Miami Dade College

Course Competencies Template – Form 112

GENERAL INFORMATION	
Course Prefix/Number: ETI-1181	Course Title: Introduction to Quality Assurance
Number of Credits: 3	
Degree Type	☐ B.A. ☐ B.S. ☐ B.A.S ☐ A.A. ☒ A.S. ☐ A.A.S. ☒ C.C.C. ☒ A.T.C. ☐ V.C.C
Date Submitted:	Effective Year/Term:
☒ New Course Competency ☐ Revised Course Competency	
Course Description (limit to 50 words or less): 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.	
Prerequisite(s): None	Corequisite(s): None

Course Competencies: (for further instruction/guidelines go to: http://www.mdc.edu/asa/curriculum.asp)

Competency 1: Upon successful completion of this course, students will demonstrate knowledge of the appropriate legislation employed for basic principles of regulation by:

1. Discussing the guidelines of federal and state agencies such as the Food and Drug Administration (FDA), the Occupational Safety and Health Administration branch of the US government (OSHA), the US Department of Agriculture (USDA), the National Institutes of Health (NIH), the Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention (CDC), and the National Research Council (NRC) that regulate the industry.

2. Discussing the laws enacted by the U.S. Congress and regulations established by the agency to protect the consumer's health, safety and pocketbook.

3. Discussing the proper use of international, federal, state, local, and organization regulations.

4. Listing national and international regulatory agencies and the corresponding legislation.

5. Defining criteria of food and drug safety.

6. Discussing the history of the FDA, and the first set of Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) regulations.

7. Defining the role and organization of the food and drug administration (FDA) and the Code of Federal Regulations (CFR).

8. Summarizing topics related to regulatory issues.

Revision Date: Draft#10--8/23/2007—3:15 PM

Approved By Academic Dean Date: _____ Reviewed By Director of Academic Programs Date: _____

9. Defining the role and organization of the environmental protection agency (EPA).

10. Explaining international harmonization efforts.

Competency 2: Upon successful completion of this course, students will demonstrate knowledge of quality systems and documentation by:

1. Comparing and contrasting quality systems in academic research laboratories, in regulated companies, and companies that comply with voluntary standards.

2. Explaining the role of the individuals staffed in product quality systems.

3. Illustrating the major principals in writing quality control and assurance documents: scientific language and common elements used in GMP/GLP documents.

4. Categorizing the importance of documentation and the types of documents commonly used in workplaces.

5. Summarizing the importance of confidentiality and security in the workplace.

Competency 3: Upon successful completion of this course, students will demonstrate knowledge of the role of quality systems in an organization by:

1. Describing regulated areas and the equipment commonly contained within these areas.

2. Summarizing the principles of raw materials handling.

3. Explaining the role of the Quality Assurance (QA) department in receiving materials, sampling, documentation review, corrective actions, recalls, audits and surveillance.

4. Describing the role of process and equipment validation in product development.

5. Describing the function of Quality Control (QC).

6. Differentiating between QC and QA.

7. Summarizing cost/benefit analysis and its relationship to quality.

8. Discussing cleaning, sanitization, microbial testing, and environmental compliance within regulated areas.

9. Explaining the concept of clean air in regulated areas and the function of high-efficiency particulate air (HEPA) filters.

10. Summarizing the importance of personal hygiene, open wounds, aseptic techniques, sterilization, sanitization, proper gowning and personnel flow in a facility.

11. Summarizing the handling procedures involved in product recall and complaints.

12. Demonstrating familiarity with the deviation reporting process.

13. Describing the function and methods of quarantine.

14. Categorizing technical issues related to manufacturing areas and systems.

Competency 4: Upon successful completion of this course, students will demonstrate knowledge of patent legislation and the processes involved in patent submission by:

1. Describing the functions of patents and explaining how patents encourage discovery.

2. Listing what products are considered patentable.

3. Explaining the stages of development for a new product.

4. Categorizing the various submission requirements and the different stages of submission with reference to the applicable section of the relevant legislation.

5. Describing current patent legislation and how it affects the approval process.

6. Comparing and contrasting the development and submission process for a new drug, biologic, product.

Competency 5: Upon successful completion of this course, students will demonstrate knowledge of the role of the Regulatory Affairs department by:

1. Describing the role of the Regulatory Affairs department and its relationship to other organization departments and external regulatory agencies.

2. Categorizing and characterizing noticeable changes based on the requirements of the Food and Drug Administration (FDA) and the European Union (EU) by performing research.

3. Explaining the function of ISO (International Organization for Standardization) quality standards.

4. Explaining the function of NIST (National Institute of Standards and Technology).

5. Comparing and contrasting the differences and similarities between Quality and Compliance.

6. Summarizing the involvement of Regulatory Affairs Department in product recall, complaint handling, deviations reporting, investigational reports, Standard Operating Procedures (SOPs), and regulatory inspections.

7. Discussing how an organization prepares for an inspection.

Competency 6: Upon successful completion of this course, students will demonstrate knowledge of the role of good manufacturing practices and good laboratory practices in product quality by:

1. Comparing and contrasting the differences between Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).
2. Describing the proper use of current GLP and GMP standards.
3. Analyzing documents commonly used in organizations.
4. Describing the importance of good practices and the need for documentation.
5. Explaining the concept of continuous training and improvement.
6. Illustrating components of quality documents and how they relate to the organization's protocols and SOPs.
7. Defining the major rules and steps to develop SOP documents.
8. Describing production facilities documents.
9. Distinguishing the numbering/labeling systems used to identify the items GMP facilities and GLP areas.
10. Explaining the types of regulated records and their importance during inspections.
11. Using on-line resources to access current regulatory standards in an organization.

Competency 7: Upon successful completion of this course, students will demonstrate understanding of the important harmonization between the validation, quality assurance, and quality control departments by:

1. Describing validation of processes and equipment.
2. Summarizing the different roles of validation group members in an organization.
3. Summarizing the role of the quality assurance group members in an organization.
4. Summarizing the role of the quality control group members in an organization.
5. Listing documentation associated with validation, quality assurance and quality control.
6. Outlining the steps of preparation for quality audits and self inspection.
7. Explaining the responsibilities of the validation, quality control and quality assurance departments in the calibration of equipments, systems and processes.