DOW INSTITUTE OF BIOLOGICAL,
BIOCHEMICAL &
PHARMACEUTICAL SCIENCES

PROFESSIONAL DIPLOMA

PHARMACEUTICAL REGULATORY SCIENCES

06-Month Intensive 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 covers key aspects of regulatory frameworks for investigational, new, and generic drugs, including guidelines from agencies like the US FDA, EMA, Health Canada, and CDSCO. The program emphasizes the importance of regulations in manufacturing pharmaceuticals, veterinary medicines, and medical devices to ensure effective and sustainable healthcare. A basic understanding and experience in the pharmaceutical profession is required as a prerequisite. This program is essential for professionals to work effectively within their organizations.

LEARNING OBJECTIVE

- **Regulatory Affairs Essentials:** Understand the foundations, principles, and best practices of regulatory affairs.
- **GMP Compliance:** Learn to apply Good Manufacturing Practices (GMP) to ensure product safety and regulatory compliance.
- **Quality Management Systems (QMS):** Gain knowledge of QMS structure and its role in maintaining quality standards in regulatory settings.
- **Regulations of Major Authorities:** Familiarize with regulations from the FDA, EMA, WHO, and their global impact.
- **Good Regulatory Practices (GRP):** Explore best practices in regulatory procedures, focusing on compliance and documentation.
- **Comprehensive CTD Documentation:** Master the Common Technical Document (CTD) format for clear and complete regulatory submissions.
- **Key Regulatory Terminologies:** Learn essential terms and concepts for a successful career in regulatory affairs.
- **Prepare for Success:** Gain practical knowledge and skills for effective regulatory implementation.

Faculty

Mr. 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, developing Canadian guidelines. His work includes contributions to drug procurement in Zambia and representation in the United States and European Pharmacopoeias. He participated in the International Conference on Harmonization, helping to develop critical 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. Syeda Rima Ishaq, has extensive experience of twenty-five years in multinational and national pharmaceutical industries mainly 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 coordinator.

President of Scientific, Technical, and International Operations & Strategic Projects at Macter International. Dr. Sajid possesses over 21 years of experience in various pharmaceutical companies. His expertise spans US FDA plant design, construction, validation, and facility approval, 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. Sajid has successfully established a Greenfield project in Malaysia, comprising two manufacturing plants for oncology and non-oncology products, both approved by the US FDA and PIC/s and established a state-of-the-art Center of Excellence R&D lab in Malaysia.Dr. Sajid's leadership has resulted in the successful navigation of various audits, including those conducted by the US FDA, PIC/s, and WHO.

Dr. Jafri is a results-oriented pharmaceutical professional with a strong track record in leading Quality and Compliance operations. He excels in implementing quality control systems that reduce product defects and enhance customer satisfaction. With extensive experience in training and mentoring teams, he has successfully increased productivity and efficiency.

At Pharma Tech Solutions, Dr. 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 by 20%, 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 by 50%, 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.

Skills & Competencies: Product Development and Launch, Team Leadersh

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 and 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 and 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 these standards, opening doors to roles in an evolving field.

CAREER PATHWAYS

Potential Roles:

- **PHARMACEUTICAL COMPANIES:** ENSURE PRODUCTS MEET REGULATORY STANDARDS AND SUPPORT COMPLIANCE IN DRUG DEVELOPMENT AND PRODUCTION.
- **HEALTH REGULATORY BODIES:** WORK ON POLICY DEVEL OPMENT, 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 (CROS):** 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.

Program Benefits

- Able to write regulatory documents
- Create a Regualtory Strategy
- Become Professional

ADMISSIONS INFORMATION

WHO CAN ENROLL:

- GRADUATES WORKING IN THEPHARMA INDUSTRY
- CANDIDATES NOMINATED BY THE PHARMA/ BIOTECH COMPANIES.
- THOSE INTERESTED IN REGULATORY AFFAIRS.

CONTACT US:

- EMAIL: lbbps@duhs.edu.pk
- PHONE: 0326-8009976

FEE PROCESSING STEPS

- REGISTRATION CONFIRMATION.
- PAYMENT SUBMISSION ACCOUNT DETAILS PROVIDED UPON REGISTRATION.
- VERIFICATION EMAIL SENT UPON RECEIPT.

TOTAL FEE: PKR 75,000/-

- **VENUE:** DMC CAMPUS (HYBRID CLASSES)
- **TIMING:** SATURDAY (05:00 PM TO 8:00 PM)
  SUNDAY (10:00 AM TO 2:00 PM)

FOR REGISTRATION

SCAN HERE:

**DOW INSTITUTE OF BIOLOGICAL,
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DOW UNIVERSITY HOSPITAL (OJHA CAMP)
OJHA CAMPUS SUPARCO ROAD,OFF. MAIN UNIVERSITY ROAD,
GULZARI-E-HIJRI, SCHEME-33, KARACHI

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