THIS PROGRAM IS DISCONTINUED EFFECTIVE FALL QUARTER 2006

PROGRAM DESCRIPTION

Designing medical devices requires an in-depth knowledge of the healthcare market, end-user requirements, safety, and regulatory compliance. The Specialized Studies Program in Medical Device Engineering addresses a recognized need of engineers involved in the medical device industry to better understand and manage the medical device engineering process. The program addresses best practices, regulatory compliance, and associated technologies that are involved in the design, development, and engineering of medical devices.

Completion of this specialized studies program serves as a foundation for further study in the Medical Product Development certificate program.

WHO SHOULD ATTEND

Engineers, biomedical engineers, scientists, regulatory management personnel, and those in other technical and non-technical disciplines that are involved in the medical device industry.

PROGRAM BENEFITS

- Achieve a fundamental understanding of anatomy and physiology as it relates to medical device engineering.
- Understand basic criteria for the development of medical devices.
- Perform medical device testing and certification analysis.
- Identify the basic regulatory and compliance issues.
- Establish a best practice approach for medical device design.

SPECIALIZED STUDIES REQUIREMENTS

Candidates must possess a fundamental understanding of the functions of the human body through Anatomy and Physiology for Clinical Studies, BME X405, or possess equivalent experience or education. The specialized studies award is provided upon successful completion of four required courses totaling 10.5 units, with a minimum grade point average of “B” or better. Upon completion of the program requirements, fill out the request for certificate and include a $35 application fee. Note: It is not necessary to be pursuing an award to enroll in individual courses.

FOR MORE INFORMATION

Please call (949) 824-5380.

CURRICULUM

PREREQUISITE COURSE

Anatomy and Physiology for Clinical Studies
BME X405 (4 units)
Whether designing investigational drugs and medical devices or conducting clinical trials, it is important to have a basic understanding of the form and function of the human body. Learn about human anatomy and physiology as related to pharmaceuticals and medical device design for clinical studies. Clinical examples and modeling techniques are used to demonstrate the applications of anatomy and physiology in the development of investigational drugs and medical devices. Course focus is on human safety in clinical studies. Prerequisite: Familiarity with basic science and biology.

CURRICULUM

REQUIRED COURSE – 10.5 UNITS

Medical Device Design and Evaluation
ENGRECE X445.23 (3 units)
Explore the opportunities and need for medical devices through the examination of mortality and morbidities with special attention to medical problems that affect patients. A market and need-driven systems engineering approach is applied to the examination of medical device design. The designs of medical devices are then studied through a layered approach of examining the underlying physiological mechanisms, the applicable biomedical sensors and actuators as well as the control processing power requirements. Exemplary medical device solutions are studied. Prerequisite: BME X405, Applied Anatomy and Physiology for Clinical Studies; or equivalent experience or education.

Medical Device Testing and Certification
BME X404 (1.5 units)
Medical products must conform to safety standards or face costly redesign and increased time to market. Advance your understanding of the safety standards that are required for marketing to the global community. Strengthen your knowledge of the specifications, procurement, manufacturing and design requirements necessary to meet the harmonized standard for medical equipment, IEC 60601-1, including the current US (UL)
Medical Device Engineering Specialized Studies Program

60601-1), Canadian (CAN/CSA C22.2 No. 601.1) and European (EN 60601-1) differences.
Prerequisites: Familiarity with the design and development of medical devices.

Medical Device Risk Management
BME X406 (3 units)
Get the facts you need about ISO 14971:2000 - a harmonized standard for Medical Device Directive 93/42/EEC for the European Union (EU), and a recognized consensus standard for the U.S. Food and Drug Administration (FDA). Increase your understanding of the risk management principles, standards, and regulations involved in medical device development. A step by step guidance will help you achieve an understanding of ISO 14971 so that you can implement and effectively use this complex standard.

Software-Controlled Medical Devices: Software Engineering and Compliance
BME X401(1.5 units)
Further your understanding of FDA regulatory requirements and how they relate to appropriate software engineering practices for medical device software development. Gain an understanding of FDA software compliance and learn how to evaluate their key software engineering activities against FDA Quality Systems Regulation (QSR) and FDA software specific guidance documents. This course is of interest to software project managers, software developers, software test engineers, quality assurance professionals, regulatory affairs professionals, and individuals interested in working in the medical device software development industry.
Prerequisites: Familiarity with FDA regulatory requirements, software engineering, and software development principles.

Fundamentals of Embedded Systems Design and Programming
EECS X497.32 (3 units)
Gain an overview of embedded systems applications and design procedures, and learn how to plan and execute complete embedded systems designs that are cost-effective and competitive. You’ll gain the knowledge needed to determine and document system requirements for new designs as well as for improving existing systems. You’ll learn analysis techniques for optimizing system specifications as well as selecting microcontrollers for specific designs. Hands-on development is facilitated with an embedded system development kit.
Prerequisite: Eecs 805, C Programming for Embedded Systems; or equivalent experience. NOTE: Required Design Kit Atmel STK500 & STK 502. Order from All American 1-800-573-ASAP.

QUARTERLY SCHEDULE OF COURSES

<table>
<thead>
<tr>
<th>COURSE #</th>
<th>PREREQUISITE COURSE</th>
<th>W</th>
<th>SP</th>
<th>SU</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>BME_X405</td>
<td>Applied Anatomy and Physiology for Clinical Studies*+ ( 4 units )</td>
<td>▼</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COURSE #</th>
<th>Required Courses (6 units)</th>
<th>WI</th>
<th>SP</th>
<th>SU</th>
<th>FA</th>
</tr>
</thead>
<tbody>
<tr>
<td>EECS_X445.23</td>
<td>Medical Device Design and Evaluation*+ ( 3 units )</td>
<td>▼</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BME_X404</td>
<td>Medical Device Testing and Certification+ ( 1.5 units )</td>
<td>▼</td>
<td>▼</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BME_X401</td>
<td>Software-Controlled Medical Devices: Software Engineering and Compliance+ ( 1.5 units )</td>
<td>▼</td>
<td></td>
<td>▼</td>
<td></td>
</tr>
<tr>
<td>BME_X406</td>
<td>Medical Device Risk Management+ ( 3 units )</td>
<td>▼</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EECS_X497.32</td>
<td>Fundamentals of Embedded Systems Design and Programming (3 units)</td>
<td>▼</td>
<td></td>
<td>▼</td>
<td></td>
</tr>
</tbody>
</table>

* Candidates must have a fundamental understanding of the functions of the human body, Applied Anatomy and Physiology for Clinical Studies, BME_X405, OR equivalent experience or education.
+Offers credit in the Medical Product Development Certificate Program.

Note: Schedules are subject to change. WI=Winter SP=Spring SU=Summer FA=Fall
REQUEST FOR SPECIALIZED STUDIES AWARD

DATE __________________________

University of California, Irvine Extension
Programs in Engineering & Science Technologies
P.O. Box 6050
Irvine, CA 92616-6050
FAX (949) 824-1220

The course in which I am now enrolled* is the last one to be completed before I am eligible to receive the certificate in:

_____________________________________

This form must be submitted, along with a filing fee of $35 during enrollment of the last course to complete the program requirements.

Names: __________________________________________

Name to be inscribed on certificate-PLEASE PRINT

Certificate to be mailed to:

____________________________________

Number and Street

____________________________________

City State Zip

____________________________________

Daytime Phone

____________________________________

Social Security Number

____________________________________

Signature

* Name of course in which you are now enrolled:

PLEASE DO NOT SUBMIT THIS FORM UNLESS YOU ARE ACTUALLY ENROLLED IN YOUR FINAL COURSE AND IT HAS STARTED.