Quality Council for Trades & Occupations
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OCCUPATIONAL QUALIFICATION CURRICULUM DOCUMENT

IN LINE WITH THE OQSF POLICY (2021) OCCUPATIONAL QUALIFICATION TYPE (NOMENCLATURE)

QUALIFICATION	TYPE (NOMENCLATURE)	TITLE (DESCRIPTOR)	NQF LEVEL	CREDITS
	Higher Occupational Certificate	Health Products Regulatory Assistant (HPRA)	5	134
CURRICULUM CODE	242213-001-00-00			
PARTNER DETAILS	**ORGANISATION NAME**	**WEBSITE ADDRESS**	**TELEPHONE NUMBER**	**LOGO**
QUALITY PARTNER - DEVELOPMENT	CHIETA	https://www.chieta.org.za/	011 628 7000	
QUALITY PARTNER – ASSESSMENT	CHIETA	https://www.chieta.org.za/	011 628 7000	

Contents

SECTION 1: CURRICULUM SUMMARY

1.1 Occupational Information:

Associated, Organising Framework for Occupations (OFO) Occupational Code and Title

242213: Health Products Regulatory Assistant (HPRA)

1.1.1 Occupation/Specialisation/Part-Qualification/Skills Programme Type, Title, NQF Level, Credits and Curriculum Code, addressed by this Curriculum.

TYPE	TITLE	NQF LEVEL	CREDITS	CURRICULUM CODE
Higher Occupational Certificate	Health Products Regulatory Assistant (HPRA)	5	134	242213-001-00-00

Alternative titles used by industry:

None

1.2 Curriculum Information:

1.2.1 Articulation for Qualifications and Part- Qualifications

(a) Horizontal Articulation: This qualification articulates horizontally within the OQSF and between other sub-framework(s) as follows:

Within OQSF -

- Occupational Certificate: Health Products Sales Representative, NQF Level 5

Between sub-frameworks -

- Higher Certificate in Healthcare Management, NQF Level 5

(b) Vertical Articulation: This qualification articulates vertically within the OQSF as follows:

- Occupational Certificate: Pharmacy Technician, NQF Level 6

(c) Diagonal Articulation: This qualification articulates diagonally across NQF levels and across SubFrameworks:

- Advanced Certificate: Pharmacy Technical Support, NQF Level 6
- National Certificate: Vocational: Primary Health, NQF Level 4

- Diploma in Community Nursing Science, NQF Level 6

(d) Validation of Entry Requirements into articulation possibilities provided:

Yes

1.3 Curriculum Structure:

1.3.1 Knowledge/Theory Modules:

- 242213-001-00-00-KM-01, Overview of current health products industry/sector, NQF Level 5, Credits 5
- 242213-001-00-00-KM-02, Anatomy and physiology, NQF Level 5, Credits 10
- 242213-001-00-00-KM-03, Health products, NQF Level 5, Credits 8
- 242213-001-00-00-KM-04, Science for the Health Product Regulatory Assistant (HPRA), NQF Level 5, Credits 3
- 242202-001-00-00-KM-05, Codes of Practice for HPRAs, NQF Level 5, Credits 3
- 242213-001-00-00-KM-06, Registrations, licensing, applications, and submissions, NQF Level 5, Credits 8
- 243302-001-00-KM-07, Vigilance and post marketing surveillance, NQF Level 5, Credits 6
- 242213-001-00-KM-08, Professional conduct, NQF Level 4, Credits 3

Total number of credits: 46

1.3.2 Practical Skills Modules:

- 242213-001-00-PM-01, Submit health product related applications to the regulatory body, NQF Level 5, Credits 18
- 242213-001-00-PM-02, Conduct code compliance activities on health products, NQF Level 5, Credits 6
- 242213-001-00-PM-03, Conduct oneself professionally and ethically, NQF Level 4, Credits 3
- 242213-001-00-PM-04, Perform vigilance and post marketing surveillance, NQF Level 5, Credits 5
- 242213-001-00-PM-05, Communicate, attend meetings and solve problems, NQF Level 4, Credits 8

Total number of credits: 40

1.3.3 Work Experience Modules:

- 242213-001-00-WM-01, Processes to submit health product registration or licensing applications to a regulatory authority, NQF Level 5, Credits 20
- 242213-001-00-WM-02, Processes to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product, NQF Level 5, Credits 8
- 242213-001-00-WM-03, Processes to submit the health product establishment's licensing applications to a regulatory authority, NQF Level 5, Credits 8
- 242213-001-00-WM-04 Processes to conduct code compliance activities on health products, NQF Level 5, Credits 6
- 242213-001-00-WM-05, Processes to perform vigilance and post marketing surveillance, NQF Level 5, Credits 6

Total number of credits: 48

Entry Requirements:

NQF Level 4, with Mathematics and Science

Recognition of Prior Learning (RPL):

RPL for Access:

Learners may use the RPL process to gain access to training opportunities for a programme of learning, qualification if they do not meet the formal, minimum entry requirements for admission. RPL assessment provides an alternative access route into a programme of learning, qualification.

Such an RPL assessment may be developed, moderated and conducted by the accredited Skills Development Provider which offers that specific qualification. Such an assessment must ensure that the learner is able to display the equivalent level of competencies required for access, based on the NQF level descriptors.

RPL for Exemption:

For exemption from modules through RPL, learners who have gained the stipulated competencies of the modules of a programme of learning, qualification through any means of formal, informal or non-formal learning and/or work experience, may be awarded credits towards relevant modules, and gaps identified for training, which is then concluded.

RPL for awarding credits:

Learners who have gained the stipulated competencies of the modules of a programme of learning, qualification through any means of formal, informal or non-formal learning and/or work experience, may be awarded credits towards relevant modules, and gaps identified for training, which is then concluded.

A valid Statement of Results is required for admission to the EISA in which confirmation of achievement is provided that all internal assessment criteria for all modules in the related curriculum document have been achieved.
Upon successful completion of the FISA, RPL learners will be issued with the QCTO certificate for the qualification. Quality Partners are responsible for ensuring the RPL mechanism and process for qualifications is approved by the QCTO.

1.6 Quality Partner for Assessment:

NAME OF BODY:	CHIETA
ADDRESS OF BODY:	72 New Road, Glen Austin AH (Grand Central), Midrand, 1685
WEBSITE:	https://www.chieta.org.za/
TELEPHONE NUMBER:	011 628 5000

1.7 List of Qualification(s)/Part- Qualification(s)/Skills Programme(s) Related to this Curriculum

a. Occupational Certificate: Health Product Code Compliance Officer, NQF level 5, 34 Credits
b. Occupational Certificate: Health Product Vigilance Officer, NQF level 5, 46 Credits

SECTION 2: OCCUPATIONAL/SPECIALISATION/PART-QUALIFICATION/SKILLS PROGRAMME PROFILE

2.1 Purpose:

The purpose of this qualification is to prepare a learner to function as a Health Products Regulatory Assistant (HPRA).

A Health Products Regulatory Assistant (HPRA) prepares, collates and submits various applications for the registration of health products, for amendments/variations on registered health products and for the renewal of licences for health products, under the supervision of either a responsible pharmacist or authorised representative. Health products include medicines, medical devices and in vitro devices (IVDs), veterinary and personal care products. These applications are submitted to the regulatory body electronically in the main. A HPRA also conducts compliance activities to ensure that promotional material and activities meet the requirements of the legal framework. A HPRA assists with vigilance and post marketing surveillance of the health products.

2.2 Tasks:

TASK	LINKS TO ELO
Apply for licences for healthcare establishments and registration of health products	Apply essential methods, procedures and techniques to submit applications pertaining to licences of healthcare establishments and registration of health products
Apply for renewals, amendments/ variations and retentions	Apply essential methods, procedures and techniques to submit applications pertaining to renewals, amendments/ variations and retentions
Conduct/perform code compliance activities on health products	Interpret and apply appropriate procedures and criteria to conduct/perform code compliance activities on health products
Conduct / perform vigilance and post marketing surveillance	Apply prescribed procedures to conduct / perform vigilance and post marketing surveillance to ensure the safe use of health products

2.3 Occupational Task Details:

2.3.1 Task 1

Apply for licences for healthcare establishments and registration of health products

(a) Unique Product or Service:

Well-prepared and compliant application documentation for registration of health products and licences of healthcare establishments

(b) Responsibilities:

- Obtain information on the registration processes, guidelines and forms for all health products
- Obtain information on the regulatory body's licensing processes, guidelines and forms for all health products
- Check and collate information collected on health products against requirements
- Perform due diligence
- Assist in compiling regulatory documentation according to requirements and the regulatory body's validation (screening) and evaluation processes
- Assist in submission of regulatory documentation according to specific formats and instruction
- Liaise and communicate with relevant internal and external stakeholders
- Identify industry experts and set-up appointments
- Engage with peers and diverse audiences such as industry professionals and cross functional stakeholders

(c) Contexts:

- Processes to collate and compiling information for applications pertaining to licences of healthcare establishments and registration of health products
- Processes to assist in submission of documentation for applications pertaining to licences of healthcare establishments and registration of health products
- Processes to communicate with stakeholders and industry experts

2.3.2 Task 2

Submit applications pertaining to renewals, amendments/ variations and retentions

(a) Unique Product or Service:

Well-prepared and compliant application documentation for renewals, amendments/ variations and retentions

(b) Responsibilities:

- Obtain the regulatory body's processes, guidelines and forms for renewals, amendments/variations and retention of all health products
- Perform due diligence
- Assist in compiling regulatory documentation for renewals, amendments/variations and retention of all health products
- Assist in submission of documentation for renewals, amendments/variations and retention of all health products

(c) Contexts:

- Processes to collate information on renewals, amendments/variations and retention of all health products
- Processes to assist in submission of documentation for renewals, amendments/variations and retention of all health products to regulatory body

2.3.3 Task 3

Conduct/perform code compliance activities on health products
(a) Unique Product or Service:

Artwork, content, labelling and activities to promote health products are according to appropriate codes

(b) Responsibilities:

- Proof read marketing and promotional material
- Proof read labelling of health and personal care products
- Check the content and artwork of promotional and educational materials for a health product
- Check promotional activities for compliance and make recommendations
- Complete and file administrative records of checks and corrections to promotional and educational materials and activities
- Receive and lodge incoming and outgoing complaints pertaining to promotional and educational materials and activities
- Attend to unethical practices regarding promotional and educational materials and activities

(c) Contexts:

- Processes to proof read marketing and promotional material and labelling of health and personal care products
- Process to check the content and artwork of promotional and educational materials and promotion activities
- Processes to receive and lodge incoming and outgoing complaints pertaining to promotional and educational materials and activities

2.3.4 Task 4

Conduct / perform vigilance and post marketing surveillance to ensure the safe usage of health products

(a) Unique Product or Service:

Health product safety ensured through vigilance and post-marketing surveillance

(b) Responsibilities:

- Assist in completing and submitting adverse reaction/event reporting forms to the regulatory body
- Assist in implement a health product recall assignment
- Assist in preparing a vigilance report
- Assist in preparing recall letters and media releases

(c) Contexts:

- Processes to assist in completing and submitting adverse reaction/event reporting forms
- Processes to assist in implementing a health product recall a
- Processes to assist in preparing a vigilance report and preparing recall letters and media releases

SECTION 3: CURRICULUM COMPONENT SPECIFICATIONS

3.1 Knowledge Module Specifications:

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-00-KM-01	Overview of current health products industry/sector	5	5	face-toface/contact, online, e-learning, mobile training unit, blended, distance
242213-001-00-00-KM-02	Anatomy and physiology	5	10	face-toface/contact, online, e-learning, mobile training unit, blended, distance
242213-001-00-00-KM-03	Health products	5	8	face-toface/contact, online, e-learning, mobile training unit, blended, distance
242213-001-00-00-KM-04	Science for the Health Product Regulatory Assistant (HPRA)	5	3	face-toface/contact, online, e-learning, mobile training unit, blended, distance
242202-001-00-00-KM-05	Codes of Practice for HPRAs	5	3	face-toface/contact, online, e-learning, mobile training unit, blended, distance
242213-001-00-00-KM-06	Registrations, licensing, applications, and submissions	5	8	face-toface/contact, online, e-learning, mobile training unit, blended, distance
243302-001-00-KM-07	Vigilance and post marketing surveillance	5	6	face-toface/contact, online, e-learning, mobile training unit, blended, distance
242213-001-00-KM-08	Professional conduct	4	3	face-toface/contact, online, e-learning, mobile training unit, blended, distance

Detailing Knowledge Module (KM) contents

242213-001-00-00-KM-01, Overview of current health products industry/sector, NQF Level 5, Credits 5

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-00-KM-01	Overview of current health products industry/sector	5	5	face-toface/contact, online, e-learning, mobile training unit, blended, distance

3.1.1 Module Details:

(a) Purpose of Knowledge Module:

The main focus of the learning in this knowledge module is to build an understanding of the health products sector and regulations and regulatory bodies.

(b) List of Knowledge Topics:

TOPIC CODE	TOPIC TITLE	% OF TIME TO BE SPENT
KM-01-KT01	The health products sector	35
KM-01-KT02	Regulations and regulatory bodies	65

(c) Detailing each topic listed above into topic elements: 1. Knowledge topic and its elements

KM-01-KT01: The health products sector (35%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0101	Global and national overview of the health products sector	15
KT0102	International and local definitions, classifications and groupings of health products (international nomenclature)	15
KT0103	Customers [e.g. doctors (GPs, specialists), veterinary doctors, pharmacy, hospitals, laboratories, medical aids, Fast Moving Consumer Goods (FMCG) outlets, state and private sectors etc.	20
KT0104	Types of suppliers [originators and generics plus biosimilars; manufacturers; distributors; wholesalers; international and local	20
	suppliers; large and small local companies; categories of HCP (Level 3) *vis a vis* health products)	

KT0105	Regulatory authorities' roles and responsibilities involved in clinical trials • National Health Research Ethics Council (NHREC) • The South African Health Products Regulatory Authority (SAHPRA) • Research Ethics Committees (RECs) • South African National Clinical Trials Register (SANCTR) • National Health Research Committee (NHRC) • Provincial Health Research Committees (PHRC)	30

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0101	Discuss, briefly, the health products sector globally and nationally	15
IAC0102	Explain international and local definitions, classifications and groupings of medicines, medical devices and in vitro devices (IVDs), complementary medicines, personal care products and veterinary products.	15
IAC0103	Describe the categories of HCP (Level 3) *vis a vis* health products	20
IAC0104	Identify the various people, entities and suppliers involved with health products	20
IAC0105	Describe, briefly, the roles and responsibilities of the regulatory Authorities involved in clinical trials	30

2. Knowledge topic and its elements

KM-01-KT02: Regulations and regulatory bodies (65%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0201	Legislation and regulations impacting on health products • Occupational Health and Safety Act (OHSA) (Act 85 of 1993) • Pharmacy Act (No. 53 of 1974)	25

	• Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) as amended • Medical Schemes Act (No. 131 of 1998) • Hazardous Substances Act (Act No. 15 of 1973) • National Health Act, 2003 (Act No. 61 of 2003) • Protection of Personal Information Act (Act 4 of 2013) • Consumer Protection Act (CPA) (No. 68 of 2008) - • Independent Communications Authority of South Africa (ICASA) (Act 13 of 2000) • Prevention and Combating of Corrupt Activities (PACCA) (Act 12 of 2004) • Trade Metrology Act (No. 77 of 1973) • Foodstuff, Cosmetics and Disinfectants Act (No. 54 of 72) • Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act (36 of 1947) • Human Tissue Act details (2004) • Allied Health Professions Act (No. 63 of 1982) • Health Professions Act (No. 56 of 74) • Legislation related to relevant professional bodies • Relevant local and international legislation and regulations (including those for MDs and IVDs), as and when applicable, and dependent on health products	
KT0202	Regulatory bodies/ institutions [South African Health Products Regulatory Authority (SAHPRA); South African Pharmacy Council (SAPC); Department of Health (DoH); World Health Organisation (WHO); International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH); European Medicines Agency (EMA); European Union Commission on Cosmetics Regulations, Directives and related Annexures; Food and Drug Administration (FDA); International Medical Device Regulators Forum (IMDRF); Global Harmonisation Working Party (GHWP); Africa Medical Devices Forum (AMDF); Therapeutic Goods Administration (TGA); International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); World Organisation for Animal Health (WOAH), founded as OIE, and its Terrestrial and Aquatic Animal Health Codes]	20

KT0203	Relevant local and international standards and practices [including ISOs (some specific ones need to be included ISO 13485, 15189,14155 (for MD and IVDs); Good Manufacturing Principles (GMP) and Good Regulatory Practices (GRP) whose aspects include legality, consistency, independence, impartiality, proportionality, flexibility, clarity, efficiency, transparency; Good Warehousing Practice (GWP]; SABS standards with respect to MDs; relevant mandatory and nonmandatory standards for cosmetics]	20
KT0204	Bodies involved in approval of clinical trial applications [(SAHPRA, ethics committees; National Health Research Ethics Council (NHREC)]	18
KT0205	National Regulator for Compulsory Specifications (NRCS)	7
KT0206	Permits for importation and exportation of health products (human and animal) [Department of Health (DoH) and Department of Agriculture, Forestry and Fisheries (DAFF)]	10

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0201	Identify and explain the relevant aspects of the legislation impacting on health products and the health products industry	25
IAC0202	Describe the functions of the various regulatory bodies involved with health products	20
IAC0203	Identify and explain the national and international codes of practice, standards and ISOs pertinent to health products	20
IAC0204	Describe the functions of the bodies involved in the approval of clinical trial applications in South Africa	18
IAC0205	Describe the functions of the NRCS	7
IAC0206	Explain the importance of adhering to legislation, regulations, codes of practice, ISOs and standards with regards to health products	10

3.1.2 Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities – physical and/or virtual • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet, library and/or e-learning facilities • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Cartridges for printers, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers.
CONSUMABLES	• Cartridges for printers, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:25

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:20

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.1.3 Exemptions

None

242213-001-00-00-KM-02, Anatomy and physiology, NQF Level 5, Credits 10

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-00-KM-02	Anatomy and physiology	5	10	face-toface/contact, online, e-learning, mobile training unit, blended, distance

3.2.1 Module Details:

(a) Purpose of Knowledge Module:

The main focus of the learning in this knowledge module is to build a basic understanding of the human anatomy, physiology and pathophysiology with respect to the therapeutic treatment options available.

(b) List of Knowledge Topics:

TOPIC CODE	TOPIC TITLE	% OF TIME TO BE SPENT
KM-02-KT01	Cardio-vascular system	10
KM-02-KT02	Urinary and renal system	9
KM-02-KT03	Respiratory system	10
KM-02-KT04	Nervous system	12
KM-02-KT05	Musculoskeletal system	8
KM-02-KT06	Gastro-intestinal system	10
KM-02-KT07	Endocrine system	8
KM-02-KT08	Lymphatic and immune system and haematology	10
KM-02-KT09	Reproductive system (male and female)	9
KM-02-KT10	Skin	9
KM-02-KT11	Special senses	5

(c) Detailing each topic listed above into topic elements:

1. Knowledge topic and its elements

KM-02-KT01: Cardio-vascular system (10%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0101	Terminology	15
KT0102	Anatomy	18
KT0103	Physiology	18
KT0104	Pathophysiology management and pharmacology	16
KT0105	Applied pharmacology and therapeutic approaches to common conditions	18
KT0106	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0101	Describe the basic anatomy and physiology of the cardiovascular system	35
IAC0102	Describe, very briefly, the primary diseases of the cardiovascular system	13
IAC0103	Describe the main diagnostic tools used for the cardio-vascular system	12
IAC0104	Explain the main terms used for the cardio-vascular system	12
IAC0105	Describe health product options used for the management of specific conditions related to the cardio-vascular system	14
IAC0106	Explain the basic pharmacology of the medicine with respect to the cardio-vascular system	14

2. Knowledge topic and its elements

KM-02-KT02: Urinary and renal system (9%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0201	Terminology	15
KT0202	Anatomy	18
KT0203	Physiology	18
KT0204	Pathophysiology management and pharmacology	16
KT0205	Applied pharmacology and therapeutic approaches to common conditions	18
KT0206	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0201	Describe the basic anatomy and physiology of the urinary and renal system	35

IAC0202	Describe, very briefly, the primary diseases of the urinary and renal system	13
IAC0203	Describe the main diagnostic tools used in the urinary and renal system	12
IAC0204	Explain the main terms used for the urinary and renal system	12
IAC0205	Describe health product options used for the management of specific conditions related to the urinary and renal system	14
IAC0206	Explain the basic pharmacology of the medicine with respect to the urinary and renal system	14

3. Knowledge topic and its elements

KM-02-KT03: Respiratory system (10%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0301	Terminology	15
KT0302	Anatomy	18
KT0303	Physiology	18
KT0304	Pathophysiology management and pharmacology	16
KT0305	Applied pharmacology and therapeutic approaches to common conditions	18
KT0306	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0301	Describe the basic anatomy and physiology of the respiratory system	35
IAC0302	Describe, very briefly, the primary diseases of the respiratory system	13
IAC0303	Describe the main diagnostic tools used in the respiratory system	12
IAC0304	Explain the main terms used for the respiratory system	12

IAC0305	Describe health product options used for the management of specific conditions related to the respiratory system	14
IAC0306	Explain the basic pharmacology of the medicine with respect to the respiratory system	14

4. Knowledge topic and its elements

KM-02-KT04: Nervous system (12%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0401	Terminology	15
KT0402	Anatomy	18
KT0403	Physiology	18
KT0404	Pathophysiology management and pharmacology	16
KT0405	Applied pharmacology and therapeutic approaches to common conditions	18
KT0406	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	**IAC DESCRIPTION**	**% OF TIME TO BE SPENT**
IAC0401	Describe the basic anatomy and physiology of the nervous system	35
IAC0402	Describe, very briefly, the primary diseases of the nervous system	13
IAC0403	Describe the main diagnostic tools used in the nervous system	12
IAC0404	Explain the main terms used for the nervous system	12
IAC0405	Describe health product options used for the management of specific conditions related to the nervous system	14
IAC0406	Explain the basic pharmacology of the medicine with respect to the nervous system	14

5. Knowledge topic and its elements

KM-02-KT05: Musculoskeletal system (8%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0501	Terminology	15
KT0502	Anatomy	18
KT0503	Physiology	18
KT0504	Pathophysiology management and pharmacology	16
KT0505	Applied pharmacology and therapeutic approaches to common conditions	18
KT0506	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	**IAC DESCRIPTION**	**% OF TIME TO BE SPENT**
IAC0501	Describe the basic anatomy and physiology of the musculoskeletal system	35
IAC0502	Describe, very briefly, the primary diseases of the musculoskeletal system	13
IAC0503	Describe the main diagnostic tools used in the musculoskeletal system	12
IAC0504	Explain the main terms used for the musculoskeletal system	12
IAC0505	Describe health product options used for the management of specific conditions related to the musculoskeletal system	14
IAC0506	Explain the basic pharmacology of the medicine with respect to the musculoskeletal system	14

6. Knowledge topic and its elements

KM-02-KT06: Gastro-intestinal system (10%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0601	Terminology	15
KT0602	Anatomy	18
KT0603	Physiology	18
KT0604	Pathophysiology management and pharmacology	16
KT0605	Applied pharmacology and therapeutic approaches to common conditions	18
KT0606	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	**IAC DESCRIPTION**	**% OF TIME TO BE SPENT**
IAC0601	Describe the basic anatomy and physiology of the gastrointestinal system	35
IAC0602	Describe, very briefly, the primary diseases of the gastrointestinal system	13
IAC0603	Describe the main diagnostic tools used in the gastro-intestinal system	12
IAC0604	Explain the main terms used for the gastro-intestinal system	12
IAC0605	Describe health product options used for the management of specific conditions related to the gastro-intestinal system	14
IAC0606	Explain the basic pharmacology of the medicine with respect to the gastro-intestinal system	14

7. Knowledge topic and its elements

KM-02-KT07: Endocrine system (8%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0701	Terminology	15
KT0702	Anatomy	18
KT0703	Physiology	18

KT0704	Pathophysiology management and pharmacology	16
KT0705	Applied pharmacology and therapeutic approaches to common conditions	18
KT0706	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0701	Describe the basic anatomy and physiology of the endocrine system	35
IAC0702	Describe, very briefly, the primary diseases of the endocrine system	13
IAC0703	Describe the main diagnostic tools used in the endocrine system	12
IAC0704	Explain the main terms used for the endocrine system	12
IAC0705	Describe health product options used for the management of specific conditions related to the endocrine system	14
IAC0706	Explain the basic pharmacology of the medicine with respect to the endocrine system	14

8. Knowledge topic and its elements

KM-02-KT08: Lymphatic and immune system and haematology (10%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0801	Terminology	15
KT0802	Anatomy	18
KT0803	Physiology	18
KT0804	Pathophysiology management and pharmacology	16
KT0805	Applied pharmacology and therapeutic approaches to common conditions	18
KT0806	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0801	Describe the basic anatomy and physiology of the lymphatic and immune system	35
IAC0802	Describe, very briefly, the primary diseases of the lymphatic and immune system	13
IAC0803	Describe the main diagnostic tools used in the lymphatic and immune system	12
IAC0804	Explain the main terms used for the lymphatic and immune system	12
IAC0805	Describe health product options used for the management of specific conditions related to the lymphatic and immune system	14
IAC0806	Explain the basic pharmacology of the medicine with respect to the lymphatic and immune system	14

9. Knowledge topic and its elements

KM-02-KT09: Reproductive system (male and female) (9%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0901	Terminology	15
KT0902	Anatomy	18
KT0903	Physiology	18
KT0904	Pathophysiology management and pharmacology	16
KT0905	Applied pharmacology and therapeutic approaches to common conditions	18
KT0906	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0901	Describe the basic anatomy and physiology of the reproductive system	35
IAC0902	Describe, very briefly, the primary diseases of the reproductive system	13

IAC0903	Describe the main diagnostic tools used in the reproductive system	12
IAC0904	Explain the main terms used for the reproductive system	12
IAC0905	Describe health product options used for the management of specific conditions related to the reproductive system	14
IAC0906	Explain the basic pharmacology of the medicine with respect to the reproductive system	14

10. Knowledge topic and its elements

KM-02-KT10: Skin (9%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT1001	Terminology	15
KT1002	Anatomy	18
KT1003	Physiology	18
KT1004	Pathophysiology management and pharmacology	16
KT1005	Applied pharmacology and therapeutic approaches to common conditions	18
KT1006	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC1001	Describe the basic anatomy and physiology of the skin system	35
IAC1002	Describe, very briefly, the primary diseases of the skin system	13
IAC1003	Describe the main diagnostic tools used in the skin system	12
IAC1004	Explain the main terms used for the skin system	12
IAC1005	Describe health product options used for the management of specific conditions related to the skin system	14
IAC1006	Explain the basic pharmacology of the medicine with respect to the skin system	14

11. Knowledge topic and its elements

KM-02-KT11: Special senses (5%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT1101	Terminology	15
KT1102	Anatomy	18
KT1103	Physiology	18
KT1104	Pathophysiology management and pharmacology	16
KT1105	Applied pharmacology and therapeutic approaches to common conditions	18
KT1106	Diagnostic tools	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	**IAC DESCRIPTION**	**% OF TIME TO BE SPENT**
IAC1101	Describe the basic anatomy and physiology of the special senses system	35
IAC1102	Describe, very briefly, the primary diseases of the special senses system	13
IAC1103	Describe the main diagnostic tools used in the special senses system	12
IAC1104	Explain the main terms used for the special senses system	12
IAC1105	Describe health product options used for the management of specific conditions related to the special senses system	14
IAC1106	Explain the basic pharmacology of the medicine with respect to the special senses system	14

3.2.2 Criteria for accreditation

Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities – physical and/or virtual • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet, library and/or e-learning facilities • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Cartridges for printers, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers.
CONSUMABLES	• Cartridges for printers, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:25

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:20

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.2.3 Exemptions

None

242213-001-00-00-KM-03, Health products, NQF Level 5, Credits 8

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-00-KM-03	Health products	5	8	face-to-face contact, online, elearning, mobile training unit, blended, distance

3.3.1 Module Details:

(a) Purpose of Knowledge Module:

The main focus of the learning in this knowledge module is to build an understanding of the various health products (medicines, medical devices and in vitro devices (IVDs), personal care products and veterinary products that the Health Products Regulatory Assistant will deal with.

(c) List of Knowledge Topics:

TOPIC CODE	TOPIC TITLE	% OF TIME TO BE SPENT
KM-03-KT01	Medicines	28
KM-03-KT02	Medical technology	28
KM-03-KT03	Veterinary products	13
KM-03-KT04	Personal care product	23
KM-03-KT05	Science-related aspects/topics	8

(d) Detailing each topic listed above into topic elements:

1. Knowledge topic and its elements

KM-03-KT01: Medicines (28%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0101	New chemical entity (NCE) pharmaceuticals	5
KT0102	Biological medicines (blood and blood products; hormones; monoclonal antibodies; immunomodulators; biosimilars; vaccines; enzymes)	5
KT0103	Biosimilar medicines	5
KT0104	Borderline products (SAHPRA guideline)	5
KT0105	Combination products	5
KT0106	Complementary and alternate medicines (CAMs) [(six (6) major 'types' namely Aromatherapy, Ayurveda, Homeopathy, Traditional Chinese Medicine, Unani Tibb and Western Herbal Medicine, as well as combination products identified in the accompanying Guideline for Complementary Medicines (Quality, Safety and Efficacy)]	10
KT0107	Relevant terminology	10
KT0108	Product lifecycle	5
KT0109	Generics medicines	5
KT0110	Over-the-counter (OTC) medicines	5

KT0111	Basics of manufacture; pharmaceutical development; description and composition of finished pharmaceutical product; control of ingredients and API; control finished product; reference standards and materials, stability, assay, validation, retention samples	10
KT0112	WHO pre-qualification	5
KT0113	Material and instructions for use (IFU) relating to all health products (professional information (PI); patient information leaflet (PIL) (applicable to all health products in this module)	5
KT0114	SAHPRA requirements for the registration of medicines	20

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0101	Discuss all the types of medicines and products listed above and describe their characteristics and uses	30
IAC0102	Discuss some of the specific aspects related to biological medicines and complementary and alternate medicines	15
IAC0103	Explain all the terminology relevant to medicines	10
IAC0104	Explain the concept of lifecycle with respect to medicines	5
IAC0105	Explain all the aspects relevant to the basics of manufacture	10
IAC0106	Discuss the advantages of WHO pre-qualification	5
IAC0107	Discuss SAHPRA's requirements for the registration of medicines	20
IAC0108	Describe the different types of instructional materials prepared for health products generally	5

2. Knowledge topic and its elements

KM-03-KT02: Medical technology (medical devices and *In Vitro* devices) (28%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0201	Types of medical technology [single use devices (i.e. syringes, catheters); implantable (i.e. hip prosthesis, pacemakers); imaging (i.e. ultrasound and CT scanners); medical equipment (i.e. anaesthesia machines, patient monitors, haemodialysis machines); software (i.e. computer aided diagnostics); in vitro diagnostics (e.g. glucometer, HIV tests); personal protective equipment (i.e. mask, gowns, gloves); surgical and laboratory instruments; software for Artificial Intelligence (AI); nanotechnology]	24
KT0202	Classification of medical devices and IVDs (Section 11 of GG 40480) (Classes A, B, C, and D from low risk to high risk)	9
KT0203	Global Medical Device Nomenclature (GMDN) (patient safety; intended use of medical devices; regulatory status; technical information; adverse events; availability; others)	8
KT0204	General medical technology safety and performance	7
KT0205	Types of licences **for medical device establishments** [manufacturer (manufacture, pack, label, service, refurbish), distributor (import, export, distribute) and wholesaler (sale, storage, transportation, and/or the onward dispatch of medical devices)]	12
KT0206	Unique device identifier	3
KT0207	Conformity assessment body and notified bodies	7
KT0208	Medical technology lifecycle	5
KT0209	Compliance and audits [first-party, internal, second-party, supplier, external and agency audits; corrective and preventive actions (CAPAs) to help drive compliance to standards and continuous improvement(s)] ISO 13485 (section on audits)	13
KT0210	Medical Device Single Audit Programme (MDSAP)	5
KT0211	Emerging technologies	7

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0201	Explain terminology associated with medical devices and IVDs	7
IAC0202	Describe the types and uses of medical devices and IVDs	22
IAC0203	Explain what is unique device identifier	2
IAC0204	Describe the GMDN nomenclature system for medical devices and IVDS and give reasons for a standardised nomenclature for medical devices and IVDs	8
IAC0205	Discuss the classification of medical devices and IVDs according to South African regulations	9
IAC0206	Identify and describe the types of licences **for medical technology establishments**	10
IAC0207	Discuss the aspect of general medical technology safety and performance	7
IAC0208	Describe the functions of a conformity assessment body and a notified body with respect to medical technology	7
IAC0209	Discuss aspects related to compliance and audits with respect to medical technology	11
IAC0210	Describe a Medical Device Single Audit Programme (MDSAP)	5
IAC0211	Explain the concept of lifecycle with respect to medical devices and IVDs	5
IAC0212	Explain emerging technologies in the context of MDs and IVDs	7

3. Knowledge topic and its elements

KM-03-KT03: Veterinary products (13%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0301	Types of veterinary medicines (biological, biosimilars, complementary and alternate medicines, generics; and vaccines associated with veterinary products)	28
KT0302	Diagnostic kits	5
KT0303	Appropriate regulations on the authorisation, manufacturing, distribution and use of veterinary products through their veterinary legislation	16

KT0304	Relevant terminology	8
KT0305	Product lifecycle	5
KT0306	Basics of manufacture; pharmaceutical development; description and composition of finished pharmaceutical product; control of ingredients and API; control finished product; reference standards and materials, stability, assay, validation, retention samples	23
KT0307	SAHPRA's requirements	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0301	Describe the various types and functions of veterinary medicines and d**escribe the r**isks and benefits of veterinary products	30
IAC0302	Describe the diagnostic kits associated with veterinary products	5
IAC0303	Explain the regulations on the authorisation, manufacturing, distribution and use of veterinary products through their veterinary legislation	15
IAC0304	Explain all the terminology relevant to medicines	8
IAC0305	Explain the concept of lifecycle with respect to veterinary medicines	5
IAC0306	Explain all the aspects relevant to the basics of manufacture of veterinary medicines	23
IAC0307	Discuss SAHPRA's requirements for the registration of **veterinary products**	14

4. Knowledge topic and its elements

KM-03-KT04: Personal care products (cosmetic and toiletry products) (23%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0401	Definitions of a cosmetic [variables exist as to whether a product is a cosmetic or borderline (product which in one country is a pharmaceutical product and in another a cosmetic)	17

KT0402	Nomenclature systems (International Nomenclature of Cosmetic Ingredients (INCI) and variations that exist worldwide)	12
KT0403	Applicable regulations and standards	16
KT0404	Mandatory requirements for labelling	10
KT0405	Claims and substantiation	12
KT0406	Stability requirements	12
KT0407	Symbols and logos commonly used	9
KT0408	Product Information File components	12

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0401	Discuss the definitions of cosmetics	17
IAC0402	Describe the nomenclature systems relevant to cosmetics	12
IAC0403	Explain the regulations and standards applicable to cosmetics	16
IAC0404	Discuss the mandatory requirements for labelling	10
IAC0405	Discuss claims and substantiation in the case of cosmetics	12
IAC0406	Explain the stability requirements with respect to cosmetics	12
IAC0407	Describe the symbols and logos used in cosmetics	9
IAC0408	Describe the components of the Product Information File	12

3.3.2 Criteria for accreditation

Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities – physical and/or virtual • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet, library and/or e-learning facilities • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Cartridges for printers, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers.
CONSUMABLES	• Cartridges for printers, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:25

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:20

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.3.3 Exemptions None

242213-001-00-00-KM-04, Science for the Health Product Regulatory Assistant (HPRA), NQF Level 5, Credits 3

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-00-KM-04	Science for the Health Product Regulatory Assistant (HPRA)	5	3	Face-to-face, or online, or mobile training unit, or blended

3.4.1 Module Details:

a. Purpose of Knowledge Module:

The main focus of the learning in this knowledge module is to build an understanding of the science aspects for the HPRA.

b. List of Knowledge Topics:

TOPIC CODE	TOPIC TITLE	% OF TIME TO BE SPENT
KM-04-KT01	Scientific studies/clinical trials	100

c. Detailing each topic listed above into topic elements:

1. Knowledge topic and its elements

KM-04-KT01: Scientific studies/clinical trials (100%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0101	Clinical research studies **(**definition; types and phases of clinical trials; clinical evaluations; principles of clinical research methodology; related concepts and aspects include pharmacoeconomics studies; pre-clinical animal studies; drug development process; step approach clinical trial analysis; trial design, relevant statistical development (power – related to sample size, statistical significance); bioavailability and bioequivalence (generics etc.); biowaivers;clinical evaluations for medical technology products (randomised); interpretation of clinical study results and reports)	55
KT0102	Key regulatory principles and processes governing the stages in the development of a pharmaceutical product. (pharmaceutical principles: formulation, design, dosage forms, dosage and posology, manufacture; analysis; packaging process and packaging materials; stability)	30
KT0103	Stages governing development of MDs and IVDs	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	**IAC DESCRIPTION**	**% OF TIME TO BE SPENT**
IAC0101	Discuss all aspects related to clinical research studies	55
IAC0102	Explain key regulatory principles and processes governing the stages in the development of a pharmaceutical product	30
IAC0103	Describe the stages governing the development of MDs and IVDs	15

3.4.2 Criteria for accreditation

Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM :NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities – physical and/or virtual • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet, library and/or e-learning facilities • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Cartridges for printers, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers.
CONSUMABLES	• Cartridges for printers, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:25

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:20

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.4.3 Exemptions

None **243302-001-00-00-KM-05, Codes of Practice for HPRAs, NQF Level 5, Credits 3**

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
243302-001-00-00-KM-05	Codes of Practice for HPRAs	5	3	Face-to-face, or online, or mobile training unit, or blended

3.5.1 Module Details:

a. Purpose of Knowledge Module:

The main focus of the learning in this knowledge module is to build an understanding of the importance of ensuring that all marketing and promotional material and activities for health products comply with the law and relevant sector's codes.

c. List of Knowledge Topics:

TOPIC CODE	TOPIC TITLE	% OF TIME TO BE SPENT
KM-05-KT01	Codes of practice	70
KM-05-KT02	Marketing and promotional and educational material and activities for health products	30

c. Detailing each topic listed above into topic elements:

1. Knowledge topic and its elements

KM-05-KT01: Codes of practice (70%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0101	The SA Code of Marketing Practice and its Guidelines managed by Marketing Code Authority (MCA)	30
KT0102	Medical Device Code of Ethical Business and Marketing Practice (SAMED)	30
KT0103	Cosmetic Advertising Code of Practice - Appendix B of the ARB Code	20
KT0104	Other relevant Industry codes such as Direct Selling Association (DSA), Health Products Association of Southern Africa (HPA), international, national and/or internal company codes of practice	20

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0101	Discuss the importance of the various codes	40
IAC0102	Discuss the salient features of the various codes	40
IAC0103	Explain the consequences of violating the codes	20

2. Knowledge topic and its elements

KM-05-KT02: Marketing and promotional and educational material and activities for health products (%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0201	Types of promotional material	30
KT0202	Medicines regulation (advertising medical product in the Medicines Act; Section 18 – sampling)	20
KT0203	Regulators' requirements (NRCS, ICASA and others)	20
KT0204	Training sales, marketing teams and others on handling reporting ADR's within company and SAHPRA protocols and their role in health product recall	15

KT0205	Approval of promotional material and activities in line with the relevant code	15

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0201	Describe the types of promotional material used for health products	35
IAC0202	Explain the requirements of regulatory agencies with regards to promotional material	25
IAC0203	Explain the regulations related to promotional material for health products	25
IAC0204	Describe the role and activities of Code Compliance Officer	15

3.5.2 Criteria for accreditation

Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM :NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities – physical and/or virtual • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet, library and/or e-learning facilities • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Cartridges for printers, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers.
CONSUMABLES	• Cartridges for printers, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:25

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:20

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.5.3 Exemptions

None

242213-001-00-00-KM-06, Registrations, licensing, applications, and submissions, NQF Level 5, Credits 8

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-00-KM-06	Registrations, licensing, applications, and submissions	5	8	Face-to-face, or online, or mobile training unit, or blended

3.6.1 Module Details:

a. Purpose of Knowledge Module:

The main focus of the learning in this knowledge module is to build an understanding of registration and registration processes, application and submission to regulatory bodies, and licensing and renewals for health products.

b. List of Knowledge Topics:

TOPIC CODE	TOPIC TITLE	% OF TIME TO BE SPENT
KM-06-KT01	Registration and licensing processes	45
KM-06-KT02	Application and submission to regulatory bodies	28
KM-06-KT03	Licensing of health products establishment	27

c. **Detailing each topic listed above into topic elements: 1. Knowledge topic and its elements**

KM-06-KT01: Registration and licensing processes (45%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0101	Overview of health products registration in South Africa	10
KT0102	Overview of health product registration in Southern Africa, East and West Africa – excludes French and Portuguese speaking countries	10
KT0103	SAHPRA's registration and deregistration processes, guidelines, forms and any other documents for registration for health products (biological medicines; complementary medicines; clinical trials; orthodox medicines; Category A – Unregistered Products; veterinary medicines, etc.)	25
KT0104	SAHPRA's licensing processes, guidelines, forms and any other documents for medical devices and IVDs	20

KT0105	SAHPRA's screening and evaluation processes	15
KT0106	ICASA's regulatory requirements	10
KT0107	SAHPRA's Guidance on Good Practice (GxP) Inspections	10

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0101	Provide an overview of health products registration in South Africa	10
IAC0102	Provide an overview of health products registration in Southern Africa, and East and West Africa	10
IAC0103	Discuss SAHPRA's registration and de-registration processes, guidelines and forms for medicines, veterinary and personal care products	25
IAC0104	Discuss SAHPRA's licensing processes, guidelines and forms for medical devices and IVDs	20
IAC0105	Discuss SAHPRA's screening and evaluation processes for health products	15
IAC0106	Discuss the requirements of ICASA with respect to MDs and IVDs	10
IAC0107	Discuss some of the important aspects of SAHPRA's site visit	10

2. Knowledge topic and its elements

KM-06-KT02: Application and submission to regulatory bodies (28%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0201	Documentation and submission formats [(technical formats; submission dossier format and content, etc.]	22
KT0202	The Common Technical Document (CTD) (applies to medicines and complementary medicines) and electronic submission format - eCTD) for the registration of health products	22
KT0203	Amendments/variations to health product registration	20
KT0204	Renewals of health product registration and health products establishment's licensing	20

KT0205	GMP/ISO/other certification	16

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0201	Describe the documentation and submission formats for medicines, cosmetics, medical devices, IVDs, and veterinary products	16
IAC0202	Discuss the aspects of the Common Technical Document (CTD)	16
IAC0203	Identify and describe SAHPRA's documents, templates and guidelines for medicines, medical devices and IVDs, veterinary health products, and cosmetics	28
IAC0204	Describe the processes and documentation for renewals of health product registration and health products establishment's licensing	14
IAC0205	Describe the processes and documentation for amendments/variations	12

IAC0206	Describe the processes and documentation for GMP/ISO certification	14

3. Knowledge topic and its elements

KM-06-KT03: Licensing pertaining to health product establishments (27%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0301	Types of licenses (manufacturers, distributors, wholesalers; packaging facilities; complementary medicine licence; nonmanufacturers; import and export licence)	25
KT0302	Application procedure (SAHPRA, SAPC and DoH website)	20
KT0303	Renewal of licences	15
KT0304	Retention of licences	15
KT0305	Amendments to licences	15
KT0306	Fees pertaining to licencing	10

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0301	Discuss the types of licences applied for by health product establishments	50
IAC0302	Describe the application procedures and documents for licences, renewal of licences, retention of licences, and amendments to licencing	50

3.6.2 Criteria for accreditation

Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM :NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities – physical and/or virtual • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet, library and/or e-learning facilities • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Cartridges for printers, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers.
CONSUMABLES	• Cartridges for printers, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:25

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:20

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.6.3 Exemptions

None

243302-000-01-KM-07, Vigilance and post-marketing surveillance, NQF Level 5, Credits 6

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
243302-000-01-KM-07	Vigilance and post marketing surveillance	5	6	Face-to-face, or online, or mobile training unit, or blended

3.7.1 Module Details:

a. Purpose of Knowledge Module:

The main focus of the learning in this knowledge module is to build an understanding of the importance pharmacovigilance. The topics below are based on documents from SAHPRA, the main regulatory body for health products.

b. List of Knowledge Topics:

TOPIC CODE	TOPIC TITLE	% OF TIME TO BE SPENT
KM-07-KT01	Pharmacovigilance	27
KM-07-KT02	Post marketing surveillance (medicines)	27
KM-07-KT03	Post marketing vigilance with respect to medical devices and IVDs	26
KM-07-KT04	Medicine recall/ withdrawal and rapid alerts (20%)	20

c. Detailing each topic listed above into topic elements:

1. Knowledge topic and its elements

KM-07-KT01: Pharmacovigilance (27%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0101	Concepts, definitions and terminology associated with pharmacovigilance and pharmacovigilance system, including the following: • Vigilance as a concept • Pharmacovigilance as a concept • Routine market surveillance includes scanning • Periodic Safety Update Reports (PSURs) • Periodic Benefit-Risk Evaluation Report (PBRER)	11
	Risk Management Plan (RMP)	

KT0102	Objectives for pharmacovigilance for the holders of certificate of registration	7
KT0103	Legal background for pharmacovigilance (Regulation 40 issued in terms of the Medicines and Related Substances Act, 101 of 1965, as amended)	7
KT0104	Aspects of a quality assured pharmacovigilance system (risk management, such as the detection, assessment, minimisation and communication relating to the risk of adverse reaction	13
KT0105	Requirements and responsibilities of the holder of certificate of registration	11
KT0106	Qualified Persons Responsible for Pharmacovigilance (QPPV) • have access to the reports of suspected adverse reactions and the PSMF for South African authorised products • qualifications of QPPV/ /local Pharmacovigilance Officer • responsibilities of the QPPV/local Pharmacovigilance Officer • back-up procedures in the case of absence of the QPPV/ local Pharmacovigilance Officer)	10
KT0107	Pharmacovigilance system master file (PSMF) • objectives • contents as pert Section 9.3 of SAHPGL-CEM-PV-02 Version 1.0 • pharmacovigilance system master file presentation, format and layout • accessibility of the pharmacovigilance system master file	9
KT0108	Pharmacovigilance quality system and training of personnel for pharmacovigilance	11
KT0109	Monitoring the performance and effectiveness of the pharmacovigilance system and its quality system	11
KT0110	SAHPRA pharmacovigilance (PV) inspection	10

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0101	Explain the concepts, definitions and terminology associated with pharmacovigilance	10
IAC0102	Give the objectives for pharmacovigilance	6
IAC0103	Provide a brief legal background for pharmacovigilance	6
IAC0104	Briefly describe the aspects of a quality assured pharmacovigilance system	12
IAC0105	Summarise the requirements and responsibilities of the holder of certificate of registration	10
IAC0106	Summarise the qualifications, experience and responsibilities of a QPPV	9
IAC0107	Describe, briefly, a pharmacovigilance system master file (PSMF) in terms of its objectives, contents, presentation and accessibility	8
IAC0108	Discuss, briefly, the main aspects related to a pharmacovigilance quality system	10
IAC0109	Discuss the importance of and aspects related to training of personnel for pharmacovigilance	10
IAC0110	Describe the processes to monitor the pharmacovigilance performance	9
IAC0111	Discuss, briefly, SAHPRA's pharmaco-vigilance inspection processes	10

2. **Knowledge topic and its elements**

KM-07-KT02: Post marketing surveillance (medicines) (27%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0201	Definition of post marketing surveillance	10

KT0202	Requirements for market surveillance [identification and selection of medicines to be monitored and factors to be considered; selection of areas or regions to be sampled and relevant criteria; types of sample collection sites; sampling plan; training of sample collectors (SAHPRA officials or delegate); sampling design; sample screening and testing; laboratory testing; evaluating results and report preparation; results dissemination; enforcement; monitoring & evaluation]	90

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0201	Define post marketing surveillance	10
IAC0202	Explain the difference between post marketing surveillance and pharmacovigilance	10
IAC0203	Explain all the requirements for market surveillance	80

3. **Knowledge topic and its elements**

KM-07-KT03: Post marketing vigilance with respect to medical devices and IVDs (26%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0301	Relevant definitions (quarantined stock (in the context of a recall); drug recall; withdrawal)	5
KT0302	Achieving post market vigilance: • evaluating reported adverse events • disseminating information that could be used to prevent or minimise the consequences of adverse events, where appropriate • modifying the device or IVD • removing the medical device or IVD from the market	15
KT0303	Vigilance exchange [(information will be exchanged on incidents and events where: corrective action, including a recall, is to be taken and there is a serious risk to the safety of patients or other users, but where the corrective action is still being determined)	13
KT0304	Adverse events (responsibilities of HCR / licensed manufacturer / licensed distributor; reportable adverse events)	13

KT0305	Event or cause of an adverse event and description (malfunction or deterioration in the characteristics or performance of a medical; inadequate design or manufacture of a device; inaccuracy in the labelling, instructions for use and/or promotional materials; significant public health concern; other information becoming available)	14
KT0306	Reports and reporting (reporting incidents with medical devices; exemptions from reporting adverse events to the regulatory authority; timeframes for submitting adverse events reports to regulatory authority; details to be included in an adverse event report)	13
KT0307	Access to medical devices involved in adverse events	7
KT0308	Recalls (actions that are not considered to be a recall; actions related to notification / initiation of a recall; factors common to all recalls that need to be considered; instances when medical devices and IVDs are recalled; stages of a recall; classification	20
	of recalls; classes and types of recall; recall letters and media release; post recall procedures; follow-up action procedures)	

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0301	Define the relevant terms in the SAHPRA document	4
IAC0302	Elaborate on how post marketing vigilance can be achieved in the case of MDs and IVDs	5
IAC0303	Discuss the concept of vigilance exchange	4
IAC0304	Define the terms adverse event and near adverse event	5
IAC0305	Describe the responsibilities of HCR / licensed manufacturer / licensed distributor with respect to adverse events	6
IAC0306	Identify the three reporting criteria for adverse events	4
IAC0307	Describe an event or cause of an adverse event and elaborate on this aspect	5
IAC0308	Describe the various aspects associated with reporting incidents with medical devices	5
IAC0309	Explain the eight exemption rules that can apply with regards to reporting adverse events to the regulatory authority	6

IAC0310	Explain the timeframes for submitting adverse events reports to regulatory authority	4
IAC0311	Describe the details to be included in an adverse event report	4
IAC0312	Discuss the aspect of access to medical devices involved in adverse events	4
IAC0313	Describe actions that are not considered to be a recall	4
IAC0314	Describe actions related to notification / initiation of a recall	4
IAC0315	State the factors common to all recalls that need to be considered	5
IAC0316	State the instances for which medical devices and IVDs are recalled	4
IAC0317	Describe the stages of a recall	4
IAC0318	State how recalls are classified	4
IAC0319	Describe the three classes of recall and the three types of recall	5
IAC0320	Describe the processes around recall letters and media letters	4
IAC0321	Describe the processes around post recall procedures	5
IAC0322	Describe follow-up action procedures	5

4. **Knowledge topic and its elements**

KM-07-KT04: Medicine recall/ withdrawal and rapid alerts (20%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0401	List of abbreviations and definitions (recall, withdrawal; parallel importation; parallel importer)	9
KT0402	Notification/Initiation of the recall	11
KT0403	Factors common to all recalls that need to be considered	15
KT0404	Classification of recalls (classes; types; action necessary)	14
KT0405	Recall notification	11
KT0406	Recall letters and media release	13

KT0407	Post recall procedures	14
KT0408	Follow-up action procedures	13

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0401	Define relevant terminology	6
IAC0402	Describe the processes around notification/initiation of the recall	8
IAC0403	Describe the factors that will prompt withdrawal/recall of a particular batch/es of a product from the market	10
IAC0404	Discuss factors common to all recalls that need to be considered	12
IAC0405	Discuss the classification of recalls	11
IAC0406	Discuss the processes around recall notification	10
IAC0407	Describe the processes around recall letters and media releases	11
IAC0408	Describe the processes around post recall procedures	12
IAC0409	Describe follow-up action procedures	11
IAC0410	Explain rapid alerts	9

3.7.2 Criteria for accreditation

Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM :NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities – physical and/or virtual • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet, library and/or e-learning facilities • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Cartridges for printers, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers.
CONSUMABLES	• Cartridges for printers, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:25

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:20

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Assessor must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:20

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.7.3 Exemptions None 242213-001-00-KM-08,

Professional conduct, NQF

Level 4, Credits 3

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-KM-08	Professional conduct	4	3	Face-to-face, or online, or mobile training unit, or blended

3.8.1 Module Details:

a. Purpose of Knowledge Module:

The main focus of the learning in this knowledge module is to build an understanding of the professional conduct of a HPRA, Health Products Code Compliance Officer (HPCCO) and Health Products Vigilance Officer (HPVO). This broadly includes ethical conduct, intercultural sensitivity and problem-solving skills. **b.** List of Knowledge Topics:

TOPIC CODE	TOPIC TITLE	% OF TIME TO BE SPENT
KM-08-KT01	Ethical conduct	60
KM-08-KT02	Stages of intercultural sensitivities	20
KM-08-KT03	Problem-solving skills	20

c. Detailing each topic listed above into topic elements:

1. Knowledge topic and its elements

KM-08-KT01: Ethical conduct (60%)

TOPIC ELEMENT CODE	TOPIC ELEMENT TITLE	% OF TIME TO BE SPENT
KT0101	Concept of ethics and principles of ethics	10
KT0102	Bioethics (includes medical ethics which focuses on issues in health care; research ethics which focuses issues in the conduct of research; environmental ethics which focuses on issues pertaining to the relationship between human activities and the environment, and public health ethics which addresses ethical issues in public health)	32
KT0103	Ethical behaviour (including integrity, honesty and transparency)	15
KT0104	Ethics in terms of product quality and associated risks (infringement can cause harm)	13
KT0105	Ethical issues regulatory professionals may encounter	13
KT0106	Ethical issues in areas of product development, compliance and clinical testing	17

Internal Assessment Criteria (IAC) and Weight

IAC CODE	IAC DESCRIPTION	% OF TIME TO BE SPENT
IAC0101	Discuss the concept of ethics and bioethics and briefly elaborate on some of the predominant debates in bioethics	30

IAC0102	Discuss ethical behaviour with specific reference to the work of a HPRA	18
IAC0103	Explain the importance of ethics in terms of product quality and associated risks, and in areas of product development, compliance and clinical testing	22
IAC0104	Identify and elaborate on ethical issues regulatory professionals may encounter	20
IAC0105	Discuss the consequences of unethical behaviour	10

2. Knowledge topic and its elements

KM-08-KT02: Stages of cultural sensitivities (20%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0201	Perceptions, judgments, and assumptions	20
KT0202	Milton Bennett's Developmental Model of Intercultural Sensitivity (six stages a person must go through to become culturally sensitive: denial, defense, commonality, minimization, cultural awareness, culturally sensitive, relativity, adaptation, and integration)	40
KT0203	Cross-cultural norms	20
KT0204	Managing cultural differences	20

Internal Assessment Criteria (IAC) and Weight

IAC CODE	**IAC DESCRIPTION**	**% OF TIME TO BE SPENT**
IAC0201	Discuss perceptions, judgments, and assumptions in the context of culture and cultural sensitivities	18
IAC0202	Discuss, briefly, Milton Bennett's Developmental Model of Intercultural Sensitivity	34
IAC0203	Discuss cross-cultural norms and explain the importance of knowing these norms	16
IAC0204	Discuss ways of managing cultural diversity	24
IAC0205	Explain the concepts cultural intelligence and intercultural competence	8

3. Knowledge topic and its elements

KM-08-KT03: Problem solving and decision-making (20%)		
TOPIC ELEMENT CODE	**TOPIC ELEMENT TITLE**	**% OF TIME TO BE SPENT**
KT0301	Challenges and matters requiring a decision	20
KT0302	Problem solving techniques [may include lateral and creative thinking, scenario planning, pros and cons, risk management; 8-step problem solving process (define the problem, clarify the problem; define the goals; identify root cause of the problem; develop an action plan; execute action plan; evaluate results; improve continuously]	80

Internal Assessment Criteria (IAC) and Weight

IAC CODE	**IAC DESCRIPTION**	**% OF TIME TO BE SPENT**
IAC0301	Discuss the difference between a challenge and a matter requiring a decision, with reference to real life examples and experiences, especially in the context of a HPRA	20
IAC0302	Discuss the various problem-solving techniques to make decisions and give an indication of when each is appropriate	80

3.8.2 Criteria for accreditation

Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities – physical and/or virtual • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet, library and/or e-learning facilities • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Cartridges for printers, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers.
CONSUMABLES	• Cartridges for printers, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession accredited training in the contents of this module
FACILITATOR/LEARNER RATIO	1:25

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:20

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.8.3 Exemptions None

Practical Skill Module (PM) Specifications:

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-PM-01	Submit health product related applications to the regulatory body	5	18	face-toface/contact, online, elearning, mobile training unit, blended, distance
242213-001-00-PM-02	Conduct code compliance activities on health products	5	6	facetoface/contact, online, elearning, mobile training unit, blended, distance
242213-001-00-PM-03	Conduct oneself professionally and ethically	4	3	facetoface/contact, online, elearning, mobile training unit, blended, distance
242213-001-00-PM-04	Perform vigilance and post marketing surveillance	5	5	facetoface/contact, online, elearning, mobile training unit, blended, distance
242213-001-00-PM-05	Communicate, attend meetings and solve problems	4	8	facetoface/contact, online, elearning, mobile training unit, blended, distance

Detailing Practical Module (PM) contents

242213-001-00-PM-01: Submit health product related applications to the regulatory body, NQF Level 5, Credits 18

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-PM-01	Submit health product related applications to the regulatory body	5	18	Face-to-face, or online, or mobile training unit, or blended

3.2.1 Module Details

(a) Purpose of the Practical Skills Module:

The focus of the learning in this module is on providing the learner an opportunity to gain practical exposure and experience on how to prepare the submission of applications for registration and amendment/variation to health products, and health products establishment licensing.

Note: The type of health product will depend on the context in which the learner finds themselves (medicine, medical devices and IVDs, veterinary products, personal care products). This is because of the way the health product sector is structured; providers and companies focus on one specific health product type. It must be noted that learner will be able to do one registration or licensing submission for a single health product type.

(b) List of Practical Skill Activities:

PRACTICAL SKILL CODE	ACTIVITY TITLE
PM-01-PS01	Prepare and submit application for registration of a health product to a regulatory body
PM-01-PS02	Submit application for an amendment or variation to a registered health product
PM-01-PS03	Submit applications for licences (initial, renewal, retention and amendment)

(c) Scope of each Practical Skill Activity:

Practical Skill 1

PM-01-PS01: Prepare and submit application for registration of a health product to a regulatory body	
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE:	
Given an assignment/s to submit application for registering a health product, computer, appropriate software, internet connection, regulatory body's requirements, physical and electronic documents that will need to be uploaded, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0101	Communicate and liaise with appropriate personnel at the regulatory body
PA0102	Obtain information regarding guidelines, forms, submission dates, modes of submissions
PA0103	Perform due diligence on the health product documentation provided by a IP holder/manufacturer
PA0104	Use the guidelines to complete forms and relevant documentation
PA0105	Prepare and complete all physical and electronic documentation required by regulator for submission, according to the requirements set by the regulatory body

PA0106	Use the appropriate submission procedure/mechanism of the regulatory body for the submission
PA0107	Upload the completed dossier
PA0108	Follow-up progress of the application for registering a health product

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	APPLIED KNOWLEDGE
AK0101	Regulatory body's requirements and registration documents for specific health product
AK0102	Regulatory body's guidelines for applying to register a specific health product
AK0103	Procedures for due diligence
AK0104	Supporting documentation
AK0105	System of regulatory body to be used for submission
AK0106	Health products specifications, information etc.

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0101	Appropriate personnel at the regulatory body are contacted according to procedure and protocol and information on guidelines, forms, submission
	dates, and modes of submissions is obtained to facilitate compilation of application dossier
IAC0102	Due diligence is performed on the health product documentation provided by an IP or manufacturer according to appropriate procedures
IAC0103	Forms and relevant documentation are completed using the guidelines and advice provided by the personnel at the regulatory body
IAC0104	All supporting physical and electronic documentation required by regulator for submission, is prepared and collated according to the requirements set by a regulatory body
IAC0105	The electronic system (or appropriated submission procedure/mechanism of the regulatory body) is utilised to complete the submission and the completed dossier is uploaded

IAC0106	The progress of the application for registering a health product is monitored as per procedure stipulated by regulatory body

Practical Skills 2

PM-01-PS02: Submit application for an amendment or variation to a registered health product	
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE:	
Given a currently registered health product and a request for an amendment/ variation, computer, appropriate software, internet connection, regulatory body's requirements, the learner must be able to	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0201	Ascertain the nature and details of the amendment/variation
PA0202	Gather and collate all the required information (physical and electronic documents that will need to be uploaded)
PA0203	Prepare documentation required by the regulator according to regulator's guidelines
PA0204	Submit amendment application through regulator's systems
PA0205	Monitor the progress of the application for amendment/variation

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	APPLIED KNOWLEDGE
AK0201	Types of amendments/variations and related details
AK0202	Processes to gather and collate information
AK0203	Regulatory body's amendment/variation guidelines for submission
AK0204	Supporting documentation
AK0205	Regulatory body's submission systems (electronic systems/portals etc.)

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0201	The nature and details of the amendment/variation are ascertained using appropriate procedures and information received is gathered and collated according to required procedures
IAC0202	Forms, documentation and supporting documents are prepared according to regulator's guidelines
IAC0203	The application for amendment/variation is submitted through the regulator's established channels
IAC0204	The progress of the application for amendment/variation on registered health product is monitored as per procedure stipulated by regulatory body

Practical Skills 3

PM-01-PS03: Submit applications for licences (initial, renewal, retention and amendment)	
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE	
Given a request to apply for a licence, computer, appropriate software, internet connection, regulatory body's requirements, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0301	Obtain information from the regulator for licensing and/or renewal of licence
PA0302	Gather and collate all the relevant supporting documentation
PA0303	Complete forms and other documentation required by the regulator
PA0304	Submit application for licensing, renewals, retention, amendments to regulatory body
PA0305	Follow-up progress of applications submitted to regulatory body
PA0306	Inform appropriate stakeholders that licence has been renewed

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	APPLIED KNOWLEDGE
AK0301	Applications for licensing (initial, renewal, retention and amendment)
AK0302	Processes to gather and collate information
AK0303	Regulatory body's guidelines for licences
AK0304	Supporting documentation
AK0305	Regulatory body's submission systems (electronic systems/portals etc.)

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0301	The nature and details of application are ascertained from the regulatory body and information received is gathered and collated according to required procedures
IAC0302	Forms, documentation and supporting documents for specific type of application for licence are prepared according to regulator's guidelines
IAC0303	The applications for licences are made through the regulator's established channels

3.1.2. Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet and library • Approved learning material aligned to the QCTO curriculum • Simulated version of regulatory body's submission system/mechanism
CONSUMABLES	• Printer cartridges, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.1.3 Exemptions

None

242213-001-00-PM– 02: Conduct code compliance activities on health products, NQF Level 5, Credits 6

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-PM-02	Conduct code compliance activities on health products	5	6	face-to-face contact, online, elearning, mobile training unit, blended, distance

3.2.2 Module Details

(a) Purpose of the Practical Skills Module:

The focus of the learning in this module is on providing the learner an opportunity to gain practical exposure and experience on how to conduct code compliance activities in a HPRA and Health Products Code Compliance Officer's (HPCCO) environment.

Note: The type of health product will depend on the context in which the learner finds themselves (medicine, medical devices and IVDs, veterinary products, cosmetic products). This is because of the way the health product sector is structured.

It must be noted that a learner will be able to conduct code compliance in only one of the four sectors covered by this qualification during the training.

(b) List of Practical Skill Activities:

PRACTICAL SKILL CODE	ACTIVITY TITLE
PM-02-PS01	Ensure compliance of promotional and educational material and activities for health products with applicable code regulations

(c) Scope of each Practical Skill Activity:

Practical Skill 1

PM-02-PS01: Ensure compliance of promotional and educational material and activities for health products with applicable code regulations
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE:

Given SOPs, promotional and educational materials, activities and relevant codes, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0101	Check promotional material and activities for code compliance with the approved regulatory authority's documentation, according to SOP
PA0102	Check that the promotional materials and activities are compliant with the relevant codes
PA0103	Coordinate the internal approval process and issue certificate
PA0104	Keep and update records of checked promotional material and activities for the required period
PA0105	Handle complaints and unethical practices, and escalate complaints and unethical practices, if required, according to relevant code and SoP
PA0106	Assist in planning and preparing for meetings

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	**APPLIED KNOWLEDGE**
AK0101	Promotional and educational materials
AK0102	Regulatory body's requirements for promotional materials and a range of activities
AK0103	Administrative functions – recording, filing and updating etc.
AK0104	Period of validity of checking and sign-off
AK0105	'Handle' means receiving and lodging complaints
AK0106	Activities include CPD meetings (plan, ensure refreshments, ensure material in and out of lecture room comply), sponsoring CPD event, HCP speaking at and attending events, e.g. international conferences, and monitoring contracts with fees)
AK0107	Meetings (types of meeting, meeting agendas and time allocation for agenda items, procedures, decisions and actions; allocation of responsibilities)

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0101	Promotional and educational material and activities for health products are checked using appropriate code and SoP
IAC0102	The internal approval process is coordinated and certificates are issued according to SOP
IAC0103	Administrative records of checked promotional and educational materials and activities are kept for the required period
IAC0104	Checks and amendments on promotional materials and activities are signed –off and administrative records are appropriately filed/saved and updated as per regulatory requirements
IAC0105	Complaints are received and lodged and escalated if required according to SoP
IAC0106	Unethical practices are handled and escalated if required according to SoP
IAC0107	Meetings are planned and arranged according to procedure

3.2.2. Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM :NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet and library • Approved learning material aligned to the QCTO curriculum • Simulated version of regulatory body's submission system/mechanism
CONSUMABLES	• Printer cartridges, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.2.3 Exemptions

None **242213-001-**

00PM–03: Conduct

oneself professionally

and ethically, NQF

Level 5, Credits 3

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-PM-03	Conduct oneself professionally and ethically	4	3	facetoface/contact, online, elearning, mobile training unit, blended, distance

3.3.1 Module Details

(a) Purpose of the Practical Skills Module:

The focus of the learning in this module is on providing the learner an opportunity to gain practical exposure and experience on how to conduct oneself professionally and ethically as a HPRA, Health Products Code Compliance Officer (HPCCO) and Health Products Vigilance Officer (HPVO).

(b) List of Practical Skill Activities:

PRACTICAL SKILL CODE	ACTIVITY TITLE
PM-03-PS01	Conduct oneself professionally and ethically in a health product regulatory environment

(c) Scope of each Practical Skill Activity:

Practical Skill 1

PM-03-PS01: Conduct oneself professionally and ethically in a health product regulatory environment	
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE:	
Given a health product regulatory environment, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT	**PRACTICAL SKILL ACTIVITY ELEMENTS**

CODES	
PA0101	Behave in a professional manner
PA0102	Maintain professional appearance
PA0103	Demonstrate professional ethical conduct at all times as per relevant code of conduct
PA0104	Deal with conflict or dissatisfied people
PA0105	Deal with negative criticism
PA0106	Deal with ethical issues that are likely to come-up in the HPRA occupation
PA0107	Establish and build rapport or professional working relationships with other professionals and service providers
PA0108	Explore opportunities for professional growth

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	APPLIED KNOWLEDGE
AK0101	Professional manner (positive body language, abiding by code of conduct, being supportive and respectful, being sensitive to diversity, organisation's confidentiality requirements etc.)
AK0102	Professional appearance [clean, personal hygiene and cleanliness, oral hygiene, nails (good condition and maintained)]
AK0103	Professional ethical conduct (integrity, honesty, transparency, punctuality, open body language, respect for internal and external stakeholders, avoiding gossip, taking pride in work, punctuality, etc.)
AK0104	Continual Professional Development of a HPRA

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0101	Professionalism and ethical conducted are demonstrated in interactions with stakeholders
IAC0102	Conflict situations, negative criticism, disagreements with colleagues and/ or dissatisfied personnel are managed with professionalism

IAC0103	Ethical issues that are likely to come-up during in the HPRA occupation are dealt with professionally
IAC0104	Rapport and professional working relationships are established using appropriate communication skills and demeanour
IAC0105	A code of conduct is adhered to in order to demonstrate professionalism and strengthen sector standards
IAC0106	A range of sources is identified to demonstrate the exploration of opportunities for professional growth

3.3.2. Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet and library • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Printer cartridges, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of accredited training relevant to the contents of this module
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.3.3 Exemptions

None

242213-001-00-PM-04: Perform vigilance and post marketing surveillance, NQF Level 5, Credits 4

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-PM-04	Perform vigilance and post marketing surveillance	5	4	face-to face/contact, online, eLearning, mobile training unit, blended, distance

3.4.1 Module Details

(a) Purpose of the Practical Skills Module:

The focus of the learning in this module is on providing the learner an opportunity to gain practical exposure and experience on how to perform vigilance as a HPRA.

(b) List of Practical Skill Activities:

PRACTICAL SKILL CODE	ACTIVITY TITLE
PM-04-PS01	Perform vigilance (including post-marketing surveillance)
PM-04-PS02	Conduct product recall

(c) Scope of each Practical Skill Activity:

Practical Skill 1

PM-04-PS01: Perform vigilance (including post-marketing surveillance)	
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE:	
Given assignment to perform vigilance, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0101	Assist in completing an Adverse Reaction Report (ADR)
PA0102	Follow-up with regulatory body on submitted report
PA0103	Assist in either training internal staff or in achieving safety reporting requirements

PA0104	Assist in training staff to comply with the code

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	APPLIED KNOWLEDGE
AK0101	Adverse reaction reporting process
AK0102	Training of internal staff
AK0103	Training/presentation skills
AK0104	Reporting forms

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0101	An adverse reaction reporting form is completed and submitted as per requirements
IAC0102	Adverse report submitted to regulatory body is followed-up as per requirements
IAC0103	Training of internal staff on safety reporting requirements is conducted using appropriate training/presentation skills

Practical Skills 2

PM-04-PS02: Assist in conducting health product recall	
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE:	
Given a SoP, assignment to recall a product, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0201	Identify the type of product recall
PA0202	Follow procedures for each of type of recall
PA0203	Communicate with all internal and external stakeholders, as per SoP
PA0204	Prepare reports as per SoP in an assistive capacity
PA0205	Prepare recall letters and media releases in an assistive capacity

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	APPLIED KNOWLEDGE
AK0201	Roles of the Vigilance Officer in product recall
AK0202	Types of product recall and associated protocols
AK0203	Actions required to be completed by HPVO and HPRA
AK0204	Communication
AK0205	Recall letters and media releases

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0201	The type of product recall is identified as per regulatory issued guidelines and SoP
IAC0202	The procedures and protocols of each of type of recall is follow, as per SoP
IAC0203	All stakeholders are communicated with, as per SoP
IAC0204	Reports, recall letters and media releases are prepared as per SoP

3.4.2. Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet and library • Approved learning material aligned to the QCTO curriculum • Simulated version of regulatory body's submission system/mechanism
CONSUMABLES	• Printer cartridges, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.4.3 Exemptions

None **242213-001-**

00PM–05:

Communicate, attend

meetings and solve

problems, NQF

Level 4, Credits 8

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-PM-05	Communicate, attend meetings and solve problems	4	8	facetoface/contact, online, elearning, mobile training unit, blended, distance

3.5.1 Module details

(a) Purpose of the Practical Skills Module:

The focus of the learning in this module is on providing the learner an opportunity to gain practical exposure and experience on how to communicate and conduct oneself professional with clients in HPRA, HPCCO and HPVO contexts.

(b) List of Practical Skill Activities:

PRACTICAL SKILL CODE	ACTIVITY TITLE
PM-05-PS01	Communicate with internal and external stakeholders
PM-05-PS02	Organise and conduct meetings
PM-01-PS03	Apply problem-solving skills in a HP environment
PM-01-PS04	Manage time

(c) Scope of each Practical Skill Activity:

Practical Skill 1

PM-05-PS01: Communicate with internal and external stakeholders
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE:

Given assignments to interact with internal and external stakeholders in a health product regulatory environment, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0101	Use appropriate verbal communication techniques when interacting with internal and external stakeholders
PA0102	Use appropriate non-verbal communication techniques when interacting
PA0103	Use appropriate writing techniques when interacting with internal and external stakeholders
PA0104	Use appropriate listening skills to fully understand stakeholders
PA0105	Use appropriate telephone techniques and etiquette
PA0106	Use appropriate written formats (emails, faxes, letters, internal memorandums), language, syntax and content appropriate to the context/situation when communicating with internal and external stakeholders
PA0107	Use technical language industry/ sector jargon (used by HPRA) appropriately
PA0108	Observe organisational/industry protocols during written and oral interaction
PA0109	Overcome barriers to communication using various techniques
PA0110	All communication is conducted ethically and appropriately

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	**APPLIED KNOWLEDGE**
AK0101	Writing formats (emails, faxes, letters, internal memorandums, reports, forms, templates)
AK0102	Writing skills (use of language, formal and informal writing; syntax; appropriate content)
AK0103	Speaking (oral) skills (tone, pitch, volume and pace; appropriate protocols to suit the client; presentation skills)
AK0104	Listening skills

AK0105	Verbal communication [(speaking) manner and tone, professional, supportive, respectful, sensitive to client, open questioning related to treatment; advantages (quick, instant response, client body language); Disadvantages – no written record, no time to consider, no paper trail)]
AK0106	Non-verbal communication [eye contact, body language, listening; advantages (written communication, detailed, recorded, clear, specific, opportunity to consider, paper trail); disadvantages (written communication, cannot see reaction, cannot change mind, no opportunity for discussion); body language - expression of feelings, easily identify anger, happiness, confusion but cannot hide feelings, can be a barrier.]
AK0107	Technical language and industry/ sector jargon used by a HPRA
AK0108	Company/organisational/sector-specific protocols for written and oral interactions
AK0109	Barriers to communication
AK0110	Diversity of clients

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0101	Appropriate verbal and non-verbal communication techniques are employed when interacting with stakeholders
IAC0102	Listening skills are employed to establish rapport with stakeholders and to understand stakeholders' requirements
IAC0103	Appropriate writing skills are employed in communication with stakeholders
IAC0104	Appropriate written formats are used for the situation/context
IAC0105	Written communication is clear, concise, accurate, spell checked and complies with rules of grammar and syntax
IAC0106	Content and layout of written communication complies with organisation's requirements
IAC0107	Telephone techniques and etiquette are appropriate to the task being performed
IAC0108	Organisation protocols are observed during interaction with client
IAC0109	Technical language and sector jargon are used appropriately and explained to client

IAC0110	Communication techniques show that barriers to communication have been overcome
IAC0111	Ethical values of the company/organisation are demonstrated in communication with client

Practical Skills 2

PM-01-PS02: Organise and attend meetings	
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE:	
Given assignment to organise and attend a meeting, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0201	Identify attendees for type of meeting
PA0202	Make physical and logistical arrangements for the meeting
PA0203	Prepare and circulate agenda, indicating date and time, agenda items and associated time allocations, expected outcomes, presentations, names of presenters, time slots, decisions to be taken etc.
PA0204	Obtain comments on the agenda and amend accordingly
PA0205	Conduct a meeting according to meeting procedure, protocols and etiquette
PA0206	Ensure meeting is recorded and minutes are taken
PA0207	Make a presentation at the meeting
PA0208	Meeting is concluded

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	APPLIED KNOWLEDGE
AK0201	Meeting preparation (physical arrangements and attendees; placing items on the agenda and the roles of participants; agenda and expected outcomes of the meeting; document pack; minutes of previous meeting)

AK0202	Conducting a meeting (effective participation by people through opportunities created; summary and recording of discussions (minutes); dealing with differing views; records compiled and checked)
AK0203	Meeting protocols; language; etc.
AK0204	Minutes (recording, sign-off)
AK0205	Presentation techniques

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0201	The attendees are identified depending on type and purpose of meeting
IAC0202	An agenda is prepared, distributed and amended as per comments received
IAC0203	Logistical arrangements are made according to meeting type and agenda
IAC0204	A meeting is conducting using appropriate procedures, protocols and etiquette
IAC0205	Presentation is made using appropriate techniques and technology
IAC0206	Meeting is closed according to protocol

Practical Skills 3

PM-01-PS03: Apply problem-solving skills to HPRA-related situations	
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE	
Given a problem likely to take place in a work situation, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0301	Identify and analyse the nature of the problem
PA0302	Use appropriate problem-solving techniques
PA0303	Use 8-step problem-solving process
PA0304	Make a decision, if required

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	APPLIED KNOWLEDGE
AK0301	Problem definition
AK0302	Problem solving techniques (lateral and creative thinking, scenario planning, pros and cons, risk management)
AK0303	8-step problem solving process

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0301	Problem is identified and analysed
IAC0302	Problem-solving techniques are used to deepen understanding of the problem
IAC0303	Problem-solving process is employed to resolve the problem and chart a way forward
IAC0304	A decision is made after following the problem-solving process

Practical Skill 4

PM-01-PS04: Manage time	
PRACTICAL SKILL ACTIVITY SCOPE OUTLINE	
Given a simulated HPRA environment, the learner must be able to:	
PRACTICAL SKILL ACTIVITY ELEMENT CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
PA0401	Highlight points in the workflow where time management is particularly crucial or difficult
PA0402	Select from a range of different time-management techniques those most appropriate for self and the specific circumstances of working in a HPRA environment
PA0403	Prioritise own tasks decisively and flexibly in the context of a HPRA environment
PA0404	Communicate effectively with team to ensure that work is completed within given timeframes

Applied Knowledge that underpins the Practical Skill

APPLIED KNOWLDEGE CODE	APPLIED KNOWLEDGE
AK0401	Repertoire of time planning and time management techniques
AK0402	Production or workflow, deadline structure, and responsibilities of colleagues and other role-players
AK0403	Workflow timeframes and how these may create conflict
AK0404	Prioritisation of tasks
AK0405	Time wasters

Internal Assessment Criteria (IAC)

IAC CODE	IAC DESCRIPTION
IAC0401	A flowchart of the production or work cycle is drawn and bottlenecks and stress points are highlighted and analysed
IAC0402	Different time-management techniques are employed to achieve targets
IAC0403	Tasks are prioritised using urgent and important categories
IAC0404	Time wasters are identified and measures are taken to prevent them

3.5.2. Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM :NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Appropriate and equipped training facilities • Computers to prepare notes, presentations and for learners to do research etc. • Access to internet and library • Approved learning material aligned to the QCTO curriculum
CONSUMABLES	• Printer cartridges, etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges, etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Facilitator must be in possession of accredited training relevant to the contents of this module
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.5.3 Exemptions None

WORK EXPERIENCE MODULE (WM) SPECIFICATIONS:

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-01	Processes to submit health product registration or licensing applications to a regulatory authority	5	20	On the job/Simulation
242213-001-00-WM-02	Processes to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product	5	8	On the job/Simulation
242213-001-00-WM-03	Processes to submit the health product establishment's licensing applications to a regulatory authority	5	8	On the job/Simulation
242213-001-00-WM-04	Processes to conduct code compliance activities on health products	5	6	On the job/Simulation
242213-001-00-WM-05	Processes to perform vigilance and post marketing surveillance	5	6	On the job/Simulation

Detailing Work Experience Module (WM) contents

242213-001-00-WM-01, Processes to submit health product registration or licensing applications to a regulatory authority, NQF Level 5, Credits 20

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-01	Processes to submit health product registration or licensing applications to a regulatory authority	5	20	On the job/Simulation

3.1.1 Module Details

(a) Purpose of the Work Experience Module:

The focus of the work experience is on providing the learner an opportunity to gain structured experience under guidance of a qualified and/or experienced HPRA, Responsible Pharmacist (RP) or Authorised Representative (AR) on submission of a health product registration or licensing application to a regulatory authority.

The work experience activities in this module may be simulated in view of the fact that access to HPRA environments may be restricted and limited for a variety of reasons, *inter alia*, intellectual property, limited number of accredited HPRA environments etc.

As far as possible, simulation must be as close to the real HPRA environment in terms of operation systems being in place, expected work rate, outputs, time constraints and other work-related pressures. The learner must emerge from this work experience having a clear idea of what it is like to operate in a 'live' HPRA environment.

As far as work experience is concerned, it is common practice to, firstly, allow the learner to observe and assist a qualified and experienced HPRA, Responsible Pharmacist or Authorised Representative, then secondly, to perform the tasks in this module under strict supervision and, finally, to perform the tasks in this module independently but subject to final check by supervisor/ mentor.

It is also possible to adopt a hybrid approach. A learner may get direct exposure to a live and authentic work environment during which some or many of the work activities may be completed. The learner can then receive the rest of the work experience through simulation. The intent is to expose the learner to all the activities in this module either through 'live' experience or simulation or both.

(b) List of Work Experience Competencies:

WORK EXPERIENCE CODE	WORK EXPERIENCE COMPETENCY TITLE
WM-01-WE01	Submit applications for registering or licensing a health product to a regulatory authority, under guidance of qualified and/or experienced HPRA/RP/AR
WM-01-WE02	Submit applications for registering or licensing a health product to a regulatory authority independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR

(c) Scope of each Work Experience Competency:

Work Experience 1

WM-01-WE01: Submit applications for registering or licensing a health product to a regulatory authority, under guidance of qualified and/or experienced HPRA/RP/AR	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE	
Given the opportunity to submit applications for registering or licensing a health product to a regulatory authority, under guidance of qualified and/or experienced HPRA/RP/AR, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0101	Communicate and liaise with appropriate personnel at a regulatory authority regarding submitting applications for registering or licensing a health product
WA0102	Perform due diligence on the health product documentation provided by a IP holder/manufacturer
WA0103	Compile and complete all documentation required by regulator for the submissions, according to the requirements set by a regulatory authority
WA0104	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for registration or licensing of a health product
WA0105	Monitor the progress of the application for registration or licensing of a heal product and compile and complete responses to regulatory authority's recommendations

WORK EXPERIENCE CODES	**SUPPORTING EVIDENCE**
SE0101	Completed health product registration or licensing application

Work Experience 2

WM-01-WE02: Submit applications for registering or licensing a health product to a regulatory authority independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE:

Given the opportunity to submit applications for registering or licensing a health product to a regulatory authority independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0201	Communicate and liaise with appropriate personnel at a regulatory authority regarding submitting applications for registering or licensing a health product
WA0202	Perform due diligence on the health product documentation provided by a IP holder/manufacturer
WA0203	Compile and complete all documentation required by regulator for the submissions, according to the requirements set by a regulatory authority
WA0204	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for registration or licensing of a health product
WA0205	Monitor the progress of the application for registration or licensing of a heal product and compile and complete responses to regulatory authority's recommendations

Supporting evidence

WORK EXPERIENCE CODES	**SUPPORTING EVIDENCE**
SE0201	Completed health product registration or licensing application

Contextualised Workplace Knowledge

WORKPLACE KNOWLEDGE	
1	Organisational policies and procedures
2	Work instructions, checklists, specifications and standards, procedures, templates
3	Organisation specific quality management system
4	Electronic systems for dossier submission

3.1.2 Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM :NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Computers • Access to the internet • Simulated version of regulatory submission system/mechanism body's
CONSUMABLES	• Printer cartridges etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Supervisor must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.1.3 Exemptions

None

3.1.4 Additional Assignments to be Assessed Externally

None

242213-001-00-WM-02, Processes to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product, NQF Level 5, Credits 8

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-02	Processes to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product	5	8	On the job/Simulation

3.2.1 Module Details

(a) Purpose of the Work Experience Module:

The focus of the work experience is on providing the learner an opportunity to gain structured experience under guidance of a qualified and/or experienced HPRA, RP or AR to submit an application for amendment/variation to a registered or licensed health product to a regulatory authority.

The work experience activities in this module may be simulated in view of the fact that access to HPRA environments may be restricted and limited for a variety of reasons, *inter alia*, intellectual property, limited number of accredited HPRA environments etc.

As far as possible, simulation must be as close to the real HPRA environment in terms of operation systems being in place, expected work rate, outputs, time constraints and other work-related pressures. The learner must emerge from this work experience having a clear idea of what it is like to operate in a 'live' HPRA environment.

As far as work experience is concerned, it is common practice to, firstly, allow the learner to observe and assist a qualified and experienced HPRA, Responsible Pharmacist or Authorised Representative, then secondly, to perform the tasks in this module under strict supervision and, finally, to perform the tasks in this module independently but subject to final check by supervisor/ mentor.

It is also possible to adopt a hybrid approach. A learner may get direct exposure to a live and authentic work environment during which some or many of the work activities may be completed. The learner can then receive the rest of the work experience through simulation. The intent is to expose the learner to all the activities in this module either through 'live' experience or simulation or both.

(b) **List of Work Experience Competencies:**

WORK EXPERIENCE CODE	WORK EXPERIENCE COMPETENCY TITLE
WM-02-WE01	Observe and assist a qualified and/or experienced HPRA/RP/AR to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product
WM-02-WE02	Submit to a regulatory authority an application for amendment/variation to a registered or licensed health product under guidance of qualified and/or experienced HPRA/RP/AR
WM-02-WE03	Submit to a regulatory authority an application for amendment/variation to a registered or licensed health product independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR

(c) Scope of each Work Experience Competency:

Work Experience 1

WM-02-WE01: Observe and assist a qualified and/or experienced HPRA/RP/AR to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE	
Given the opportunity to observe and assist a qualified and/or experienced HPRA/RP/AR to submit to a regulatory authority an application for amendment/variation, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0101	Ascertain the nature and details of the amendment/variation
WA0102	Perform due diligence on the health product documentation provided by a IP holder/manufacturer
WA0103	Compile and complete all documentation required by regulator for the submission of an application for amendment/variation, according to the requirements set by a regulatory authority
WA0104	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for amendment/variation to a health product
WA0105	Monitor the progress of the application for amendment/variation to a health product and compile and complete responses to regulatory authority's recommendations

WORK EXPERIENCE CODES	**SUPPORTING EVIDENCE**
SE0101	Observation checklist to be signed off by supervisor
SE0102	Completed application for amendment/variation to a registered or licensed health product

Work Experience 2

WM-02-WE02: Submit to a regulatory authority an application for amendment/variation to a registered or licensed health product under guidance of qualified and/or experienced HPRA/RP/AR
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE:

Given the opportunity to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product under guidance of qualified and/or experienced HPRA/RP/AR, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0201	Ascertain the nature and details of the amendment/variation
WA0202	Perform due diligence on the health product documentation provided by a IP holder/manufacturer
WA0203	Compile and complete all documentation required by regulator for the submission of an application for amendment/variation, according to the requirements set by a regulatory authority
WA0204	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for amendment/variation to a health product
WA0205	Monitor the progress of the application for amendment/variation to a health product and compile and complete responses to regulatory authority's recommendations

Supporting evidence

WORK EXPERIENCE CODES	**SUPPORTING EVIDENCE**
SE0201	Completed application for amendment/variation to a registered or licensed health product

Work Experience 3

WM-02-WE03: Submit to a regulatory authority an application for amendment/variation to a registered or licensed health product independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE:	
Given the opportunity to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**

WA0301	Ascertain the nature and details of the amendment/variation
WA0302	Perform due diligence on the health product documentation provided by a IP holder/manufacturer
WA0303	Compile and complete all documentation required by regulator for the submission of an application for amendment/variation, according to the requirements set by a regulatory authority
WA0304	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for amendment/variation to a health product
WA0305	Monitor the progress of the application for amendment/variation to a health product and compile and complete responses to regulatory authority's recommendations

Supporting evidence

WORK EXPERIENCE CODES	SUPPORTING EVIDENCE
SE0301	Completed application for amendment/variation to a registered or licensed health product

Contextualised Workplace Knowledge

	WORKPLACE KNOWLEDGE
1	Organisational policies and procedures
2	Work instructions, checklists, specifications and standards, procedures, templates
3	Organisation specific quality management system
4	Electronic systems for dossier submission

3.1.2 Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM :NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Computers • Access to the internet • Simulated version of regulatory body's submission system/mechanism
CONSUMABLES	• Printer cartridges etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Supervisor must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.2.3 Exemptions

None

3.2.4 Additional Assignments to be Assessed Externally

None

242213-001-00-WM-03, Processes to submit the health product establishment's licensing applications to a regulatory authority, NQF Level 5, Credits 8

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-03	Processes to submit the health product establishment's licensing applications to a regulatory authority	5	8	On the job/Simulation

3.3.1 Module Details

(a) Purpose of the Work Experience Module:

The focus of the work experience is on providing the learner an opportunity to gain structured experience under guidance of a qualified and/or experienced HPRA/RP/AR to submit the health product establishment's licensing applications to a regulatory authority.

The work experience activities in this module may be simulated in view of the fact that access to HPRA environments may be restricted and limited for a variety of reasons, *inter alia*, intellectual property, limited number of accredited HPRA environments etc.

As far as possible, simulation must be as close to the real HPRA environment in terms of operation systems being in place, expected work rate, outputs, time constraints and other work-related pressures. The learner must emerge from this work experience having a clear idea of what it is like to operate in a 'live' HPRA environment.

As far as work experience is concerned, it is common practice to, firstly, allow the learner to observe and assist a qualified and experienced HPRA, Responsible Pharmacist or Authorised Representative, then secondly, to perform the tasks in this module under strict supervision and, finally, to perform the tasks in this module independently but subject to final check by supervisor/ mentor.

It is also possible to adopt a hybrid approach. A learner may get direct exposure to a live and authentic work environment during which some or many of the work activities may be completed. The learner can then receive the rest of the work experience through simulation. The intent is to expose the learner to all the activities in this module either through 'live' experience or simulation or both.

(b) **List of Work Experience Competencies:**

WORK EXPERIENCE CODE	WORK EXPERIENCE COMPETENCY TITLE
WM-03-WE01	Submit health product establishment's licencing applications to a regulatory authority, under guidance of qualified and/or experienced HPRA/RP/AR
WM-03-WE02	Submit health product establishment's licencing applications to a regulatory authority independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR

(c) Scope of each Work Experience Competency:

Work Experience 1

WM-03-WE01: Submit health product establishment's licencing applications to a regulatory authority, under guidance of qualified and/or experienced HPRA/RP/AR	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE	
Given the opportunity to submit health product establishment's licencing applications to a regulatory authority, under guidance of qualified and/or experienced HPRA/RP/AR, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0101	Prepare documentation required by the regulator according to regulator's guidelines
WA0102	Use the appropriate submission procedure/mechanism of a regulatory authority to submit health product establishment's licencing applications (initial, renewal, retention and amendment)
WA0103	Monitor the progress of a health product establishment's licencing applications and compile and complete responses to regulatory authority's recommendations
WA0104	Set-up and maintain a documentation system

WORK EXPERIENCE CODES	SUPPORTING EVIDENCE
SE0101	Completed application for renewal of licence for health products

Work Experience 2

WM-03-WE02: Submit health product establishment's licencing applications to a regulatory authority independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE:	
Given the opportunity to submit health product establishment's licencing applications to a regulatory authority independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0201	Prepare documentation required by the regulator according to regulator's guidelines
WA0202	Use the appropriate submission procedure/mechanism of a regulatory authority to submit health product establishment's licencing applications (initial, renewal, retention and amendment)
WA0203	Monitor the progress of a health product establishment's licencing applications and compile and complete responses to regulatory authority's recommendations
WA0204	Set-up and maintain a documentation system

Supporting evidence

WORK EXPERIENCE CODES	**SUPPORTING EVIDENCE**
SE0201	Completed application for renewal of licence for health products

Contextualised Workplace Knowledge

WORKPLACE KNOWLEDGE	
1	Organisational policies and procedures
2	Work instructions, checklists, specifications and standards, procedures, templates
3	Organisation specific quality management system
4	Electronic systems for submissions for variations, amendments, renewals, retentions

3.3.2 Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Computers • Access to the internet • Simulated version of body's regulatory submission system/mechanism
CONSUMABLES	• Printer cartridges etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Supervisor must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.3.3 Exemptions

None

3.3.4 Additional Assignments to be Assessed Externally

None

242213-001-00-WM-04, Processes to conduct code compliance activities on health products, NQF Level 5, Credits 6

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-04	Processes to conduct code compliance activities on health products	5	6	On the job/Simulation

3.4.1 Module Details

(a) Purpose of the Work Experience Module:

The focus of the work experience is on providing the learner an opportunity to gain structured experience under guidance of a qualified and/or experienced HPRA/RP/AR/ Health Product Code Compliance Officer (HPCCO) to conduct code compliance activities on health products.

The work experience activities in this module may be simulated in view of the fact that access to HPRA environments may be restricted and limited for a variety of reasons, *inter alia*, intellectual property, limited number of accredited HPRA environments etc.

As far as possible, simulation must be as close to the real HPRA environment in terms of operation systems being in place, expected work rate, outputs, time constraints and other work-related pressures. The learner must emerge from this work experience having a clear idea of what it is like to operate in a 'live' HPRA environment.

As far as work experience is concerned, it is common practice to, firstly, allow the learner to observe and assist a qualified and experienced HPRA, Responsible Pharmacist, Authorised Representative or HPCCO, then secondly, to perform the tasks in this module under strict supervision and, finally, to perform the tasks in this module independently but subject to final check by supervisor/ mentor.

It is also possible to adopt a hybrid approach. A learner may get direct exposure to a live and authentic work environment during which some or many of the work activities may be completed. The learner can then receive the rest of the work experience through simulation. The intent is to expose the learner to all the activities in this module either through 'live' experience or simulation or both.

(b) **List of Work Experience Competencies:**

WORK EXPERIENCE CODE	WORK EXPERIENCE COMPETENCY TITLE
WM-04-WE01	Observe and assist a qualified and/or experienced HPRA/RP/AR/HPCCO to conduct code compliance activities on a health product
WM-04-WE02	Conduct code compliance activities on a health product under guidance of qualified and/or experienced HPRA/RP/AR/HPCCO
WM-04-WE03	Conduct code compliance activities on a health product independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR/HPCCO

(c) Scope of each Work Experience Competency:

Work Experience 1

WM-04-WE01: Observe and assist a qualified and/or experienced HPRA/RP/AR/HPCCO to conduct code compliance activities on a health product	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE	
Given the opportunity to observe and assist a qualified and/or experienced HPRA/RP/AR/HPCCO to conduct code compliance activities on a health product, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0101	Check promotional and educational materials for accuracy of both content (including technical details) and artwork of health product, as per SoP
WA0102	Check that the promotional activities are compliant with the relevant codes, as per SoP
WA0103	Approve materials and activities, file and update records of checked promotional and educational material for the required period, as per SoP
WA0104	Handle incoming and outgoing complaints and unethical practices, and escalate them, if required, according to relevant code and SoP
WA0105	Review company SoP against local and international codes and practices, suggest updates to the SoP and identify differences between them

WORK EXPERIENCE CODES	SUPPORTING EVIDENCE
SE0101	Observation checklist to be signed off by supervisor

SE0102	Approved promotional and educational materials and activities for health product

Work Experience 2

WM-04-WE02: Conduct code compliance activities on a health product under guidance of qualified and/or experienced HPRA/RP/AR/HPCCO	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE:	
Given the opportunity to conduct code compliance activities on a health product under guidance of qualified and/or experienced HPRA/RP/AR/HPCCO, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0201	Check promotional and educational materials for accuracy of both content (including technical details) and artwork of health product, as per SoP
WA0202	Check that the promotional activities are compliant with the relevant codes, as per SoP
WA0203	Approve materials and activities, file and update records of checked promotional and educational material for the required period, as per SoP
WA0204	Handle incoming and outgoing complaints and unethical practices, and escalate them, if required, according to relevant code and SoP
WA0205	Review company SoP against local and international codes and practices, suggest updates to the SoP and identify differences between them

Supporting evidence

WORK EXPERIENCE CODES	**SUPPORTING EVIDENCE**
SE0201	Approved promotional and educational materials and activities for health product

Work Experience 3

WM-04-WE03: Conduct code compliance activities on a health product independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR/HPCCO
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE:

Given the opportunity to conduct code compliance activities on a health product independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR/HPCCO, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0301	Check promotional and educational materials for accuracy of both content (including technical details) and artwork of health product, as per SoP
WA0302	Check that the promotional activities are compliant with the relevant codes, as per SoP
WA0303	Approve materials and activities, file and update records of checked promotional and educational material for the required period, as per SoP
WA0304	Handle incoming and outgoing complaints and unethical practices, and escalate them, if required, according to relevant code and SoP
WA0305	Review company SoP against local and international codes and practices, suggest updates to the SoP and identify differences between them

Supporting evidence

WORK EXPERIENCE CODES	**SUPPORTING EVIDENCE**
SE0301	Approved promotional and educational materials and activities for health product

Contextualised Workplace Knowledge

WORKPLACE KNOWLEDGE	
1	Organisational policies and procedures
2	Work instructions, checklists, specifications and standards, procedures, templates
3	Organisation specific quality management system

3.4.2 Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Computers • Access to the internet • Simulated version of regulatory submission system/mechanism body's
CONSUMABLES	• Printer cartridges etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities
	• Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Supervisor must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.4.3 Exemptions

None

3.4.4 Additional Assignments to be Assessed Externally

None

242213-001-00-WM-05, Processes to perform vigilance and post marketing surveillance, NQF Level 5, Credits 6

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-05	Processes to perform vigilance and post marketing surveillance	5	6	On the job/Simulation

3.5.1 Module Details

(a) Purpose of the Work Experience Module:

The focus of the work experience is on providing the learner an opportunity to gain structured experience under guidance of a qualified and/or experienced HPRA/RP/AR/Health Products Vigilance Officer (HPVO) to perform vigilance and post marketing surveillance.

The work experience activities in this module may be simulated in view of the fact that access to HPRA environments may be restricted and limited for a variety of reasons, *inter alia*, intellectual property, limited number of accredited HPRA environments etc.

As far as possible, simulation must be as close to the real HPRA environment in terms of operation systems being in place, expected work rate, outputs, time constraints and other work-related pressures. The learner must emerge from this work experience having a clear idea of what it is like to operate in a 'live' HPRA environment.

As far as work experience is concerned, it is common practice to, firstly, allow the learner to observe and assist a qualified and experienced HPRA, Responsible Pharmacist, Authorised Representative or HPVO, then secondly, to perform the tasks in this module under strict supervision and, finally, to perform the tasks in this module independently but subject to final check by supervisor/ mentor.

It is also possible to adopt a hybrid approach. A learner may get direct exposure to a live and authentic work environment during which some or many of the work activities may be completed. The learner can then receive the rest of the work experience through simulation. The intent is to expose the learner to all the activities in this module either through 'live' experience or simulation or both.

(b) **List of Work Experience Competencies:**

WORK EXPERIENCE CODE	WORK EXPERIENCE COMPETENCY TITLE
WM-05-WE01	Observe a qualified and/or experienced HPRA/RP/AR/HPVO to perform vigilance and post marketing surveillance
WM-05-WE02	Perform vigilance and post marketing surveillance under guidance of qualified and/or experienced HPRA/RP/AR/HPVO
WM-05-WE03	Perform vigilance and post marketing surveillance independently but subject to final check by qualified and/or experienced HPRA/RP/AR/HPVO

(c) Scope of each Work Experience Competency:

Work Experience 1

WM-05-WE01: Observe a qualified and/or experienced HPRA/RP/AR/HPVO to perform vigilance and post marketing surveillance	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE	
Given the opportunity to observe a qualified and/or experienced HPRA/RP/AR/HPVO to perform vigilance and post marketing surveillance, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**

WA0101	Handle adverse event reporting as per SoP or regulatory authority's guidance document and/or software application
WA0102	Handle product recall as per SoP or regulatory authority's guidance document

WORK EXPERIENCE CODES	SUPPORTING EVIDENCE
SE0101	Observation checklist to be signed off by supervisor
SE0102	Adverse reaction report
SE0103	Product recall report

Work Experience 2

WM-05-WE02: Perform vigilance and post marketing surveillance under guidance of qualified and/or experienced HPRA/RP/AR/HPVO	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE:	
Given the opportunity to perform vigilance and post marketing surveillance under guidance of qualified and/or experienced HPRA/RP/AR/HPVO, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0201	Handle adverse event reporting as per SoP or regulatory authority's guidance document and/or software application
WA0202	Handle product recall as per SoP or regulatory authority's guidance document

Supporting evidence

WORK EXPERIENCE CODES	SUPPORTING EVIDENCE
SE0201	Adverse reaction report
SE0202	Product recall report

Work Experience 3

WM-05-WE03: Perform vigilance and post marketing surveillance independently but subject to final check by qualified and/or experienced HPRA/RP/AR/HPVO	
WORKPLACE EXPERIENCE COMPETENCY SCOPE OUTLINE:	
Given the opportunity to perform vigilance and post marketing surveillance under guidance of qualified and/or experienced HPRA/RP/AR/HPVO, the learner will be able to:	
WORK EXPERIENCE COMPETENCY ELEMENT CODES	**WORK EXPERIENCE COMPETENCY ELEMENTS**
WA0301	Handle adverse event reporting as per SoP or regulatory authority's guidance document and/or software application
WA0302	Handle product recall as per SoP or regulatory authority's guidance document

Supporting evidence

WORK EXPERIENCE CODES	**SUPPORTING EVIDENCE**
SE0301	Adverse reaction report
SE0302	Product recall report

Contextualised Workplace Knowledge

WORKPLACE KNOWLEDGE	
1	Organisational policies and procedures
2	Work instructions, checklists, specifications and standards, procedures, templates
3	Organisation specific quality management system

3.5.2 Criteria for accreditation

Add additional line spaces as required. Requirements, against which Skills Development Providers (SDP) and Assessment Centres, will be accredited, as listed below.

Physical Requirements:

SKILLS DEVELOPM :NT PROVIDER (SDP)	
EQUIPMENT & TOOLS	• Computers • Access to the internet • Simulated version of regulatory submission system/mechanism body's
CONSUMABLES	• Printer cartridges etc.

ASSESSMENT CENTRE	
EQUIPMENT & TOOLS	• Appropriate and equipped assessment facilities • Access to internet, computers, etc.
CONSUMABLES	• Printer cartridges etc.

Human Resource Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
QUALIFICATIONS & EXPERIENCE	• Supervisor must be in possession of a NQF Level 6 health products regulatory or related qualification, and • Must have 2 years' experience working in the health products regulatory environment
FACILITATOR/LEARNER RATIO	1:12

ASSESSMENT CENTRE	
QUALIFICATIONS & EXPERIENCE	• Individual experienced in administering assessments
FACILITATOR/LEARNER RATIO	1:5

Legal Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)	
	Compliance with the OHS Act

ASSESSMENT CENTRE	
	Compliance with the OHS Act

Additional Requirements:

SKILLS DEVELOPMENT PROVIDER (SDP)
None

ASSESSMENT CENTRE
N/A

3.5.3 Exemptions

None

3.5.4 Additional Assignments to be Assessed Externally

None

3.4 POSSIBLE SEQUENCING AND INTEGRATION

Listing and order of modules in the sequence in which these modules will follow each other during delivery/implementation. This allows for integration of KM, AM (PM/ WM) as work logically flows.

ORDER	MODULE TITLE	MODULE CODE	LEVEL	CREDITS
1.	Overview of current health products industry/sector	242213-001-00-00-KM-01	5	5
2.	Anatomy and physiology	242213-001-00-00-KM-02	5	10
3.	Health products	242213-001-00-00-KM-03	5	8
4.	Science for the Health Product Regulatory Assistant (HPRA)	242213-001-00-00-KM-04	5	3
5.	Registrations, licensing, applications, and submissions	242213-001-00-00-KM-06	5	8
6.	Submit health product related applications to the regulatory body	242213-001-00-PM-01	5	18
7.	Processes to submit health product registration or licensing applications to a regulatory authority	242213-001-00-WM-01	5	20
8.	Processes to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product	242213-001-00-WM-02	5	8
9.	Processes to submit the health product establishment's licensing applications to a regulatory authority, NQF Level 5, Credits 8	242213-001-00-WM-03	5	8
10.	Codes of Practice for HPRAs	242213-001-00-00-KM-05	5	3
11.	Conduct compliance activities on health products	242213-001-00-PM-02	5	6
12.	Processes to conduct code compliance activities on health products	242213-001-00-WM-04	5	6
13.	Vigilance and post marketing surveillance	243302-001-00-KM-07	5	6

14.	Perform vigilance and post marketing surveillance	242213-001-00-PM-04	5	5
ORDER	**MODULE TITLE**	**MODULE CODE**	**LEVEL**	**CREDITS**
15.	Processes to perform vigilance and post marketing surveillance	242213-001-00-WM-05	5	6
16.	Professional conduct	242213-001-00-KM-08	4	3
17.	Conduct oneself professionally and ethically	242213-001-00-PM-03	4	3
18.	Communicate, attend meetings and solve problems	242213-001-00-PM-05	4	8

SECTION 4. STATEMENT OF WORK EXPERIENCE

QUALIFICATION	QUALIFICATION TITLE/DESCRIPTOR	NQF LEVEL	CREDITS
Higher Occupational Certificate	Health Products Regulatory Assistant (HPRA)	5	134

CURRICULUM CODE	242213-001-00

LEARNER DETAILS

NAME:	
ID NUMBER:	

EMPLOYER DETAILS

COMPANY NAME:	
ADDRESS:	
SUPERVISOR NAME:	
WORK TELEPHONE:	
E-MAIL:	

242213-001-00-WM-01, Processes to submit health product registration or licensing applications to a regulatory authority, NQF Level 5, Credits 20

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-01	Processes to submit health product registration or licensing applications to a regulatory authority	5	20	face-to-face/ contact, online, elearning, mobile training unit, blended, distance, etc.

WORK EXPERIENCE MODULE DETAILS

WM-01-WE01: Submit applications for registering or licensing a health product to a regulatory authority, under guidance of qualified and/or experienced HPRA/RP/AR

WM-01-WE01	SCOPE WORK EXPERIENCE	DATE	SIGNATURE
WA0101	Communicate and liaise with appropriate personnel at a regulatory authority regarding submitting applications for registering or licensing a health product		
WA0102	Perform due diligence on the health product documentation provided by an IP holder/manufacturer		
WA0103	Compile and complete all documentation required by regulator for the submissions, according to the requirements set by a regulatory authority		
WA0104	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for registration or licensing of a health product		
WA0105	Monitor the progress of the application for registration or licensing of a heal product and compile and complete responses to regulatory authority's recommendations		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0101	Completed health product registration or licensing application		

WM-01-WE02: Submit applications for registering or licensing a health product to a regulatory authority independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR			
WM-01-WE02	**SCOPE WORK EXPERIENCE**	**DATE**	**SIGNATURE**
WA0201	Communicate and liaise with appropriate personnel at a regulatory authority regarding submitting applications for registering or licensing a health product		
WA0202	Perform due diligence on the health product documentation provided by a IP holder/manufacturer		
WA0203	Compile and complete all documentation required by regulator for the submissions, according to the requirements set by a regulatory authority		
WA0204	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for registration or licensing of a health product		
WA0205	Monitor the progress of the application for registration or licensing of a heal product and compile and complete responses to regulatory authority's recommendations		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0201	Completed health product registration or licensing application		

NUMBER	**CONTEXTUALISED WORKPLACE KNOWLEDGE**	**DATE**	**SIGNATURE**
1.	Organisational policies and procedures		
2.	Work instructions, checklists, specifications and standards, procedures, templates		
3.	Organisation specific quality management system		
4.	Electronic systems for dossier submission		
NUMBER	**ADDITIONAL ASSIGNMENTS TO BE ASSESSED EXTERNALLY**	**DATE**	**SIGNATURE**
1.	**None**		

42213-001-00-WM-02, Processes to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product, NQF Level 5, Credits 8

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-02	Processes to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product	5	8	face-to-face/ contact, online, elearning, mobile training unit, blended, distance, etc.

WORK EXPERIENCE MODULE DETAILS			
WM-02-WE01: Observe and assist a qualified and/or experienced HPRA/RP/AR to submit to a regulatory authority an application for amendment/variation to a registered or licensed health product			
WM-02-WE01	**SCOPE WORK EXPERIENCE**	**DATE**	**SIGNATURE**
WA0101	Ascertain the nature and details of the amendment/variation		
WA0102	Perform due diligence on the health product documentation provided by a IP holder/manufacturer		
WA0103	Compile and complete all documentation required by regulator for the submission of an application for amendment/variation, according to the requirements set by a regulatory authority		
WA0104	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for amendment/variation to a health product		
WA0105	Monitor the progress of the application for amendment/variation to a health product and compile and complete responses to regulatory authority's recommendations		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0101	Observation checklist to be signed off by supervisor		

SE0102	Completed application for amendment/variation to a registered or licensed health product		

WM-02-WE02: Submit to a regulatory authority an application for amendment/variation to a registered or licensed health product under guidance of qualified and/or experienced HPRA/RP/AR

WM-02-WE02	SCOPE WORK EXPERIENCE	DATE	SIGNATURE
WA0201	Ascertain the nature and details of the amendment/variation		
WA0202	Perform due diligence on the health product documentation provided by a IP holder/manufacturer		
WA0203	Compile and complete all documentation required by regulator for the submission of an application for amendment/variation, according to the requirements set by a regulatory authority		
WA0204	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for amendment/variation to a health product		
WA0205	Monitor the progress of the application for amendment/variation to a health product and compile and complete responses to regulatory authority's recommendations		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0201	Completed application for amendment/variation to a registered or licensed health product		

WM-02-WE03: Submit to a regulatory authority an application for amendment/variation to a registered or licensed health product independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR

WM-02-WE03	SCOPE WORK EXPERIENCE	DATE	SIGNATURE
WA0301	Ascertain the nature and details of the amendment/variation		
WA0302	Perform due diligence on the health product documentation provided by a IP holder/manufacturer		

WA0303	Compile and complete all documentation required by regulator for the submission of an application for amendment/variation, according to the requirements set by a regulatory authority		
WA0304	Use the appropriate submission procedure/mechanism of a regulatory authority for the submission of an application for amendment/variation to a health product		
WA0305	Monitor the progress of the application for amendment/variation to a health product and compile and complete responses to regulatory authority's recommendations		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0301	Completed application for amendment/variation to a registered or licensed health product		

NUMBER	**CONTEXTUALISED WORKPLACE KNOWLEDGE**	**DATE**	**SIGNATURE**
1.	Organisational policies and procedures		
2.	Work instructions, checklists, specifications and standards, procedures, templates		
3.	Organisation specific quality management system		
4.	Electronic systems for dossier submission		
NUMBER	**ADDITIONAL ASSIGNMENTS TO BE ASSESSED EXTERNALLY**	**DATE**	**SIGNATURE**
1.	**None**		

242213-001-00-WM-03, Processes to submit the health product establishment's licensing applications to a regulatory authority, NQF Level 5, Credits 8

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-03	Processes to submit the health product establishment's licensing applications to a regulatory authority	5	8	face-toface/contact, online, e-learning, mobile training unit, blended, distance, etc.

WORK EXPERIENCE MODULE DETAILS			
WM-03-WE01: Submit health product establishment's licencing applications to a regulatory authority, under guidance of qualified and/or experienced HPRA/RP/AR			
WM-03-WE01	**SCOPE WORK EXPERIENCE**	**DATE**	**SIGNATURE**
WA0101	Prepare documentation required by the regulator according to regulator's guidelines		
WA0102	Use the appropriate submission procedure/mechanism of a regulatory authority to submit health product establishment's licencing applications (initial, renewal, retention and amendment)		
WA0103	Monitor the progress of a health product establishment's licencing applications and compile and complete responses to regulatory authority's recommendations		
WA0104	Set-up and maintain a documentation system		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0101	Completed application for renewal of licence for health products		
WM-03-WE02: Submit health product establishment's licencing applications to a regulatory authority independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR			
WM-03-WE02	**SCOPE WORK EXPERIENCE**	**DATE**	**SIGNATURE**

WA0201	Prepare documentation required by the regulator according to regulator's guidelines		
WA0202	Use the appropriate submission procedure/mechanism of a regulatory authority to submit health product establishment's licencing applications (initial, renewal, retention and amendment)		
WA0203	Monitor the progress of a health product establishment's licencing applications and compile and complete responses to regulatory authority's recommendations		
WA0204	Set-up and maintain a documentation system		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0201	Completed application for renewal of licence for health products		

NUMBER	**CONTEXTUALISED WORKPLACE KNOWLEDGE**	**DATE**	**SIGNATURE**
1.	Organisational policies and procedures		
2.	Work instructions, checklists, specifications and standards, procedures, templates		
3.	Organisation specific quality management system		
4.	Electronic systems for submissions for variations, amendments, renewals, retentions		
NUMBER	**ADDITIONAL ASSIGNMENTS TO BE ASSESSED EXTERNALLY**	**DATE**	**SIGNATURE**
1.	None		

242213-001-00-WM-04, Processes to conduct code compliance activities on health products, NQF Level 5, Credits 6

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-04	Processes to conduct code compliance activities on health products	5	6	face-toface/contact, online, e-learning, mobile training unit, blended, distance, etc.

WORK EXPERIENCE MODULE DETAILS

WM-04-WE01: Observe and assist a qualified and/or experienced HPRA/RP/AR/HPCCO to conduct code compliance activities on a health product

WM-04-WE01	SCOPE WORK EXPERIENCE	DATE	SIGNATURE
WA0101	Check promotional and educational materials for accuracy of both content (including technical details) and artwork of health product, as per SoP		
WA0102	Check that the promotional activities are compliant with the relevant codes, as per SoP		
WA0103	Approve materials and activities, file and update records of checked promotional and educational material for the required period, as per SoP		
WA0104	Handle incoming and outgoing complaints and unethical practices, and escalate them, if required, according to relevant code and SoP		
WA0105	Review company SoP against local and international codes and practices, suggest updates to the SoP and identify differences between them		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0101	Observation checklist to be signed off by supervisor		
SE0102	Approved promotional and educational materials and activities for health product		

WM-04-WE02: Conduct code compliance activities on a health product under guidance of qualified and/or experienced HPRA/RP/AR/HPCCO			
WM-04-WE02	**SCOPE WORK EXPERIENCE**	**DATE**	**SIGNATURE**
WA0201	Check promotional and educational materials for accuracy of both content (including technical details) and artwork of health product, as per SoP		
WA0202	Check that the promotional activities are compliant with the relevant codes, as per SoP		
WA0203	Approve materials and activities, file and update records of checked promotional and educational material for the required period, as per SoP		
WA0204	Handle incoming and outgoing complaints and unethical practices, and escalate them, if required, according to relevant code and SoP		
WA0205	Review company SoP against local and international codes and practices, suggest updates to the SoP and identify differences between them		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0201	Approved promotional and educational materials and activities for health product		
WM-04-WE03: Conduct code compliance activities on a health product independently but subject to quality checks by qualified and/or experienced HPRA/RP/AR/HPCCO			
WM-04-WE03	**SCOPE WORK EXPERIENCE**	**DATE**	**SIGNATURE**
WA0301	Check promotional and educational materials for accuracy of both content (including technical details) and artwork of health product, as per SoP		
WA0302	Check that the promotional activities are compliant with the relevant codes, as per SoP		
WA0303	Approve materials and activities, file and update records of checked promotional and educational material for the required period, as per SoP		
WA0304	Handle incoming and outgoing complaints and unethical practices, and escalate them, if required, according to relevant code and SoP		
WA0305	Review company SoP against local and international codes and practices, suggest updates to the SoP and identify differences between them		

	SUPPORTING EVIDENCE	DATE	SIGNATURE
SE0301	Approved promotional and educational materials and activities for health product		

NUMBER	CONTEXTUALISED WORKPLACE KNOWLEDGE	DATE	SIGNATURE
1.	Organisational policies and procedures		
2.	Work instructions, checklists, specifications and standards, procedures, templates		
3.	Organisation specific quality management system		

NUMBER	ADDITIONAL ASSIGNMENTS TO BE ASSESSED EXTERNALLY	DATE	SIGNATURE
1.	None		

242213-001-00-WM-05, Processes to perform vigilance and post marketing surveillance, NQF Level 5, Credits 6

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-WM-05	Processes to perform vigilance and post marketing surveillance	5	6	face-toface/contact, online, e-learning, mobile training unit, blended, distance, etc.

WORK EXPERIENCE MODULE DETAILS

WM-05-WE01: Observe a qualified and/or experienced HPRA/RP/AR/HPVO to perform vigilance and post marketing surveillance

WM-05-WE01	SCOPE WORK EXPERIENCE	DATE	SIGNATURE
WA0101	Handle adverse event reporting as per SoP or regulatory authority's guidance document and/or software application		
WA0102	Handle product recall as per SoP or regulatory authority's guidance document		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0101	Completed health product registration or licensing application		

SE0102	Adverse reaction report		
SE0103	Product recall report		

WM-05-WE02: Perform vigilance and post marketing surveillance under guidance of qualified and/or experienced HPRA/RP/AR/HPVO

WM-05-WE02	SCOPE WORK EXPERIENCE	DATE	SIGNATURE
WA0201	Handle adverse event reporting as per SoP or regulatory authority's guidance document and/or software application		
WA0202	Handle product recall as per SoP or regulatory authority's guidance document		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0201	Adverse reaction report		
SE0202	Product recall report		

WM-05-WE03: Perform vigilance and post marketing surveillance independently but subject to final check by qualified and/or experienced HPRA/RP/AR/HPVO

WM-05-WE03	SCOPE WORK EXPERIENCE	DATE	SIGNATURE
WA0301	Handle adverse event reporting as per SoP or regulatory authority's guidance document and/or software application		
WA0302	Handle product recall as per SoP or regulatory authority's guidance document		
	SUPPORTING EVIDENCE	**DATE**	**SIGNATURE**
SE0301	Adverse reaction report		
SE0302	Product recall report		

NUMBER	CONTEXTUALISED WORKPLACE KNOWLEDGE	DATE	SIGNATURE
1.	Organisational policies and procedures		
2.	Work instructions, checklists, specifications and standards, procedures, templates		
3.	Organisation specific quality management system		

NUMBER	ADDITIONAL ASSIGNMENTS TO BE ASSESSED EXTERNALLY	DATE	SIGNATURE
1.	None		