Course Outline and Policies

For Health Services Academy Islamabad

Course title:	Certificate in Pharmacovigilance
Instructors:	Subject experts Dr Abdur Rasheed, Dr Ahmad Hussen Tareq, Dr Atta Abbas
Instructor CV/Profile	Dr Abdur Rasheed, a renowned regulatory expert with DRAP, Ex-head of Pharmacy services division and Professor at Health Services Academy Islamabad, Pakistan. Dr Ahmad Hussen Tareq, Pharmacist and PhD from Nanyang Technological University, Singapore and Massachusetts Institute of Technology, USA Associate Professor in HSA and lead of think tank. Dr Atta Abbas is a regulatory experts with decades of experience of in Pharmacovigilance and related affairs. He has served as secretary pharmacy council of Pakistan and looking forward to train professionals in the regulatory science.
Course Fee	Pakistani Candidates: PKR 20,000/- Overseas Candidates: USD 150/-

Class details	
Class Timing and Room	Online
Session Day(s)	Weekdays

Course Description
Pharmacovigilance is designed to serve healthcare professionals to expand their knowledge and practice of detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. It attracts great interest to Pharmacists as well as other health professionals including Doctors, Nurses, Aids, Nutritionists, and complementary therapists.

Course Objective

The basic objective of pharmacovigilance is the safe use of drugs, patient safety, and, ultimately, safeguarding public health. To achieve this goal, national regulators and international organizations should empower healthcare professionals and the public to report more adverse drug reactions (ADRs). Pharmacovigilance is therefore an activity contributing to the protection of patients and maintaining public health.

Course Learning Outcomes

Knowledge Outcomes

- Principles of pharmacovigilance
- Role and importance of pharmacovigilance
- Maintain a robust monitoring system for new safety issues.
- Implement effective approaches to minimize risk.
- Install procedures for rapid decision making and triggering actions in case of (immediate) safety concerns
- Improve patient care and safety in relation to the use of medicines and all medical and paramedical (services that support medical work, such as nursing, first aid, radiography) interventions.
- Improve public health and safety in relation to the use of medicines.

Abilities Outcomes

- Acting to protect public health (including regulatory action).
- Managing information on products under additional monitoring, and products that have been withdrawn.
- Identifying and reducing the risk of medication errors before and after the authorization of a medicine.

Skills Outcomes

- Assessing and coordinating studies after marketing through post-authorization safety studies and post-authorization efficacy studies.
- Carrying out inspections to ensure company pharmacovigilance systems comply with good pharmacovigilance practice.
- Communicating in a clear, effective and timely manner about safety-related issues to relevant stakeholders.
- Interacting with and engaging key stakeholders, including patients, healthcare professionals.
- Continuous development and improvement of systems (including IT infrastructure), guidelines and standards, and promotion of research to address knowledge gaps

Teaching and Learning Methodology
This course will build on presentations, videos, readings, case studies and assignments. This course rests on several components – self-study, case discussions, interaction, as well as implementing Strategies to practice and application in the subject area: • Self-Study: • Student-Instructor Interaction online. • Discussion of selected questions, finding of examples, answering of questions etc. • Group Discussions. • Group project to practice and for application of concepts. • Preparation of short assignments. • Final report/project and discussion on a selected topic.

Course Plan				
Session	Chapters	Session Topic	Assessments	%
1	Pharmacovigilance	• Introduction • Definition of Pharmacovigilance • General aims • Specific aims • Pharmacovigilance center (PvC) • Why pharmacovigilance is increasing? • History of Pharmacovigilance • Examples of product recalls due to toxicity • Responsibilities		
2	Why we do need pharmacovigilance?	• Adverse Drug Reactions (ADR) • Changes that occur from the PV findings • What should be reported? • Who can report? • Report to whom? • Reporting Requirement		
3	WHO Pharmacovigilance programme	• Safety alerts • Vaccine Safety Net • Information for general public • Information for health professionals		
4	Pharmacovigilance programme of Pakistan (PVPP)	• Introduction • Goals & Objectives • Governance structure • Monitoring & Evaluation • Reporting trends • Application/Role of Pharmacovigilance		

5	**Pharmacovigilance Methods**	• Spontaneous Reports • Targeted spontaneous reporting (TSR) • Active surveillance • Cohort event monitoring ➢ Introduction ➢ Objectives and methodology ➢ Minimum reporting requirements ➢ How to report ➢ What to report ➢ When to report Who should report ➢ Follow-up ➢ Sharing the results ➢ Data entry		
6	**Pharmacovigilance Data Management and Case Processing**	• Importance of safety monitoring • Sources of report • Spontaneous report • Literature • Solicited sources • Contractual agreements • Regulatory authority sources • Call centers • Triage of cases • The minimum information required for reporting purpose • Case processing • Data entry into safety database • Narratives • Medical coding • QC review • Medical review • Different Pharmacovigilance Software		

Prerequisite Skills and Knowledge to take this Course
Academic Conduct
At HSA academic honesty is mandatory. Absolutely no plagiarism/ cheating in any examination, quiz, assignment, report, and/or presentation by any student is tolerated.
Attendance Policy
• Students are required to regularly attend all lectures, computer laboratory sessions, seminars and fieldwork as may be specified. In case, a student accumulates more than the allowed number of absences, he will not be eligible for the Diploma for Professional Development. • The provision of absences is only for emergencies. • If absent on the final examination the certificate will not be issued. • Students who are unable to appear for the final exam are required to submit a written application stating the reason for not appearing for the exam. HSA reserves the right to approve or deny such applications. If approved, the student will be allowed to sit for the exam within one month. Failure to do so, the student will only be given a Certificate of Attendance. • The attendance on the first day of the Diploma is a must. • A student must attend 80% of the classes to be eligible for the certificate. • Students are required to be in time for their sessions. After 10 minutes of the start of class, the entrant will be marked late. • Maximum of 4 late attendances will be allowed. Decision will be made by the faculty. • It is expected that the students will always maintain proper dress code.
CONDUCT AND DISCIPLINE
A disciplinary action, leading to rustication, will be taken against students whose conduct is found objectionable at any time during study. The faculty and Vice Chancellor HSA will be the decision maker.

EVALUATION AND GRADING

The performance of participants is evaluated through continuous observation of the student's performance in the Diploma – the extent to which he/she participates in discussions and the case studies and exercises.

There will be quizzes, monthly hourly exams, and final exams at the end of the program. The total marks for passing the Diploma will be 60 out of a total of 100 marks.

Participants, who do not meet attendance or any other eligibility criteria, will not be allowed to appear in the final examination.

In the rating of participants, the following grading plan is used:

A+	95 - 100
An	87 - 94
B+	81 -86
B	72 - 80
C+	66 - 71
C	60 - 65
F	below 60 (Fail)