SOUTH AFRICAN QUALIFICATIONS AUTHORITY

REGISTERED QUALIFICATION:

Occupational Certificate: Health Products Code Compliance Officer

SAQA QUAL ID	**QUALIFICATION TITLE**			
125104	Occupational Certificate: Health Products Code Compliance Officer			
ORIGINATOR				
Development Quality Partner - CHIETA				
PRIMARY OR DELEGATED QUALITY ASSURANCE FUNCTIONARY			**NQF SUB-FRAMEWORK**	
QCTO - Quality Council for Trades and Occupations			OQSF - Occupational Qualifications Sub-framework	
QUALIFICATION TYPE	**FIELD**		**SUBFIELD**	
Part-Qualification	Field 09 - Health Sciences and Social Services		Curative Health	
ABET BAND	**MINIMUM CREDITS**	**PRE-2009 NQF LEVEL**	**NQF LEVEL**	**QUAL CLASS**
Undefined	34	Not Applicable	NQF Level 05	Regular-ELOAC
REGISTRATION STATUS		**SAQA DECISION NUMBER**	**REGISTRATION START DATE**	**REGISTRATION END DATE**
Registered		EXCO 0936/25	2025-11-13	2029-11-13
LAST DATE FOR ENROLMENT		**LAST DATE FOR ACHIEVEMENT**		
2030-11-13		2033-11-13		

In all of the tables in this document, both the pre-2009 NQF Level and the NQF Level is shown. In the text (purpose statements, qualification rules, etc), any references to NQF Levels are to the pre-2009 levels unless specifically stated otherwise.

This qualification does not replace any other qualification and is not replaced by any other qualification.

PURPOSE AND RATIONALE OF THE QUALIFICATION

Purpose:
The purpose of Occupational Certificate: Health Products Code Compliance Officer is to prepare a learner to operate as a Health Product Code Compliance Officer.

A Health Product Code Compliance Officer conducts compliance activities in a health product regulatory environment. They ensure compliance of promotional and educational material and activities to applicable industry code regulations.

A qualified learner will be able to:
- Conduct/perform code compliance activities on health products.

Achieving this part-qualification will provide several benefits to the learner, including:
- Being able to carry out a range code compliance activities with respect to promotional material and activities related to health products.
- Acquiring in-depth knowledge of code compliance activities and processes for health products
- Taking an important step into the health products sector with the prospect of acquiring higher or related qualifications in the field.
- Acquisition of a formal qualification in health products environment if they do not already have a qualification
- Increasing the opportunity of gaining employment with companies that manage health product applications for registration and licensing. Considering South Africa's huge unemployment rate, a qualification like this has the potential to get learners into meaningful employment.

Typical graduate attributes include proficiency, efficiency, and effectiveness in preparing dossiers for registration and renewal of health products. The Health Products Code Compliance Officer (HPCCO) is a person of integrity and high ethical standards as they ensure that all promotional material and activities designed for health products meet the requirements of the regulatory framework.

Rationale:
No health product may be sold in South Africa unless it has been registered with an appropriate regulatory body. This qualification covers medicines, medical devices and in vitro devices (IVDs), complementary medicines, personal care products and veterinary products. Currently, the South African Health Products Authority (SAHPRA) registers health products as defined by the Medicines Act 101 of 1965 and its Amendments - whether they are manufactured local or abroad - to ensure safety, efficacy, and quality

The marketing or promotion of health products is very strictly controlled through application of the relevant sector codes by the Health Products Code Compliance Officer (HPCCO) or a Responsible Pharmacist (RP) or an Authorised Representative (AR) as long as they are trained as a HPCCO. The qualification plays a very critical role in ensuring that sector codes are applied to all promotional and educational materials and activities.

Unfair promotional practices carried out impact negatively on other companies promoting their products through fair practices.

In spite of their critical role, there is no qualification registered on the NQF for this much-needed part-qualification. This is the first time a qualification for this occupation is being developed. Current training is disparate and carried out by companies that register, license and market health products. There is a need to standardise such disparate training and set the benchmark for the occupation.

As the number of health products grows significantly in view of scientific advancement (the plethora of health products being a case in point), this qualification becomes critical to ensure that the public is exposed to promotional material for health products that has been subject to regulatory scrutiny prior to approval. The challenges stemming from misinformation regarding health products will always be there and this emphasises the responsibility of the Health Products Code Compliance Officer (HPCCO).

The safety of the public is paramount when it comes to using or consuming health products and the application of the relevant compliance codes will strengthen the public's confidence in products that have been approved.
Additionally, ensuring that promotional activities for health products occur within the ambit of the regulatory framework maintains fairness in the sector and companies abiding by the compliance codes are not affected negatively. Hence, this part-qualification ensures that the interests of the health product sector are protected.

The part-qualification has the potential of creating employment as it is needed in the industry and there is a potential uptake of the qualification by significant number of learners. Increased employment will translate into increased benefits for the economy.

Typical learners will be those currently practising as Health Products Code Compliance Officers who have been operating without training on a formal qualification. Other learners could include matriculants or those with a relevant higher education qualification wishing to enter the health products regulatory field.

Learners working towards this part-qualification will find that the acquisition of competencies embedded in the modules will either enable them to either obtain employment or add value to their job performance if they are already employed.

In the development of this qualification, the following stakeholders were consulted:
- Training providers.

- Regulator.
- Employers/employer organisations.

There are no similar Qualification(s) and Part-Qualifications registered on the NQF, and no Skills Programmes approved by the QCTO.

LEARNING ASSUMED TO BE IN PLACE AND RECOGNITION OF PRIOR LEARNING

Recognition of Prior Learning (RPL):
RPL for Access to Training:
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.

RPL for Access to the External Integrated Summative Assessment (EISA):
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.

Entry Requirements:
An NQF Level 4 qualification, with Mathematics and Science.

RECOGNISE PREVIOUS LEARNING?

Y

QUALIFICATION RULES

This qualification is made up of compulsory Knowledge, Practical Skill and Work Experience Modules:

Knowledge Modules:
- 242213-001-00-KM-01, Overview of Current Health Products Industry/Sector, NQF Level 5, 5 Credits.
- 242213-001-00-KM-03, Health Products, NQF Level 5, 8 Credits.
- 242202-001-00-KM-05, Codes of Practice for HPRAs, NQF Level 5, 3 Credits.
- 242213-001-00-KM-08, Professional Conduct, NQF Level 4, 3 Credits.

Total number of credits for Knowledge Modules: 19

Practical Skill Modules:
- 242213-001-00-PM-02, Conduct Compliance Activities on Health Products, NQF Level 5, 6 Credits.
- 242213-001-00-PM-03, Conduct Oneself Professionally and Ethically, NQF Level 5, 3 Credits.

Total number of credits for Practical Skill Modules: 9

Work Experience Modules:
- 242213-001-00-WM-04, Processes to Conduct Code Compliance Activities on Health Products, NQF Level 5, 6 Credits.

Total number of credits for Work Experience Modules: 6

EXIT LEVEL OUTCOMES

1. Interpret and apply appropriate procedures and criteria to conduct/perform code compliance activities on health products.

ASSOCIATED ASSESSMENT CRITERIA

Associated Assessment Criteria for Exit Level Outcome 1:
ELO 1: Interpret and apply appropriate procedures and criteria to conduct/perform code compliance activities on health products

- Check the contents and artwork of promotional and educational materials for a health product for compliance to relevant codes and standard operating procedures (SoPs).
- Check promotional activities for compliance with the relevant codes and SoPs and make recommendations for activities that do not comply.
- Complete checks and corrections to promotional and educational materials and appropriately file/save and update activities and administrative records as per regulatory requirements.
- Receive and lodge and escalate incoming and outgoing complaints pertaining to promotional and educational materials and activities if required according to SoP.
- Handle and escalate unethical practices regarding promotional and educational materials and activities if required according to SoP.

Integrated Assessment:
Integrated Summative Assessment
Integrated Assessment involves all the different types of assessment tasks required for a particular part qualification, such as written assessment of theory and practical demonstration of competence. To achieve this, the Internal Assessment Criteria (IAC) for all modules as found in the QCTO curriculum document must be followed.

An accredited SDP should implement a well-designed, formal, relevant, final internal Summative Assessment strategy for all modules to prepare learners for the EISA. These assessments evaluate learning achievements relating to the achievement of each module of the relevant components of the part-qualification.

Internal Summative Assessments are developed, moderated, and conducted by the SDP at the end of each module or after integration of relevant modules, e.g., applied knowledge tests, workplace tasks, practical demonstrations, simulated tasks/demonstrations, projects, case studies, etc.

INTERNATIONAL COMPARABILITY

An international comparability study is undertaken to identify qualifications or courses similar to this qualification in terms of scope, cognitive levels and content of the curricula. In essence, the purpose of this exercise is to benchmark the HPCCO qualification against comparable qualifications or courses in two other countries, namely, Canada and New Zealand.

Country: Canada
Institution: Regulatory Affairs Professional Society (RAPS) Online University

Purpose:
Regulatory Affairs Professional Society (RAPS) Online University offers a number of certificates and courses mentioned below (a - c). While there is no specific course that the South African Health Product Code Compliance Officer (HPCCO) qualification can be compared to, there are modules which when combined as shown below can resonate with the South African qualification.
Entry requirements are not specified but they are all post-school courses.

The courses are briefly discussed below.
a) Regulatory Affairs Certificate: Medical Devices and Pharmaceuticals (Dual) - duration almost 12 months.
Core modules are:

- Ethics
- Global Regulatory Strategy for Medical Devices
- Global Regulatory Strategy for Pharmaceuticals
- Medical Devices: Definition and Lifecycle
- Pharmaceuticals: Definition and Lifecycle
- Role of the Regulatory Professional

These are followed by elective modules.

b) Regulatory Affairs Certificate: Pharmaceuticals - duration not given but learner has 12 months in which to complete the course.
Core modules are:

- Ethics.
- Global Regulatory Strategy for Pharmaceuticals.
- Pharmaceuticals: Definition & Lifecycle.
- Role of the Regulatory Professional.

These are followed by elective modules.

c) Regulatory Affairs Certificate: Medical Devices - duration not given but learner has 12 months in which to complete the course.
Core modules are:

- Ethics
- Global Regulatory Strategy for Medical Devices
- Medical Devices: Definition & Lifecycle
- Role of the Regulatory Professional

The modules that can be combined are:

- Ethics
- Role of the Regulatory Professional
- Ethics□Essential Tools for Regulatory Professionals
- Medical Devices: Advertising and Promotion in the US
- Pharmaceuticals: Advertising and Promotional Labelling in the US
- Effective Regulatory Communication

Similarities:
The above set of modules when taken cumulatively closely resemble the HPCCO qualification. The above similarities are based on appropriate modules that can be combined to constitute a course that is similar to the South African qualification.

Differences:
There are no differences because there is no specific course dedicated to Health Product Code Compliance Officer.

Country: New Zealand
Qualification title: Certificate in Regulatory Practice
Level 5

Purpose:
The purpose of New Zealand Certificate in Regulatory Practice (Level 5) with strands in Audit, Inspection, and Investigation provide people who work in frontline operational regulatory roles with knowledge and skills transferable across the regulatory sector as well as those relevant to their functional area. The NZ regulatory qualifications or compliance are written generically and can be applied to almost every sector of human activity.

The generic outcomes are:

- Perform regulatory activities using a risk-based approach to achieve regulatory outcomes (5 credits)
- Engage effectively with stakeholders, including regulated persons or the regulated sector, to achieve regulatory outcomes (5 credits)
- Plan, manage and review regulatory audits or inspections or investigations, to achieve regulatory outcomes (15 credits)

The Audit Strand of this qualification resonates with the South African HPCCO qualification.

The following modules have relevance:
Gather and manage evidence and other information using relevant audit practices and techniques, analyse levels of conformance, and recommend or implement interventions that will improve or achieve conformance outcomes in an audit context (15 credits)

Monitor conformance levels of audit subjects in response to interventions (5 credits)

Similarities:
- Perform regulatory activities using a risk-based approach to achieve regulatory outcomes
- Engage effectively with stakeholders, including regulated persons or the regulated sector, to achieve regulatory outcomes
- Gather and manage evidence and other information using relevant audit practices and techniques, analyse levels of conformance, and recommend or implement interventions that will improve or achieve conformance outcomes in an audit context

Differences:
- Plan, manage and review regulatory audits or inspections or investigations, to achieve regulatory outcomes (15 credits)
- Monitor conformance levels of audit subjects in response to interventions. (5 credits)

Conclusion:
An analysis of the qualification and training programme in the international countries shows a significant level of similarities in many respects between this qualification and those in countries identified for benchmarking purposes.

ARTICULATION OPTIONS

This qualification provides opportunities for horizontal and vertical articulation options.

Horizontal Articulation:
- Higher Occupational Certificate: Health Products Regulatory Assistant (HPRA), NQF Level 5.
- Higher Certificate in Healthcare Management, NQF Level 5.

Vertical Articulation:
- Occupational Certificate: Pharmacy Technician, NQF Level 6.

Note: This qualification will reach its registration end date on 30 December 2025. The last date of enrolment is 30 December 2026.

Diagonal Articulation:
- National Certificate: Vocational: Primary Health, NQF Level 4.

MODERATION OPTIONS

N/A

CRITERIA FOR THE REGISTRATION OF ASSESSORS

N/A

NOTES

Additional Legal or Physical Entry Requirements:
- None.

Criteria for the accreditation of providers
The curriculum title and code are: Health Products Code Compliance Officer, 242213-001-00-01.

Encompassed Trade:
This qualification encompasses the following trades as recorded on the NLRD:
- None.

Assessment Quality Partner (AQP)
CHIETA

Associated Qualification(s)/Part- Qualifications(s):
- Higher Occupational Certificate: Health Products Regulatory Assistant (HPRA), NQF Level 5, 134 Credits.
- Occupational Certificate: Health Products Vigilance Officer, NQF Level 5, 57 Credits.

LEARNING PROGRAMMES RECORDED AGAINST THIS QUALIFICATION:

NONE

PROVIDERS CURRENTLY ACCREDITED TO OFFER THIS QUALIFICATION:

This information shows the current accreditations (i.e. those not past their accreditation end dates), and is the most complete record available to SAQA as of today. Some Primary or Delegated Quality Assurance Functionaries have a lag in their recording systems for provider accreditation, in turn leading to a lag in notifying SAQA of all the providers that they have accredited to offer qualifications and unit standards, as well as any extensions to accreditation end dates. The relevant Primary or Delegated Quality Assurance Functionary should be notified if a record appears to be missing from here.

NONE
