MSP 130 Safety Systems and Processes

COURSE DESCRIPTION:

Prerequisites: MSP 120
Corequisites: None

This course introduces product safety systems and the collection and processing of safety data. In this course students will understand the importance of quality data, learn each step involved in case processing and have hands-on experience in entering cases. Upon completion of this course, students will become familiar with the process for a case from beginning to end for pre-marketing and post-marketing cases. Course Hours Per Week: Class, 3. Lab, 3. Credits: 4.

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 each step in case processing
2. Understand the importance of quality data
3. Understand the need for data coding
4. Discuss the development, maintenance and use of the safety database
5. Understand the functions needed for a compliant product safety/pharmacovigilance department

OUTLINE OF INSTRUCTION:

I. Understand each step in case processing
   - A. Where the data are collected – clinical vs. post-marketing
   - B. How the data are recorded
   - C. How the data are entered
   - D. How the data are reviewed
   - E. How the data are coded
   - F. How the data are assessed
   - G. How the data are reported
   - H. How the data are stored
   - I. The process for revision/updating information in the database
   - J. Safety database outputs e.g., MedWatch/CIOMS forms, line listings, tabulations
   - K. Standard operating procedures (SOPs) vs. work instruction

II. Understand the importance of quality data
   - A. Identification of essential data fields
   - B. Data collection and entry
   - C. Query process
   - D. Edit checks
   - E. Data reconciliation

III. Understand the need for data coding

A. The Medical Dictionary for Regulatory Activities (MedDRA) for coding medical history and adverse events
B. WHO Drug dictionary for coding drugs
C. EudraVigilance Medicinal Product Dictionary (EVMPD

IV. Discuss the development, maintenance and use of the safety database
A. Key components of the safety database
B. Differentiate the clinical studies database and the safety database
C. Data reconciliation between systems
D. Discuss the setup of different systems
E. MSSO: Standardized MedDRA Queries
F. Monitoring of "Medically Important" predefined events
G. Trend Analysis

V. Understand the functions needed for a compliant product safety/pharmacovigilance department
A. ICSR Processing
B. Aggregate Reporting
C. Signal Detection
D. Risk Management
E. Quality Management
F. Training
G. Compliance
H. QPPV Office (EU)

REQUIRED TEXTBOOK AND MATERIAL:

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