic	Hours	Type	Assignments
1	Introduction	3	Lecture	
2	Basic concepts of medical instrumentation	3	Lecture	
3	Basic sensors and principles	3	Lecture	Homework 1
4	Amplifiers and signal processing (1)	3	Lecture	
5	Amplifiers and signal processing (2)	3	Lecture	
6	The origin of biopotential	3	Lecture	Homework 2
7	Biopotential electrodes	3	Lecture	
8	Biopotential amplifiers	3	Lecture	
9	Blood pressure and sound	3	Midterm Report	
10	Midterm Exam Week	3	Lecture	
11	Medical imaging systems	3	Lecture	Homework 3
12	Therapeutic and prosthetic devices	3	Lecture	
13	Electrical safety	3	Lecture	
14	R&D model of medical device	3	Lecture	
15	Testing of medical instrument	3	Lecture	Homework 4
16	Certification of medical instrument	3	Lecture	

17	Quality Management System	3	Lecture	
18	Final Exam Week	3	Final Report	

Workload: There will be 4 homework submissions (10 % each), 2 paper presentations (30 % each for midterm and final report).

Grading: Evaluation by Score
90~99 (equal to A)
80~89 (equal to B)
70~79 (equal to C)
Below 70 (equal to F)

Late Assignments: All homework assignments were are due within two weeks and must be uploaded to the folder in the e-learning system at the end of the day of submission. Late assignment submissions will be penalized 30%. Besides, late submission for more than 5 days will not be accepted.