National University

الجامعة الوطنية - السودان

National University - Sudan

MASTER OF PHARMACEUTICAL REGULATORY AFFAIRS

Overview

The Master of Pharmaceutical Regulatory Affairs is a postgraduate programme designed to prepare professionals for regulatory, quality, and compliance roles within the pharmaceutical, medical device, cosmetic, nutraceutical, and healthcare industries. The programme provides advanced knowledge and practical skills in regulatory science, product registration, quality systems, pharmacovigilance, and international regulatory requirements. Graduates will be equipped to manage regulatory processes throughout the product lifecycle and ensure compliance with national and international standards.

Program Objectives

The program aims to enable graduates to:

- Understand and interpret regulatory requirements across the full spectrum of healthcare product lifecycles.
- Develop and implement regulatory strategies for pharmaceutical and healthcare products.
- Manage regulatory submissions and ensure compliance during pre-market and post-market phases.
- Apply principles of Good Regulatory Practice and international regulatory standards.
- Contribute to quality assurance, risk management, pharmacovigilance, and regulatory decision-making processes.

Learning Outcomes

Upon successful completion of the program, graduates will be able to:

- Work effectively in pharmaceutical, food, cosmetic, nutraceutical, and medical device industries.
- Ensure organizational compliance with applicable laws, regulations, and quality standards.
- Apply pharmaceutical quality and safety measures in regulatory practice.
- Manage product registration, regulatory documentation, and compliance activities.

- Evaluate regulatory risks and contribute to product lifecycle management.
- Apply national and international regulatory requirements in healthcare settings.

Admission Requirements

Applicants must satisfy the regulations of the Ministry of Higher Education and Scientific Research and the Faculty of Graduate Studies and Scientific Research.

Eligible applicants include holders of:

• B.Sc. (Honours) in Pharmacy with a minimum grade of Good (Second Class) or CGPA ≥ 2.5.

• B.Sc. (Honours) in Medical Engineering with a minimum grade of Good (Second Class) or CGPA ≥ 2.5.

• B.Sc. (Honours) in Veterinary Medicine with a minimum grade of Good (Second Class) or CGPA ≥ 2.5.

• B.Sc. (Honours) in Pharmacy, Medical Engineering, or Veterinary Medicine (Third Class) plus a qualifying program of 12 credit hours.

Curriculum Structure

Total Credits: 35 Credit Hours

Duration: 15 Months (Three Semesters)

Semester One

- Research Methodology
- Statistics and Drug Development
- Pharmaco-informatics and Communication Skills
- Biopharmaceutics and Therapeutic Product Development
- Regulatory Affairs

Semester Two

- Good Regulatory Practice
- Pharmaceutical Quality Management Systems

- Regulatory Documentation and Validation
- Quality Audit and Regulatory Compliance
- Quality Assurance and Drug Regulations
- Project Management for Pharmaceutical Professionals
- Pharmaceutical Marketing Regulations

Semester Three

- Regulatory and Good Pharmacovigilance Practice
- Regulatory Aspects of Generic Pharmaceutical Products
- Regulatory Aspects of Medical Devices
- Regulatory Aspects of Dietary Supplements, Nutraceuticals and Cosmetics
- Dissertation

Teaching and Learning Methods

The program utilizes a variety of teaching approaches, including:

- Lectures
- Tutorials
- Workshops
- Seminars
- Practical training and site visits

Teaching and Learning Methods

- Lectures
- Tutorials
- Seminars
- Workshops
- Practical Training and Site Visits

- Independent Research and Dissertation Work

Language of Instruction

- English

Career Opportunities

Graduates may pursue careers as:

- Regulatory Affairs Specialists and Managers
- Drug Registration and Licensing Officers
- Pharmacovigilance Specialists
- Quality Assurance and Quality Management Professionals
- Regulatory Compliance Officers
- Medical Device Regulatory Specialists
- Pharmaceutical Industry Consultants
- Clinical Research and Regulatory Associates
- Regulatory Agency and Public Health Professionals
- Pharmaceutical Project Managers

Award

Upon successful completion of all academic and research requirements, graduates will be awarded the degree of Master of Pharmaceutical Regulatory Affairs from the National University–Sudan.

For further information, please contact the Faculty of Graduate Studies and Scientific Research, National University – Sudan:

Website: https://postgraduate-pa.nu.edu.sd/

E-mail: pharmapostgraduate@nu.edu.sd

National University

NU.EDU.SD

Better Education Better World