DOW INSTITUTE OF BIOLOGICAL,
BIOCHEMICAL &
PHARMACEUTICAL SCIENCES

PROFESSIONAL DIPLOMA

PHARMACEUTICAL REGULATORY SCIENCES

06 MONTHS PROGRAM

JOIN **PAKISTAN'S PREMIER REGULATORY SCIENCES PROGRAM** AND SHAPE THE FUTURE OF **HEALTHCARE!**

PROGRAM **STRUCTURE**

This program is consisted on a series of streams. Each stream provide detailed knowledge and understanding on the subject matter.

GENERAL INTRODUCTION

STREAM 01	**INTRODUCTION OF REGULATORY AFFAIRS**
STREAM 02	**PRE-MARKET EVALUATION OF DRUGS (CTD)**
STREAM 03	**CURRENT GOOD MANUFACTURING PRACTICES**
STREAM 04	**QUALITY MANAGEMENT SYSTEM**
STREAM 05	**PHARMACEUTICAL PROCESSES & SYSTEMS**
STREAM 06	**PRODUCTION (STERILE AND NON STERILE DRUG MANUFACTURING)**
STREAM 07	**QUALITY CONTROL (CHEMICAL AND MICROBIOLOGY)**
STREAM 08	**CLINICAL TRIALS (GCP, GLP)**
STREAM 09	**SUPPLY CHAIN MANAGEMENT**
STREAM 10	**POST-MARKET APPROVAL & RELEVANT GUIDELINES**

WHY **REGULATORY AFFAIRS?**

With rapid growth in Pakistan's Healthcare, Pharmaceutical, and Biotechnology sectors, Regulatory Professionals are in high demand. Skilled specialists who understand compliance and quality standards are essential to navigating industry requirements. This diploma equips you with the expertise to meet standards, And create oppurtunities in an evolving field.

LEARNING **OBJECTIVES**

1. **REGULATORY AFFAIRS ESSENTIALS:**

   Understand the foundations, principles, and best practices of regulatory affairs.

2. **GMP COMPLIANCE:**

   Learn to apply Good Manufacturing Practices (GMP) to ensure product safety and regulatory compliance.

3. **QUALITY MANAGEMENT SYSTEMS (QMS):**

   Gain knowledge of QMS structure and its role in maintaining quality standards in regulatory settings.

4. **REGULATIONS OF MAJOR AUTHORITIES:**

   Familiarize with regulations from the FDA, EMA, WHO,PIC/s and their global impact.

5. **GOOD REGULATORY PRACTICES (GRP):**

   Explore best practices in regulatory procedures, focusing on compliance and documentation.

6. **COMPREHENSIVE CTD DOCUMENTATION:**

   Master the Common Technical Document (CTD) format to meet standards of international, regulatory submissions.

7. **KEY REGULATORY TERMINOLOGIES:**

   Learn essential terms and concepts for a successful career in regulatory affairs.

8. **PREPARE FOR SUCCESS:**

   Gain practical knowledge and skills for effective regulatory implementation.

ADMISSIONS **INFORMATION**

WHO CAN ENROLL

Graduates working in the pharma industry
Candidates nominated by the Pharma-Biotech companies.
Those who are interested in regulatory affairs.

ENROLLING PROCESS

- REGISTERATION FORM
- SHORTLISTING
- FEES SUBMISSION
- ENROLLMENT

REGISTER NOW

CLASSES SCHEDULE

WEEKEND CLASSES: Hybrid Classes (Inperson and Online)
Saturday (04:00 pm to 07:00 pm)
Sunday (10:00 am to 2:00 pm)

TOTAL FEE

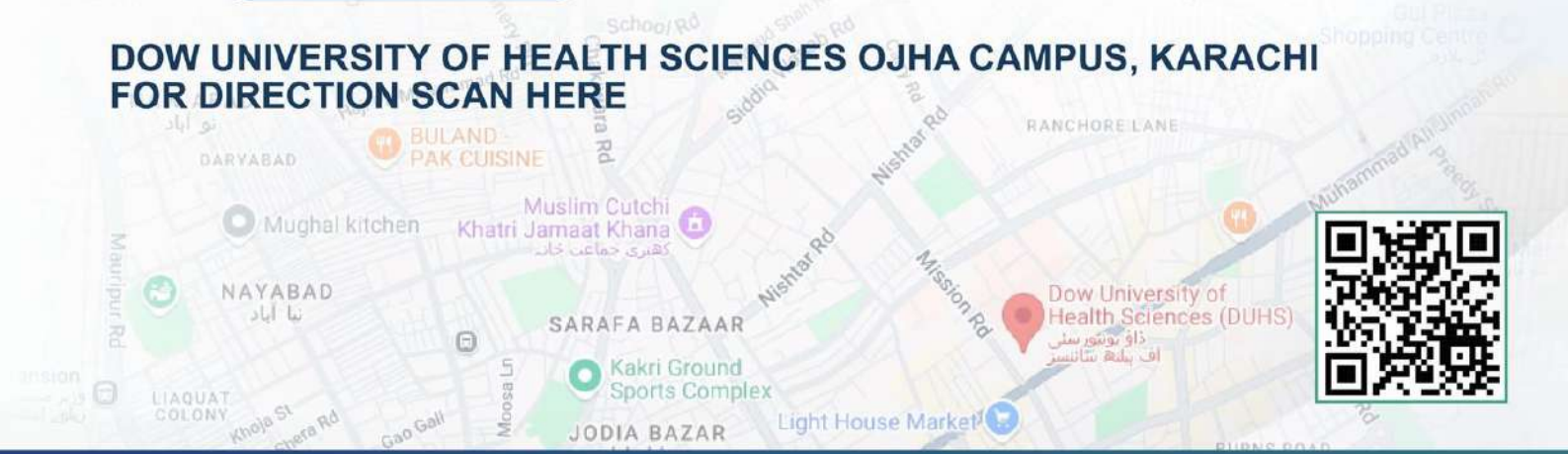
Rs. 75,000/-

CONTACT US

Email: bd.ibbps@duhs.edu.pk
Phone: 0326-8009976

VENUE

DOW UNIVERSITY OF HEALTH SCIENCES OJHA CAMPUS, KARACHI
FOR DIRECTION SCAN HERE



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ABOUT THE **PROGRAM**

This professional diploma program in Pharmaceutical Regulatory Sciences covers key aspects of regulatory frameworks for Innovator & Generic drugs, products including guidelines from agencies like the US FDA,EMA, Health Canada, PIC/s ICH and Drug Regulatory Authority of Pakistan (DRAP). The program emphasizes the importance of regulations in manufacturing pharmaceutical, veterinary medicines, and medical devices to ensure effective and sustainable healthcare. A basic understanding in the pharmaceutical profession is required as a prerequisite. This program is essential for professionals to work effectively within their organizations.

This Program will provide professionals in the pharmaceutical industry with a thorough understanding of the drug development process and the regulations that govern it. The course ensures a comprehensive overview by covering key topics such as international guidelines, drug registration processes, regulation of medical devices and combination products, clinical trials, marketing regulations, and expedited drug approvals. Students also learn about submission requirements, post-approval changes, and regulatory documentation tools. Delivered online with interactive and practical components, the course equips participants with the knowledge and skills to navigate the complex regulatory landscape effectively.

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MR. MUJAHID HUSSAIN

Director Technical - Chemistry, Manufacturing Control & Pharma Services at Sami Pharmaceuticals Pvt Ltd.

Mr. Mujahid Hussain is an accomplished professional with an M. Phil. in Chemistry and expertise as a Lead Auditor, holding certifications in ISO 17025, ISO 9001, ISO 14001, and ISO 45001. With extensive experience in the pharmaceutical industry, he has worked with leading organizations such as SAMI Pharma, US Pharmacopeia, Merck, and CCL Pharma. A recognized GxP expert, he has expertise in manufacturing, R&D, regulatory affairs, quality operations, engineering, and supply chain, and is skilled in designing and qualifying pharmaceutical manufacturing units in compliance with international standards. Mr. Mujahid has led audits and inspections by WHO, EU, and other regulatory bodies and provided technical assistance to local manufacturers, helping them achieve WHO Prequalification and GMP compliance. He is also dedicated to training pharmaceutical professionals in GxP, LMS, PQMS, and international regulatory standards.

GUEST **SPEAKERS**

MR. HANIF AJARI

Director Export Network, Inst. Business & CS at Getz Pharma

DR. ANJUM SHAFFI

Communication Chair for the American Society for Quality (ASQ) chapter in Canada

ADV.RASHID MUREED

Head of Chambers at Cepal & Corporation

DR. ZAHEER ABBASI

Senior Pharmaceutical Consultant

DR. SADIA ASIM

Director at Dow Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS)

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FACULTY **MEMBERS**

MR. SYED SULTAN GHANI
International Pharmaceutical Consultant

Mr. Syed Sultan Ghani is a former senior executive at Health Canada, where he directed the Bureau of Pharmaceutical Sciences and managed the Quality and Bioavailability Programme for pharmaceutical evaluations. He has extensive international experience in drug regulations, including compliance and enforcement, and chaired the cGMP Committee, develop Canadian guidelines. His contributions to drug procurement in Zambia and representation in the United States and European Pharmacopoeias is remarkable. He participated in the International Conference on Harmonization, helping to develop guidelines. With 39 years at Health Canada, he received multiple awards for his service, including from the FDA. He currently consults for USP PQM Plus.

DR. SHAHNAWAZ SAJID
(President of Scientific, Technical,
& International Operations & Strategic Projects
at Macter International)

Dr. Shahnawaz Sajid possesses over 21 years of experience in various pharmaceutical companies. His expertise spans US FDA plant design, construction, validation, and facility approvals, as well as ANDA submissions, including NCE-1, CGT products, and DMF approvals. He has served as the Senior Vice President and Chief Operating Officer (COO) at Novugen Pharma, (Malaysia) Sdn Bhd, Dr. Shahnawaz Sajid has successfully established a Greenfield project in Malaysia, comprising two manufacturing plants for oncology and non-oncology products, approved by the US FDA and PIC/s and he also established a state-of-the-art Center of Excellence R&D lab in Malaysia. Dr. Shahnawaz Sajid's leadership has resulted in the successful navigation of various audits, including those conducted by the US FDA, PIC/s, and WHO.

DR. IFTIKHAR JAFRI

(Consultant at United state Pharmacopeia convention)

Dr. Iftikhar Jafri is a oriented pharmaceutical professional in leading Quality and Compliance operations. With extensive experience in training and mentoring teams. At Pharmatech Solutions, Dr. Iftikhar Jafri led a team of Generic Product Developers in the successful launch of new products, achieving regulatory approval and significantly boosting market share. He implemented a quality control system that reduced product defects improving overall product quality and driving revenue growth. Additionally, he established a post-market surveillance system for early detection of safety issues, ensuring compliance with regulatory standards. His comprehensive training program reduced onboarding time creating a skilled workforce and minimizing market complaints. He also oversaw production and material planning, collaborating with supply chain teams to secure high-quality raw and packaging materials from GMP-compliant sources, ultimately enhancing cost efficiency and product profitability.

DR. SYEDA RIMA ISHAQ (PH.D)

CEO RIConsultants & Co.,

Dr. Syeda Rima Ishaq has extensive experience of 25 years in multinational and national pharmaceutical industries in the domain of product development, regulatory compliance, quality control, quality assurance, pharmaceutical manufacturing, facility designing and utilities. She had consulted World Health Organization (WHO) in the area of Infection Prevention and Control and through USAID consulted United States Pharmacopeia (USP) under Promoting Quality Medicine (PQM) to establish first Personal Protective Equipment (PPE) testing laboratory in Pakistan under public sector. Recently she consulted through USP, National Health Laboratories in Cambodia, and Laos for WHO prequalification and ISO/IEC 17025. As auditor, she is qualified to conduct Quality and Environmental Management System audits as Lead Auditor for ISO 9001, ISO 14001, and Medical Devices ISO 13485. She had successfully organized technical seminars under the umbrella of Pakistan Pharmaceutical Educational Foundation (PPEF) and represented Drug Information Authority (DIA), USA in Pakistan as a coordinator.

CAREER **PATHWAYS**

PHARMACEUTICAL COMPANIES:
Ensure products meet regulatory standards and support compliance in drug development and production.

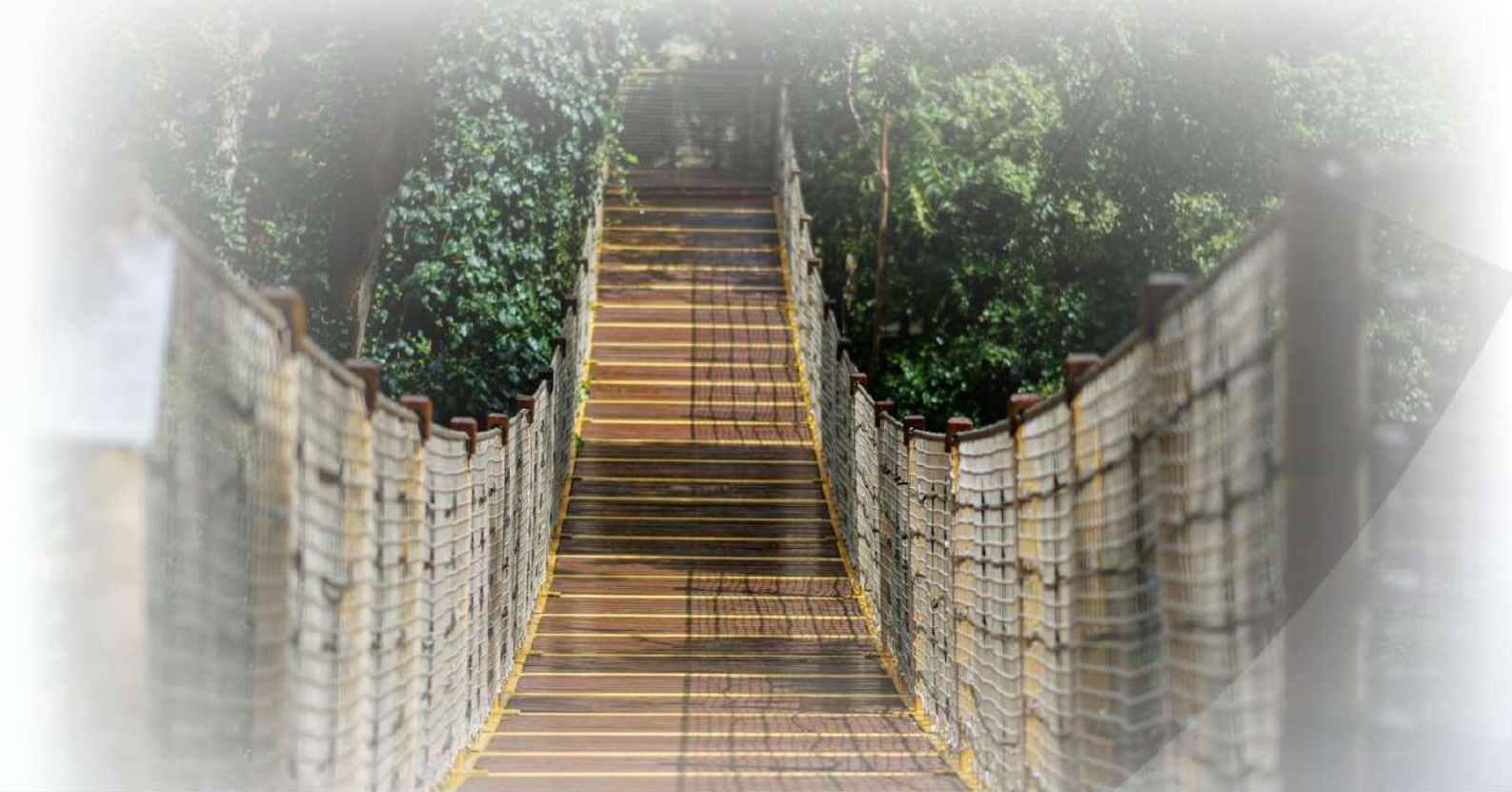
HEALTHCARE REGULATORY BODIES:
Work on policy development, compliance audits, and regulatory enforcement.

RESEARCH INSTITUTIONS:
Oversee research compliance, clinical trials, and ethical standards.

BIOTECHNOLOGY FIRMS:
Ensure innovative products align with regulatory frameworks.

CONTRACT RESEARCH ORGANIZATIONS (CRO):
Support compliance and quality management for outsourced research and trials.

Each of these organizations seeks regulatory professionals skilled in navigating complex standards, making this diploma a valuable step toward high-demand roles in the field.



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