HEALTH SERVICES ACADMY, ISLAMABAD
COURSE SYLLABUS & POLICIES

Course title	Regulatory Affairs and Health Policy
Instructors	Dr Abdur Rashid, Dr Ahmad Hussen Tareq Miss.Fahmida Aslam Other Regulatory Experts
Instructor Profile	Dr Abdur Rashid, 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. Fahmida Aslam (PhD Scholar), International Food and Drug Policy Law and research center, Shenyang Pharmaceutical University, China. She also works as a Young Scholar in the institute of Regulatory Science, Tsinghua University, China.
Course Fee	Pakistani Candidates:PKR120,000/- Overseas Candidates: USD 1000/-

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

Course Description
The aim of regulatory science is to ensure standardization in healthcare regulations and policies to keep patients safe. Regulatory Affairs certificate program prepares graduates with the transferable skills needed to build successful careers in a variety of sectors requiring regulatory affairs expertise and training. This program will build on your prior knowledge to advance your education

Course Learning Outcomes

Knowledge Outcomes

- Knowledge of Pakistani and international healthcare legislation and regulations, such as Good Manufacturing Practices (GMPs), Good Clinical Practices (GCPs), Good Documentation Practices (GDPs), International Standards Organization (ISO), Food and Drug Act Regulations, Regulatory Compliance/Inspection, Drug Establishment Licensing, and related standards and guidelines.
- Product Development Process.
- Quality Control Process.

Abilities Outcomes

- Understand the submission procedure to the Therapeutic Products Program (TPP) for medicine, medical device, or biologic, together with supporting paperwork.
- Define drug (prescription and non-prescription)/medical device/biologic submission process requirements.

Skills Outcomes

- Demonstrate problem-solving skills in the context of pharmacovigilance and post-market surveillance.
- Demonstrate strong interviewing and negotiating abilities in the administration of a clinical trial.
- Collaborative interpersonal skills.

Teaching and Learning Methodology

This course will build on presentations, videos, readings, case studies, and assignments. Self-study, case discussions, interaction, and implementing Strategies to practice and application in the subject area are all included in this course.

• Self-Assessment:

• Interaction between students and instructors via the internet.

• Discussing selected questions, locating examples, responding to queries, and so on.

• Discussions in groups

• Work on a group project to practice and apply concepts.

• Final report/project, as well as a discussion on a chosen topic.

Course Objective

Our objective and mission are to provide industry-relevant professional, technical, theoretical, and hands-on experience to our students so that they can thrive in the field of Regulatory Affairs. Through a collaborative relationship between students and the program, we aim to build work-ready learners upon graduation.

in healthcare legislation, regulation, pharmaceuticals, devices, biologics, and health policies.

Session	Modules	Session Topic	Credit hours
1	**Health care regulatory environment**	Introduction • Basic Understanding and Terminologies • Why Regulatory Affairs(RA)? • RA Objectives. • Types of Companies Hiring RA Professionals. • Qualities of RA Professional	1
2	**The regulatory authority of Pakistan(DRAP)**	• DRAP Act 2012 • Dynamic progression of Pakistan biopharmaceutical laws, • Differentiation between law vs regulation, • DRAP and industry compliance functions, • Policy-guided science, cases that shape the evolution of regulatory compliance. • Health and OTC Rules 2014 • Medical Devices Rules 2018 • National Bioethics Rules 2021	1
3	**Regulatory policy**	• The United States • European Union Asia & Pacific Rim • Laws and Regulations Governing Human Research • Stringent Regulatory Authorities • Regulatory Systems of Organization of Islamic Countries (OIC)	1
4	**Management of regulatory submissions**	• Law and Health Policy of Drugs and Devices under the DRAP and fundamental of regulatory affairs (RA) • Methodological regulatory filing around the world. • Pre-market regulatory submission • Submission evaluation and post-market analysis.	2

5	**Advanced Topics in Regulatory Affairs**	• Advertising and promotion of therapeutics goods. • current trends, regulations, and issues in digital advertising, including mobile applications and social media. • Decision-making and risk assessments in advertising and promotion.	2
6	**Post Approval Activities and Compliance**	• After drug registration, the follow-up of the related documents • Impact on Drug pricing after drug registration • The pharmacovigilance and adverse events reporting mechanism.	1
7	**Pharmaceutical compounds / Biologics/Medical devices**	• CTD format for registration of Pharmaceutical products includes oral and IV dosage forms • CTD format for registration of Biologics and biotechnological products • Registration of medical devices for the diagnostics and bioanalytical analysis industry.	3
8	**Data Analysis & Presentation Capabilities in Regulatory Affairs**	• Understanding of statistical data and processes • Types of statistical analysis • Practice applying the basic statistical concepts to data and their utility in regulatory decision-making. • Review of published literature to examine design, accuracy, and effectiveness of studies for use in regulatory processes	3
9	**Individual Project Reports**	• Written - discussions & Oral Presentations	

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 the 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)

Eligibility Criteria

Healthcare and other professionals related in pursue post graduate certification in Regulatory affairs. It will include :-

- Multinational and National Pharmaceutical firms/licensee,
- Public Health Specialist,
- Regulatory affairs personnel,
- Pharmaceutical employees dealing with import and export,
- Common Technical Documents preparing personnel,
- Clearing agents/firms,
- Private firms preparing Dossiers of therapeutic goods,
- Firms manufacturing Herbal/ Traditional/ Nutraceuticals/Chinese/Medical devices/Milk and Dairy products, Life and Wellness products,
- Pharmacy graduates, Clinical Pharmacists, Hospital Pharmacists,
- Federal and Provincial Drug inspectors,
- Academia, Researchers, Scientists,
- Consultants, Specialists, Nephrologist, Urologist, Physicians & Others
- Contract Research Organizations Personnel,
- Clinical Trial Investigators and Enthusiast,
- Bioavailability/Bioequivalence centers Personnel,
- Bioanalytical laboratories, Regulatory Affairs Enthusiasts,
- Healthcare Regulators, International Regulatory Affairs Consultants,
- Veterinarians, Hakims, Homeopaths, (5 yrs course)
- Nurses and Other Allied Health Professionals.
- Fisheries, Aquatic animals experts, livestock industry, poultry related personnel
- Environmental Specialist,

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