

Program Title: Engineering Technology
Specialization Tract: Medical Quality Systems

- **Specialization Concepts and Content:** The purpose of this certificate is to prepare students to meet the critical industry-specific educational needs for quality assurance, laboratory specialization, and regulatory standards that are required for the biomedical industry for initial employment with an occupational title as laboratory technician, research associate, clinical data manager, document manager, quality assurance technician, quality systems auditor, and quality compliance specialist in various specialized areas of regulated industries, or to provide supplemental training for persons previously or currently employed in these occupations.

VI. INTENDED OUTCOMES: After successfully completing this program, the student will be able to perform the following:

- 12.0 Demonstrate knowledge of the Food and Drug Administration (FDA) regulations and compliance for biomedical systems.
- 13.0 Demonstrate knowledge in the design and manufacture of biomedical systems.
- 14.0 Demonstrate knowledge of risk management for biomedical products development and production.
- 15.0 Demonstrate knowledge of quality audits for biomedical systems.

Florida Department of Education

Student Performance Standards

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12.0 DEMONSTRATE KNOWLEDGE OF THE FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS AND COMPLIANCE FOR BIOMEDICAL SYSTEMS --The student will be able to:

- 12.01 Describe how the FDA is organized.
- 12.02 locate the Code of Federal Regulations (C.F.R.) specific to the FDA regulations that apply to biomedical systems manufacturers.
- 12.03 Describe the role of the FDA's standing advisory committee, the Center for Devices and Radiological Health (CDRH).
- 12.04 Define medical devices, products, and systems and their federal classifications.
- 12.05 Explain the 510(k) Premarket Notification Process including Applications (PMA).
- 12.06 Explain an investigational device exemption (IDE).
- 12.07 Explain the reasons for the pre-amendments for Class III Devices.
- 12.08 Describe and explain the Federal Food, Drug, and Cosmetic Act (FDCA).
- 12.09 Define and describe good laboratory and clinical practices.
- 12.10 Define and describe the quality system regulations (QSRs).
- 12.11 Define and describe Current Good Manufacturing Practices
- 12.12 Define and describe foreign regulatory systems, i.e., the European Union (EU).
- 12.13 Apply ISO 13485/ISO 13488 quality systems to medical devices and biomedical systems.

13.0 DEMONSTRATE KNOWLEDGE IN THE DESIGN AND MANUFACTURE OF BIOMEDICAL SYSTEMS --The student will be able to:

- 13.01 Describe uses for which products could be designed.
- 13.02 Apply the steps involved in the design process.
- 13.03 Describe how a design team is organized.
- 13.04 Define, describe, and list product specifications.
- 13.05 Define and describe reverse engineering.
- 13.06 Describe, list, and apply failure modes and effects analysis (FMEA) to increase product safety.
- 13.07 Analyze product reliability.
- 13.08 Describe concurrent product and process development.
- 13.09 Describe and compare installation and operation qualifications.
- 13.10 Recognize process optimization.
- 13.11 Develop and analyze process flow maps.
- 13.12 Differentiate between verification and validation.
- 13.13 Describe and determine how a design requirement is verified.
- 13.14 Describe and analyze how customer needs are validated.
- 13.15 Describe how a process output can be verified.
- 13.16 Describe and analyze process capability.
- 13.17 Define the terms associated with production scale-up.
- 13.18 Discuss and analyze inventory management.
- 13.19 Describe and analyze production scheduling.
- 13.20 Describe a market release package with multiple components.
- 13.21 Determine a root cause of a problem is determined.

14.0 DEMONSTRATE KNOWLEDGE OF RISK MANAGEMENT FOR BIOMEDICAL PRODUCTS DEVELOPMENT AND PRODUCTION --The student will be able to:

- 14.01 Describe the FDA's definition of risk management.
- 14.02 Explain how the subparts to the FDA's regulatory requirements 21 CFR 820 Quality System Regulation (QSR) relate to risk management.
- 14.03 Explain the process of identifying the key risk management activities critical to a successful risk management process.
- 14.04 Develop a comprehensive risk management plan.
- 14.05 Identify internal and external sources for determining product hazards.
- 14.06 Estimate a risk using risk analysis tools and techniques.
- 14.07 Evaluate a risk using risk evaluation tools and techniques.
- 14.08 Identify the steps associated with risk control.
- 14.09 Identify the risk elements that can be reduced to decrease the risk associated with a hazard.
- 14.10 Describe the process of verification and explain its role in risk control.
- 14.11 Explain the relationship between risk control measures and the introduction of new hazards.
- 14.12 Explain the difference between residual risk and overall residual.
- 14.13 Develop a risk management report.
- 14.14 List and describe the elements of corrective action and preventive action (CAPA) and how they relate to post production information.

15.0 DEMONSTRATE KNOWLEDGE OF QUALITY AUDITS FOR BIOMEDICAL SYSTEMS -
The student will be able to:

- 15.01 Define terms associated with quality auditing.
- 15.02 Describe the characteristics of internal and external quality audits.

- 15.03 Describe the relationship between the quality audit and the FDA regulatory requirement 21 CFR 820.20 (c).
- 15.04 List factors that can influence the credibility of quality audits.
- 15.05 Describe the purpose and characteristics of a confidentiality agreement.
- 15.06 Describe the auditor's responsibilities when illegal or unsafe conditions or activities are discovered during an audit.
- 15.07 Identify sources in a medical device manufacturing organization that generate performance history data for review prior to performing a quality audit.
- 15.08 Identify the quality auditing strategies for data collection.
- 15.09 Describe the purpose and scope of the quality audit opening and closing meetings.
- 15.10 Identify auditable quality records in a medical device manufacturing company as defined by the FDA regulatory requirements 21 CFR 820.180.
- 15.11 Describe the relationship of risk and criticality in analyzing audit data.
- 15.12 Describe the difference between compliance issues and effectiveness issues and giving examples of each.
- 15.13 Describe record retention requirements.
- 15.14 Identify effective communication techniques that can be successfully used in a quality audit.
- 15.15 Conduct a simulated audit that conforms to FDA regulatory requirements.
- 15.16 Write a comprehensive audit report.