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!**

ABOUT THE **PROGRAM**

This professional diploma program in pharmaceutical regulatory sciences is organized into several streams. The curriculum provides a full understanding of numerous facets of pharmaceutical regulatory sciences, including knowledge of regulatory bodies such as the US FDA, EMA, and Health Canada, regarding investigational, new, and generic pharmaceuticals. There are numerous rules in place to ensure that the manufacturing of pharmaceutical products, veterinary medicine, therapeutic equipment, and other items is efficient and capable of providing individuals with long-term healthcare. A pre-requisite for pursuing a career in pharmaceutical regulatory sciences is fundamental knowledge and experience in the pharmaceutical field. It is critical for any business or institution to have such a program in place so that pharmaceutical professionals may perform effectively inside their own organization.

All participants shall learn about Regulatory Affairs, GMP Compliance, Quality Management Systems, and the regulations of the major regulatory bodies in order to successfully conduct regulatory operations. Furthermore, this diploma course is designed to provide an overall awareness of Good Regulatory Practices and support functions, as well as illustrate the importance of full documentation of CTD and ICH guidelines along with other terminologies used in the program.
This program consists of a series of streams. Each stream gives in-depth knowledge and understanding of the topic area.

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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,PK/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.

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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	**GENERAL INTRODUCTION**
STREAM 02	**REGULATIONS AND GUIDELINES**
STREAM 03	**PRE-MARKET EVALUATION OF DRUGS**
STREAM 04	**CURRENT GOOD MANUFACTURING PRACTICES**
STREAM 05	**QUALITY MANAGEMENT SYSTEM**
STREAM 06	**PHARMACEUTICAL PROCESSES AND SYSTEMS**
STREAM 07	**DRUG DEVELOPMENT & MANUFACTURING TECHNOLOGY**
STREAM 08	**QUALITY CONTROL & METHOD VALIDATION**
STREAM 09	**BIOLOGICALS, BIOSIMILARS AND CLINICAL STUDIES**
STREAM 10	**SUPPLY CHAIN, GOOD DISTRIBUTION PRACTICES (GDP), AND COLD CHAIN MANAGEMENT**
STREAM 11	**POST-MARKETING SURVEILLANCE AND PHARMACOVIGILANCE**

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.

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. IZHAR HUSSAIN

(Executive Director, IBBPS)

Dr. Izhar Hussain is the Executive Director of IBBPS and Director of DILS at Dow University of Health Sciences, with over 40 years of leadership across academia and the pharmaceutical industry, including a decade at IBA's Center for Executive Education and senior roles at Abbott Pakistan spanning South Korea, India, the UAE, Saudi Arabia, and Egypt. He holds a Ph.D. in Pharmaceutics and an MBA in Marketing, is a Certified Director and Six Sigma Black Belt, and serves on multiple editorial boards and education governance bodies, including as Chairman of the Fatimiyah Education Network's Education Board.

DR. SHAHNAWAZ SAJID

Chief Executive Officer-Global &
Strategic Operations at High-Q Pharmaceuticals

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. 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.

MR. HANIF AJARI

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

Mohammed Hanif is a distinguished professional with over 30 years of global experience in pharmaceuticals, supply chain management, finance, and strategic business planning. As the Director of Global Export Network, Institutional Business, and Company Secretary at Getz Pharma, he oversees exports across 40 countries with a portfolio worth USD 150 million. His expertise spans international logistics, regulatory compliance, tender management, and enterprise-level certifications such as PICs, WHO, and SAP-HANA accreditation.

Alongside his corporate leadership, Hanif actively contributes as a consultant to esteemed institutions including the World Bank and the Global Fund, where he facilitated the release of USD 550 million for Anti-TB initiatives. He serves as Lead Faculty for WHO EMRO in Public Health and Hospital Management, specializing in supply chain and logistics. As visiting faculty at IBA Karachi and other institutions, he imparts knowledge on global supply chain, financial supply chain management, and strategic healthcare operations.

SHABNAM PERVEEN

Registered Pharmacist – Pharmaceutical Professional
Member of International society of Pharmacovigilance

Shabnam Perveen is a proactive and results-oriented pharmaceutical professional with over a decade of experience in leading multinational and national organizations. Her expertise spans Quality Assurance (QA), Quality Management Systems (QMS), Pharmacovilance (GvP), Environmental Health & Safety (EHS), and Pharmacovigilance. She has successfully established and managed quality operations, developed regulatory-compliant systems, and implemented international best practices to enhance organizational performance and compliance.

MR. MUJAHID HUSSAIN
Director, Genetics Pharmaceuticals

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 **FACILITATORS**

DR. ANJUM SHAFFI

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

ADV. RASHID MUREED

Head of Chambers at Cepal & Co.

ATIQ-UR-RAHMAN

Director, FortDice, Dubai & Principal Consultant

ABDUL MUGHEES MUDDASSIR

Deputy Director

Drug Regulatory Authority of Pakistan (DRAP)

REFERENCE MATERIAL- COURSE MATERIAL AND NOTES, RECOMMENDED TEXTBOOKS.

1. Pharmaceutical Regulatory Affairs: An Introduction for Life Scientists C. F. Harrison
2. Regulatory Affairs in the Pharmaceutical Industry: Ira R. Berry
3. Remington: Essentials of Pharmaceutics
4. ICH, WHO, FDA & Health Canada Guideline

Health Canada

World Health Organization

FDA

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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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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

CLASSES SCHEDULE

WEEKEND CLASSES: Onsite and Online Classes

BLENDED LEARNING OPPORTUNITY: Two Days in-person sessions in following cities of Pakistan.
LAHORE - ISLAMABAD

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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FEEDBACK

"This six-month diploma provided valuable insight into the evolving pharmaceutical regulatory environment and strengthened understanding of global compliance frameworks. It enhanced professional knowledge of regulatory sciences and industry challenges in local and international markets.

I sincerely thank Dow University of Health Sciences faculty members and visiting experts for their guidance."

Syed Atif Raza
Sr. Manager - International Export Logistics & Compliances at Getz Pharma.

"I sincerely appreciate the Regulatory Diploma Programme conducted by highly experienced mentors who provided excellent guidance and practical insights. Special thanks to Sir Sultan Ghani, Sir Iftkhar Ahmed Jaffri, Dr. Syeda Reema Ishaq, Sir Shahnawaz Sajid, Sir Hanif Ajari, Sir Mujahid Hussain, Dr. Rashid Mureed, Dr. Sadia Asim, and organizers.

The programme has significantly enhanced my professional knowledge and understanding in the field of regulatory affairs, and I truly appreciate the efforts of everyone involved."

Sharjeel Aurangzeb
Export Manager Galaxy Group Of Companies.

"It was a great experience and honor for me to become a DOWIAN . I really enjoyed my time spent with high level professionals who were well equipped with the Content knowledge

The course outline was fine enough yet there is a substantial margin to enhance the supply chain segment.

All the teachers were outstanding and supportive indeed. Thanks to the faculty members particularly Miss Naveen who provided all out support to students. Thanks for providing such a high level professionals platform."

Syed Imran Ali
Muller & Phipps Pvt Ltd.

"Hey, the Regulatory Diploma Programme has been a very informative and valuable learning experience for me. Through this programme, I gained better understanding of regulatory affairs, professional ethics, documentation, and industry standards. The teachers and coordinators were supportive and explained the topics clearly. I also improved my communication skills, confidence, and professional knowledge during this course. The activities and assignments helped me learn practical concepts effectively.

Overall, this diploma programme enhanced my learning experience and prepared me for future opportunities in the professional field. I am thankful to all the instructors and management for organizing such a beneficial programme."

Dr Maham Iqbal Khan
Clinical Research Coordinator at Helix Pharma

"Enrolling in the Professional Regulatory Sciences diploma at DUHS has been a turning point for my professional growth. The program bridges the gap between academic theory and the actual demands of the pharmaceutical industry. The modules on quality compliance and regulatory strategies gave me practical tools that I've already started using in my current role.

The instructors were incredibly knowledgeable and always willing to share their industry experience, which made the classes engaging and relevant.It's an intense but incredibly rewarding program for anyone serious about stepping up their career in regulatory affairs."

Aimon Mehak
Assistant Manager Regulatory Affairs
(Martin Dow Limited)

I would like to sincerely thank all teachers and course coordinators for successfully conducting this diploma program. As a Pharm-D professional with a background in Hospital Pharmacy, I was recently transferred to the Pharmacy Procurement and Supply Chain Department, and this course has greatly supported my transition.

It strengthened my understanding of pharmaceutical regulations, compliance, quality management systems, and supply chain processes, along with key regulatory requirements such as DRAP registration, GMP, CEP, COA, API sourcing, BA/BE studies, ISO standards, US-FDA regulations, ICH guidelines, and PIC/S compliance.

Overall, it has enhanced my professional skills and confidence in my current role.

Agha Ammar Raza
Group Senior Manager Pharmacy Purchase

"The Diploma in Pharmaceutical Regulatory Sciences at Dow University of Health Sciences has been a great learning experience. The program provides a strong understanding of pharmaceutical regulations, quality systems, clinical trials, and international regulatory standards.

One of the best aspects of the diploma is learning from experienced industry professionals who share valuable real-world insights.

The weekend and hybrid format is also very convenient for working individuals.

More hands-on workshops and industry exposure could further improve the program. Overall, it is a valuable course for anyone interested in building a career in pharmaceutical regulatory sciences."

Anum Sami
Executive at Oncogen Pharma

The Pharmaceutical Regulatory Science Diploma Programme at Dow University of Health Sciences has been a highly valuable and enriching experience for me. The programme provided comprehensive knowledge of pharmaceutical regulations, quality management systems, drug registration procedures, validation, and international regulatory guidelines. The course content was relevant to current industry practices.

The faculty members were highly experienced, supportive, and professional. Their interactive teaching style and practical case-study discussions made complex concepts easier to understand and encouraged professional growth throughout the programme.

Overall, it is an excellent programme for professionals seeking career growth and expertise in regulatory sciences.

Iqra Khan
Regulatory affairs Officer at
AsianContinental Pvt. Ltd.

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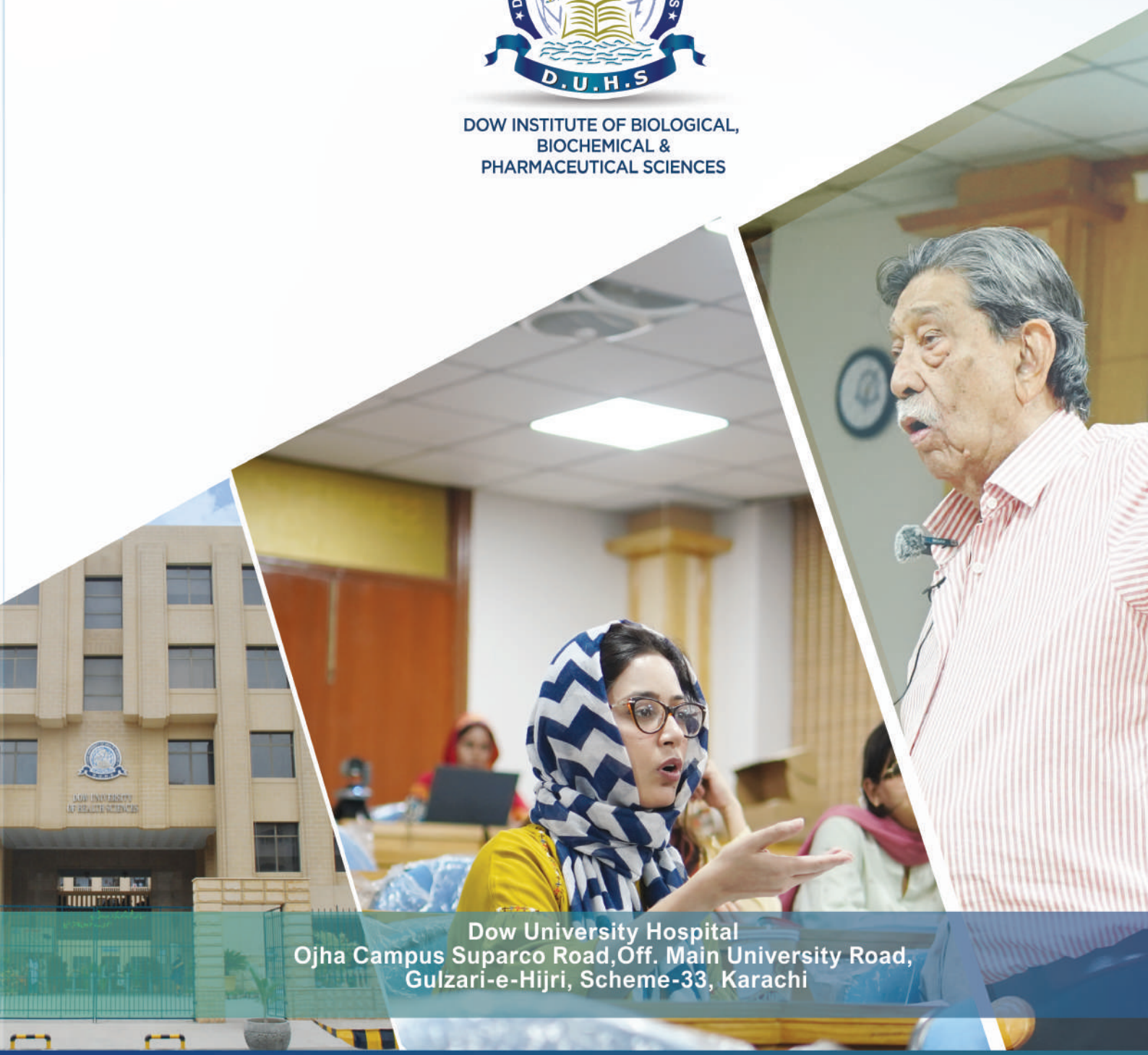

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