MSP 110 Introduction to Medical Product Safety

COURSE DESCRIPTION:

Prerequisites: Admission to the Medical Product Safety/Pharmacovigilance or Clinical Trials Research Associate programs

Corequisites: None

This course provides a comprehensive introduction to medical product safety and pharmacovigilance. Topics will include an overview of the key components of and process to monitor product safety, product safety terminology and regulations that govern product safety and pharmacovigilance. Upon completion of this course, students will be able to describe the process for monitoring the safety of drugs, diagnostics, medical devices, and biologics throughout a product's lifecycle. Course Hours Per Week: Class, 3. Lab, 0.

LEARNING OUTCOMES:

Upon completion of this course, the student will demonstrate basic cognitive and practical knowledge and skills in each of the following areas:

1. Understand the history and evolution of pharmacovigilance
2. Define key medical product safety terms
3. Understand Good Pharmacovigilance Practices and the regulations relating to medical product research
4. Understand the ethical aspects of medical product safety
5. Describe the overall process to evaluate, monitor, and report the safety of drugs, devices, and biologics
6. Describe medical product safety as a profession

OUTLINE OF INSTRUCTION:

I. Understand the history and evolution of pharmacovigilance
   A. Timeline of historic events leading to medical product safety regulation
   B. U.S. and global laws governing the safety of medical products

II. Define key medical product safety terms
   A. Defining product safety and pharmacovigilance
   B. Understanding benefit-risk concepts
   C. Adverse effects versus adverse reaction
   D. Terms relating to drugs, devices, biologics and other medical products
   E. Terms relating to the product safety process
   F. What is risk management and signal detection?

III. Understand Good Pharmacovigilance Practices and the regulations relating to medical product research
   A. Overview of applicable adverse event related regulations and the regulatory reporting process
   B. Review major medical product regulators (FDA, EMA, MHRA, PMDA, Health Canada, etc.)
   C. Overview of MedWatch, CIOMS, ICH, and other medical product safety regulatory constructs

IV. Understand the ethical aspects of medical product safety
    A. Declaration of Helsinki
    B. Informed consent
    C. Institutional Review Boards/Ethics Committee

V. Describe the overall process to evaluate, monitor, and report the safety of drugs, devices, and biologics
    A. Roles and responsibilities of product safety professionals
    B. Differences in product safety processes in varying organizations (i.e. pharmaceutical, device, biologic company, contract research organization, etc.)
    C. Components of a safety monitoring program
    D. Components of pharmacovigilance including collection, detection, assessment, monitoring and preventing of adverse effects with medical products
    E. Types and sources of data
    F. Medical safety monitoring at different stages during a product lifecycle (i.e. preclinical, clinical, post-market)
    G. Use of key performance indicators
    H. Types of reporting (spontaneous, clinical, aggregate, solicited, etc.)

VI. Describe medical product safety as a profession
    A. Knowledge and skills necessary to work as a safety professional
    B. Career opportunities for safety professionals
    C. Current issues and trends relating to medical product safety
    D. Professional organizations for safety professionals
    E. Discuss transition to product safety career

REQUIRED TEXTBOOK AND MATERIAL:

The textbook and other instructional material will be determined by the instructor.