# ADVANCED DIPLOMA IN PHARMACEUTICAL SCIENCES

AdvDip (Pharmaceutical Sciences) - NQF Level 7 (132 credits)

**Qualification code: ADPS20**

*SAQA ID: 110727, CHE NUMBER: H/H16/E091CAN*

Campus where offered: Arcadia Campus

## REMARKS

a. *Admission requirement(s):*
Any relevant NQF Level 6 Health- or Pharmaceutical Sciences-related degree or diploma from a South African university or any relevant three-year bachelor's degree or a three-year diploma with at least two years' experience in the pharmaceutical industry.

Holders of any other equivalent South African or international qualification may also be considered, see Chapter 1 of Students' Rules and Regulations.

b. *Selection criteria:*
Admission is subject to selection by a departmental selection panel. Prospective students will be evaluated based on the marks obtained in the previous qualification and/or work experience.

Acceptance is subject to available capacity according to the Student Enrolment Plan (SEP). Applicants will be informed of their status per official letter from the Office of the Registrar, alternatively, they can check their application status on the TUT website, www.tut.ac.za.

c. *Recognition of Prior Learning (RPL), equivalence and status:*
See Chapter 30 of Students' Rules and Regulations.

d. *Intake for the qualification:*
January only.

e. *Presentation:*
Block-mode classes offered on Saturdays over a period of two years.

f. *Minimum duration:*
One or two years depending on the programming offering.

g. *Exclusion and readmission:*
See Chapter 2 of Students' Rules and Regulations.

## CURRICULUM

### FIRST YEAR

| CODE | MODULE | NQF-L | CREDIT |
|---|---|---|---|
| BPY107V | Biopharmaceutics and Pharmacology | (7) | (24) |
| CRS107V | Clinical Research | (7) | (24) |
| QMD107V | Quality of Medicines | (7) | (24) |
| TOTAL CREDITS FOR THE YEAR: | | | **72** |

### SECOND YEAR

| CODE | MODULE | NQF-L | CREDIT |
|---|---|---|---|
| MGO107V | Medicine Governance | (7) | (24) |

| | | | |
|---|---|---|---|
| PHD107V | Pharmaceutical Development Process | (7) | (24) |
| RPS107V | Introduction to Research Methodology: Pharmaceutical Sciences | (7) | (12) |

TOTAL CREDITS FOR THE YEAR: **60**

TOTAL CREDITS FOR THE QUALIFICATION: **132**

## MODULE INFORMATION (OVERVIEW OF SYLLABUS)

The syllabus content is subject to change to accommodate industry changes. Please note that a more detailed syllabus is available at the Department or in the study guide that is applicable to a particular module. At time of publication, the syllabus content was defined as follows:

### B

**BIOPHARMACEUTICS AND PHARMACOLOGY (BPY107V)** **CONTINUOUS ASSESSMENT**

***(Module custodian: Department of Pharmaceutical Sciences)***

Physiology of the gastro-intestinal tract and drug absorption. Concept of drug bioavailability including routes of drug administration, physiology of the GIT and factors that affect bioavailability. Dosage regimens and routes of drug administration. An introduction to basic pharmacology. Drug disposition (absorption, distribution metabolism and excretion) in the body. Fundamental knowledge of drug pharmacokinetics, bioavailability and pharmacology as used in comparative bioavailability studies. Bioequivalence. Students will develop skills in determining bioavailability of drugs using in-vitro and in-vivo methods as well as using data from such studies to determine bio-equivalence. (Total notional time: 240 hours)

### C

**CLINICAL RESEARCH (CRS107V)** **CONTINUOUS ASSESSMENT**

***(Module custodian: Department of Pharmaceutical Sciences)***

The central areas of pre-clinical research and development, applying the key terms, concepts, facts, principles, rules and theories in pre-clinical research, clinical trial design in accordance with the ICH Guidelines with emphasis on controls in clinical trials. Clinical trial protocols and regulatory authority and independent ethics committee approval. Life cycle of a clinical trial. Ethical aspects of clinical trials. Good Clinical Practice. Good Laboratory Practice. (Total notional time: 240 hours)

### I

**INTRODUCTION TO RESEARCH METHODOLOGY: PHARMACEUTICAL SCIENCES (RPS107V)** **CONTINUOUS ASSESSMENT**

***(Module custodian: Department of Pharmaceutical Sciences)***

The purpose of this module is to provide a student with detailed knowledge as well as an ability to apply and evaluate the key terms, concepts, facts, principles, rules and theories of research in the pharmaceutical sciences field. (Total notional time: 120 hours)

### M

**MEDICINE GOVERNANCE (MGO107V)** **CONTINUOUS ASSESSMENT**

***(Module custodian: Department of Pharmaceutical Sciences)***

The role of the pharmaceutical regulatory scientist, South African legislative process and key concepts in the process of law making; Key concepts of Medicines and Related Substances Act, 1965 (Act No. 101 of 1965); The Pharmacy Act, 1974 (Act No. 53 of 1974) consolidated); the international pharmaceutical arena and its impact on S.A. regulatory practice; the classification medicinal products and Complementary and Alternative Medicines (CAMs); Requirements for medicine registration in S.A.; the South African Common Technical Document (CTD) Guidelines as well as the South African Health Products Regulatory Authority (SAHPRA) post registration processes. (Total notional time: 240 hours)

## P

**PHARMACEUTICAL DEVELOPMENT PROCESS (PHD107V)** **CONTINUOUS ASSESSMENT**

***(Module custodian: Department of Pharmaceutical Sciences)***

The steps in the Pharmaceutical Development Process of a drug into a pharmaceutical dosage form. The stages of preformulation, characterisation of the active pharmaceutical ingredient, the design and formulation of an appropriate dosage form and briefly the manufacturing process, record keeping, packaging and stability aspects. Various dosage forms, advantages, disadvantages, routes of administration, formulation development and rationale for choice of excipients, specifications, official and legal requirements for active pharmaceutical ingredients, excipients and finished products, manufacturing requirements specific to each dosage form. (Total notional time: 240 hours)

## Q

**QUALITY OF MEDICINES (QMD107V)** **CONTINUOUS ASSESSMENT**

***(Module custodian: Department of Pharmaceutical Sciences)***

A wide range of topics associated with quality assurance, good manufacturing practices, quality control, validation, design and control of the manufacturing environment, including manufacturing procedures, documentation, raw materials, human resources and facilities and equipment for manufacturing of pharmaceutical products. Appropriate processes of information gathering within the field of drug development process and good manufacturing practices in order to produce quality medicinal products. Compliance with current Good Manufacturing Practices (cGMP). Differences between GMP, QA, and QC in pharmaceutical manufacturing. (Total notional time: 240 hours)