BE467: Product Design and Innovation in Biomedical Engineering

FALL 2015

Professors: Gregory T. Martin and Thomas L. Szabo

MEETINGS: 2 Hours / Week; Fall Semester Mondays and Wednesdays 4-5 or 5-6 PM in Photons 203, 8 St. Mary's St., except as noted

Students are taught the basic project skills and regulatory principles required to develop a commercial medical device. Lectures and case studies are augmented by real world examples combining both an academic and industrial perspective. Subject matter includes problem identification, product conceptualization, and design, and intellectual property, formal development including design controls, risk management and FDA regulatory requirements. Student teams will apply their acquired course knowledge and their engineering skills to design a conceptual medical device.

This is a required co-requisite to BE465 in the fall for BME Seniors.

Grading: Project Report/Presentation 30%, Exams 30%, Assignments 30% Participation 10%

Course setup: Each student has been assigned to either section A1 or A2. Students will participate in teams of approximately four to five to work on a semester long product task. If you are in section A1 you can be part of a team formed from those in A1 and likewise, if you are in A2, from A2. There will be 3 quizzes and a final project report. The semester ends with a series of presentations from each team. Lectures and information will be posted on Blackboard Learn. Frequent reviews for updates recommended.

Contact Information:

Professor Gregory T. Martin
ERB 406
44 Cummington St.
Tel 1-617-358-6925
Office hours: By appointment
gtmartin@bu.edu

Professor Thomas L. Szabo
ERB 341
44 Cummington St.
Tel 1-617-358-4390
Office hours: By appointment
tlszabo@bu.edu

Course Assistant: Megan Spreitzer
ERB 220
Tel 1- (617)-353-7609
mspreitz@bu.edu

Course texts and sources:

Medical Device Quality Systems Manual with 11, 210/211, 820 and QSR Audit Checklist

21 CFR 11, 50, 54, 56, 807, 812, 814, 820, 510K & PMA - Medical Device Combination

Order from http://www.gmppublications.com/ or available free online as needed

Additional reading assignments will be posted/emailed to students

FDA Case Studies will be posted/emailed to student for preclass reading assignments

Course Website:

Blackboard BE 467 Fall 2015
<table>
<thead>
<tr>
<th>Lecture</th>
<th>Topic</th>
</tr>
</thead>
</table>
| 1       | Course Structure, Logistics and Objectives  
Wednesday, September 2  PHO 203: A1 4pm; A2 5 pm |
| &nbsp; | AS1  What makes this a medical device? Describe career goals & course expectations. Due Sept. 8. Bring hard copy to class & post PDF to Blackboard by class time. Form teams by midnight Sept. 8 |
| 2       | Project Team Discussions, Teamwork and Project Grab Bag  
Wednesday, September 9.  Note one day only: different meeting place! SCI 113 Metcalf Science Building, 590 Commonwealth Ave. |
| &nbsp; | AS2  Select team and sign up individually under the same group number on Blackboard (BB) by 9/13 midnight. |
| 3       | Problem Identification and Need Statements  
Monday September 14  PHO 203: A1 4pm; A2 5 pm |
| &nbsp; | AS3  Meet with team to discuss the medical device for your project and email your selection to us by midnight, September 15 |
| 4       | Problem Identification and Need Statements Workshop  (feedback on device selection by class time)  
Wednesday September 16  PHO 203: A1 4pm; A2 5 pm |
| &nbsp; | AS4  Reselect device, if needed. Prepare Project Problem and Need Statement - hard copy and PDF to Blackboard by midnight September 23 |
| 5       | Introduction to the Product Development Process and Regulations  
Monday September 21  PHO 203: A1 4pm; A2 5 pm |
| 6       | The Product Development Process  
Wednesday September 23  PHO 203: A1 4pm; A2 5 pm |
| 7       | Design Verification and Validation  
Monday September 28  PHO 203: A1 4pm; A2 5 pm |
| &nbsp; | AS5  Functional and Performance Specifications Exercise in class, September 28 |
| 8       | Design Verification and Validation Workshop  
Wednesday September 30  PHO 203: A1 4pm; A2 5 pm |
| 9       | Quiz 1 Covering Problem Identification and Need, Product Development Process, Specifications  
Monday October 5 , Room TBA |
| 10      | Quality Systems  
Wednesday October 7 |
| 11      | Risk Management Lecture  
Tuesday October 13 |
| 12      | Hazards and Harms Analysis and FMEA Workshop  
Wednesday October 14 |
<p>|   | AS7  Prepare Project Product FMEA – turn in Word doc by noon, October 19. |</p>
<table>
<thead>
<tr>
<th>Week</th>
<th>Event Description</th>
</tr>
</thead>
</table>
| 13   | Introduction to Intellectual Property (Part 1) (Saunders)  
Monday October 19  
AS8 Perform a prior art search for your device; describe novelty of your device |
| 14   | Introduction to Intellectual Property (Part 2) (Saunders)  
Wednesday October 21  
AS9 Write patent claims for your device |
| 15   | IP Workshop- Assignment Reviews  
Monday October 26  
AS10 Combine AS8 and AS9 as an IP report for your device, turn Word doc in to BB by midnight, Oct 27. |
| 16   | FDA Regulatory Requirements Overview and Product Classification  
Wednesday October 28 |
| 17   | FDA Product Classification Workshop – Case study  
Monday November 2  
AS11 Project Product Classification and Identify Predicate Devices - in class Case study questions –Nov. 2 |
| 18   | Quiz 2 Covering Risk Management, Harm and Hazards, FMEA, & IP  
Room TBA  
Wednesday November 4 |
| 19   | Pre Market Notification Process - 510K Clearance, PMA and Preclinical Studies  
Monday November 9 |
| 20   | FDA 510k, PMA & Clinical Workshop, Wednesday, November 11,  
AS12 Case study November 11 |
| 21   | International standards and Guidelines  
Monday November 16 |
| 22   | Quiz 3 Covering FDA Regulatory Requirements, Product Classification, Predicate Devices,  
Clinals, & Standards / Presentation guidelines  
Room TBA  
Wednesday November 18 |
| 23   | Beginning Project Presentations  
Monday November 23  
No class  
Monday, November 24  
Thanksgiving Recess  
Wednesday, November 25 - Sunday, November 29 |
| 24   | Project Presentations  
Monday November 30 |
| 25   | Project Presentations  
Wednesday Dec 2 |
Project Presentations
Monday Dec 7

Project Presentations
Wednesday Dec 9

BIOMEDICAL ENGINEERING DEPARTMENT
BOSTON UNIVERSITY
BE 467 Faculty Fall 2015

Gregory T. Martin, Ph.D.
Director, Coulter Program
Boston University
gtmartin@bu.edu
http://www.bu.edu/bme/research/coulter/contact/

Thomas L. Szabo, Ph.D.
Research Professor
Biomedical Engineering
Mechanical Engineering
Boston University
tlszabo@bu.edu
http://www.bu.edu/bme/people/professionalandresearch/szabo/

Steven Saunders, J.D.
BU ENG 1989
Patent Attorney
Sunstein Kann Murphy & Timbers, Boston
Hub Angels, Launchpad Venture Group, Boston
SSaunders@sunsteinlaw.com
http://sunsteinlaw.com/s-saunders/