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## Doctor of Philosophy in Regulatory Science (Full Time)

## About the programme

In a recent market survey in which industries were asked what skill sets are needed to develop regulatory leaders, attention was drawn to three types of capabilities: outstanding people and project management skills, a good capability to understand and work within transnational organizations to make globally relevant decisions, and a broader knowledge of policy and business than is typically acquired at junior and mid-levels of the regulatory career structure. A further pressing problem is the graying of the current high-level regulatory professional. Most of the current leadership in Regulatory Science comes from individuals on the verge of retirement. These individuals learned on-the-job slowly as the regulations developed and now are leaving the field; the next generation of leaders will not have the same luxury.

The aim is to provide advanced knowledge on development of new tools, standards and current trends on assessment of safety, efficacy, quality and performance of regulated products.

The graduates will be accountable for their own learning and professional training by:

(a) conceptualizing, designing and implementing a project which will increase knowledge that is applicable or contributes new insights in Regulatory Science;

(b) evaluating ideas and making informed judgements on complex issues or challenges in the field of specialization;

(c) communicating ideas, methodologies and conclusions clearly and effectively to specialist and non-specialist audiences

If we are to assure that new technologically sophisticated products make it to the marketplace, we must find new ways of benchmarking best practices and shortening the critical path that now exceeds a decade for most innovative pharmaceuticals and devices. Graduates will

* become highly skilled in critical thinking and analysis.
* expertly discuss concepts of right, wrong, good and bad.
* demonstrate clear understanding of moral principles and their application in everyday life.
* demonstrate the ability to read and interpret philosophical texts.
* demonstrates how to extract a specific topic within its relevant larger philosophical context.
* demonstrate proficiency in writing philosophical essays that have coherent theses and acceptable supporting arguments.
* demonstrate the ability to use conceptual frameworks including epistemological, ethical, metaphysical, as well as other philosophical specializations.

### **Admission Requirements**

1. Candidates for the Ph.D. Regulatory Science programme shall possess any of the following qualifications:

* An M.Sc. Regulatory Science Degree with a minimum CGPA of 4.00 out of 5.00 from this center or an equivalent qualification from any other approved university.
* An M. Phil. Regulatory Science Degree with a minimum CGPA of 4.00 from this center or an equivalent qualification from any other approved university.
* At least a CGPA of 4.00 in 1 of M.Phil. coursework courses at the end of the stipulated minimum duration for the M. Phil. programme.

1. All candidates in the aforementioned three categories shall be subjected to a selection process by the center involving proposal writing and an oral interview.
2. Satisfy all other requirements of the School of Postgraduate Studies.

### **Duration for Ph.D.**

Those with Master Degree will have a minimum duration for a full time programme is six (6) semesters while the maximum duration is ten (10) semesters. Those who converted from M.Phil to Ph.D. will have a minimum of six (6) semesters and a maximum of ten (10) semesters to run a full time programme.

### **Graduation Requirement**

A. A candidate admitted with an M. Sc. Degree (herein referred to as regular candidate) shall carry a minimum workload of 30 units which must include the following:

1. 6 units of elective M.Phil. Coursework
2. 6 units Ph.D. Term papers
3. 6 units of Research Seminars
4. 12 units of Research Thesis

B. A student admitted into the Ph.D. programme via M. Phil. conversion or M. Phil. degree shall carry a minimum workload of 2 made up as follows:

1. 6 Units Ph.D. Term papers
2. 6 Units of Research Seminars
3. 12 Units of Research Thesis

### **List of Courses for Ph.D. in Regulatory Science**

|  |  |  |  |
| --- | --- | --- | --- |
| **Course Code** | **Course Title** | **Status** | **Units** |
| RSC 951 | Translational Medicine: An Overview | Compulsory | 2 |
| RSC 952 | Validation Requirements for Medical Products | Compulsory | 2 |
| RSC 953 | Approaches to Drug Discovery | Compulsory | 2 |
| RSC 991 | Research Seminar I | Compulsory | 3 |
| RSC 992 | Research Seminar II | Compulsory | 3 |
| RSC 999 | Research Thesis | Compulsory | 12 |
|  | **Total** |  | **24** |

### 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 951: Translational Medicine: An Overview**

Translational medicine is the continuum – often known as “bench to bedside” – by which the biomedical community takes a focused point of view to move research discoveries from the laboratory into clinical practice to diagnose and treat patients. This desire to see a rapid progression from laboratory bench to hospital bedside brings with it huge hurdles that must be addressed and overcome – technological, ethical and regulatory. Thus, this introductory course is designed to provide an overview of principles and concepts underlying drug discovery and development as seen through the eyes of the industry, including terminology of translational science. This course introduces you to ways in which promising research discoveries move from the laboratory (bench) into clinical practice (bedside) to diagnose and treat patients, a process commonly referred as “Translational Science” or “Translational Medicine.”  It should give you a basic understanding of the principles and concepts underlying drug discovery and development as seen through the eyes of industry.  It will examine the use of different types of pharmaceutical interventions, from patented to generic to over-the counter drugs, dietary supplements and alternative medicines.  You will learn about the challenges of illicit and counterfeit drugs, with a view to their regulatory, ethical and societal challenges.  Selected cases studies will be critically reviewed and emerging “hot” topics discussed.  This course is directed at students interested in drug discovery research, chemistry, biology, pharmacology, biochemistry, toxicology, formulations, pharmaceutical industry, NAFDAC.  It would also be useful for business analysts, entrepreneurs and venture capitalists interested in understanding the pharmaceuticals industry.

**RSC 952 Validation Requirements for Medical Products**

Regulated industries, such as medical product manufacturing, must adopt and adhere to complex compliance procedures to ensure their final product meets quality, safety and purity requirements so that it is safe for distribution and / or sale. As one of the essential pharmaceutical commercialization requirements, validation assures consistent reproduceable and repeatable results as part of the Quality Management System (QMS) for testing and manufacturing processes.  In this course, we will follow the progression of the testing and manufacturing validation activities over time in the pharmaceutical industry, beginning with equipment qualification, computer system validation (CSV), cleaning validation, laboratory instruments, testing and methods validation, manufacturing process and environmental monitoring validation for accuracy and precision, security, reliability, consistency and productivity.  You will see how business concepts merge with project management and science, to assure and keep products safe and in compliance with applicable regulations.

**RSC 953 Approaches to Drug Discovery**

Examines the process of drug discovery from selection of disease and therapeutic target to characterization and validation of lead drug candidates. Specific areas of interest are focused on steps related to target validation, genomics/bioinformatics, high-throughput screening, chemistry, pharmacokinetics and pharmacology. An introduction to biopharmaceuticals, such as gene therapy and recombinant DNA technology. Business aspects of bringing new drugs to the market will be discussed in the context of preclinical drug discovery as well as topics that companies must consider when involved in drug discovery and development, such as the financial aspects of starting up a pharmaceutical enterprise, the regulatory process, liability and litigation, and patent law.

**RSC 991: Research Seminar I**

Presentation of Pre-Proposal seminar. Progress Report on Research Findings

**RSC 992: Research Seminar II**

Presentation of Research Project Report for Thesis Title Defense (Pre-APC Seminar)

The student is expected to present a seminar in line with the prevailing School of Postgraduate Studies Academic Planning Committee (APC) format, highlighting the project’s contribution to knowledge

**RSC 999: Research Thesis**

Students will undertake research projects in specific areas of Regulatory Science