WHAT IS PHARMACOVIGILANCE?

Pharmacovigilance (PV) is defined by WHO as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem.

As such, pharmacovigilance heavily focuses on adverse drug reactions (ADRs), which are defined as any response to a drug which is harmful and unintended, including lack of efficacy.
Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients. Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and guidance. Medicines and Medical Devices have to comply to their respective Directives.

Key Tasks

1. Setting up of the Pharmacovigilance Site Master File (PSMF)
2. Literature searches on all active ingredients in a product
3. Individual Case Safety Reports Handling
4. Medical information requests
5. Urgent safety review and PRAC requests

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