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## Master of Science in Regulatory Science (Full Time)

## About the Programme

Regulatory Science is the application of the scientific method to improve the development, review, and oversight of new drugs, biologics, and devices that require regulatory approval prior to dissemination. It can also be described as a methodological means of determining the impact and value of the rules, principles, and laws governing regulated research. Training of workforce in regulatory science makes promising scientists aware of, regulatory science as an attractive, respected career option. The programme will build capacity in the areas of inspection, safety evaluation, manufacturing control, and quality control of pharmaceuticals and medical devices, as well as inspection and internal audit, such as Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), and Good Clinical Practice (GCP).

The objectives of the programme are:

* To adequately address both the academic and industry higher level of regulatory science knowledge and skills needs within a single programme
* Apply principles of basic and applied pharmaceutical sciences in drug and biologics discovery and development.
* Devise and implement global strategies for drug, biologic, and device development and evaluation
* To increase the critical mass of higher caliber regulatory science professionals and potential regulatory science academics in the region in line with global trends
* To train higher-level regulatory science personnel with greater potential for productive regulatory science academic career and professional practice, a cadre of personnel that is in great demand but in short supply locally, regionally, and globally.

Graduates of the department are expected to: exhibit an expert understanding of an academic field of knowledge by:

1. having systematically acquired a substantial body of intellectual skill and experience that is grounded in contemporary developments in an academic field;
2. creating and communicating original scholarship of a quality to satisfy peer review, extending the frontier of the field of knowledge and potentially meriting publication;

(c) demonstrating thorough knowledge of research principles and methods applicable in advanced academic inquiry.

###  **Admission Requirements**

Applicant for admission into this programme must have credit passes in English, Mathematics, Physics, Chemistry and Biology in ‘O’ level or its equivalent at one sitting and hold a Bachelor’s degree in science-related disciplines- Pharmacy, Medicine & Surgery, Dentistry, Biochemistry, Physiotherapy, Radiography, Medical Laboratory Sciences, Microbiology, Pharmacology and Nursing with a minimum of Second Class Lower division from any approved University. All candidates shall be subjected to a selection process involving written examination and or oral interview. Satisfy all other admission requirements of the School of Postgraduate Studies.

### **Graduation Requirements**

To obtain an M.Sc. in Regulatory Science, a candidate must satisfy a minimum of **24 units** of courses in minimum of two (2) semesters and with cumulative grade point average (CGPA) of 2.40 at 800 level made up as follows:

1. 14 units of compulsory theory courses
2. 2 units of research seminar
3. 4 units of research project
4. 4 units of elective courses

The duration of the programme shall be minimum of two (2) semesters and maximum of four (4) semesters.

### **List of Courses and No. of Units by Levels in tabular form**

|  |
| --- |
| **800 LEVEL FIRST SEMESTER** |
| **Course Code** | **Course Title** | **Status** | **Unit** |
| RSC 811 | Introduction to Medical Product Regulation | Compulsory | 2 |
| RSC 812 | Regulation of Pharmaceuticals, Biologic Products and Medical devices | Compulsory | 2 |
| RSC 813 | Structure & Management of Clinical Trials | Compulsory | 2 |
| PCH 801 | Quality Assurance System & Total Quality Management  | Compulsory | 2 |
| BME 803 |  Research Methods & Biostatistics | Compulsory | 2 |
| MPY 853 | Ethics & Public Administration | Compulsory | 2 |
| TOX 811 | Biochemical and Molecular Toxicology | Elective | 2 |
| RSC 814 | Introduction to Food Safety  | Elective | 2 |
| RSC 815 | Quality Assurance for Drugs, Biologics and Medical Devices | Elective | 2 |
| RSC 816 | Biomedical Products and the Law | Elective | 2 |
| MPY 861 | Business Ethics I | Elective | 2 |
| BME 802 | Basic Biomedical Sciences | Elective | 2 |
| **Total number of units** | **Compulsory****Elective** | **12****12** |

**SECOND SEMESTER**

|  |  |  |  |
| --- | --- | --- | --- |
| **Course Code** | **Course Title** | **Status** | **Unit** |
| PCL 811 | Adverse Drug Reactions & Pharmacovigilance | Compulsory | 2 |
| RSC 828 | Research Seminar on Recent Advances in Regulatory Science | Compulsory | 2 |
| RSC 829 | Research Project  | Compulsory | 4 |
| RSC 821 | Introduction to Drug & Food Toxicology | Elective | 2 |
| RSC 822 | Regulation of food and Dietary supplements/Herbal medicine | Elective | 2 |
| RSC 823 | Biomedical Auditing Principles  | Elective | 2 |
| BME 811 | Signals and Systems | Elective | 2 |
| **Total number of units** | **Compulsory****Elective** | **8****8** |

### Summary of number of units compulsory and elective courses to be taken/available at each Level

|  |  |  |  |
| --- | --- | --- | --- |
|  | **First semester** | **Second semester** | **Total** |
| **Level** | Units of Compulsory Courses  | Units of Elective Courses Available | Units of Compulsory Courses  | Units of Elective Courses Available | Total of Compulsory Courses  | Total of Elective Courses Available |
| **800** | **12** | **12** | **8** | **8** | **20** | **20** |

### **Course Contents/Description**

**RSC 811: Introduction to Medical Product Regulation**

Regulatory Science and its importance. Roles of a host of regulatory bodies: WHO, NAFDAC, SON, NDLEA, PCN, PGMAN, FMOH, IPAN. Agencies overlap to oversee the production of medical and health-care products. Other regulatory agencies include the the Environmental Protection Agency (water, pesticides), the Federal Ministry of Trade and Commerce (advertising practices), and the Consumer Protection Agency. Regulatory bodies and their requirements. Product registration and licensing. Designed for students new to regulatory science.

**RSC 812: Regulation of Pharmaceutical, Biologic Products and Medical devices**

The course will explore the relationships between scientific discovery, testing and regulatory oversight. It will look at the rules governing prescription and over-the-counter drugs and look at the changes that are introduced by the burgeoning influence of genetic engineering and biological product development. It will consider the practical issues facing regulatory specialists as they work with the NAFDAC and other international regulatory bodies to secure and keep product approval. Legal framework for drug regulation ethical issues in drug/biologic/device development and drug/biologic/device use; global regulatory guidance approaches; types of communications with NAFDAC, including Investigational New Drug (IND) application, New Drug Application (NDA), and Abbreviated New Drug Application (ANDA) requirements, and clearance and Premarket Approvals / Biologics Licensing Applications (PMA/BLA) approval requirements; chemistry, manufacturing, and control (CMC) issues; and post-marketing topics.

**RSC 813: Structure & Management of Clinical Trials**

Essential features of clinical trials: 1) basic study design; 2) study population; 3) planned statistical analysis; 4) enrollment of subjects; 5) regulatory requirements; and 6) ethical issues. Bioethical and practical concerns that shape the design of clinical trials. How trials are carried out, and how they are managed and documented. Clinical research designs and statistical analyses utilized in medical-product research. Features of clinical trials in specialized populations such as AIDS, cancer, pediatrics and psychiatry. Current trends for accelerating drug development.

**RSC 814: Introduction to Food Safety**

Importance of safe and “healthy foods” Basic concepts of food science and food safety: fundamental food chemistry, food composition and nutrient interactions, food processing, food engineering, food stability and preservation, food sensory qualities, food toxicology, food microbiology, and food biotechnology. Modern topics, such as product labeling and health claims, forms of food adulteration, safety of food additives and coloring, emerging food processing technologies. Physical principles, physiological processes, and regulatory guidelines in food science and food safety. Safety assessment of food. Students will discuss these concepts and experience their principles through classroom demonstrations and personal local market surveys.

**RSC 815: Quality Assurance for Drugs, Biologics and Medical Devices**

Assurance of quality through post-marketing surveillance, internal audits and regulatory inspections. Regulations needed to ensure the quality of drugs, medical devices and biologics. Principles necessary for the interpretation and implementation of a quality system including QSR, ISO 13485 and ICH. Good Manufacturing Practice (cGMP) requirements for medical devices. methods for designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices. Regulations and guidelines that ensure the quality of medical devices and combination products.

**RSC 816: Biomedical Products and the Law**

Laws governing medical products. Legal implications and liabilities in the chain of product-development activities. History of laws related to medical product development, commercialization and clinical use, and relevant legal cases whose decisions have been important in establishing precedents and guiding interpretations of legal theory over the years. Laws, regulations and institutions governing medical products in Nigeria. The regulatory process, liability and litigation, and patent law. Criminal and civil acts, contracts, negligence, and ethical concepts as they relate to the medical profession. Managed care, Health Insurance Acts, and other health care legislative rulings.

**RSC 821: Introduction to Drug & Food Toxicology**

The course examines the safety assessment of these products as the students develop a general understanding of the toxicological tools and regulations associated with drugs, herbal and food components. The fundamental concepts of pharmacokinetics and absorption, distribution, metabolism and excretion (ADME) will be applied to historical and contemporary drug and food products. Students will develop critical thinking skills through discussions, critical problem-solving experiences, and case report analyses of drug and food components.

**RSC 822: Regulation of food and Dietary supplements/Herbal medicine**

This course explores the regulatory dynamics of foods and their components, including intentional additives and possible contaminants, dietary supplements, and herbal medicines, and examines the contentious nature of international regulations associated with these products. Review of contemporary domestic and global food regulations. History of food regulations specialized nutrition regulations that include infant formula and dietary supplements, as well as food terrorism and federal inspection and enforcement jurisdictions, plus international food law. Intersection of food and dietary supplements.

Experts share their expertise and address the current and future state of regulations that governed these products. Students experience the production and regulatory differences between foods and dietary supplements through field trips to production and manufacturing facilities of food products and dietary supplements, and critically review these differences through discussions, oral presentations, and written assessments.

**RSC 823: Biomedical Auditing Principles**

Use of inspections and audits to ensure the quality of health care products to maintain standards when manufacturing is outsourced abroad. Audits determine if companies comply with regulations set out in the Food, Drug and Cosmetic. The regulations set out requirements for companies to conduct internal audits of their own manufacturing, storage and distribution activities, including areas such as adverse event reporting, customer complaint handling and recall procedures. Use audits to ensure that companies conducting animal studies (GLP) and/or human clinical trials (GCP) comply with regulatory requirements. Students will be introduced to all aspects of auditing during the development and manufacturing of drugs, devices, dietary supplements and biologics.

**RSC 828: Research Seminar on Recent Advances in Regulatory Science**

Students will be required to make seminar presentation on Recent Advances in Regulatory Science. The objective is to train graduate students how to search for, write-up and orally present scientific information approved before formally registering in the course.

**RSC 829: Research Project**

Application of research techniques and development of research methodologies to solve problems in any aspect of Regulatory Science

**PCH 801: Quality Assurance System & Total Quality management**

The importance of Quality Control of Pharmaceuticals, Manufacturing processes that are well-understood, consistent and highly controlled. A process is generally considered well-understood when (1) all critical sources of variability are identified and explained; (2) variability is managed by the process; and (3) product quality can be accurately predicted while accounting for materials, manufacturing, environmental, and other conditions. Veterinary medicines and Agrochemicals, Personnel, facilities and Documentation, Standard Operating Procedures (SOPs), Pharmacopoeia Monographs (USP, BP, BPC, EuP etc.). Study the rules governing good laboratory and manufacturing practices and explore how they mesh with ISO and European standards, CE marking and quality systems regulations. Relevant equipment and manuals needed to establish a standard Drug Quality Control Laboratory; Regulatory Aspects of Drug and Chemicals. Risk analysis and documentation, and audit.

**BME 803: Research Methods & Biostatistics**

Introduction to statistical techniques used for analysis of basic and clinical/Biomedical Engineering data. Probability theory, Sampling theory, Hypothesis Testing, Non-parametric methods, Computer Applications. SPSS, Epi-info Software. Sampling methods and types of sampling; Statistical evaluation; Parametric and non-parametric; Correlation, Regression; Null hypothesis; etc.

**MPY 853: Ethics & Public Administration**

Ethical foundation of public policy. Social roles and individual responsibility. The common good, public interest and corporate goals. Preferential treatment, desert, discrimination. Social justice and the ethics of ethnic balancing. Corruption and abuse of power in the public sector

**MPY 861: Business Ethics**

Introduction to business principles appropriate to medical products, including supply and demand, product entry-exit strategies, financing, reimbursement, marketing and pricing in global marketplace. Profits, consumer protection, rights of clients, confidentiality and basic rights of business environmental, moral rights of consumers and morality of business. Sales, marketing, new product development and strategic intelligence and their influence on business decisions as a new product moves from the bench to the market and into obsolescence. Application of traditional ethical theories to decision-making in business. Ethics and corporate social responsibility. The connection between ethics, business and religion. Ethics and employer-employee relationship. Ethics and corporate governance. Ethics and sales/marketing; the morality of in-built obsolescence. Taking Ethical decisions in Business Management: the categorical imperative, the conventional ethic, the disclosure rule, the ends means ethics etc.

**TOX 811: Biochemical and Molecular Toxicology**

An outline of the basics of molecular biology, drug/receptor interactions, receptors and ion channels, regulation of second messengers and drug metabolism. Biochemical and molecular actions of environmental chemicals and toxicants, and assessment of cellular damage by biochemical measurements and other state-of-the-art technologies. Biochemical and molecular mechanisms of drug/chemical toxicities

**BME 802: Basic Biomedical Sciences**

This course introduces students to the structure and function of anatomy, physiology and chemical constituents of living systems. The course provides a system-based review of the structure and function, normal as well as abnormal, of cells, organs and systems. Emphases will be based on those structures/functions that are important in biomedical engineering. Case studies will also be included to introduce the importance of medical sciences related to biomedical engineering. Physiology of Body Fluids and excitable Tissues; nervous and endocrine systems; Organ systems; general metabolism Homeostasis and thermoregulation.

**BME 811: Signals and Systems**

It forms an integral part of engineering systems in many diverse areas, including seismic data processing, communications, speech processing, image processing, defense electronics, consumer electronics, and consumer products. The course presents and integrates the basic concepts for both continuous-time and discrete-time signals and systems. It addresses the following topics: classifications of signals and systems, basic signal operations, linear time-invariant (LTI)systems, time-domain analysis of LTI systems, signal representation using Fourier series, continuous-time Fourier transform, discrete-time Fourier transform, and Laplace transform. Filtering and filter design, modulation, and sampling for both analog and digital systems, as well as exposition and demonstration of the basic concepts of feedback systems for both analog and digital systems.

**PCL 811: Adverse Drug Reactions and Pharmacovigilance**

Types of adverse drug reactions; Occurrence and recognition in the community. Roles of the prescriber, the pharmacist and the patient in recognising and documenting ADRs. Adverse Drug Events. Pharmacovigilance-Risk management plan. Regulatory authorities and the pharmaceutical industry, Health care professionals. Design of ADRs and Pharmacovigilance cards/forms for use in hospitals, community pharmacy and by the community or populace. Their roles and responsibility in ADR reporting and Pharmacovigilance Alerts.