REGULATORY POLICY AND REGULATIONS

EBME 480Q

COURSE DESCRIPTION: Introduction of wireless health technologies: spectrum, licensed versus unlicensed; personal area networks; body area networks; ultra-wideband low energy level short-range radios; wireless local area networks; wide area networks. The Federal system: separation of powers; the executive branch and its departments; the House of Representatives and its committees; the Senate and its committees; the FCC; policy versus regulatory versus legislative. What is a medical device: FDA; classification system; radiation-emitting products; software; RF in medical devices; converged medical devices; international aspects. Regulation of health information technology and wireless health: American Recovery and Reinvestment Act; Patient Protection and Affordable Care Act; FCC/FDA MoU; CMS and Reimbursement; privacy and security. (3 credit hours)

FACULTY: To be announced.


ADDITIONAL MATERIAL: Reading references posted on the Blackboard site.

COURSE OBJECTIVES: This course is designed to provide students with an understanding of medical device regulatory policy and regulations, including consideration of wireless health devices.

COURSE GRADE:
Quizzes (30%): ~ biweekly
Homework (40%): 4 assignments, ~ biweekly
Project (30%): Preparation and simulated submission of a wireless health device application to the FDA.

COURSE SCHEDULE:
WK 1 Wireless health technologies
WK 2 Wireless health technologies – continued
WK 3 The Federal system
WK 4 The Federal system – continued
WK 5 The Food and Drug Administration
WK 6 The classification system
WK 7 The classification system – continued
WK 8 Radiation emitting products; software
WK 10 RF in medical devices
WK 11 Converged medical devices; international aspects
WK 12 American Recovery and Reinvestment Act
WK 13 Patient Protection and Affordable Care Act
WK 14 FCC/FDA Memorandum of Understanding; CMS and reimbursement
WK 15 Privacy and security

University Student Ethics Policy
http://studentaffairs.case.edu/ai/policy.html

Violations of the Student Ethics Policy will result in failure in the assignment in question or the course, or referral to the academic integrity board as per university policy.

All forms of academic dishonesty including cheating, plagiarism, misrepresentation, and obstruction are violations of academic integrity standards. Cheating includes copying from another’s work, falsifying problem solutions or laboratory reports, or using unauthorized sources, notes or computer programs. Plagiarism includes the presentation, without proper attribution, of another’s words or ideas from printed or electronic sources. It is also plagiarism to submit, without the instructor’s consent, an assignment in one class previously submitted in another. Misrepresentation includes forgery of official academic documents, the presentation of altered or falsified documents or testimony to a university office or official, taking an exam for another student, or lying about personal circumstances to postpone tests or assignments. Obstruction occurs when a student engages in unreasonable conduct that interferes with another's ability to conduct scholarly activity. Destroying a student's computer file, stealing a student's notebook, and stealing a book on reserve in the library are examples of obstruction.

http://engineering.case.edu/sandiego