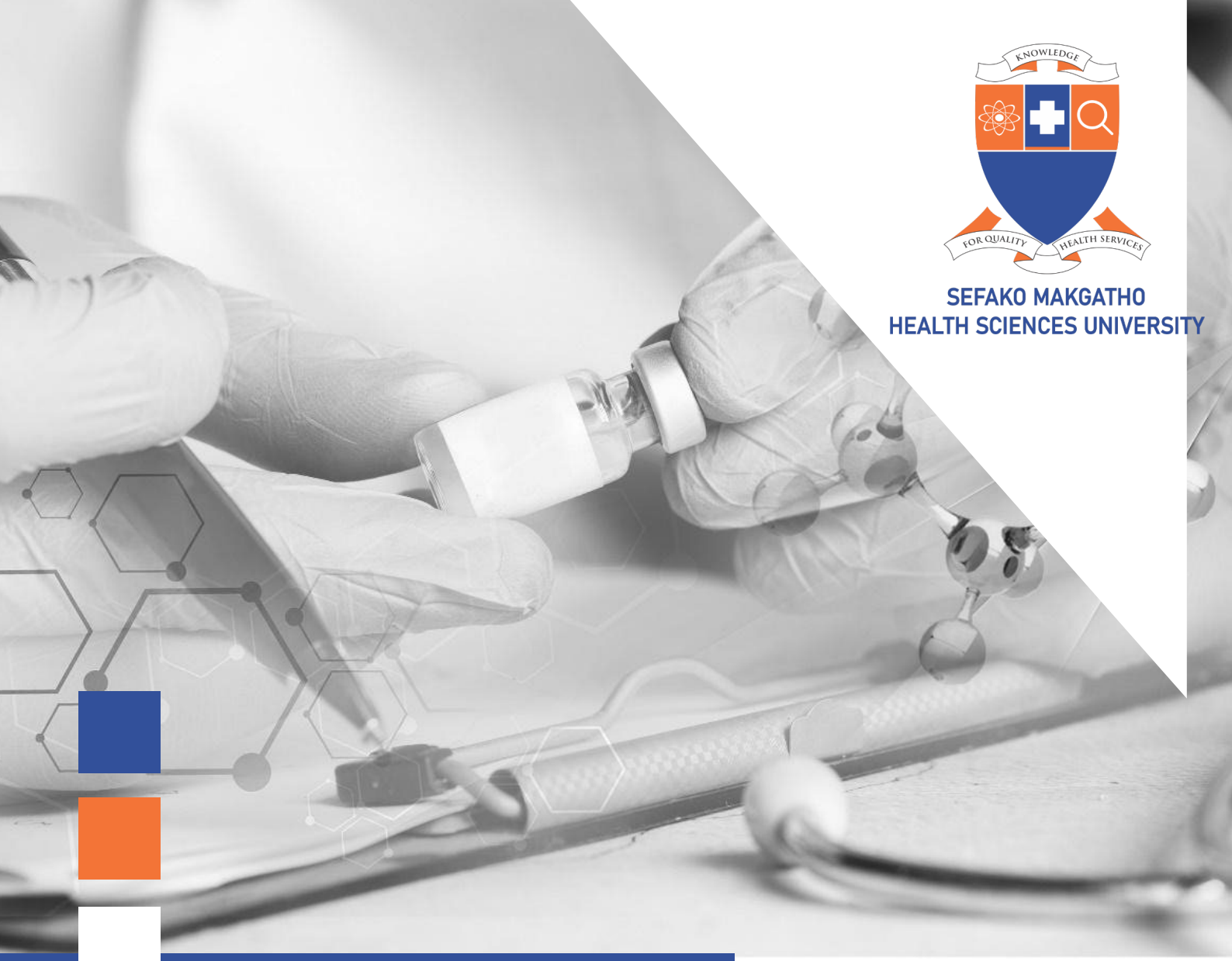

SEFAKO MAKGATHO
HEALTH SCIENCES UNIVERSITY

PROGRAMME HANDBOOK

SCHOOL OF PHARMACY

POSTGRADUATE DIPLOMA IN PHARMACEUTICAL REGULATORY AFFAIRS

(PDRP01)

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1. INTRODUCTION

1.1 Welcome Message

Welcome to the Post Graduate Diploma in Pharmaceutical Regulatory Affairs (PDRP01) presented by the Department of Pharmaceutical Sciences, School of Pharmacy, Sefako Makgatho Health Sciences University. The course gives you an opportunity to pursue a career in the pharmaceutical and healthcare industries. This programme aims to broaden the knowledge and skill-set, in ensuring the quality, safety and effectiveness of a wide range of pharmaceutical products, medical devices for human use as well as their registration for marketing. This qualification further assists in pursuing master's degree in pharmaceutical regulatory affairs, as long the remaining course specific requirements are met. We are looking forward to a very productive and working relationship with you.

1.2 School Mission & Vision

School Vision:

Transforming pharmacy health care services through excellence and innovation.

School Mission:

School of Pharmacy provides training and education in pharmacy degree and non-degree programmes through excellence in teaching, learning, innovative research and community engagement.

Values:

The values that will guide students, faculty and administrative staff are:

- **Accountability**: We are obliged to answer for the execution of our responsibilities. Accountability cannot be delegated, whereas responsibility can be delegated without abdicating accountability.
- **Effective leadership:** we are results-driven and focus on achieving strategic objectives and positive outcomes.
- **Efficiency:** We pledge to be efficient stewards of the resources entrusted to our care to ensure maximum benefit for the university.
- **Excellence:** Performance excellence in the core and operational functions of the university.
- **Integrity:** We act with integrity in accordance with the highest academic, professional, and ethical standards.
- **Respect:** We respect and honour the dignity of each person, embrace civil discourse, and foster a diverse, inclusive, and safe community.
- **Student centred:** Promoting student-centeredness as the heart of the academic enterprise.

- **Ubuntu**: ubuntu encompasses respect, dignity, value, acceptance, sharing, co-responsibility, humaneness, social justice, fairness, personhood, morality, group solidarity, compassion, conciliation, et cetera

1.3 Programme Overview

The program's intended purpose is to train students to become working professionals in Pharmaceutical Regulatory Affairs. At the end of this course, students will:

- cover the core topics one must know to effectively lead others within regulatory agencies or the regulatory department of a pharmaceutical company.
- cover critical areas such as regulatory frameworks, drug development processes, quality assurance, compliance standards, and pharmacovigilance.
- gain a comprehensive understanding of the complex and evolving regulatory landscape in the pharmaceutical industry.
- equip with the necessary knowledge and skills to create high-quality applications for the registration of health products, ensuring compliance with National Health and Drug Policies.

These goals will be achieved by mastering the following exit level outcomes (ELO's):

1. Compilation of the general, regional, and labelling requirements for a medicine registration application in compliance with the Medicines and Related Substance Act, 1965 (Act 101 of 1965), the Pharmacy Act, 1974 (Act 53 of 1974), and the SAHPRA Guidelines and in line with the National Health and the National Drug Policies

2. Compliance with enabling and other relevant legislation of the registration and control of health products (medicines, medical devices and IVDs).

3. Analysis, evaluation and justification of good manufacturing practice (GMP) aspects to obtain positive GMP compliance status for the registration and control of medicines.

4. Compilation of the licence and permit applications in compliance with the Medicines & Related Substances Act, 1965 (Act 101 of 1965), Pharmacy Act, 1974 (Act 53 of 1974), and the SAHPRA Guidelines, in line with the National Health and National Drug Policies required for the Health Products Industry.

5. Select, apply, and engage with appropriate risk-based science for procedures, processes and/or techniques in pharmaceutical regulatory affairs.

6. Analyse, and evaluate researched information to address scientific / technical challenges within pharmaceutical regulatory affairs

1.4 Programme Coordinator and Contact Information

The programme is coordinated by Dr Madan Poka and should you require information or need assistance, kindly send all communication at regulatory@smu.ac.za. Staff involved in the programme, with their contact details, are listed in Table 1. Invited guest speakers or guest lecturers will present on specific topics during some of the contact sessions.

Table 1: Staff details

Name	Telephone	E-mail
Dean of School: Prof PH Demana	(012) 521 - 4080	patrick.demana@smu.ac.za
Head of Department: Pharmaceutical Sciences Dr MS Poka	(012) 521- 4212	Madan.poka@smu.ac.za
Lecturer Joy van Oudtshoorn	(012) 521 - 3898	joyvo@icon.co.za
Programme Administration: Ms Jabulile Mahlanghu	(012) 521 - 4212	jabu.mahlangu@smu.ac.za

2. PROGRAMME STRUCTURE

2.1 Entry Requirements

B.Pharm NQF Level 8 or cognate scientific bachelor's degree on NQF Level 7 or cognate Advanced Diploma on NQF Level 7. Candidates without B.Pharm are expected to have at least two years of experience in the pharmaceutical manufacturing sector. **Candidates who hold a qualification obtained outside of South Africa must submit the Evaluation of Foreign Qualification certificate from the South African Qualifictions Authority (SAQA).**

2.2 Selection Criteria

After the closing date for applications, a paper selection is conducted, based on all the information received. Only candidates whose applications meet all the requirements (e.g. complete academic records, referees' reports) by the due date will be considered for selection guided by the rules and regulations of the University's selection committee. Students who meet the admission criteria will be screened for access to this programme regardless of gender and race according to the SMU Selection and Admission Policy.

Note: *Please note that space for this program are limited. Preference will be given to applicants who hold a Bachelor of Pharmacy (B.Pharm) degree and/or have relevant*

experience in the pharmaceutical industry, including areas such as manufacturing, quality assurance, quality control, and regulatory affairs. Consideration will also be given to ensure appropriate demographic representation in line with institutional and national transformation objectives. In addition, spaces for applicants with foreign qualifications are limited to a maximum of two. Meeting the minimum requirements does not guarantee selection.

2.3 NQF Levels and Credits

Module name	NQF Level of the module	No. of credits per module	Compulsory or elective	Semester (1,2)	Duration (Weeks)
Module 1: MRAI081 Administrative Information	8	20	Compulsory	1	8
Module 2: MREL081 Enabling Legislation and Licensing	8	20	Compulsory	1	4
Module 3: MGMP081 Good Manufacturing Practice (GMP)	8	20	Compulsory	1	6
Module 4: MRGP082 Other Good Practices	8	16	Compulsory	2	5
Module 5: MRQB082 Quality and Bioequivalence	8	24	Compulsory	2	8
Module 6: MRSE082 Safety and efficacy	8	20	Compulsory	2	5

Total course credits = 120 credits (NQF Level 8)

2.4 Programme Duration

Minimum duration (years) for completion: 1 Year

Maximum duration (years) for completion: 2 years

A student who interrupts his/her studies retains credit for modules passed for a maximum period of two years, subject to Rule G10 in the General Calendar of the Sefako Makgatho Health Sciences University (see Rule G9).

2.5 Medium of Instruction

The medium of instruction is English. Students must therefore be fluent in written and spoken English. Group work and class discussions will also be conducted in English. Please conduct all communication during the contact sessions in English.

2.6 Teaching and Learning Methods

Tutorials

- Live, instructor or guest Lecture led sessions via the Learning management system (LMS), Black Board. Learners will engage in **two interactive sessions per week**, each spanning two hours (2 hours) of guided instruction.
- Pre-recorded video lectures. All the interactive sessions will be recorded and placed on the LMS for self-paced learning and reinforcement of key topics. Note that these records are only allowed to be accessed by registered students and cannot be downloaded.

Discussion Forums and Peer Engagement:

- Moderated discussion boards on Blackboard: These sessions include assignment presentations, case discussions, Q&A readings etc. (Once a week for one hour)
- Non-Moderated Small Group Sessions: Self-directed group work in virtual breakout rooms on the Black board. Students work in their designated small working groups on matters such as assignments, case studies etc. (Once a week for one hour)

2.7 Study Guides

Each module will have a study guide. The study guides only provide the time schedule, topics and their respective general learning objectives. It does not contain descriptions of the topics. You need to use the objectives as a guide in consulting references on the specific topics in order to assist you to understand and utilise the information to enhance your knowledge and to attain the required competency.

the School of Pharmacy, Sefako Makgatho Health Sciences University. Violators of this copyright will be prosecuted.

2.8 Study Materials

A prescribed list of references that include various national and international guidelines will be provided at the end of each module guide that are specific to the content of the module. Students download these guidelines from respective websites and use them as study material.

2.9 Contact Sessions

The contact sessions will include presentations on the theoretical background to the topics, interactive class discussions as well as small group activities on certain topics. If you cannot attend a contact session for whatever reason, you need to submit a fully completed “Request for leave of absence from formal academic activities” form to the course secretary within 24 hours (see Appendix 1).

2.10 Assessment and Evaluation

As set out in the institutional assessment policy, formative assessment will be utilised within each module as set out in the relevant module descriptor. Formative assessment facilitates learning and the required competencies to successfully complete the outlined summative requirements of each module. The assessment strategy includes feedback after formative assessment to ensure constructive learning opportunities for students and continuous assessment as learning opportunities. The assessment strategy is further supported by comprehensive assessment plans for each module as set out in the module descriptors.

As required by the institution, formative assessment for each module will comprise 60% of the final module mark and summative assessment 40%. Assessments are aligned with SMU’s Assessment Policy and SMU General Academic Rules.

MINIMUM REQUIREMENTS

Subminimum requirements will apply as follows:

- A module mark is comprised of formative assessments, which weighs 60% and summative assessments 40%
- For all components of the formative evaluation, a minimum of 40% must be obtained. If this has not been obtained, the component has to be repeated.

- To qualify for summative assessment a minimum of 40% for formative evaluation must be obtained.
- Final pass mark of the module (Total Formative plus Summative mark): 50%
- If the final mark achieved for a module is 50% or more, but the summative assessment mark is below 40%, the student will sit for a supplementary examination.
- If the module mark is between 45% and 49%, supplementary assessment will be given to pass the module, only in the case when summative assessment mark from standard exam is above 40%.
- Calculation of the final mark following a supplementary test or assessment will be the same as that after the test or assessment with the supplementary test or assessment mark substituting the test or assessment mark. The maximum final mark allocated can only be 50%.
- A deferred examination will only be allowed if the student has a valid medical certificate and has notified the school in advance. A completed *"Request for leave of absence from formal academic activities"* (Appendix 1) form with the supporting documents, e.g. Medical Certificate, must be submitted to the course coordinator within 24 hours of the examination.

Note: *Students are reminded that they are expected to adhere to all institutional policies and procedures as outlined in the general rules of the school and university. These rules govern academic conduct, assessment, discipline, and student responsibilities. For full details, students should consult the SMU General Calander and School of Pharmacy Calander available on the institution's website.*

2 CURRICULUM OVERVIEW

Module Code	MRAI081
Module Name	Administrative Information
Purpose of the module	This core module is designed to consolidate and expand knowledge gained throughout undergraduate learning. The module will address the administrative and regional requirements for the application for, and maintenance of, the registration of a medicine and will prepare the student's scientific reasoning and ability or skill to determine the correct, true and relevant information required, and in addition, will ultimately fulfil the criteria of the Exit Level Outcomes (ELO).
Content (list topics):	Legislative administrative details of applicant, facilities and product, submission of product information, registration procedures of relevant international authorities, submission of variations, literature-based submissions, local legislation, and national health and medicine policies.
Exit Level Outcomes addressed by this module	ELO 1: The PGDip (Pharmaceutical Regulatory Affairs) student will interrogate practices and demonstrate the ability to assess processes of the general, regional, and labelling requirements for a health products registration application in compliance with the Medicines and Related Substance Act, 1965 (Act 101 of 1965), the Pharmacy Act , 1974 (Act 53 of 1974), and the South African Health Products Regulatory Affairs (SAHPRA) Guidelines and in line with the National Health and the National Drug Policies. ELO 2: The PGDip (Pharmaceutical Regulatory Affairs) student will demonstrate knowledge of and engagement with enabling and other relevant legislation of the registration and control of health products (medicines, medical devices and IVDs). ELO 3: The PGDip (Pharmaceutical Regulatory Affairs) student will demonstrate the ability to use a range of specialised skills to analyse, evaluate and justify good manufacturing practice (GMP) aspects to obtain positive GMP compliance status for the registration and control of health products. ELO 4: The PGDip (Pharmaceutical Regulatory Affairs) student will access, process and manage information in order to critically review information in compiling of the licence and permit applications in compliance with the Medicines & Related Substances Act, 1965 (Act 101 of 1965), Pharmacy Act, 1974 (Act 53 of 1974), and the SAHPRA Guidelines, in line with the National Health and National Drug Policies required for the Health Products Industry.
Learning outcomes	**Assessment Criteria**
1. The student must be able to describe the need for medicine regulation	1.1 Recognise the potential pharmaceutical risks involved up to and after the administration of a medicine 1.2 List and apply objective and basic principles to demonstrate quality, safety, and efficacy (QSE)

	1.3 Describe the Authority's liaison with international authorities/bodies
2. The student must compile and submit an application for the registration of a medicine to SAHPRA	2.1 Apply knowledge specific to South African requirements to compile Module 1 of the application for the registration of a medicine in South Africa 2.2 Compile the application form, Module 1.2.1, for the registration of a medicine 2.3 Conclude which information is correct, true, and relevant to the compilation of the application for the registration of a medicine 2.4 Compile and submit the application for the registration of a medicine following the appropriate procedures prescribed by SAPHRA 2.5 Convert the data of historical registration applications to the current application form (ZA eCTD) for the registration of a medicine in South Africa
3 The student must compile and submit applications for safety and other updates to the professional information and patient information leaflet of a medicine	3.1 Apply knowledge specific to South African requirements to compile Module 1.3 and 1.5.1 of the application for the registration of a medicine in South Africa 3.2 Conclude which information is correct true and relevant to the compilation of the application for the update of safety and other information to the professional information and patient information leaflet 3.3 Compile and submit the application for the amendment/change/variation to the product information (professional information or patient information leaflet) of a medicine following the appropriate procedures prescribed by SAPHRA 3.4 Convert the data of historical registration application product information to the current application form (ZA eCTD) for the registration of a medicine in South Africa
4 The student must compile and submit applications for changes to manufacturing, production, quality aspects of a medicine	4.1 Apply knowledge specific to South African requirements to compile Module 1.5.2 of the application for the registration of a medicine in South Africa 4.2 Compile and submit the application for the changes to the manufacturing, production or quality aspects of a medicine following the appropriate procedures prescribed by SAPHRA 4.3 Demonstrate the equivalent performance of the changed product in comparison to that approved prior to the change. 4.4 Conclude which information is correct true and relevant to the compilation of the application for the changes to the pharmaceutical quality related aspects of an approved medicine or an application being assessed by the authority 4.5 Convert the data of historical registration applications' quality information to the current application form (ZA eCTD) for the registration of a medicine in South Africa

5 The student must compile and submit applications for changes to the applicant, applicant name, or facilities of a medicine	5.1 Apply knowledge specific to South African requirements to compile Module 1.7, 1.2.1, and 1.11 of the application for the registration of a medicine in South Africa 5.2 Conclude which information is correct true and relevant to the compilation of the application for the changes to the applicant or facilities, or name changes of the applicant or facilities, of an approved medicine or one being assessed by the authority 5.3 Compile and submit the application for applicant or facility, or name changes of applicant or facility following the appropriate procedures prescribed by SAPHRA 5.4 Convert the data of historical registration applications' applicant or facility changes to the current application form (ZA eCTD) for the registration of a medicine in South Africa
6 The student must compile and submit applications for changes to the product name of a medicine	6.1 Apply knowledge specific to South African requirements to compile Module 1.2.1 of the application for the registration of a medicine in South Africa 6.2 Conclude which information is correct true and relevant to the compilation of the application for a change to the product name of a medicine 6.3 Compile and submit the application for the change in name of a medicine following the appropriate procedures prescribed by SAPHRA
7 The student must compile and submit applications for changes to the scheduling status of a medicine	7.1 Apply knowledge specific to South African requirements to compile the application for a change in the scheduling status of a medicine in South Africa 7.2 Conclude which information is correct true and relevant to the compilation of the application for the registration of a medicine 7.3 Compile and submit the application for the change in scheduling status of a medicine following the appropriate procedures prescribed by SAPHRA
Pre-requisite modules for this module:	None, entry Module
Co-requisites modules for module:	None
Assessment strategy	Formative Assessment Methods: Assignment Summative Assessment Methods: Exam or case studies

Module Code	MREL081
Module Name	Enabling Legislation and Licensing
Purpose of the module	This core module is designed to consolidate and expand knowledge gained throughout undergraduate learning. The module will revisit the enabling legislation and application thereof to demonstrate quality, safety, and efficacy of medicines, and to prepare the student's integration of knowledge for successful reasoning, evaluation and selection of the correct, true, and relevant information required for the application for and maintenance of the registration of a medicine, and will ultimately fulfil the criteria of the Exit Level Outcomes (ELO).
Content (list topics):	Enabling local legislation: Medicines and Related Substances Act, 1965 (Act 101 of 1965), Pharmacy Act, 1974 (Act 53 of 1974,) National Health Policy, National Drug Policy, Hazardous Substances Act, 1973 (Act 15 of 1973), Fertilizers, Farm feeds, Seeds and Remedies Act, 1947 (Act 36 of 1947) for Veterinary medicines
Exit Level Outcomes addressed by this module	ELO 1: Compilation of the general, regional, and labelling for a medicine registration application in compliance with the Medicines Act, the Pharmacy Act, and the SAHPRA Guidelines and in line with the National Health and the National Drug Policies. ELO 2: Compliance with enabling and other relevant legislation for the registration and control of health products (medicines, medical devices and IVD'). ELO 3: Analysis, evaluation, and justification of good manufacturing practice (GMP) aspects to obtain positive GMP compliance status for the registration and control of medicines. ELO 4: Compilation of the licence and permit applications in compliance with the Medicines Act, Pharmacy Act, and the SAHPRA Guidelines, in line with the National Health and National Drug Policies required for the Health Products Industry.
Prescribed/recommended texts	Medicines and Related Substances Act, 1965 (Act 101 of 1965), Pharmacy Act, 1974 (Act 53 of 1974), National Health Policy, National Drug Policy, Hazardous Substances Act, 1973 (Act 15 of 1973), Fertilizers, Farm feeds, Seeds and Remedies Act, 1947 (Act 36 of 1947) for Veterinary medicines
Learning outcomes	**Assessment Criteria**
1. Student must be able to apply the legislation to compile medicine registration applications in the specific disciplines.	1.1 Apply legislation related to Medicine Registration Applications: • Orthodox including Biologicals • Complementary • Veterinary 1.2 Apply legislation related to Medical Devices and IVDs

2. Student must be able to apply for required professional registrations, licences and permits to operate in the relevant sections of the Pharmaceutical Industry.	2.1 Demonstrate knowledge about the obtaining of licences, and registrations: • Pharmacy • Applicant • Manufacturer, Export, Import • Wholesaling, Distribution • Company • Permits, S21 exemptions, Narcotics 2.2 Describe the procedure to pay the applicable application and/or registration fees: • Pharmacy • Applicant • Manufacturer, Export, Import • Wholesaling, Distribution • Company • Permits, S21 exemptions, Narcotics
3. Student must be able to evaluate advertising material of pharmaceutical products	3.1 Advertising • Claims • Statements 3.2 Pricing
4. Student must be able to submit applications in accordance with the relevant legislation	4.1 Clinical trials • Obtain approval • Register the trial on the database 4.2 Single exit pricing • Obtain and maintain approval
5 Student must be able to successfully apply for the licences required for orthodox medicines in the Pharmaceutical Industry	5.1 Apply for the relevant licences of the pharmaceutical industry in accordance with legislation 5.2 Initiate and defend GMP compliance inspection outcomes (SAHPRA) 5.3 Initiate and defend GPP compliance inspection outcomes (SAPC) 5.4 List and obtain permits for all the relevant activities within the pharmaceutical industry 5.5 Complete the required annual returns for Narcotics in accordance with the convention on Psychotropic substances of 1971 and Single Convention on Narcotic Drugs, 1961
6 Successfully apply for the licenses required for complementary medicine in the Complementary medicine industry	6.1 Submit the licence applications for complementary medicines in compliance with the relevant legislation 6.2 Initiate and defend GMP inspection outcomes 6.3 Initiate and defend GPP inspection outcomes 6.4 The student must be able to list and obtain permits or exemption applications for all the relevant activities within the complementary medicines industry

7 Successfully apply for the licences required for medical devices in the Medical Device Industry	7.1 Submit the licence applications to import and market medical devices and IVDs in compliance with the relevant legislation
Pre-requisite modules for this module:	MRAI011 Administrative Information
Co-requisite modules for module:	N/A
Assessment strategy	Formative Assessment Methods: Assignment Summative Assessment Methods: Exam or case studies

Module Code	MGMP081
Module Name	Good Manufacturing Practice (GMP)
Purpose of the module	This core module is designed to consolidate and expand knowledge gained throughout undergraduate learning. The module will revisit and expand the application of pharmaceutical sciences and pharmacy to the study of the development, production and distribution of medicines, to support the demonstration of quality, safety and efficacy of medicines required for the application for and maintenance of the registration of a medicine and will ultimately fulfil the criteria of the Exit Level Outcomes (ELO).
Content (list topics):	Good Manufacturing Practice (GMP), Good Wholesale Practice (GWP), Good Distribution Practice (GDP), quality standards, pharmaceutical production.
Exit Level Outcomes addressed by this module	ELO 3: The PGDip (Pharmaceutical Regulatory Affairs) student will demonstrate the ability to use a range of specialised skills to analyse, evaluate and justify good manufacturing practice (GMP) aspects to obtain positive GMP compliance status for the registration and control of health products. ELO 4: The PGDip (Pharmaceutical Regulatory Affairs) student will access, process and manage information in order to critically review information in compiling of the licence and permit applications in compliance with the Medicines & Related Substances Act, 1965 (Act 101 of 1965), Pharmacy Act, 1974 (Act 53 of 1974), and the SAHPRA Guidelines, in line with the National Health and National Drug Policies required for the Health Products Industry. ELO 5: The PGDip (Pharmaceutical Regulatory Affairs) student will demonstrate an understanding and engagement with appropriate risk-based science to construct the procedures, processes and/or techniques in pharmaceutical regulatory affairs. ELO 6: The PGDip (Pharmaceutical Affairs) student will critically engage with researched information in order to address scientific and/or technical challenges within pharmaceutical regulatory affairs.
Prescribed/recommended texts	ICH website (https://www.ich.org) e.g. Q 7-14 etc., PICS website (https://picscheme.org/en/picscheme), WHO website (https://www.who.int/) , EMA website (https://www.ema.europa.eu/en), FDA website (https://www.fda.gov/), SAHPRA website (https://www.sahpra.org.za)

Learning outcomes	Assessment Criteria
1. Student must be able to appraise the need for Good Manufacturing Practice	1.1 Develop and maintain the Quality Management System (QMS) required for medicines 1.2. Assess compliance with Good Documentation Practice (GDocP) for the relevant levels of risk 1.3. Appraise Quality Risk Management (QRM)
2 Student must be able to assess the application of GMP for orthodox and complementary medicines	2.1 Discuss the quality management philosophy and essential elements of GMP as stipulated in the SA Guide to GMP Chapters and its annexes for medicinal dosage forms 2.2 Initiate GMP inspections and follow up inspection outcomes using QRM principles 2.3 Initiate GPP inspections and follow up inspection outcomes using QRM principles
3 Student must be able to describe the key/critical personnel responsibilities	3.1 Demonstrate knowledge about the responsibilities of key personnel including the Responsible Pharmacist, Quality Assurance and Senior Management. 3.2 Assess the scientific relevance and applicability of other country specific related responsibilities and / or country specific interpretation/implementation of responsibilities
4 Student must be able to determine the responsibilities of third-party stakeholders	4.1 Demonstrate knowledge about the responsibilities of and requirements for vendors and suppliers 4.2 Assess the scientific relevance and applicability of other country specific GMP related requirements and / or country specific interpretation/implementation of GMP requirements
5 Student must be able to appraise and identify GMP principles and requirements relating to medicine registration applications	5.1 Demonstrate knowledge about common and product specific requirements and common, non-product specific requirements 5.2 Demonstrate knowledge about scientific justification of requirements of PICs, WHO, and other authorities
Pre-requisite modules for this module:	MREL011 Enabling Legislation and Licensing
Co-requisite modules for module:	N/A
Assessment strategy	Formative Assessment Methods: Assignment Summative Assessment Methods: Exam or case studies

Module Code	MRGP082
Module Name	Other Good Practices
Purpose of the module	This core module is designed to consolidate and expand knowledge gained throughout undergraduate learning. The module will revisit and expand the application of the relevant principles and ethics, [good pharmacy practice (GPP), good clinical practice (GCP), good regulatory practice (GRP) and good laboratory practice (GLP)], required to support the student in integrating the knowledge for the successful reasoning, evaluation and the ability/skill to determine the correct, true, and relevant information for the application for and maintenance of registration of a medicine, and will ultimately fulfil the criteria of the Exit Level Outcomes (ELO).
Content (list topics):	Good Pharmacy Practice (GPP), Good Clinical Practice (GCP), Good Regulatory Practice (GRP), regulatory affairs, regulatory frameworks and instruments, Good Laboratory Practice (GLP), principles and practices of analytical techniques.
Exit Level Outcomes addressed by this module	ELO 3: The PGDip (Pharmaceutical Regulatory Affairs) student will demonstrate the ability to use a range of specialised skills to analyse, evaluate and justify good manufacturing practice (GMP) aspects to obtain positive GMP compliance status for the registration and control of health products. ELO 4: The PGDip (Pharmaceutical Regulatory Affairs) student will access, process and manage information in order to critically review information in compiling of the licence and permit applications in compliance with the Medicines & Related Substances Act, 1965 (Act 101 of 1965), Pharmacy Act, 1974 (Act 53 of 1974), and the SAHPRA Guidelines, in line with the National Health and National Drug Policies required for the Health Products Industry. ELO 5: The PGDip (Pharmaceutical Regulatory Affairs) student will demonstrate an understanding and engagement with appropriate risk-based science to construct the procedures, processes and/or techniques in pharmaceutical regulatory affairs. ELO 6: The PGDip (Pharmaceutical Affairs) student will critically engage with researched information in order to address scientific and/or technical challenges within pharmaceutical regulatory affairs.
Prescribed/recommended texts	SAPC website (GPP) (https://www.pharmcouncil.co.za), SA GCP https://www.sahpra.org.za/wp-content/uploads/2021/06/SA-GCP-2020_Final.pdf), ICH https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf), Declaration of Helsinki, WHO website (https://www.who.int)

Learning outcomes	Assessment Criteria
1. Student must be able to appraise the need for Good Pharmacy Practice (GPP)	1.1 Discuss the underlying philosophy and essential elements of Good Pharmacy Practice (GPP) 1.2 Interpret the necessity of professional standards in GPP1.3
2. Student must be able to appraise the need for Good Clinical Practice (GCP) for clinical research	2.1 Discuss the good clinical practice principles and essential elements 2.2 Determine the key ICH-GCP requirements and regulatory expectations regarding the conduct of trials in comparison with those for South African GCP requirements 2.3 Discuss the reporting requirements for clinical trials 2.4 Compare the responsibilities of the various stakeholders 2.5 Elaborate on the potential data integrity concerns and the importance of data integrity
3. Student must be able to appraise the need for Good Regulatory Practice (GRP)	3.1 Discuss the principles and essential elements of good regulatory practice relating to the registration of medicines 3.2 Demonstrate the practical application of GRP in risk assessment of technical and other identified regulatory deficiencies
4. Student must be able to appraise Good Laboratory practice (GLP)	4.1 Discuss good analytical laboratory practice principles and essential elements relating to the application for and maintenance of registration of medicines
Pre-requisite modules for this module:	MGMP011 Current Good Manufacturing Practice
Co-requisite modules for module:	N/A
Assessment strategy	Formative Assessment Methods: Assignment Summative Assessment Methods: Exam or case studies

Module Code	MRQB082
Module Name	Quality and Bioequivalence
Purpose of the module	This core module is designed to consolidate and expand knowledge gained throughout undergraduate learning. The module will revisit and expand the application of the pharmaceutical sciences, pharmacy, and biopharmaceutics to support the student in integrating the knowledge for successful reasoning, evaluation and determination of the correct true and relevant information to demonstrate quality and bioequivalence for the application for and maintenance of the registration of medicines and will ultimately fulfil the criteria of the Exit Level Outcomes (ELO).
Content (list topics):	Quality i.e. active pharmaceutical Ingredient (API) finished pharmaceutical product (FPP), stability. Bioequivalence i.e. pharmaceutical availability & bioequivalence, biowaivers, biosimilars.
Exit Level Outcomes addressed by this module	ELO 4: The PGDip (Pharmaceutical Regulatory Affairs) student will access, process and manage information in order to critically review information in compiling of the licence and permit applications in compliance with the Medicines & Related Substances Act, 1965 (Act 101 of 1965), Pharmacy Act, 1974 (Act 53 of 1974), and the SAHPRA Guidelines, in line with the National Health and National Drug Policies required for the Health Products Industry. ELO 5: The PGDip (Pharmaceutical Regulatory Affairs) student will demonstrate an understanding and engagement with appropriate risk-based science to construct the procedures, processes and/or techniques in pharmaceutical regulatory affairs. ELO 6: The PGDip (Pharmaceutical Affairs) student will critically engage with researched information in order to address scientific and/or technical challenges within pharmaceutical regulatory affairs.
Prescribed/recommended texts	Quality & Bioequivalence Guidelines: SAHPRA, ICH, EMA, FDA, TGA, HC, WHO and other websites for orthodox, biological, veterinary and complementary medicines.

Learning outcomes	Assessment Criteria
1. Student must be able to successfully compile the Active pharmaceutical ingredient data required for the application for and maintenance of registration of orthodox medicines in the Pharmaceutical Industry	1.1 Understand the relevant South African and International guidelines to assess, compile and submit the - Active pharmaceutical ingredient (API) synthesis, starting materials and intermediates, and stability, in accordance with the relevant guidelines and requirements for API GMP compliance - API specifications and justification, analytical procedures, validation, reference standards, container closure systems in accordance with the requirements for application for and maintenance of registration of medicines - Assess, compile, and demonstrate the equivalence of APIs manufactured by different routes of synthesis and/or manufacturers, with or without the certificates of the EDQM or WHO (CEP and CPQ respectively) in accordance with the requirements for the maintenance of registration of medicines. 1.2 Assess the query, and justify or amend as appropriate, the data submitted in support of the quality and stability of the API when queried by the Authority (SAHPRA). 1.3 Assess, compile, and justify or amend the required variations/amendments to the data submitted in support of the quality and stability of the API when changed by the API manufacturer 1.4 List the impurity risks and assess the relevance of each impurity risk to the API impurity profile and submit these accordingly as appropriate for the requirements for the application for and maintenance of registration of medicines.

2. Successfully compile the Final product data required for the application for and maintenance of registration of orthodox medicines in the Pharmaceutical Industry	2.1 Understand the relevant South African and International guidelines to assess, compile and submit the - Final product development, manufacture in accordance with the relevant guidelines and requirements for the application for and maintenance of registration of medicines - Final product (FP) specifications and justification, analytical procedures, validation, reference standards, container closure systems, and stability, in accordance with the requirements for the application for and maintenance of registration of medicines - the equivalence of FPs manufactured by different FP and API manufacturers, in accordance with the requirements for the maintenance of registration of medicines 2.2 Assess the query, and justify or amend as appropriate, the data submitted in support of the quality and stability of the FP when queried by the Authority (SAHPRA). 2.3 Assess, compile, and justify/amend the required variations/amendments to the data submitted in support of the quality and stability of the FP when changed by the FP manufacturer 2.4 List the impurity risks and assess the relevance of each impurity risk, to the final product impurity profile and submit these accordingly as appropriate for the requirements for the application for and maintenance of registration of medicines
3. Successfully compile the Quality Module required for registration of complementary medicines in the Pharmaceutical Industry	3.1 Understand the relevant South African and International guidelines to assess, compile and submit the scientifically and technically appropriate data in support of the - quality and stability of the ingredients of complementary medicines - quality and stability of the final complementary medicine 3.2 Assess the query, and justify or amend as appropriate, the data submitted in support of the quality and stability of the FP when queried by the Authority (SAHPRA). 3.3 Assess, compile, and justify/amend the required variations/amendments to the data submitted in support of the quality and stability of the medicine when changed by the API or FP manufacturer 3.4 Assess, compile, and justify/amend the final product pharmaceutical performance data in support of the efficacy of complementary medicines in the Pharmaceutical Industry

4. Successfully compile the Final product pharmaceutical performance data required for the registration of orthodox medicines in the Pharmaceutical Industry	4.1 Understand the relevant South African and International guidelines to assess, compile and submit the - Final product performance data (pharmaceutical availability or biowaiver, bioavailability or bioequivalence, or biosimilars) in accordance with the relevant guidelines and requirements for the application for and maintenance of registration of medicines including orphan medicines - equivalence of pharmaceutical performance / bioequivalence of medicines manufactured by different FP manufacturers with API from different API manufacturers in accordance with the requirements for the application for and maintenance of registration of medicines 4.2 Assess the query, and justify or amend as appropriate, the data submitted in support of the pharmaceutical performance/bioequivalence of the FP in anticipation of, and when queried by the Authority (SAHPRA). 4.3 Assess, compile, and justify/amend demonstrate the final product performance (pharmaceutical- or bioavailability or equivalence) for variations/amendments to the final product, when changed by the FP manufacturer 4.4 List the impurity risks and assess the relevance of each impurity risk, to the final product impurity profile and submit these accordingly as appropriate for the requirements for the application for and maintenance of registration of medicines
Pre-requisite modules for this module:	MRGP012 Related Good Practices
Co-requisites modules for module:	N/A
Assessment strategy	Formative Assessment Methods: Assignment Summative Assessment Methods: Exam or case studies

Module Code	MRSE012
Module Name	Safety and efficacy
Purpose of the module	This core module is designed to consolidate and expand knowledge gained throughout undergraduate learning. The module will revisit and expand the scientific application of pharmacology to the demonstration of the safety and efficacy of medicines, to support the student in integrating the knowledge to successful reasoning, evaluation and determination of the correct true and relevant safety and efficacy information for the application for and maintenance of the registration of medicines, and will ultimately fulfil the criteria of the Exit Level Outcomes (ELO).
Content (list topics):	Safety and efficacy: SAHPRA and ICH Clinical safety, efficacy, pharmacovigilance, pharmacology and pharmacokinetics guidelines, essential drug list (EDL).
Exit Level Outcomes addressed by this module	ELO 1: The PGDip (Pharmaceutical Regulatory Affairs) student will interrogate practices and demonstrate the ability to assess processes of the general, regional, and labelling requirements for a health products registration application in compliance with the Medicines and Related Substance Act, 1965 (Act 101 of 1965), the Pharmacy Act , 1974 (Act 53 of 1974), and the South African Health Products Regulatory Affairs (SAHPRA) Guidelines and in line with the National Health and the National Drug Policies. ELO 2: The PGDip (Pharmaceutical Regulatory Affairs) student will demonstrate knowledge of and engagement with enabling and other relevant legislation of the registration and control of health products (medicines, medical devices and IVDs). ELO 5: The PGDip (Pharmaceutical Regulatory Affairs) student will demonstrate an understanding and engagement with appropriate risk-based science to construct the procedures, processes and/or techniques in pharmaceutical regulatory affairs.
Prescribed/recommended texts	SAHPRA, ICH, FDA, EMA, TGA, HC websites for safety, efficacy, pharmacovigilance, pharmacology and related guidelines for orthodox, biological and complementary medicines.
Learning outcomes	**Assessment Criteria**

1. Student must be able to apply for and maintain the new chemical entity (NCE) medicine information required for the registration of orthodox including biological medicines	1.1 Understand the relevant South African legislation and International guidelines to - Apply for the Professional information in accordance with the relevant guidelines and requirements - Apply for the Patient information leaflet in accordance with the relevant guidelines and requirements - Reference and cross reference Professional Information with supporting evidence and/or literature, in accordance with the requirements for the application for and maintenance of registration of medicines 1.2 Assess the query, and justify or amend as appropriate, the data submitted in support of safety and efficacy of the FPP when queried by the Authority (SAHPRA). 1.3 Assess, compile, and justify or amend the required variations/amendments to the data submitted in support of safety and efficacy as necessitated by clinical evidence 1.4 Compile and submit pharmacovigilance outcomes in accordance with the requirements for the application for and maintenance of registration of medicines 1.5 Submit Pharmacovigilance and risk management plans required for the registration of medicines
2 Student must be able to apply for and comply with clinical trial requirements	Understand the relevant South African and International guidelines clinical trials to ● apply for ● report on ● amend the application ● terminate the study ● lock the database and close.
3. Student must be able to apply for and maintain the medicine information required for the registration of complementary medicines	Understand the relevant South African and International guidelines to ● apply for high or low risk indications ● amend/update the professional information
4. Student must be able to apply for and maintain the medicine information required for the registration of veterinary including biological medicines	Understand the relevant South African and International guidelines to ● apply for the professional veterinary medicine information ● amend/update the veterinary medicine information
Pre-requisite modules for this module:	MRQB012 Quality & Bioequivalence
Co-requisites modules for module:	N/A
Assessment strategy	Formative Assessment Methods: Assignment Summative Assessment Methods: Exam or case studies

4. ACADEMIC SUPPORT SERVICES

4.1 Student Support Services

If you require any assistance in relation to Ithute Blackboard Learning Management System, please contact E-Learning Support at the Centre for University Teaching and Learning using any one of the following contact details:

Email Address	***Telephone Number***	***Building Number***
students.elearningsupport@swave.smu.ac.za	*012 521 3982*	*eLearning Lab*

5. TEACHING AND LEARNING APPROACH

The course will be presented using face-to-face online sessions facilitated by the Learning Management System (Black Board). During semester 1 & 2, face-to-face online sessions contact will be conducted on selected days of the week or as a single block, based on the teaching requirements of the module. This blended learning embraces the 'flipped classroom' approach, facilitating a dynamic and interactive learning environment. Students will be required to complete various forms of assessments and activities as integrated throughout all modules of the programme. Lectures and course notes will be delivered online, giving students the flexibility to cover the material at their own convenience during the week.

6. STUDENT RESPONSIBILITIES

6.1 Code of Conduct

The university strives to ensure that its academic environments are conducive to learning and that the students are afforded time and space to learn and perform to the best of their abilities. In order for us to work productively in this module, please let us all behave appropriately towards each other during learning sessions, respecting professional, departmental and university regulations that guide the conduct of the students.

You are expected to participate actively in class discussions so you may enable your own learning and develop your own knowledge and thoughts. Punctuality is of utmost importance, and it also shows your regard for all the different stakeholders of the module. Take cognizance

of making special arrangements if you may need to miss or arrive late for class, making sure that you make means to catch up on the class work missed.

6.2 Attendance Requirements

Evidence of class attendance of 75% as a minimum requirement in planned formal contact sessions, for each module/course, as determined by School rules. All activities that cannot be attended should be preceded by a completed “REQUEST FOR LEAVE OF ABSENCE FROM FORMAL ACADEMIC ACTIVITIES” form. See Appendix 1. Supporting documents, e.g. Medical Certificate, must accompany the form. Leave form and supporting documents should be submitted to the department secretariat within 7 days of absenteeism. Sick tests and examinations will only be scheduled for students that have followed the correct procedure and have submitted their medical certificate.

6.3 Dress Code

Dress code for classes is comfortable, but still professional.

7. AVOIDING PLAGIARISM

Plagiarism (from Latin plagiare "to kidnap") is the practice of claiming, or implying, original authorship or incorporating material from someone else's written or creative work, in whole or in part, into one’s own without adequate acknowledgment. This includes changing the word order, leaving out words or changing some of the words.

Plagiarism is a serious academic misconduct that should be avoided at all costs. If you adopt and/or adapt or use or imply the words, thoughts or ideas from someone else, you should provide reference to that source of information, using appropriate referencing method.

All your assignments and reports must reflect your own original work and therefore should be subjected to an electronic plagiarism check prior to submission to enable you to avoid plagiarism.

8. GRIEVANCE PROCEDURES

In planning the activities of this course, we considered that we would work with you to make this a positive experience for all parties involved. However, if at any time during the time of this module you may face some challenges and wish to raise some concerns, problems or complaints related to the module, please follow the procedures suggested below:

- All the matters of grievance should be first directed to the lecturer/module convenor in writing.
- If the matter may not be resolved with the lecturer/module convenor, you may consult the Course coordinator.
- If the matter may not be resolved with the Course coordinator, you may consult the Head of Department
- If the matter remains unresolved with the Head of Department, you may contact the Dean of the School.

9. TIME-TABLE & WORK PLAN

Please note that below time-table and work plan is tentative and subjected to changes.

Module 1	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7**	**Week 8**
MRAI011	**Medicine registration**	**Application forms**	**Product information**	**Inspectorate**	**Amendments/ variations**	**Amendments contd. Names, Scheduling**	**Literature submissions**	**Assessments**
Monday Class Tut 1 - 2h	Introduction to PGDip The need for and objectives of the registration of medicines	Forms Application form, ZACTD/MRF1/MBR 1 Regional evaluation procedures, requirements, QOS, QIS, SCoRE, validation templates	Labelling, i.e. the professional information (PI), patient information leaflet (PIL) and label.	Module 1.7 Inspectorate API and FP release Licences /GMP certificates Site Master File (SMF) Pharmacovigilance	Amendments /variations Equivalent performance before and after change	Conversion of MRF1 product information to current CTD, and eCTD baseline submissions	Literature submissions, reference medicines, and bridging. Orphan, and borderline products	Assignment 1 and 2 presentations
		Foreign registration status	Comparison of the headings and contents of the PI and PIL					
Tasks	Websites: SAHPRA, EU EMA, USA FDA, UK MHRA, Australia TGA, Canada HC, WHO	Develop references, guidelines, and communications database	Compile a PI, PIL and label for chosen molecule and dosage form. Prepare an example of a label for the blister and outer carton of a tablet, and direct container and outer carton of a 5 g cream Compare the contents of the	Compile Module 1.7 for chosen molecule and dosage form	Consolidate/integrate Amendment communications & guidelines Develop reference database	Prepare template/SOP for • change of scheduling status • change of proprietary name • transfer of applicant • additional manufacturer Review templates for change of	Case studies	

Module 1	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7**	**Week 8**
MRAI011	**Medicine registration**	**Application forms**	**Product information**	**Inspectorate**	**Amendments/ variations**	**Amendments contd. Names, Scheduling**	**Literature submissions**	**Assessments**
			SAHPRA and EU SmPC guidelines in table format.			scheduling status, change of product name, change of applicant		
Wednesday Class Tut 2 - 2h	The International and SA regulatory environments, Application form, CTD Module 1	General information, dosage forms, Medicine particulars, Type of application, Data as proof of efficacy.	CM labelling Veterinary labelling MD and IVD labelling	Inspectorate and release API and FP release	Amendments/ variations contd.	Names	Workshop/discussion Task templates	Assignment 1 and 2 presentations
	SI system, document presentation and readability	CM low and high-risk claims		Licences/GMP certificates Site Master File Pharmacovigilance	Amendment schedule format	Scheduling		
Tasks	Develop references, guidelines, and communications database	Assemble relevant forms and templates for licences, certificates, CVs, application and other letters, regional evaluation procedures	Compile Module 1 assessment report template Develop reference database	Develop reference database	Consolidate/integrate Amendment communications & guidelines Develop amendment review outcome template/letter to applicant	Collect and appraise labelling of at least two of each Category A, B, C, and D medicines Develop references, guidelines, and communications database		
Friday Deliberations	References	Labelling presentations	Labelling	Consolidated/ Integrated Variations guideline	Assessment report template	Assignment/tasks – Labelling/Names	Assignment/tasks	Quiz
	Reading list Q&A	Reading list Q&A	Reading list Q&A	Reading list Q&A	Reading list Q&A	Reading list Q&A	Reading list Q&A	

Module 1	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7**	**Week 8**
MRAI011	**Medicine registration**	**Application forms**	**Product information**	**Inspectorate**	**Amendments/ variations**	**Amendments contd. Names, Scheduling**	**Literature submissions**	**Assessments**
	Assignment/tasks	Assignment/tasks	Assignment/tasks	References	References	References	References	
Reading	The Regulatory Authority	Proprietary names	Medicine register details	Fees	Submission/ validation			
	Regulatory Partnerships	Advertising	Variation guidelines and	Orphan products	Working documents			
	General information gdl	Variation guidelines and communications	communications	Borderline products	Names & Scheduling			
	Reading list	Reading list	Reading list	Reading list	Reading list			
Assignment 1	Compile Module 1 for a new medicine, choose molecule & dosage form	-		Submission Assignment 1				
Assignment 2	Compile assessment report and deficiency letter	-	-	-	Submission Assignment 2			

Module 2	**Week 1**	**Week 2**	**Week 3**	**Week 4**
MREL011	**Enabling legislation**	**Advertising and CTs**	**Narcotics and Complementary Medicines**	**Assessment**
Monday **Class Tut 1** - 2 h	Enabling legislation for Orthodox, CM, and Veterinary medicines, Compounding, Narcotics Act and General Medicines Regulations	Advertising Prescription Medicines, OTC and Category D medicines, MDs, IVDs	Enabling legislation for CM/Category D medicines, Narcotics	**Presentations**: Assignments 1 and 2 Tasks
	When a medicine is registerable			
Tasks	Develop legislation and related, guidelines, and communications database	Evaluate and report on five medicine advertisements and medicine labelling	Develop an assessment tool for CT applications and a template for the assessment report	
	Compile an assessment tool and SOP for review of Module 1.7 with appropriate references	Compile a template for reporting on assessments of advertising and medicine labelling		
Wednesday **Class Tut 2** – 2 h	**Enabling legislation for MDs and IVDs and regulatory framework**	**Enabling legislation for CTs**	**Enabling legislation for single exit pricing of medicines**	**Presentations**: Assignments 1 and 2
	Licences and relevant fees	CT registers	Exclusions/exemptions	
	S21 Applications			
Tasks	Compile an assessment tool and SOP for review of licensing applications with appropriate references (in preparation of Assignment 2)	Write an SOP/template to compile a clinical trial (CT) application with appropriate references	Write an SOP/template to compile pricing application with appropriate references	
	Develop SOPs to compile licence applications to import and market medicines, MDs and IVDs and a S21 application for access to an unregistered medicine (in preparation of Assignment 1)	List the fees and describe the procedures to pay applicable application and/or registration fees for a pharmacy, an applicant, manufacturer, export import licence, wholesaling, distribution, permits incl narcotics, S21 exemption applications.	List and describe how to apply for permits or exemption applications for all the relevant activities within the complementary medicine industry.	
Friday **Deliberations**	Licensing applications, assessment of licensing applications S21 applications	Advertisements and labelling CT applications	Assessment tool Advertising SOP/template for compiling pricing applications	**Case studies:** GMP FP & API and CRO inspection outcomes. Advertising. Labelling

Reading	Act and Regulations	Advertising code and Advertising authority		
	Reading list	Reading list/PICs aide memoires	Reading list/PICs SOPs	
Assignment 1	Write SOPs to complete applications for each of the licences and permits, with appropriate references	Submit assignment		
Assignment 2		Compile an assessment tool for the evaluation of licence and permit applications, and a template for the deficiency outcome letter to the applicant	Submit assignment and tasks	

Module 3	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
MGMP011	**Good Manufacturing Practice**			**GxP**		**Assessment**
Monday **Class Tut 1** - 2h	Scientific Risk-based GMP for 21st century The need for and objectives of Pharmaceutical Quality System (PQS)	Good Manufacturing practice (GMP), Key Personnel, and Good Documentation Practice (GDocP)	Outsourcing vendors/suppliers Agreements Validation and qualification	GMP for API QP GMP responsibilities GMP inspections FP and API	GDP, GWP, GLP	Assignment 1 and 2 presentations
	PICs, ICH, WHO	PICs, ICH, WHO	PICs, ICH, WHO	PICs, ICH, WHO	PICs, ICH, WHO	
Tasks	Develop references, guidelines, and communications database for, PQS, GMP, and GMP related inspections Develop a table of contents (ToC) for a PQS	Compare EU Qualified Person (QP) and ZA Responsible Pharmacist (RP) responsibilities and legislated mandatory requirements	Compile SOPs for Complaints and Recalls Compile an SOP for deviations	Compile inspection aide memoires for FP and API GMP compliance inspections	Compile GDP, GWP, and GLP compliance inspection report templates and deficiency letter templates	
Wednesday **Class Tut 2** - 2h	Quality Risk Management (QRM) permeating all aspects of GxP	Quality Assurance (QA) , API and FP release	Storage and transportation, Post Importation Testing (PIT), technology transfer,	CRO inspections	Deliberations of task templates/SOPs/	Assignment 1 and 2 presentations
		PQR	Stability testing/ZA Climate			
	PICs, ICH, WHO	PICs, ICH, WHO	PICs, ICH, WHO	PICs, ICH, WHO	PICs, ICH, WHO	
Tasks	GMP requirements for sterile, vaccines, solid oral dosage forms	GMP requirements for suspension, creams and ointments, CMs.	Appraise transportation requirements, PIT and technology transfer Develop reference database	Compile inspection aide for the analytical laboratory and CRO inspection. Develop reference database	Develop reference database	
Friday **Deliberations**	References	QP, RP, and rp	ZA Climate	Inspection aide memoires	Inspection aide memoires	Case studies
	Readings Q&A	Readings Q&A	Readings Q&A	References	Readings Q&A	
	Assignment/tasks			Readings Q&A	References	

Module 3	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
MGMP011	**Good Manufacturing Practice**			**GxP**		**Assessment**
Reading	Reading list	Reading list	Reading list	Reading list	Reading list	
	PICS training material	PICS Training material	SMF PICS training material			
Assignment 1	Peer review/edit inspection reports	-	Submission Assignment 1			
Assignment 2	Compile GMP inspection report template and deficiency letter template	-	-	-	Submission Assignment 2	

Module 4	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**
MGRP012	**Good Practices: GCP**	**Good Practices: GCP/GRP**	**Good Practices: GRP/GCLP**	**Good Practices: GPP**	**Assessment**
Monday **Class Tut 1** - 2h	GCP SA GCP, ICH GCP, Protocol and CRF design, Essential Study documentation	GCP Management of Adverse events Informed consent, Monitoring,	GRP/ Data management and computerised systems	SAPC Good Pharmacy Practice Scope of practice Core principles GPP Standards guidelines	Presentations: Assignment 1 and 2 presentations Tasks
	PICs, ICH, WHO	Standard Operating Procedures, Archiving			
Tasks	Develop references, guidelines, and communications database for GCP	Document management systems Logbook/register, and register of logbooks/registers	Review data management and computerised systems for CTs and Bioequivalence studies. Appraise principal differences	Compare GMP and GPP, appraise differences re common activities, premises, procurement, storage, and distribution	
Wednesday **Class Tut 2** - 2h	Source data, Declaration of Helsinki and Ethics	Good Regulatory / review Practice WHO, ZA, FDA	GCLP, GLP, GP pharmaceutical QC laboratories,	SAPC Good Pharmacy Practice GPP requirements for compounding	Presentations: Assignments 1 and 2
	Data management, Computerised systems for CTs	ICH Specification for pdf documents	GP for pharmaceutical microbiology laboratories		
	Study medication and GMP Annex 13				
Tasks	Compare ICH and ZA GCP and appraise differences	Develop references, guidelines, and communications database for: GCP Good documentation practice Document management systems SI system ICH M4 guidelines Edit Module 1, 2, 3 templates, SOPs, and documents	Develop references, guidelines, and communications database for GRP Edit Module 1, 2, 3 templates, SOPs, and documents for compliance with good documentation practice and Good regulatory practice	Compare GMP and GPP, appraise differences re compounding Edit Modules 1,2,3 templates, SOPs, and other documents	
Friday **Deliberations**	Differences between ICH GCP and ZA GCP	Document management systems	Appraise differences between the principles of CTs and BE	GPP Edited documents	Case Studies
	Readings Q&A	Readings Q&A	Readings Q&A	References	

Module 4	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**
MGRP012	**Good Practices: GCP**	**Good Practices: GCP/GRP**	**Good Practices: GRP/GCLP**	**Good Practices: GPP**	**Assessment**
	Assignment	Assignment/tasks	Assignment/tasks	Readings Q&A	
Reading	Guidelines for preparation of a CRO master file (MF) ICH M4 guidelines	WHO A manual for National Medicines Regulatory Authorities (NMRAs) 2nd Ed 2011	PIC/S computerised systems in regulated 'GxP environments PIC/S inspector aide-memoire	Guidelines on bioanalytical method validation	
	Reading list	Reading list	Reading list	Reading list	
	Guidance for organisations performing in vivo bioequivalence studies	Good regulatory practices in the regulation of medical Products WHO TRS no 1033, 2021	Good clinical laboratory practice (GCLP)	Good Pharmacy practice EU, USA, Aus	
	A risk-based approach to monitoring of clinical investigations Glove use information leaflet	Good practices for pharmaceutical QC laboratories Guidelines for preparing a laboratory information file	PIC/S Data Management and data integrity PIC/S Inspection aide-memoires data integrity, and chromatographic systems		
Assignment 1	Develop a SOP for compiling a CT application and subsequent amendments and reports	-	Submission Assignment 1		
Assignment 2		Compile CRO and CRO analytical lab inspection aide memoire, report template, and deficiency letter template		Submission Assignment 2	

Module 5	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7**	**Week 8**
MQQB012	**Quality and Bioequivalence**	**Bioequivalence**	**Bioequivalence 3.2.R**	**CTD Module 3.2.S CTD Module 3.2.P**	**CTD Module 3.2.S CTD Module 3.2.P**	**CTD Module 3**	**Regional**	**Assignments**
Monday **Class Tut 1** - 2h	CTD Module 3: API / FP Pharmaceutical Availability and Equivalence ICH / EMA / FDA / WHO	Bioequivalence contd. Reference / comparator products	Biowaivers	CTD 3.2.S API CEP, CPQ Orthodox Complementary medicines	Intermediates Impurities	Container closure systems	Regional requirements QOS, QIS, BTIF, SCoRE, Reliance	Presentation: Assignment 1
Tasks	Develop references, guidelines, and communications database for Quality & BE	Compile Module 3.2.R.1 Compile assessment tool for BE study	Compile a biowaiver application Appraise biowaiver application templates	Compile Module 3.2.S Orthodox and Complementary medicines	Compile 3.2.R.2 and 3.2.R.3 and 3.2.R.4	Compile Module 3.2.S.6 and 3.2.P.7	Compile remaining regional requirements	
Wednesday **Class Tut 2** - 2h	Bioavailability Bioequivalence (BE) Proof of BE concept	Solubility Dissolution, Comparative dissolution and reference products	CTD 3.2.R	CTD 3.2.P Pharmaceutical Product: Orthodox Complementary medicines	Stability testing	Amendments/ Variations: Orthodox Biological Veterinary CM	Post importation testing Batch manufacturing records	Presentation: Assignment 2
Tasks	Review EMA, FDA, WHO, ICH guidelines and databases Develop guidelines, communications, forms, template data base for Quality and BE.	Review IGDRP/IPRP and WHO application templates/information and communications for Module 3 Develop guidelines, communications, forms, template database.	Appraise comparative dissolution profiles Develop guidelines, communications, forms, template database for Module 3.	Compile 3.2. P Develop guidelines, communications, forms, template data base for Module 3.	Compile Module 3.2.8 Respond to impurity, stability, and other deficiencies Develop guidelines, communications, forms, template data base for Module 3.	Respond to BE, dissolution, biowaiver deficiencies Case studies	Reference product case studies	

Module 5	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7**	**Week 8**
MQQB012	**Quality and Bioequivalence**	**Bioequivalence**	**Bioequivalence 3.2.R**	**CTD Module 3.2.S CTD Module 3.2.P**	**CTD Module 3.2.S CTD Module 3.2.P**	**CTD Module 3**	**Regional**	**Assignments**
Friday Deliberations	Tasks	Tasks/BE Assessment tool	Tasks	Deficiencies	Tasks	Tasks	Tasks	Case Studies
	Readings Q&A	Readings Q&A	Readings Q&A	References	Readings Q&A	Readings Q&A	Readings Q&A	
	Assignment	Assignment/tasks		Readings Q&A				
Reading	BE guidelines	ICH M4 Q guidelines	Quality guidelines					
	Reading list	Reading list	Reading list	Reading list	Reading list	Reading list		
Assignment 1	Compile Module 3 for the chosen molecule and dosage form	-			Submission Assignment 1			
Assignment 2		Compile an assessment tool/template for Module 3, report and deficiency letter					Submission Assignment 2	

Module 6	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**
MRSE012	**Safety and Efficacy**				
Monday **Class Tut 1** - 2h	CTD Modules 2.4/5/6/7 and 4 and 5 The CTD (Mod 2, 4 and 5) Safety and Pharmacovigilance (PV), Risk management plans (RMP)	Module 5, Module 2.5 and 2.7 : Clinical Trials Bioequivalence studies	Safety updates	Complementary medicines high and low risk indications	Presentations: Assignments 1 and 2
Tasks	Develop references, guidelines, and communications database for Safety and Efficacy.	Develop references, guidelines, and communications database for Clinical trials	Develop references, guidelines, and communications database for safety and ADR reporting	Compile CM professional information leaflet tool/ guide	
		Compile directions/SOP to register and report on CTs	Compile a tool / SOP for all required CT reports and CT registers		
Wednesday **Class Tut 2** - 2h	Module 5, Module 2.5 Module 2.7 Efficacy Ethics	Clinical trials contd reports and local requirements	Labelling for NCEs PI and PIL	Veterinary medicines safety and efficacy, professional information	Presentations: Assignments 1 and 2
Tasks	Edit and finalise the application for registration assignment	Describe how to apply for, report on, amend the application terminate the CT and lock the database and close	Reference and cross reference the professional information and patient information leaflet	Develop references, guidelines, and communications database for Safety and Efficacy of veterinary medicines.	
Friday	Tasks	Tasks	Tasks	Tasks	Quiz
Deliberations	Readings Q&A	Readings Q&A	Readings Q&A	References	
	Assignment	Assignment/tasks		Readings Q&A	
Reading	ICH M4 S and ICH M4E	ICH Safety and Efficacy guidelines			
	Reading list	Reading list	Reading list	Reading list	
Assignment 1	Compile Professional information and patient information leaflet/and/or SOPs for their compilation	-	Submission Assignment 1		

Module 6	Week 1	Week 2	Week 3	Week 4	Week 5
MRSE012	**Safety and Efficacy**				
Assignment 2		Compile assessment report and report deficiency letter. Assess and report on PI applied for		Submission Assignment 2 Submission summative assignment application for the registration of a medicine commenced in Module 1	

APPENDIX 1: REQUEST FOR LEAVE OF ABSENCE

School of Pharmacy

SEFAKO MAKGATHO
HEALTH SCIENCES UNIVERSITY

P. O. Box 218
Medunsa
0204
Tel: (012) 521 4212
Fax: (012) 521 3992

POSTGRADUATE DIVISION: PGDIP PHARM REG AFF

REQUEST FOR LEAVE OF ABSENCE FROM FORMAL ACADEMIC ACTIVITIES

Student name and surname: _____

Student number: _____

Date absent: _____

Activity missed: _____

Reason for absence: _____

_____

_____

_____

Documents attached: _____

_____

_____

_____

Signature of student: _____

Date: _____

Signature of HOD / Course Coordinator: _____

Date: _____