South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

14 March 2023

GUIDELINE ON MEDICAL DEVICE QUALITY MANUAL

This guideline is intended to provide recommendations to applicants wishing to submit applications for a licence to manufacture, import, distribute and export a medical device, including *In Vitro* diagnostics medical devices (IVDs). It represents the South African Health Products Regulatory Authority's current thinking on the safety, quality and performance of medical devices and IVDs. It is not intended as an exclusive approach. The Authority reserves the right to request any additional information to establish the safety, quality and performance of a medical device or IVD in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The Authority is committed to ensure that all registered medical devices and IVDs will meet the requirements of the Essential Principles relating to quality, safety and performance. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the CEO and the website.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue, industrial comments incorporated and published for implementation	August 2017
2	Administrative Update	November 2019
3	- Content structured on the new SAHPRA Guideline Template - Old Guideline no. 8.07 changed to a new document number SAHPGL-MD-05	March 2023

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

Contents

Document History 1
Glossary 3
1. INTRODUCTION 4
1.1 Purpose 4
1.2 Scope 4
2. LEGAL PROVISION 4
3. QUALITY MANUAL 4
3.1 Company Details 4
3.2 Quality Management System 5
3.3 Site Information 5
3.4 Index 7
4. REFERENCES 8
5. VALIDITY 8

Glossary

Abbreviation/ Term	Meaning
IVD	*In vitro diagnostic*
QMS	Quality Management System
ISO	International Organization for Standardization

1. INTRODUCTION

A person who makes application for a license to import, manufacture, distribute, wholesale or export a medical device in South Africa must implement and maintain a documented quality management system which is relevant to one or more stages of the life cycle of the medical device, as required by clause 5 of the Regulations for Medical Devices and IVDs.

1.1 Purpose

The purpose of this guideline is to assist manufacturers and distributors to compile a documented quality management system aligned with the iso standard required for medical devices, ISO 13485.

1.2 Scope

The scope of this guideline is to identify the minimum requirements of the Quality Manual which a person who makes application for and holds a licence to import, manufacture, distribute or export a medical device, including an *in vitro diagnostic* (IVD) medical device, must prepare and maintain up to date at all times.

2. LEGAL PROVISION

Refer to the Medicines and related substances Act 101 of 1965 as amended and General Regulations relating to Medical Devices and IVDs. ISO 13485:2016 Medical Device quality management systems.

3. QUALITY MANUAL

The Quality Manual must provide an overview of the documented quality management system which is in operation and must include information about the organization, the facility/ies, the key personnel, the quality assurance policy/ies, procedures, work instructions, controls and activities which are undertaken by the organization to demonstrate its ability to provide medical devices and related services that consistently meet the South African regulatory requirements.

A summary of the key information in the Quality Manual, as aligned to the ISO13485 framework, is noted in **Table 1** below.

The following information must be included in the Quality Manual:

3.1 Company Details

- Company registered name and company registration number or in the case of a natural person the person's full name and Identity Number.

- Registered physical address.
- Registered postal address.
- SAHPRA Licence details, including type of licence, licence number and period of validity.
- The number and type of facilities in South Africa.

3.2 Quality Management System

- The scope and span of the Quality Management System (QMS) (i.e. the QMS for one or multiple sites).
- Details of the standard to which the QMS is implemented and the status of the certification thereof, e.g., certification to the latest version of ISO13485:2016 and period of validity.
- An overview of the formal procedures within the QMS and a description of the interaction between the procedures, including vigilance, reporting adverse events to the SAHPRA, recall and change controls.
- The type and risk class of medical device products imported, manufactured, distributed, exported or serviced
- Whether the medical devices are currently distributed for human or veterinarian use.
- Details of the organization of personnel, roles and responsibilities (organization chart).

3.3 Site Information

The following company information is to be completed for each site where any manufacturing and storage activity, such as, but not limited to - manufacture, sterilization, packing, labelling, storage, reprocessing (cleaning) and service takes place:

- Physical address;
- Postal Address;
- Telephone: Office hours;
- Key Contact Persons & contact details (email and telephone) for each:
    - Authorised Representative: (24-hour telephone number)

  - Managing Director
  - Operations/Product Manager; Quality Assurance Manager; Regulatory Affairs Manager (where relevant)

- Details of the access controls and security control measures in place;
- Details of the structure of the building where product is manufactured, packed, serviced and stored, including type of floors, type of walls, type of ceilings, etc.
- Approximate size of the spaces (m2) in which manufacturing, packing, labelling, storage, reprocessing and service takes place.
- Details of the ventilation / air controls and environmental controls.
- Details of equipment, such as the following equipment (list as relevant):
  - Water treatment plant
  - Air handling unit
  - Sluice for wastewater
  - Sterilisation
- Special structural and or safety features / characteristics of the facility, manufacturing and storage areas
- Street map where the facility located.
- Site and facility plan
- Details of the number of employees engaged in the key departments

3.4 Index

The following is an exemplary quality manual index:

	SUBJECT	ISO 13485 REFERENCES
1	Cover page, table of contents	==========
2	Company profile (refer below)	==========
3	Control and distribution	==========
4	Quality Management System	4.0
	General requirements	4.1
	Documentation requirements	4.2
5	Management Responsibility	5.0
	Management commitment	5.1
	Customer focus	5.2
	Quality Policy	5.3
	Planning	5.4
	Responsibility, authority and communication	5.5
	Management review	5.6
6	Resource Management	6.0
	Provision of resources	6.1
	Human resources	6.2
	Infrastructure	6.3
	Work environment and contamination control	6.4
7	Product Realization	7.0
	Planning of product realization	7.1
	Customer Related Processes	7.2
	Design and development	7.3
	Purchasing	7.4
	Production and service provision	7.5
	Control of monitoring and measuring equipment	7.6
8	Measurement, Analysis and Improvement	8.0
	General	8.1
	Monitoring and measurement	8.2
	Control of Nonconforming Product	8.3
	Analysis of data	8.4

	SUBJECT	ISO 13485 REFERENCES
	Improvement	8.5
9	**List of procedures**	==========
10	**Glossary of terms**	==========
11	**Process flow chart**	==========
12	**Quality Policy**	==========
13	**Organization structure**	==========

4. REFERENCES

The following related documents are referenced:

4.1 ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes.

5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the old guideline for Medical Device Quality Manual, document number 8.07. It will be reviewed on this timeframe or as and when required.