MSP 250 Medical Product Safety Research Fieldwork II

COURSE DESCRIPTION:

Prerequisites: MSP 130 and CTR 220
Corequisites: None

This course provides advanced work experience in a medical product safety/pharmacovigilance research setting. Emphasis is placed on the refinement of professional skills and the practice of curriculum concepts in diverse medical product safety research areas. Upon completion, students should be able to apply research theory to medical product safety/pharmacovigilance practices. Course Hours Per Week: Lab, 24. Semester Hours Credit, 8.

LEARNING OUTCOMES:

The student will demonstrate the ability to apply, in a research setting, basic cognitive and practical knowledge and skills in the areas of:

1. Medical product safety and pharmacovigilance (MPSP)
2. The role and responsibilities of a Drug Safety Associate or Pharmacovigilance Associate as a member of the safety team at the pharmaceutical/medical device industry or in a contract research organization
3. Regulatory, legal, and governing parameters as they impact safety reporting
4. Understanding of and proper utilization of medical product safety coding
5. Understanding of case handling and organization
6. Understanding of safety reporting procedures
7. Planning and preparing for a compliance audit
8. Professional appearance and attitude and respect others rights and values
9. Reconciliation of personal and professional goals with supervisor's objectives and policies
10. Effective and timely workplace behaviors consistent with the role and responsibility of a Medical Product Safety/Pharmacovigilance student

OUTLINE OF INSTRUCTION:

I. Observation of MPSP at the fieldwork site(s)
II. Completion of selected MPSP planning activities
III. Completion of selected ongoing MPSP activities
IV. Completion of selected MPSP compliance evaluation activities
V. Completion of other assignments as designated by the site(s), supervisor(s), and faculty
VI. Closure with the site's clients and supervisor

REQUIRED TEXTBOOK AND MATERIAL:

No textbook required

SUPERVISOR'S RESPONSIBILITIES:

A. The supervisor will orient the student to the facility, including identifying other disciplines involved in the MPSP process at the specific site.

B. The supervisor will arrange for a quiet place to provide feedback to the student on an individual basis, ensuring privacy and confidentiality.

C. The supervisor will identify one project that the student can observe for at least two sessions, so that the student can adequately accomplish their fieldwork assignments.

D. The supervisor will provide the opportunity for the student to observe and participate in a MPSP research project.

E. Pharmaceutical company or contract research organization experiences may include, but not be limited to data entry, case processing, writing case narratives, preparing safety reports, etc.

STUDENT'S RESPONSIBILITIES:

A. Students are responsible for confirming their fieldwork with the clinical site supervisor at least one week prior to the scheduled time to determine hours, dress code, materials needed, location of the site facility and directions to the initial meeting place.

B. During the first session, students should review their individual objectives and assignments of the fieldwork experience with their supervisor.

C. The student will identify the specific type MPSP project in place at the specific fieldwork site and identify the roles of specific disciplines involved in the coordination of clinical research projects.

D. The student will receive information from the site supervisor regarding:
   i. The pharmaceutical drug or medical device that is the subject of the safety report
   ii. The known effects of the pharmaceutical drug or medical device, both beneficial and adverse
   iii. The phase of development in which the product is currently being researched
   iv. The regulatory status of the product
   v. The protocol design and objectives of the study
   vi. Members and roles of the MPSP team

E. The student will observe the supervisor while interacting in meetings, collecting relevant data, and performing study-required tasks.

F. During the clinical research industry site rotation, the student will observe and participate in, as appropriate, planning meetings, medical monitor site visits, case report processing and review, and other administrative responsibilities related to the MPSP project.