Quality Management System
Requirements for Medical Devices

Presenter

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Dip Pharm, Dip Production Management, SABS Textile Diploma

Introduction

Simone is an industrial pharmacist with a production, R&D and technical background having experience in regulatory affairs, quality management, validation, intellectual property, manufacturing and productivity improvement.

Simone is a member of MDMSA, SAFHE, SAAPI and sits on the SABS technical & SAHPRA ITG committees, is a SANAS technical expert for medical devices as was extensively involved with SAMED on the regulatory, market access and local manufacturing committees over 20+years. Simone also provided a medical textile market evaluation to expand textile medical devices for the SA Cotton Cluster and participated in the MRC medical device Landscape analysis.

Simone's company Rudolph-Shortt consultancy cc trading as ISOhealthSA, offers expert consultation in foods, cosmetic, disinfectant, medicine and medical device regulatory affairs; for many products and services good manufacturing practices and quality management systems design, development and implementation, with auditing, process improvement and training to manage operational risk, achieving compliance and driving business improvement.

The company works with small to medium enterprises around South Africa and surrounding neighbouring counties e.g Swaziland, Lesotho, Botswana in the food, beverage, cosmetics, medical device and pharmaceutical industries.
The company has earned its reputation as a leading consultation service provider with technically qualified specialists with vast practical industry experience, which includes, Implementation, design or improvement of operational management, systems realising process realignment and cost savings initiatives.

ISOhealthSA has local and international experience in pharmaceuticals, toiletries, food stuffs and medical devices regulations, quality and product safety systems, project management, occupational Health & Safety, and technical developments including process and product validation.

The Course:

The registration of medical devices and IVDs and establishment licencing in South Africa is governed by the provisions and requirements of the Medicines and Related Substances Control Act No. 101 of 1965, (hereafter 'the Act') and the Regulations and Guidelines published in terms thereof.

SANS ISO 13485 is a South African National Standard for “Medical devices — Quality management systems (QMS) — Requirements for regulatory and is therefore the industry standard for medical devices.

The standard “specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning, and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support). The requirements in this International Standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical, devices, sterilization services, calibration services, distribution services, and maintenance services) to such, organizations.”

The QMS also requires that a risk-based approach is applied to the control of the appropriate processes needed for the quality management system, which includes that the International Standard is complementary to the technical requirements for product that are necessary to meet customer and applicable regulatory requirements for safety and performance.

It’s important to understand and interpret ISO3485 to be able to implement an effective Quality Management System and provision of procedures for ISO13485 processes.

Who should take this course?

Individuals involved in Production, Distribution, Regulatory Affairs, Quality Assurance, Responsible Pharmacists, and Authorized Representatives for medical devices

Course Content:

This course will be presented on the Microsoft Teams Platform.

DAY 1: Wed, 21 October 2026 (9am – 1pm)

1. Medical Device
2. Quality
3. ISO vs GMP
4. Quality Management system

DAY 2: Thu, 22 October 2026 (9am – 1pm)

5. ISO13485 (the 8 Clauses)
6. Certification vs Accreditation

Course Outcomes:

At the end of this course the attendee will have a clear understanding of:

1. Quality Management Systems and ISO13485 Requirements