WIRELESS HEALTH PRODUCT DEVELOPMENT

EBME 480S

COURSE DESCRIPTION:
Integrating application requirements, market data, concept formulation, design innovation and manufacturing resources for creating differentiated wireless health products that delight the user. Learning user-centric product development best practices, safety, security and privacy considerations, and risk management planning. Understanding the regulatory process. Identifying and managing product development tradeoffs. (3 credit hours)

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TEXTBOOKS:
Reliable Design of Medical Devices, 3rd Edition 2012.
Richard C. Fries. CRC Press.

ADDITIONAL MATERIAL: Reading references posted on the Blackboard site.

PREREQUISITES: 480Q, 480R

COURSE OBJECTIVES: This course is designed to provide the students with the concepts and techniques involved in successful product development. We focus on building skills in practical assessment of healthcare product design.

COURSE GRADE:

Exams (30%): 3, ~ every 5 weeks
Homework (40%): 6 assignments, ~ biweekly
Project (30%): Evaluate, re-design, build and demonstrate an improved product for an existing medical end-to-end solution.

COURSE SCHEDULE:

WK 1  Overview of medical product development
WK 2  Applying principles to re-design products
WK 3  User centered product development
WK 4  Intellectual property as a product differentiator and strategic tool
WK 5  Product requirements – working with marketing- and customer-facing teams
WK 6  Product concept definition – market requirements document, business plan
WK 7  Product development lifecycle and process
WK 8  Reliability, safety and risk management; Regulatory processes and requirements
WK 9  NO CLASS – SPRING BREAK
WK 10 Tradeoffs in hardware and software design
WK 11 Verification and validation of medical products including human factors and usability testing
WK 12 Design transfer and manufacturing
WK 13 Product management and development team
WK 14 Product marketing and sales
WK 15 Applying principles to design new products

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.

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