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OCCUPATIONAL PART-QUALIFICATION CURRICULUM DOCUMENT

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

	TYPE (NOMENCLATURE)	TITLE (DESCRIPTOR)	NQF LEVEL	CREDITS
PART- QUALIFICATION	Occupational Certificate	Health Products Vigilance Officer	5	46
CURRICULUM CODE	242213-001-00-02			

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	

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SECTION 1: CURRICULUM SUMMARY

1.1 Occupational Information:

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

242213: Health Products Regulatory Assistant (HPRA)

1.1.2 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
Occupational Certificate	Health Products Vigilance Officer	5	46	242213-001-00-02

1.1.3 Alternative titles used by industry:

None

1.2 Curriculum Information:

1.2.1 Articulation for Qualifications and Part- Qualifications

(a) Horizontal Articulation:

This part 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 part-qualification articulates diagonally across NQF levels and across Sub-Frameworks:

- 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
- 243302-001-00-KM-07, Vigilance and post marketing surveillance, NQF Level 5, Credits 6

Total number of credits: 32

1.3.2 Practical Skills Modules:

- 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

Total number of credits: 8

1.3.3 Work Experience Modules:

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

Total number of credits: 6

1.4 Entry Requirements:

NQF Level 4, with Mathematics and Science

1.5 Recognition of Prior Learning (RPL):

1.5.1 RPL for Access:

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

Such an RPL assessment may be developed, moderated and conducted by the accredited Skills Development Provider which offers that specific part 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.

1.5.2 RPL for Exemption:

For exemption from modules through RPL, learners who have gained the stipulated competencies of the modules of a part-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.

1.5.3 RPL for awarding credits:

Learners who have gained the stipulated competencies of the modules of a part-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 partqualification. Quality Partners are responsible for ensuring the RPL mechanism and process for partqualification 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. Higher Occupational Certificate, Health Products Regulatory Assistant (HPRA), NQF Level 5, Credits 134

b. Occupational Certificate: Health Products Code Compliance Officer (HPCCO), NQF level 5, Credits 34

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 Vigilance Officer.

A Health Products Vigilance Officer (HPVO) conducts vigilance and post-marketing surveillance activities in a health product regulatory environment. They ensure registered and licensed health products are continuously safe to use by monitoring the occurrence of adverse events and assisting with requests for product recall. 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.

2.2 Tasks:

TASK	LINKS TO ELO
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

Conduct / perform vigilance and post marketing surveillance (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 implementing 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 assignment
- 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-to-face contact, online, elearning, mobile training unit, blended, distance
242213-001-00-00-KM-02	Anatomy and physiology	5	10	face-to-face contact, online, elearning, mobile training unit, blended, distance
242213-001-00-00-KM-03	Health products	5	8	face-to-face contact, online, elearning, mobile training unit, blended, distance
242213-001-00-00-KM-04	Science for the Health Product Regulatory Assistant (HPRA)	5	3	face-to-face contact, online, elearning, 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

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-to-face contact, online, elearning, 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 suppliers; large and small local companies; categories of HCP (Level 3) *vis a vis* health products)	20
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) • 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)	25

	• 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

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-to-face contact, online, elearning, 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 contact, online, elearning, mobile training unit, blended, distance

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

243302-000-01-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 contact, online, elearning, mobile training unit, blended, distance

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) • Risk Management Plan (RMP)	11
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 of recalls; classes and types of recall; recall letters and media release; post recall procedures; follow-up action procedures)	20

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 • Internal assessment plan and assessments
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

3.7.3 Exemptions

None

Practical Skill Module (PM) Specifications:

MODULE CODE	MODULE TITLE	NQF LEVEL	CREDITS	MODE OF DELIVERY
242213-001-00-PM-03	Conduct oneself professionally and ethically	4	3	face-to-face contact, online, e-learning, mobile training unit, blended, distance
242213-001-00-PM-04	Perform vigilance and post marketing surveillance	5	5	face-to-face contact, online, e-learning, mobile training unit, blended, distance

Detailing Practical Module (PM) contents 242213-001-00-PM–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	face-to-face 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 CODES	**PRACTICAL SKILL ACTIVITY ELEMENTS**
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

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

3.3.3 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

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	1:5

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

WORK EXPERIENCE MODULE (WM) SPECIFICATIONS:

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

Detailing Work Experience Module (WM) contents

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

3.1.1 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/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

3.1.2 Criteria for accreditation

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

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-KM-01	5	5
2.	Anatomy and physiology	242213-001-00-KM-02	5	10
3.	Health products	242213-001-00-KM-03	5	8
4.	Science for the Health Product Regulatory Assistant (HPRA)	242213-001-00-KM-04	5	3
5.	Vigilance and post marketing surveillance	243302-001-00-KM-07	5	6
6.	Perform vigilance and post marketing surveillance	242213-001-00-PM-04	5	5
7.	Processes to perform vigilance and post marketing surveillance	242213-001-00-WM-05	5	6
8.	Conduct oneself professionally and ethically	242213-001-00-PM-03	4	3

SECTION 4. STATEMENT OF WORK EXPERIENCE

QUALIFICATION	QUALIFICATION TITLE/DESCRIPTOR	NQF LEVEL	CREDITS
Occupational Certificate	Health Products Vigilance Officer	5	46

CURRICULUM CODE	242213-001-00-02

LEARNER DETAILS

NAME:	
ID NUMBER:	

EMPLOYER DETAILS

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

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		