Pune District Education Association's

Seth Govind Raghunath Sable College of Pharmacy, Saswad

Value Addition Course

Advance Diploma in Pharmacovigilance and Clinical Research

In Association with Elite Institute of Pharma Skill, Chinchwad, Pune-411019

The drug development industry is changing in a way where innovation and drug safety are not separate from one another. New business models are maturing leading to the development of new generation therapies and to a coexistence of these newer drugs and well known blockbuster treatments from the past. Pharmacovigilance is now an essential component of the life cycle of almost all healthcare related products. This is because of a demand for safer and more effective drugs and changes in regulations applicable to their research, development and marketing. Many global companies have developed their own pharmacovigilance centers in all major clinical research regions around the world including India.

In addition, local drug companies in these regions are also stepping up their work in research and development for both promising new molecules as well as generics. This business report also emphasizes the shifting focus of key drug companies towards outsourcing their pharmacovigilance functions to smaller specialized pharmacovigilance service providers. Developing regions such as India, Latin America etc are slowly becoming a hub for pharmacovigilance business.

Pharmacovigilance involves many lead scientific activities that have increased in complexity due to coercion of potential markets & larger volumes of data. Pharmacovigilance depicts pharmacological science, which is also known as drug safety. It is to collect, discover, estimate, monitor and prevent adverse effects of those pharmaceutical drugs that are in the market and in development. It has its focus mainly on Adverse Drug Reactions (ADR's), which may occur with various dose levels. Improper uses of medication such as overdose / abuse, or misuse are also considered in reporting of adverse drug reactions. The objective of pharmacovigilance is to eventually identify the detrimental effects of drugs & to minimize the possible harm that can be caused to patients.

Clinical studies are an essential component of the much larger R&D landscape for bringing safe and effective medicinal products to the marketplace. Along with this fundamental and legitimate concept, pharma-biotech sector and the community at large are acknowledging the need to speed up the methods of drug development so that the discoveries of the laboratory are not shelved but rather successfully translated into clinical practice.

Objective:-

To provide participants with a broad understanding of the basic principles employed within Clinical Research and pharmacovigilance both domestically and internationally.

Benefits:-

- Successful candidates can get an internship/ Job opportunity in Pharmacovigilance & Clinical Research Organisation.
- Boosting skills and knowledge to the level expected of a Clinical Research and Pharmacovigilance Professional.
- Training Program trains students to put together, evaluate and organize data related to drug side effects so as to make regulatory decisions pertaining to marketed drugs.

Program Structure:-

No.	Module
1	Introduction to Clinical Research & Advancement of ICH-GCP
2	Ethical & Regulatory Aspects of Clinical Trails
3	Operations Aspects of Clinical Trails
4	Medical Coding
5	Pharmacovigilance at a Glance
6	Signal management, ADR Reporting System & Dictionaries
7	Regulatory Aspects of Pharmacovigilance
8	Career orientation and Interview Preparation

Eligibility (Target students): All Final year students of B.Pharm & M.Pharm

Duration of course: 30 hrs