MSP 115 Medical Product Safety Regulations

COURSE DESCRIPTION:

Prerequisites: MSP 110
Corequisites: None

This course provides an overview of national and global regulations governing the safety of medical products including drugs, diagnostics, medical devices, and biologics. Topics include a review of the regulatory agencies, regulations for pre-clinical, clinical, and post-market product safety, and regulations governing the process for monitoring product safety. Upon completion, students should be able to demonstrate a basic understanding of regulatory processes associated with clinical research and describe effective means of compliance.
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. Apply regulatory, legal, and governing parameters within a clinical research project
2. Understand the differences between legislation, regulations, and guidances in each of the world regions
3. Describe the role of other organizations involved with product safety monitoring
4. Differentiate the regulations and guidances relating to different points in the product lifecycle (i.e. preclinical, clinical, post-market)
5. Identify the regulatory and legal documents associated with a clinical research project or study relating to product safety

OUTLINE OF INSTRUCTION:

I. Apply regulatory, legal, and governing parameters within a clinical research project
   A. Review the history of medical product approval/registration and product safety requirements
   B. Identify the domestic and international regulatory agencies and branches that impact the product
   C. safety process and describe the structure of these entities (including (FDA, EMA, MHRA, PMDA, Health Canada, etc.)
   D. Describe the process of regulatory compliance within the context of clinical research and product safety
   E. Describe how the product safety process is related to the overall product approval/registration process

II. Understand the differences between legislation, regulations, and guidances in each of the world regions
   A. United States
   B. European Union
   C. Japan
   D. Rest of world

III. Describe the role of other organizations involved with product safety monitoring
    A. The Council for International Organizations of Medical Science (CIOMS)
    B. International Conference on Harmonization (ICH)

IV. Differentiate the regulations and guidances relating to different points in the product lifecycle (i.e. preclinical, clinical, post-market)
    A. Understand regulatory requirements outlined in 21 CFR 312.32 IND Safety Reporting and 312.33 Annual Reports
    B. Understand regulatory requirements outlined in 21 CFR 314.80 Postmarketing Reporting of Adverse Drug Experiences
    C. Describe how pharmaceutical companies comply with 21 CFR 314.80

V. Identify the regulatory and legal documents associated with a clinical research project or study relating to product safety
    A. Reporting (FDA MedWatch 3500A, CIOMS, etc.)
    A. E2B and M2

REQUIRED TEXTBOOK AND MATERIAL:

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