

Pharmacovigilance & Regulatory Affairs Diploma (29 Cr. h)

Professional Diplome

First semester (15 Cr. h)

| No. | Course code | Courses | L | P |
|---------------------------|-------------|--|-----------|---|
| 1 | 0601632 | Pharmacovigilance –I | 3 | 1 |
| 2 | 0609601 | Pharmacoepidemiology | 2 | - |
| 3 | 0609602 | Pharmacotherapy | 3 | 2 |
| 4 | 0609603 | Adverse drug reactions and drug interactions | 2 | - |
| 5 | 0601633 | Ethics and regulations | 2 | - |
| Total credit hours | | | 15 | |

*1 credit hour practical is 2 hours session weekly

Second semester (14 Cr. h)

| No. | Course code | Courses | L | P |
|---------------------------|-------------|-------------------------|-----------|---|
| 6 | 0601634 | Pharmacovigilance –II | 3 | 1 |
| 7 | 0601635 | Biostatistics | 2 | 2 |
| 8 | 0601636 | Capstone Project | - | 3 |
| 9 | 0609604 | Evidence based medicine | 2 | - |
| 10 | | Elective course | 1 | - |
| Total credit hours | | | 14 | |

Elective courses

| No. | Course code | Courses | L | P |
|-----|-------------|---------------------------------------|---|---|
| 1 | 0609605 | Pharmacovigilance of special products | 1 | - |
| 2 | 0609606 | Care of special populations | 1 | - |

Course Description

First semester (15 Cr. h)

| Course Name | Teaching h/week | | Credit hours | Code No. |
|--|-----------------|---|--------------|----------|
| | L | P | | |
| Pharmacovigilance –I | 3 | 1 | 4 | 0601632 |
| <p>Description: The course aims to provide basic knowledge of principles for good pharmacovigilance practice, highlighting the critical requirement for the spontaneous reporting of adverse drug events, to ensure drug and patient safety. It demonstrates the different reporting forms including Individual Case Safety Reports (ICSRs) and CIOMS forms, the proper application of MedDRA (Medical Dictionary for Regulatory Activities) and causality assessment. It also provides basic skills for benefit- risk evaluation, signal management, how to deal with emerging safety issues, as well as risk management and risk minimization measures. Finally, it will guide on communicating safety information to healthcare professionals and consumers.</p> | | | | |

| Course Name | Teaching h/week | | Credit hours | Code No. |
|--|-----------------|-----|--------------|----------|
| | L | P | | |
| Pharmacoepidemiology | 2 | --- | 2 | 0609601 |
| <p>Description: Pharmacoepidemiology is the fundamental science in drug safety and a corner stone in making patient safety decisions. By the end of the course, the student should be able to define pharmacoepidemiology and related concepts. To distinguish between different types of pharmacoepidemiology studies. To identify various sources used for collecting data and judge the quality of these data. To outline methodological approaches and statistical methods used in pharmacoepidemiology studies. And finally, to develop a surveillance program for drug use.</p> | | | | |

| Course Name | Teaching h/week | | Credit hours | Code No. |
|---|-----------------|---|--------------|----------|
| | L | P | | |
| Pharmacotherapy | 3 | 2 | 5 | 0609602 |
| <p>Description: In this course, the students will gain knowledge about retrieval & overview of different guidelines for cardiovascular, nephrology, neuropsychiatric, gastrointestinal, hematological endocrine and oncological disorders and the most encountered conditions in intensive care units. Problem-based learning approach will be used with an emphasis on the most frequently reported adverse drug reactions & medications errors in different settings. The students will also be able to design & monitor therapeutic plans for these patients to ensure proper use of drugs in addition to preventing & solving drug-related problems.</p> | | | | |

| Course Name | Teaching h/week | | Credit hours | Code No. |
|--|-----------------|---|--------------|----------|
| | L | P | | |
| Adverse drug reactions and drug interactions | 2 | - | 2 | 0609603 |
| <p>Description: This course aims to provide basic knowledge about adverse drug reactions and medication errors, their classifications, and types as well as drug interactions. It will help identify the importance of monitoring the adverse drug events and decrease or prevent drug interactions as well as skills required for taking the required measures to improve drug safety.</p> | | | | |

| Course Name | Teaching h/week | | Credit hours | Code No. |
|--|-----------------|----|--------------|----------|
| | L | P | | |
| Ethics and regulations | 2 | -- | 2 | 0601633 |
| <p>Description: The course aims to provide the students with ethical regulatory guidelines of pharmacovigilance nationally and internationally. Medical products law, data protection and patent protection, insurance coverage, and informed consent. It will also cover security of database.</p> | | | | |

Second semester (14 Cr. h)

| Course Name | Teaching h/week | | Credit hours | Code No. |
|--|-----------------|---|--------------|----------|
| | L | P | | |
| Pharmacovigilance –II | 3 | 1 | 4 | 0601634 |
| <p>Description: This Course aims to provide the knowledge and hands on training from the pharmaceutical industry point of view, to prepare candidates to serve as Qualified Person for Pharmacovigilance (QPPV) in various national, international and multinational pharmaceutical companies. It consists of several chapters that are drawn up to implement the good pharmacovigilance practice in accordance with the national and international guidelines. It will also provide knowledge on different Pharmacovigilance systems, including Pharmacovigilance System Master File (PSMF), Periodic Safety Update Report (PSUR) and the Addendum of Clinical Overview (ACO), as well as the Risk Management Plan (RMP). It will also help to understand the key messages on handling pharmacovigilance audits and inspections.</p> | | | | |

| Course Name | Teaching h/week | | Credit hours | Code No. |
|--|-----------------|---|--------------|----------|
| | L | P | | |
| Biostatistics | 2 | 2 | 4 | 0601635 |
| <p>Description: This course aims to provide basic knowledge about descriptive statistics that would include description, measures of location and spread, standard deviation and normal distribution. Different study designs and calculation methods of probability will be addressed. Concept of confidence interval and difference of two population means will be discussed. The student should be able to interpret biostatistics differences in clinical trials. The students will be trained on how to choose the power of the study, to perform sample size calculations. The use of the R programming language as a tool for analyzing data will also be introduced.</p> | | | | |

| Course Name | Teaching h/week | | Credit hours | Code No. |
|--|-----------------|---|--------------|----------|
| | L | P | | |
| Capstone Project | -- | 3 | 3 | 0601636 |
| <p>Description: students will conduct research projects within academic, clinical, industrial, regulatory, or private body. Students will give presentation and/or submit a hard copy of the project.</p> | | | | |

| Course Name | Teaching h/week | | Credit hours | Code No. |
|---|-----------------|----|--------------|----------|
| | L | P | | |
| Evidence based medicine | 2 | -- | 2 | 0609604 |
| Description: During this course student will use concepts obtained in epidemiology course to help solving clinical problems. Students need to acquire knowledge and develop skills to determine the validity of decision taken when they provide care to patients from the best evidence available sound clinical research and patients' values and preferences. | | | | |

Elective courses

| Course Name | Teaching h/week | | Credit hours | Code No. |
|---|-----------------|----|--------------|----------|
| | L | P | | |
| Pharmacovigilance of special products | 1 | -- | 1 | 0609605 |
| Description: The course introduces the students to pharmacovigilance activities for special products including vaccines, biological products, herbal remedies, or supply & devices. The students will gain general knowledge about the three types of post-marketing pharmacovigilance (drug safety surveillance, drug abuse and adverse effects monitoring and safety monitoring of these special products). The performance of pharmacovigilance activities in Egypt and its application on applies on marketing authorization holders based on the Egyptian Drug Authority (EDA) regulations will be discussed. Guidelines with pharmacovigilance requirements for these products shall also be considered including immunogenicity and adulteration which are included in the safety specification of biologicals & herbal products, respectively. | | | | |

| Course Name | Teaching h/week | | Credit hours | Code No. |
|---|-----------------|----|--------------|----------|
| | L | P | | |
| Care of special populations | 1 | -- | 1 | 0609606 |
| Description: The course reinforces general principles pertaining to the care of the special populations including geriatric, paediatrics, obese, pregnant & lactating females' patient. The goal is to enhance the student pharmacist's competence in caring for these populations. Topics will focus on the physiological, psychological, physical, ethical, social, economic and therapeutic issues. Monitoring & preventing drugs misadventures in these populations will be thoroughly discussed. Each lecture incorporates topics and activities pertinent to providing patient-centered care in these populations. | | | | |