MSP 110,

IV. Understand the ethical aspects of medical product safety
    A. Declaration of Helsinki
    B. Informed consent
    C. Institutional Review Boards/Ethics Committee

V. Describe the overall process to evaluate, monitor, and report the safety of drugs, devices, and biologics
    A. Roles and responsibilities of product safety professionals
    B. Differences in product safety processes in varying organizations (i.e. pharmaceutical, device, biologic company, contract research organization, etc.)
    C. Components of a safety monitoring program
    D. Components of pharmacovigilance including collection, detection, assessment, monitoring and