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PHARMACOVIGILANCE AND RISK MANAGEMENT FOR DRUG SAFETY

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ABSTRACT

Pharmacovigilance (PV) plays a key role in the healthcare system through assessment, monitoring and discovery of interactions amongst New drugs and their effects in human medicinal product are designed to cure, prevent or treat diseases; however, there are also risks particularly adverse drug reactions (ADRs) can cause serious harm to patients. Thus, for safety medication ADRs monitoring required for each medicinal product throughout its life cycle, during development of drug such as pre-marketing including early stages of drug design, clinical trials, and post-marketing surveillance. PV is concerns with the detection, assessment, understanding and prevention of ADRs.

Risk management is a systematic approach to identifying, assessing, and understanding, acting on, and communicating risk issues. All drugs have risks associated with their use, including adverse reactions, interactions between drugs, and the risk that the product may not work as effectively as expected. Manufacturers, regulators, health professionals, and patients all perform risk management activities. A proactive approach to risk management of drug safety is vital throughout the whole life-cycle of a medicinal product. Our Pharmacovigilance Planning and Risk Management course will critically explore existing and developing strategies to plan and optimize risk management activities for known and potential risks of a newly approved product.

KEYWORDS: Pharmacovigilance, Adverse drug reaction, risk management, Drug safety

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