July 2010

Florida Department of Education
Curriculum Framework

Program Title: **Medical Quality Systems**
Career Cluster: **Manufacturing**

CCC	
CIP Number	0615000005
Program Type	College Credit Certificate (CCC)
Program Length	15 Credit Hours
CTSO	SkillsUSA
SOC Codes (all applicable)	29-2071, 31-9092, 29-2012, 51-9082, 11-9111, 17-2031, 19-4021
Targeted Occupation List	http://www.labormarketinfo.com/wec/TargetOccupationList.htm

Purpose

This certificate program is part of the Engineering Technology AS/AAS degree program (0615000001).

A College Credit Certificate consists of a program of instruction of less than sixty (60) credits of college-level courses, which is part of an AS or AAS degree program and prepares students for entry into employment (Rule 6A-14.030, F.A.C.).

This program offers a sequence of courses that provides coherent and rigorous content aligned with challenging academic standards and relevant technical knowledge and skills needed to prepare for further education and careers in the manufacturing career cluster; provides technical skill proficiency, and includes competency-based applied learning that contributes to the academic knowledge, higher-order reasoning and problem-solving skills, work attitudes, general employability skills, technical skills, and occupation-specific skills, and knowledge of all aspects of the manufacturing career cluster.

The content includes but is not limited to specialized courses used in the medical device manufacturing areas in quality assurance.

Laboratory Activities

Laboratory activities are an integral part of this program and include the proper use of computers, software, and specialized material related to quality manufacturing.

These activities include instruction in the use of safety procedures, tools, equipment, materials, and processes related to these occupations. Equipment and supplies should be provided to enhance hands-on experiences for students.

Special Notes

Career and Technical Student Organization (CTSO)

SkillsUSA is the appropriate career and technical student organization for providing leadership training and reinforcing specific career and technical skills. Career and Technical Student Organizations provide activities for students as an integral part of the instruction offered. The activities of such organizations are defined as part of the curriculum in accordance with Rule 6A-6.065, F.A.C.

Accommodations

Federal and state legislation requires the provision of accommodations for students with disabilities as identified on the secondary student's IEP or 504 plan or postsecondary student's accommodations plan to meet individual needs and ensure equal access. Postsecondary students with disabilities must self-identify, present documentation, request accommodations if needed, and develop a plan with their postsecondary service provider. Accommodations received in postsecondary education may differ from those received in secondary education. Accommodations change the way the student is instructed. Students with disabilities may need accommodations in such areas as instructional methods and materials, assignments and assessments, time demands and schedules, learning environment, assistive technology and special communication systems. Documentation of the accommodations requested and provided should be maintained in a confidential file.

Standards

After successfully completing this program, the student will be able to perform the following:

01.0 Demonstrate knowledge of the Food and Drug Administration (FDA) regulations and compliance for biomedical systems.
02.0 Demonstrate knowledge in the design and manufacture of biomedical systems.
03.0 Demonstrate knowledge of risk management for biomedical products development and production.
04.0 Demonstrate knowledge of quality audits for biomedical systems.

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Florida Department of Education
Student Performance Standards

Program Title: **Medical Quality Systems**
CIP Number: **0615000005**
Program Length: **15 Credit Hours**
SOC Code(s): **29-2071, 31-9092, 29-2012, 51-9082, 11-9111, 17-2031, 19-4021**

This certificate program is part of the Engineering Technology AS/AAS degree program (0615000001). At the completion of this program, the student will be able to:

01.0 Demonstrate knowledge of the Food and Drug Administration (FDA) regulations and compliance for biomedical systems -The student will be able to:

- 01.01 Describe how the FDA is organized.
- 01.02 Locate the Code of Federal Regulations (C.F.R.) specific to the FDA regulations that apply to biomedical systems manufacturers.
- 01.03 Describe the role of the FDA's standing advisory committee, the Center for Devices and Radiological Health (CDRH).
- 01.04 Define medical devices, products, and systems and their federal classifications.
- 01.05 Explain the 510(k) Premarket Notification Process including Applications (PMA).
- 01.06 Explain an investigational device exemption (IDE).
- 01.07 Explain the reasons for the pre-amendments for Class III Devices.
- 01.08 Describe and explain the Federal Food, Drug, and Cosmetic Act (FDCA).
- 01.09 Define and describe good laboratory and clinical practices.
- 01.10 Define and describe the quality system regulations (QSRs).
- 01.11 Define and describe Current Good Manufacturing Practices.
- 01.12 Define and describe foreign regulatory systems, i.e., the European Union (EU).
- 01.13 Apply ISO 13485/ISO 13488 quality systems to medical devices and biomedical systems.

02.0 Demonstrate knowledge in the design and manufacture of biomedical systems – The student will be able to:

- 02.01 Describe uses for which products could be designed.
- 02.02 Apply the steps involved in the design process.
- 02.03 Describe how a design team is organized.
- 02.04 Define, describe, and list product specifications.
- 02.05 Define and describe reverse engineering.
- 02.06 Describe, list, and apply failure modes and effects analysis (FMEA) to increase product safety.
- 02.07 Analyze product reliability.
- 02.08 Describe concurrent product and process development.
- 02.09 Describe and compare installation and operation qualifications.
- 02.10 Recognize process optimization.
- 02.11 Develop and analyze process flow maps.
- 02.12 Differentiate between verification and validation.
- 02.13 Describe and determine how a design requirement is verified.
- 02.14 Describe and analyze how customer needs are validated.

02.15 Describe how a process output can be verified.
02.16 Describe and analyze process capability.
02.17 Define the terms associated with production scale-up.
02.18 Discuss and analyze inventory management.
02.19 Describe and analyze production scheduling.
02.20 Describe a market release package with multiple components.
02.21 Determine a root cause of a problem is determined.

03.0 Demonstrate knowledge of risk management for biomedical products development and production – The student will be able to:

03.01 Describe the FDA's definition of risk management.
03.02 Explain how the subparts to the FDA's regulatory requirements 21 CFR 820 Quality System Regulation (QSR) relate to risk management.
03.03 Explain the process of identifying the key risk management activities critical to a successful risk management process.
03.04 Develop a comprehensive risk management plan.
03.05 Identify internal and external sources for determining product hazards.
03.06 Estimate a risk using risk analysis tools and techniques.
03.07 Evaluate a risk using risk evaluation tools and techniques.
03.08 Identify the steps associated with risk control.
03.09 Identify the risk elements that can be reduced to decrease the risk associated with a hazard.
03.10 Describe the process of verification and explain its role in risk control.
03.11 Explain the relationship between risk control measures and the introduction of new hazards.
03.12 Explain the difference between residual risk and overall residual.
03.13 Develop a risk management report.
03.14 List and describe the elements of corrective action and preventive action (CAPA) and how they relate to post production information.

04.0 Demonstrate knowledge of quality audits for biomedical systems – The student will be able to:

04.01 Define terms associated with quality auditing.
04.02 Describe the characteristics of internal and external quality audits.
04.03 Describe the relationship between the quality audit and the FDA regulatory requirement 21 CFR 820.20 (c).
04.04 List factors that can influence the credibility of quality audits.
04.05 Describe the purpose and characteristics of a confidentiality agreement.
04.06 Describe the auditor's responsibilities when illegal or unsafe conditions or activities are discovered during an audit.
04.07 Identify sources in a medical device manufacturing organization that generate performance history data for review prior to performing a quality audit.
04.08 Identify the quality auditing strategies for data collection.
04.09 Describe the purpose and scope of the quality audit opening and closing meetings.
04.10 Identify auditable quality records in a medical device manufacturing company as defined by the FDA regulatory requirements 21 CFR 820.180.
04.11 Describe the relationship of risk and criticality in analyzing audit data.

04.12 Describe the difference between compliance issues and effectiveness issues and giving examples of each.
04.13 Describe record retention requirements.
04.14 Identify effective communication techniques that can be successfully used in a quality audit.
04.15 Conduct a simulated audit that conforms to FDA regulatory requirements.
04.16 Write a comprehensive audit report.