

# SPC St. Petersburg College

## COURSE SYLLABUS

Biomedical Device Design Development and Manufacturing  
Summer 2015

Syllabus Addendum: [www.spcollege.edu/addendum](http://www.spcollege.edu/addendum)

### **Instructor Information**

Name

Email:

### **Academic Department**

Dean:

Office Location:

Phone:

Email:

Program Director:

Office Location:

Phone:

Email:

### **Course Description:**

This course will provide an understanding of the processes and procedures using the Food and Drug Administration (FDA) regulation and compliance for the designing and manufacturing of medical devices. Topics include the design process, design tools and management, product and process development, documentation, verification and validation, post market surveillance, and corrective and preventative actions. 33 contact hours

### **Important Dates and Times**

**Course Dates:** May 20-July 29

**Class Meeting Day:** Wednesday

**Course Hours:** 5:30-8:30 PM

**Class Location:**

### **Textbook:**

*Medical Device Design: Innovation from concept to market by Peter J Ogrodnik*

**SBN-13:** 978-0123919427 **ISBN-10:** 0123919428

### **Learning Outcomes and Objectives:**

Upon completing BMD 0241- Biomedical Device Design Development and Manufacturing, the student will be able to:

1. Understand the classifications of medical devices and provide examples
2. Understand and define terms and regulations associated with medical device and design
3. Understand and utilize the five step process of medical device design
4. Understand an application the ISO 13485 medical device design and development
5. Understand and discuss the assigned textbook material as it applies to medical device design and manufacturing

### **Evaluation**

There will be assigned projects, case studies, and online activities. There will also be exams and quizzes that will be taken over the 11 weeks of the course. All assigned activities must be completed by the end of the course. Make-up projects will be given in only extreme circumstances (i.e family emergencies, injury, etc.)

### **Attendance and Withdrawal Policy**

The college-wide attendance policy can be seen in the syllabus addendum. The policy notes that each instructor is to exercise professional judgment and define “active participation” in class (and therefore “attendance”), and publish that definition in each syllabus. For this class, attendance is defined as arriving to class on time and participating in classroom activities (lectures, projects, online activities, labs, etc.) **80% of the class time, by 80% semester reporting attendance date.** If a student fails to participate as defined above, they will be automatically dropped from the class.

### **Class & Online Activities**

Scheduled classes will include lecture, and presentations to provide a mix of self and group directed learning to compliment lectures by the instructor and guest speakers. Text reading will be assigned to provide details on core concepts used in industry that applicable to medical device design, development and manufacturing. A class project will be assigned that follows the overall course outline, this project will include milestones that must be met at the midpoint in the class. The project must be completed and turned in before the last week of class and will account for approximately 50% of the final grade.

### **Grading Policy**

All assigned coursework is graded on a Pass/Fail basis. Students not achieving a Pass on 80% of the assignments will not be able to apply for credit through the Experiential Learning Program or articulation towards the proposed A.S. Degree in Biomedical Technology or Engineering Technology at St. Petersburg College.

### **STU DEN T' S EXPEC T ATI O NS AND I NSTRUC TOR'S EXPEC T ATI O NS**

College-wide student expectations are located in the Syllabus Addendum:

### **Student Survey of Instruction (SSI)**

The student survey of instruction is administered I courses each semester. It is designed to improve the quality of instruction at St. Petersburg College. All students responses are confidential and anonymous and will be used solely for the purpose of performance improvement. The survey will be available online, and will be active towards the end of the semester.

### **Hurricane Emergency Preparedness**

In the event that a hurricane or other natural disaster causes significant damage to St. Petersburg College facilities, you may be provided the opportunity to complete you course work online. Following the event, please visit the college web site for an announcement of the College's plan to resume operations.

### **Assigned Homework Activities**

All assigned homework activities must be completed by the assigned dates.  
Assigned activities include:

- Assigned Chapters (to be read before class time)
- Vocabulary and key term sheets
- Discussion Posts
- Individual Assignments
- Case Studies
- Group Project

### **Syllabus Changes**

The professor has the right to change or modify the syllabus as he/she sees fit. Notifications of changes will be made to the students. However, once the notifications have been made, it is the responsibility of the student to adhere to the changes.

# BMD 0241 Biomedical Device Design Development & Manufacturing

## Class Schedule (Tentative) – Summer 2015

Class Dates	Topics & Assignments	In Class Activities	Assignments & Due Dates
<b>Lesson 1</b> 5/20/15	<b>Course Syllabus &amp; Overview</b>  <b>Chapters 1&amp;2</b> <ul style="list-style-type: none"> <li>• Introduction</li> <li>• Classifying Medical Devices</li> </ul>	FDA.gov Medical Device Design Video  Lecture/PowerPoint	Complete Chapter Vocabulary and Terms  <b>Assignment 1- May 24 by 11:00PM!!</b>  <b>FDA Online Quiz Certificates DUE by 6/10/15!</b>
<b>Lesson 2</b> 5/27/15	<b>Chapters 8&amp;6</b> <ul style="list-style-type: none"> <li>• Design Realization/Project Management (only 8.1-8.3)</li> <li>• Generating Ideas &amp; Concepts</li> </ul> <b>Group Project Overview</b>	<b>Assignment 1 review</b>  Lecture/PowerPoint  Group Activity	<u>Quiz due June/3/15</u>  Complete Chapter Vocabulary and Terms
<b>Lesson 3</b> 6/3/15	<b>Chapter 3</b> <ul style="list-style-type: none"> <li>• The Design Process _possible guest speaker_</li> </ul>	<b>Lecture/Online</b>  Group meetings- <u>during the week on your own</u>	<b>Quiz 1- Chapters 1,2,6,8 DUE-10 point</b>  Complete Chapter Vocabulary and Terms <b>Assignment 2- June 9 by 11!!</b>  Discovery Gate- <u><b>June 17 in class</b></u>
<b>Lesson 4</b> 6/10/15	<b>Chapter 5</b> <ul style="list-style-type: none"> <li>• Developing Your Product Design Specification</li> </ul>	Lecture/PowerPoint  Group Meetings/ Present Discovery gate	Complete Chapter Vocabulary and Terms  Discovery Gate- <u><b>June 17 in class</b></u>

<b>Class Dates</b>	<b>Topics &amp; Assignments</b>	<b>In Class Activities</b>	<b>Assignments &amp; Due Dates</b>
<b>Lesson 5</b> 6/17/15	<b>Chapter 7</b> <ul style="list-style-type: none"> <li>• <b>Quality in Design</b></li> </ul>	Lecture/PowerPoint Group Meeting	<b><u>DUE:</u></b> <b><u>Discovery Gate</u></b>  Complete Chapter Vocabulary and Terms
<b>Lesson 6</b> 6/24/15	<b>Chapter 4</b> <ul style="list-style-type: none"> <li>• <b>Implementing Design Procedures</b></li> </ul>	Lecture/PowerPoint Group Meeting	Complete Chapter Vocabulary and Terms  Inputs Document- <b><u>July 1 in class</u></b>
<b>Lesson 7</b> 7/1/15	<b>Chapter 9</b> <ul style="list-style-type: none"> <li>• <b>Evaluation (Validation and Verification)</b></li> </ul>	Lecture/PowerPoint Group Meeting/ Present Inputs	<b><u>DUE:</u></b> <b><u>Inputs Document</u></b>  <b>Quiz 2-</b> Chapters 3,5,7,4 <b>DUE-10</b> points  Complete Chapter Vocabulary and Terms
<b>Lesson 8</b> 7/8/15	<b>Chapter 10&amp;11</b> <ul style="list-style-type: none"> <li>• <b>Manufacturing Supply chain</b></li> <li>• <b>Labeling and Instructions for Use</b></li> </ul>	Lecture/PowerPoint Group Meeting	Complete Chapter Vocabulary and Terms  Outputs Document- <b><u>July 15 in class</u></b>
<b>Lesson 9</b> 7/15/15	<b>Chapter 12</b> <ul style="list-style-type: none"> <li>• <b>Post Market Surveillance</b></li> </ul>	Lecture/PowerPoint Group Meeting/ Present Outputs	<b><u>DUE:</u></b> <b><u>Outputs Document</u></b>  Complete Chapter Vocabulary and Terms

<b>Class Dates</b>	<b>Topics &amp; Assignments</b>	<b>In Class Activities</b>	<b>Assignments &amp; Due Dates</b>
<b>Lesson 10</b> 7/22/15	<b>Chapters 13&amp;14</b> <ul style="list-style-type: none"> <li>• <b>Protecting your IP</b></li> <li>• <b>Obtaining Regulatory Approval to Market</b></li> </ul>	Lecture/PowerPoint Group Meeting	Complete Chapter Vocabulary and Terms  Verification & Validation/ Launch- <b><u>July 29 in class</u></b>
<b>Lesson 11</b> 7/29/15	<b>Final</b>  <b>Final Project Presentations</b>	Presentations	<b><u>DUE</u></b> Verification & Validation/ Launch  <b>Final Quiz</b> -Chapters 9,10,11,12,13,14 <b>DUE</b> - 20 points

*“This product was funded by a grant awarded by the U.S. Department of Labor’s Employment and Training Administration. The product was created by the grantee and does not necessarily reflect the official position of the U.S. Department of Labor. The U.S. Department of Labor makes no guarantees, warranties, or assurances of any kind, express or implied, with respect to such information, including any information on linked sites and including, but not limited to, accuracy of the information or its completeness, timeliness, usefulness, adequacy, continued availability, or ownership.”*