Miami Dade College

Course Description

ETI1172 | Introduction to Quality Assurance | 3.00 credits

This course describes the role and aspects of quality systems and Regulatory affairs in research laboratories, regulated companies, and firms that comply with voluntary standards. Topics include stages in development and submission of drugs and medical devices, patents legislation, and quality systems such as auditing, standard procedures, good manufacturing and laboratory practices.

Course Competencies

Competency 1: The student will understand the foundational principles of regulatory affairs by:

1. Analyzing the role of regulatory bodies in drug and medical device approval processes
2. Evaluating the impact of quality systems on compliance and product safety
3. Interpreting relevant legislation surrounding patents and intellectual property in the healthcare sector

Competency 2: The student will apply quality management concepts in laboratory settings by:

1. Developing standard operating procedures (SOPs) for laboratory practices
2. Conducting audits to assess compliance with good manufacturing practices (GMP)
3. Implementing corrective actions based on quality assessment findings

Competency 3: The student will evaluate the stages of drug and medical device development by:

1. Mapping the regulatory submission pathways for various types of medical products
2. Identifying key milestones in product development and their corresponding regulatory requirements
3. Critiquing case studies of successful and failed submissions to regulatory agencies

Competency 4: The student will engage in active participation in quality systems management by:

1. Collaborating on quality improvement initiatives within regulated environments
2. Facilitating training sessions on quality assurance and regulatory compliance
3. Leading discussions on best practices for maintaining quality standards in research and development

Learning Outcomes

- Solve problems using critical and creative thinking and scientific reasoning
- Formulate strategies to locate, evaluate, and apply information