MSP 220 Signal Detection and Risk Assessment

COURSE DESCRIPTION:

Prerequisites: MSP 130
Corequisites: None

This course provides a basic understanding of how data are analyzed in order to identify safety signals and determine a product's risk profile. The course also emphasizes the overarching reason for the evaluation of medical product safety and pharmacovigilance, i.e., to ensure a medical product has a favorable benefit-risk balance throughout its lifecycle. Topics include the rationale and methods used in analyzing single cases vs. aggregate data. Upon completion of this course students will have a better understanding of the relevance of the material learned in the previous courses e.g., case processing, safety systems, safety reporting and regulations as it relates to benefit-risk, as well as the importance and need for ongoing benefit-risk assessments. Students will also have a basic understanding of how signaling and risk assessments are done. 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 benefit-risk concepts
2. Discuss approach to signal detection and management in clinical development as well as post-marketing settings
3. Understand signal management
4. Understand the [illegible]