

## **Pharmacovigilance & Regulatory Affairs Diploma**

### Pharmaceutics & Clinical Pharmacy and Pharmacy Practice

The department responsible for recommending the award of the degree is  
the department of Clinical Pharmacy and Pharmacy  
Practice

**(Professional diploma 29 Cr. h)**

### **Introduction to the program:**

The program aims to prepare pharmacists to acquire skills to work in the field of pharmacovigilance in terms of identifying and predicting potential side effects of drugs, as well as methods of reporting them to pharmacovigilance centres to reach patient safety goals.

### **Mission**

To enable pharmacist to be competent pharmacovigilant officers in order to improve patient care and safety in relation to use of medicines and all medical and paramedical intervention.

### **Vision**

The diploma provides knowledge and develop skills to become competent pharmacovigilant specialist. Promote understanding, education, and clinical training in fundamentals of adverse drug reactions, regulations and guidelines (Egypt and major global regions). Pharmacovigilance and regulatory affairs diploma enhances communication to health professionals and public community.

## **Objectives**

The pharmacovigilance and regulatory affairs diploma provides students with a wide range of knowledge and skills e.g:

- Monitor and report medication misadventure including adverse effects of drugs used in the public, hospitals, and clinical trials.
- Develop periodic safety update reports on medications through efficient monitoring systems to reduce the risk of harm from potential adverse reactions and drug interactions.
- Detect, classify and report medication errors and carry out root cause analysis, to prevent medication errors from happening again.
- Identifying early warning signs of adverse drug effects and minimising the risk of serious side effects.
- Compile data on adverse events from clinical trials and ad hoc reports.
- Follow-up pharmacovigilance cases, as well as data accuracy, clinically valid case assessment, and regulatory reporting status assessment.
- Inform the relevant Regulatory Authorities of any unfavourable circumstances.
- Encourage the safe and efficient use of medical products, particularly by promptly informing patients, medical professionals, and the general public on the safety of medical products.
- Provide the knowledge and hands on training from the clinical healthcare settings & also pharmaceutical industry point of view to prepare candidates to serve as qualified personal for pharmacovigilance.