St. Petersburg College

SPC

APPROVED COURSE OUTLINE

Credit(s) 3.00
Contact Hours 47.00
Effective Term: Spring 2008 (390)

ETI 2041
Medical Device Design and Manufacturing
Engineering and Building Arts Department

Requisites:
Prerequisite: REA 0007

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.

Course Topics:

- None

Learning Outcomes and Objectives:

1. The student will demonstrate an understanding of design and the tools used in the design process by:
a. explaining the definition of design.
b. describing uses for which products could be designed.
c. analyzing the steps involved in the design process.
d. describing and analyzing barriers to design.
e. discussing the role of brainstorming.

2. The student will demonstrate an understanding of design management by:
a. defining the design team.
b. determining how a design team is organized.
c. determining and listing team success factors.
d. describing the role of the Team Leader.
e. recognizing and listing the team outputs.

3. The student will demonstrate an understanding of product definition by:
a. recognizing how customer needs are determined.
b. recognizing how a company's needs are determined.
c. analyzing how competition is evaluated.

4. The student will demonstrate an understanding of product documentation by:
a. defining, describing, and listing product specification.
b. analyzing design requirements.
c. identifying the requirements for software related documentation.
d. determining the types files required including the design history file (DHF), the devicemaster record (DMR) and the design history record (DHR).
e. classifying risk management activities.

5. The student will demonstrate an understanding of product development by:
a. defining and describing reverse engineering.
b. describing component selection criteria.
c. organizing vendor selections.
d. describing, listing, and applying failure modes and effects analysis (FMEA) to increase product safety.
e. analyzing product reliability.

6. The student will demonstrate an understanding of process development by:
a. describing concurrent product and process development.
b. explaining how equipment is selected.
c. describing and comparing installation and operation qualifications.
d. describing how process limits are determined.
e. recognizing process optimization.
f. developing and analyzing process flow maps.
g. developing and analyzing process FMEAs.

7. The student will demonstrate an understanding of design verification and validation by:
a. differentiating between verification and validation.
b. listing and describing the steps in verification and validation.
c. describing and determining how a design requirement is verified.
d. describing and analyzing how customer needs are validated.

8. The student will demonstrate an understanding of process validation by:
a. describing how a process output can be verified.
b. describing and analyzing process capability.
c. determining how a process is validated.

9. The student will demonstrate an understanding of production scale-up by:
a. describing pilot production.
b. defining the terms associated with production scale-up.
c. describing line balancing.
d. discussing and analyzing inventory management.
e. describing and analyzing production scheduling.
f. determining and listing operator training.

10. The student will demonstrate an understanding of product launch by:
a. describing a market release package using advertisements, instructional videos, and training materials.
b. describing sales force training.
c. discussing user training.
d. describing staged release.

11. The student will demonstrate an understanding of post market surveillance by:
a. describing the types of knowledge and feedback that can be obtained using the following measures:
1. quality Improvement
2. risk analysis confirmation
3. training requirements
4. device misuse
5. adequacy of instructions for use
6. changing performance trends
b. describing how product information is obtained by customer complaints and warranty claims.
c. explaining how product information is obtained by feedback other than complaints.
d. describing what types of complaints are reported to the FDA.
e. listing the types of issues necessitate a product recall.

12. The student will demonstrate an understanding of corrective and preventative action (CAPA) by:
a. recognizing why a corrective action request would be generated.
b. describing how ownership of a corrective action is determined.
c. describing how a problem is defined, isolated, and contained.
d. determining and analyzing how the root cause of a problem is determined.
e. describing and determining how a corrective action is chosen.
f. explaining how a corrective action is implemented and validated.

Criteria Performance Standard:
Upon successful completion of the course the student will, with a minimum of 70% accuracy, demonstrate mastery of each of the above stated objectives through classroom measures developed by individual course instructors.

Representative Textbooks:
None

Relevant Dates:
C&I Approval: 11/13/2007, BOT Approval: 12/17/2007, Effective Term: Spring 2008 (390)

History of Changes:

(Submitted as 2060; State approved as 2041
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Related Programs:

1. Engineering Technology Associate in Science (ENG-AS) (520) (Pending)
2. Engineering Technology Associate in Science (ENG-AS) (480) (Historical)
3. Engineering Technology Associate in Science (ENG-AS) (445) (Historical)
4. Engineering Technology Associate in Science (ENG-AS) (505) (Active)
5. Medical Quality Systems Certificate without Financial Aid Eligibility (MEDQS-CT) (400) (Active)

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