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## Master of Science in Pharmacovigilance (Full Time)

## About the Programme

Pharmacovigilance is an emerging area of medical sciences with focus on assessing adverse drug reactions and improving drug therapy. This pharmacovigilance programme is designed to give students theoretical and practical knowledge in the field of pharmacovigilance. To train individuals that will be relevant to the pharmaceutical industry and health sector in the areas of improving drug and herbal therapy and minimizing adverse drug reactions. We intend to collaborate with experts from the industries to drive this program.

The aim is to train and produce world class professionals, equipped with requisite measures of knowledge and skills in pharmacovigilance that can solve adverse drug reactions related problems. The programme will

* produce skilled and competent Pharmacovigilance professionals who can work effectively at different levels in Pharmacovigilance departments of Pharmaceutical manufacturing and marketing companies, Drug Regulatory Agencies and Health facilities.
* provide training opportunities, and conducting state-of-the-art pharmacovigilance research in order to prepare the students for careers in independent research or related careers in academia, industry or government
* optimise the science of pharmacovigilance through collaboration with drug regulatory agency and health sectors.

The graduates of this programme will

* Have ability to undertake pharmacovigilance related research
* Able to collaborate with relevant agencies to promote pharmacovigilance
* Have competence in optimizing pharmacovigilance activities
* Search compile, analyze and evaluate reports about adverse drug reactions in scientific literature and databases.
* Understand various methods utilized in pharmacovigilance.
* Assess and analyze warnings, risk management and risk communication about adverse drug reactions.
* Assess and analyze the effects and safety of medicines.
* To understand pharmacovigilance from a regulatory perspective.
* Explain the importance of pharmacogenomics for individual variation in adverse drug reactions.

### **Admission Requirements**

A candidate for the M.Sc. Pharmacovigilance programme must possess credit passes in English, Mathematics, Physics, Chemistry and Biology in ‘O’ level or its equivalent at one sitting and a minimum of second-class lower bachelor degree or its equivalent in Pharmacy, Medicine, Dentistry, Nursing or Pharmacology from any approved University.

### **Graduation Requirements**

To obtain an M.Sc. in Pharmacovigilance, a candidate must satisfy a minimum of **24 units** of courses in minimum of two (2) semesters and with cumulative grade point average (CGPA) of 2.40 at 800 level made up as follows:

1. 14 units of compulsory theory courses
2. 2 units of Research seminar
3. 4 units of Research project
4. 4 units of elective theory courses

The duration of the programme shall be minimum of two (2) semesters and maximum of four (4) semesters.

### **List of Courses and No of Units by Levels in tabular form**

|  |
| --- |
| **800 LEVEL FIRST SEMESTER** |
| **COURSE CODE** | **COURSE TITLE** | **STATUS**  | **UNITS** |
| PVG 811 | Overview of Pharmacovigilance | Compulsory | 2 |
| PVG 812 | Spontaneous Reporting Systems (SRS) and Case assessments | Compulsory | 2 |
| PUH 801 | Medical Statistics  | Compulsory  | 2 |
| PCH 801 | Drug Quality Assurance and Total Quality Management | Compulsory | 2 |
| PCL 807 | Advanced Pharmacy Practice, Research Methodology & Medicine Regulations | Compulsory | 2 |
| PCL 811 | Adverse Drug Reactions & Pharmacovigilance | Compulsory | 2 |
| PVG 813 | Pharmacovigilance communication | Elective | 2 |
| PCH 808 | Biotransformation reactions, Pharmacogenomic/Pharmacogenetics & Personalized medicines | Elective | 2 |
|  | **Total Units** | **Compulsory****Elective** | **12****4** |

|  |
| --- |
| **800 LEVEL SECOND SEMESTER** |
| **COURSE CODE** | **COURSE TITLE** | **STATUS**  | **UNITS** |
| PVG 821 | Pharmacovigilance regulations  | Compulsory | 2 |
| PVG 828 | Research Seminar on Recent Advances in Pharmacovigilance and Pharmacoepidemiology | Compulsory | 2 |
| PVG 829 | Research Project | Compulsory | 4 |
| PVG 822 | Pharmacovigilance and Risk Management Systems | Elective | 1 |
| PVG 823 | Signal Detection and Management | Elective | 2 |
| PVG 824 | Medication error (ME): definition, impact, detection | Elective | 1 |
| PVG 825 | Post-Authorization Observational Studies and Clinical Trials in PV | Elective | 2 |
| PVG 826 | Pharmacovigilance of Herbal Medicines | Elective | 2 |
| RSC 821 | Regulation of Pharmaceutical, Biologic Products and Medical devices | Elective | 2 |
|  | **Total Units** | **Compulsory****Elective** | **8****10** |

### Summary of number of units compulsory and elective courses to be taken/available at each Level

|  |  |  |  |
| --- | --- | --- | --- |
|  | **First semester** | **Second semester** | **Total** |
| **Level** | Units of Compulsory Courses  | Units of Elective Courses Available | Units of Compulsory Courses  | Units of Elective Courses Available | Total of Compulsory Courses  | Total of Elective Courses Available |
| **800** | **12** | **4** | **8** | **10** | **20** | **14** |

### **Course Contents/Description**

**PVG 811: Overview of Pharmacovigilance (PV)**

Definitions of adverse event (AE) and adverse drug reaction (ADR). The scope of PV. Persons and parties involved in PV: their concerns, competences and interactions. The increasing complexity and challenges of PV History of PV. Important ADRs and methodological and organisational developments. The origin of modern PV: thalidomide and the emergence of ADR reporting and drug legislation. Major disasters and their impact on PV: OCs–VTE, HRT–breast cancer, Cerivastatin–rhabdomyolysis, Coxibs–cardiovascular death, etc. The shaping of institutions, international cooperation and information exchange. Focus on methods: spontaneous reporting. Pharmacoepidemiology. Data bases and linkage. Data mining. Genetic testing.

**PVG 812**: **Spontaneous Reporting Systems (SRS) and Case Assessment**

Definition, settings. Potential and limitations of SRS Definition. Potential and achievements of SRs. SRS settings and resources. Sources of spontaneous reports (SRs): Healthcare professionals (HCPs). Patients. Companies. Media. Detecting, documenting and reporting of AEs/ADRs: Methods. Forms. Routes. Software. Places and institutions collecting spontaneous reports. Informational limitations of SRs: Incomplete. No denominator. Biases. Proposed caveats. Stimulated, mandatory, solicited and targeted reporting. Computerised ICSR databases: Requirements and structure. Administration

Completeness. Accuracy and precision of the report. Certainty of the diagnosis. Seriousness and severity of the AE/ADR. Causality of the AE: Purpose. Criteria and problems of the assessment. Causality of the AE: Common general and specific assessment methods. Outcome ratings, shortcomings. Reports related to vaccines. Herbals and specific situations. Reports about adverse events following immunisation (AEFI): Specific features. Causality assessment with AEFI. Reports about AEs/ADRs with herbal medicines. Reports about AEs/ADRs related to pregnancy and lactation. Reports about drug-drug interactions, drug abuse and poisoning.

**PVG 813 : Pharmacovigilance Communication**

Context and guidance. Public health goals. Scene and climate. Theories and guidance. Legal framework. Experience on communication effectiveness. Crisis management, Communication with patients and healthcare professionals. Tools, channels and processes. Individual communication. Mass communication. Involvement of the public. Tools and channels Impact. Feedback and evaluation. Communication with patients and healthcare professionals: Contents and presentation. Specific medications and hazards. Interaction among stakeholders. Media Communication for involvement of the public in PV processes. Interactions between stakeholders throughout the communication process. Interaction between stakeholders in relation to risk management plans. Specifics for interaction with scientific and general media.

**PVG 821: Pharmacovigilance Regulations**

Facilities at pharmaceutical companies. Marketing authorisation holders. Wholesalers and distributors. Good PV Regulations. Pharmacovigilance system and SOPs. Crisis management plan; QPPV. Staff resources (scientific and administrative). Financial resources. Technical equipment Databases (ADR reports). Performance tools. Statistical tools and methods for analyses. Product-related archives. Correspondence archives. Library and access to electronic literature databases. Study reports. Periodic Safety Update Reports (PSURs). Periodic Benefit Risk Evaluation Reports (PBRERs). Other documents: DSUR; RMP, REMS; Renewal dossiers; Reports on request.

**PVG 822: Pharmacovigilance and Risk Management Systems**

Risk Management Plans (RMPs). Inspections. Pharmacovigilance systems: Definition. Stakeholders. Operation. Definition and elements Contents of the ‘Pharmacovigilance System’ document. Master file concept Pharmacovigilance systems of pharmaceutical companies. Marketing authorisation holders (MAHs) and distributors. Pharmacovigilance systems of regulatory authorities

Standard operating procedures (SOPs). Maintenance of the pharmacovigilance systems. Product-related risk management systems. Rationale for establishing risk management systems and objectives. Establishing a risk management system: Starting point and responsibilities.

**PVG 823: Signal Detection and Management**

Definition of a signal; Sources. Potentials. Detection by non-statistical medical means. What is a ‘signal’?–definitions by WHO, CIOMS, others. What a signal may indicate: New ADR. Higher severity or frequency. Risk factors. Wrong medication. Product faults. Sources of information which may constitute a signal: ADR databases. Case-control surveillance. Other sources. Basic requirements for signal detection and management. Stakeholders in the signal detection and management process. Detection of signals for new ADRs from ADR case-series by non-statistical medical means: Disproportionality statistics for signal detection in spontaneous ISCR databases. Principles of statistical data mining in ICSR databases. Calculating proportional reporting ratios (PRRs) and reporting odds ratios (RORs).

**PVG 824**: **Medication Error (ME): Definition, Impact, Detection**

Definition and typology of MEs. Demarcation from off-label use. ME statistics and impact on public health Victims. Medical situations and medications typical for MEs. Detection of MEs: National spontaneous reporting schemes for professionals. Detection of MEs: Methods in specific healthcare settings for professionals. Detection of MEs: Patient reporting. ME reports: Description and assessment. Description of clinical patient aspects. Description of procedural and patient adherence aspects. Assessment of the proximal/immediate cause. Contributing system factors. Root cause analysis (RCA). Assessment of avoidability/preventability.

**PVG 825: Post-authorisation Observational Studies and Clinical Trials in PV**

Definition and objectives of post-authorisation studies. General requirements. Specific studies. Non-interventional studies. Pharmacoepidemiology. Post-authorisation studies for confirmation of signals and providing data on ADR frequency and causality. Observational studies: General formal and scientific requirements. Opportunities. Limitations. Population-oriented post-authorisation studies: Disease studies. Drug utilisation studies. Post-authorisation randomised clinical trials in particular ‘large simple trials’ (LSTs). Important observational studies and their strengths and weaknesses. Cohort studies in general: Design, conduct, statistical analysis and presentation of results. Cohort-event monitoring (CEM) including PEM as specific applications. Case-control studies. Definition of bias and confounding and principles of dealing with them.

**PVG 826:** **Pharmacovigilance of Herbal Medicines**

Prevalence and types of herbal medicines use, Integration of herbal medicines into national health care scheme, adverse reactions and herbal medicine toxicities, interactions of herbal medicines with orthodox medicines, disposition of herbal medicines practitioners to reporting adverse reactions to herbal medicines.

**PVG 828: Research Seminar on Recent Advances in Pharmacovigilance and Pharmaco-epidemiology**

Students will be required to make seminar presentation on Pharmaco-epidemiology. The objective is to train graduate students how to search for write up and totally present scientific information.

**PVG 829: Research**

Application of Research Techniques and Development of Research Methodologies to solve problems in any aspect of Pharmacovigilance.

**PUH 801: Medical Statistics** This course is to equip students with statistical analysis of experimental data. Design, conduct and interpretation of clinical and epidemiological studies. Standard statistical concepts of data description. Hypothesis testing including test statistics, correlation, p-values, significance levels, confidence levels and linear regression.

**PCH 801:   Drug Quality Assurance & Total Quality Management**

The importance of Quality Control of Pharmaceuticals, Veterinary medicines and Agrochemicals. Personnel. Facilities and Documentation. Standard Operating Procedures (SOPs). Pharmacopoeia Monographs (USP, BP, BPC, EuP etc.). Relevant equipment and manuals needed to establish a standard Drug Quality Control Laboratory. Regulatory Aspects of Drug and Chemicals: Quality Control. Functions of Regulatory bodies such as WHO, NAFDAC PCN, PGMAN, FMOH, IPAN etc. Total Quality Management (TQM). Quantitative Aspects of Pharmaceutical Analysis: Acid- Base titrimetry. Redox titrimetry. Gravimetry. Separation Techniques: Extraction Methods and Chromatography (TLC, CC, HPLC, GC, GC/MS, Super Critical Fluid Chromatograph). Electrochemistry Capillary Electrophoresis. UV/Visible Spectroscopy. Fluorescence/Phosphorescence. Atomic Absorption Spectroscopy (AAS), Validation of Analytical procedures.

**PCL 807: Advanced Pharmacy Practice Research Methods & Medicine Regulation**

Research Design: Preliminary considerations. Selection of a design. Review of literature. Use of theory and writing strategies. Ethical considerations. Designing Research. Introduction and purpose statement. Research questions and hypothesis. Quantitative and Qualitative Methods. Sampling Methods and Types of Sampling. Statistical evaluation: Parametric and non-parametric. Correlation. Regression. Null Hypothesis. Research methods. Protocols and procedures. Clinica1 Trials. Bioavailability and Pharmacokinetic Studies. Quality Evaluation. Regulatory bodies and the requirements. Product registration and licensing.

**PCL 811: Adverse Drug Reactions & Pharmacovigilance**

Adverse Drug Reactions (ADRs) and Adverse drug events (ADEs): Occurrence and recognition in the Community. Role of prescriber. The pharmacist and patient in recognizing and documenting ADRs.

Pharmacovigilance. Risk Management Plan. Regulatory authorities and the Pharmaceutical Industry. Health care performed. Design of ADR and Pharmacovigilance cards/funds for use in hospital. Community Pharmacy and by the Community or the populace. Their roles and responsibilities in ADR reporting and pharmacovigilance clients.

**PCH 808: Biotransformation Reactions, Pharmacogenomic / Pharmacogenetics & Personalized Medicines**

Drug metabolism studies: Hepatic microsomal biotransformation. Enzyme systems and metabolic pathways involving reactions such as oxidation, reduction, hydrolysis and conjugation reaction (Phase 1, Phase 2 and Phase 3 bioreactions). Non-microsomal metabolic transformations involving some of the above-mentioned phases. Mechanism of biotransformation of specific groups in drugs and biological effects of such drugs. Literature review and current concepts in Drug Biotransformation. Methods in metabolic studies: In vitro and in vivo studies- Preparation of tissue homogenates. Preparation and purification of pure enzymes, such as the “Oxidases” (e.g. oxidise). Methods in isolation, identification, and Characterization and metabolites. Biochemical methods of identifying the enzyme systems catalyzing biotransformation reactions. The use of specific inhibitors and indicators. Principles of Pharmacogenomics and personalized medicines (Drug Development e.g. Vaccines against HIV and Malaria).

**RSC 821: Regulation of Pharmaceutical, Biologic Products and Medical devices**

The course will explore the relationships between scientific discovery, testing and regulatory oversight. It will look at the rules governing prescription and over-the-counter drugs, and look at the changes that are introduced by the burgeoning influence of genetic engineering and biological product development. It will consider the practical issues facing regulatory specialists as they work with the NAFDAC and other international regulatory bodies to secure and keep product approval. Legal framework for drug regulation ethical issues in drug/biologic/device development and drug/biologic/device use; global regulatory guidance approaches; types of communications with NAFDAC, including Investigational New Drug (IND) application, New Drug Application (NDA), and Abbreviated New Drug Application (ANDA) requirements, and clearance and Premarket Approvals / Biologics Licensing Applications (PMA/BLA) approval requirements; chemistry, manufacturing, and control (CMC) issues; and post-marketing topics.