University of Puerto Rico Mayagüez Campus
College of Engineering.
Industrial Engineering Department

Course Syllabus

General Information

Course Number: ININ 5105
Course Title: Introduction to Medical Device Design Methods
Credit-Hours: 3 hours

Course Description

This course presents the fundamental methods for medical device development. It is designed for students interested in a comprehensive study of the medical device development process, from concept ideation to marketing. It discusses methods that aid completing the procedures of product definition, design, risk management, production planning and market introduction, in an environment of multiple stakeholders, FDA (Food and Drug Administration) regulations and intellectual property protections. The course includes case studies illustrating important considerations to manage the complexities of the development process.

Prerequisites

ININ 4020 or INME 4055 or INEL 4205 or INQU 4008

Textbook

- **Ogrodnik, P.J., (2012). Medical Device Design: Innovation from concept to market, Elsevier.**

References

- Baura, G., (2011). Medical Device Technologies: A Systems Based Overview Using Engineering Standards. Elsevier.
- Taktak, A.F., Ganney, P., Long, D., and White, (2014). Clinical Engineering: A Handbook for Clinical and Biomedical Engineers. Elsevier.
- Medina, L.A., (2012). A comprehensive approach for medical device development: Incorporating regulations, critical factors and design for X in modeling a conceptual framework (Doctoral Dissertation), The Pennsylvania State University, University Park, PA.
- Medina, L.A., Okudan-Kremer, G.E., and Wysk, R.A. (2013). Supporting Medical Device Development: A Standard Product Design Process Model. Journal of Engineering Design, 24, 2, 83-119.
- Medina, L.A., Jankovic, M., Okudan-Kremer, G.E., and and Yannou, B. (2013). An Investigation of Critical Factors in Medical Device Development through Bayesian Networks. Expert Systems with applications, 40, 17, 7034–7045.
- Kucklick, T.R., (2012). The Medical Device R&D Handbook, 2nd ed. Taylor & Francis. [Available on http://library.uprm.edu]
- Díaz Lantada, A., (2011). Handbook of Active Materials for Medical Devices – Advances and Applications. Pan Stanford Publishing Pte. Ltd. [Available on http://library.uprm.edu]

Purpose

This course serves as an elective for bachelors' and masters' degrees in Industrial Engineering. The purpose of the course is to introduce students to medical device design methods.

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Course Goals

After completing the course, the student should be able to:

- Define what is a medical device within the scope of the FDA.
- Distinguish between the fundamental methods to develop a medical device, which includes from concept ideation to marketing.
- Identify the interactions between the development procedures and the flow of information between them.
- Apply risk management techniques to identify, analyze, control and monitor the risks associated with design solutions.
- Recognize FDA regulatory requirements for medical devices in the Unites States, which include FDA classifications (e.g. regulation number, product code, risk), submission types and Quality systems regulation.
- Describe standards and intellectual property protections in the context of medical device development.
- Evaluate important factors for medical device development depending on their relevance to the business, hierarchical level and impact on success.
- Discuss and calculate basic statistics related to the planning of clinical trials.

All students are expected to come to class on time, and prepared; do all assigned readings and related homework; actively participate in class discussions; and satisfy all assessment criteria to receive credit for the course.

Department and Campus Policies

Class attendance: Class attendance is compulsory. The University of Puerto Rico, Mayagüez Campus, reserves the right to deal at any time with individual cases of non-attendance. Professors are expected to record the absences of their students. Frequent absences affect the final grade, and may even result in total loss of credits. Arranging to make up work missed because of legitimate class absence is the responsibility of the student. (Bulletin of Information Undergraduate Studies).

Absence from examinations: Students are required to attend all required examinations. If a student is absent from an examination for a justifiable reason acceptable to the professor, he or she will be given a special examination. Otherwise, he or she will receive a grade of zero of "F" in the examination missed. (Bulletin of Information Undergraduate Studies)

Final examinations: Final written examinations must be given in all courses unless, in the judgment of the Dean, the nature of the subject makes it impracticable. Final examinations scheduled by arrangements must be given during the examination period prescribed in the Academic Calendar, including Saturdays. (See Bulletin of Information Undergraduate Studies).

Partial withdrawals: A student may withdraw from individual courses at any time during the term, but before the deadline established in the University Academic Calendar. (See Bulletin of Information Undergraduate Studies).

Complete withdrawals: A student may completely withdraw from the University of Puerto Rico, Mayagüez Campus, at any time up to the last day of classes. (See Bulletin of Information Undergraduate Studies).

Disabilities: After been identified with the professor and the institution, the students with disabilities will receive reasonable accommodations in their courses and evaluations. For more information, please contact *The Office of Quality of Life* at the Student Dean's Building, 787-265-5467 ó 787-832-4040 exts. 5467, 3107 ó 3894.

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Ethics: Any academic fraud is subject to the disciplinary sanctions described in article 14 and 16 of the revised General Student Bylaws of the University of Puerto Rico contained in Certification 018- 1997-98 of the Board of Trustees. The professor will follow the norms established in articles 1-5 of the Bylaws.

General Topics

Lecture	Topic
1-2	Part I: Introduction to medical products -What is a medical device? -Conceptual model of the medical device development landscape -Quality and engineering ethics
3-6	Part II: The development process -Development methodology -Design reviews, verification, validation -Risk management -Documentation
7-10	Part III: Regulatory requirements for medical devices -FDA classifications and submission types (PMA, 510(k), HDE) -Combination products -Global harmonization task force -Quality systems regulation -Surveillance and recalls
11-12	Part IV: Standards and intellectual property protections
13-14	Part V: Critical factors in medical device development -Internal versus external factors -Hierarchical levels: organization, environment, development process and product levels -Measures of success
15-20	Part VI: Good laboratory practices and clinical trials -Statistical concepts -Animal/In vitro safety studies -Statistics for designs and analysis of clinical trials
21-24	Part VII: Manufacturing processes -Prototypes -Process planning -Quality compliance and validation
25-28	Part VIII: Market introduction and post-launch -Market and customer analysis -Financial analysis and reimbursement strategy -Product branding, physician training, product/process continuous improvement

*All readings are from professor notes.

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