MSP 120 Safety Reporting

COURSE DESCRIPTION:

Prerequisites: MSP 115
Corequisites: None

This course provides an overview of the criteria utilized in determining how safety data are reported. In addition, students will learn the purpose, content and format of the various reports that include safety information. Upon completion of this course, students will have a basic understanding of the difference between expedited and periodic reporting, the criteria used in this determination, as well as, the purpose and content of each type of safety report.
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. Differentiate expedited versus periodic/aggregate reporting
2. Describe the various safety reports
3. Classify event information
4. Understand key topics/aspects of an ICSR including the importance of the case narrative
5. Discuss topics relating to safety reporting in clinical trials
6. Understand safety reporting for devices, cosmetics, consumer products and OTC products

OUTLINE OF INSTRUCTION:

I. Differentiate expedited versus periodic/aggregate reporting
   A. Marketed vs. investigational products
   B. Regulatory requirements (US and EU)

II. Describe the various safety reports
   A. Individual case safety reports (ICSR)
   B. Aggregate reports e.g., CIOMS II line listings, SUSAR listings
   C. Development safety update report (DSUR)
   D. Periodic benefit risk evaluate report (PBRER)
   E. Periodic adverse drug experience report (PADER)
   F. Risk management plans (RMPs)/risk evaluation and mitigation strategies (REMS)
   G. Annual Product Reviews (APRs)

III. Classify event information
   A. Determine seriousness and clinical significance
   B. Determine if the case qualifies for expedited reporting
   C. Determine event causality (single case vs aggregate reporting; pre-marketing versus post-marketing)
   D. Determine event expectedness/listedness

IV. Understand key topics/aspects of an ICSR including the importance of the case narrative
    A. Sources
    B. Data Elements
    C. Elements of a good narrative
    D. Follow-up
    E. Special situations e.g., pregnancy, lack of efficacy, product technical complaints (PTCs), legal cases

V. Discuss topics relating to safety reporting in clinical trials
    A. Reporting Unblinding
    B. Trend monitoring
    C. Medical Safety Review
    D. Reconciliation
    E. AOSE
    F. Comparator/co-medication
    G. Reporting to manufacturer
    H. Safety queries

VI. Understand safety reporting for devices, cosmetics, consumer products and OTC products
    A. Medical devices
    B. Cosmetics/Consumer products
    C. Over-the-Counter (OTC) products

REQUIRED TEXTBOOK AND MATERIAL:

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