SAAPI
South African Association of Pharmacists in Industry

ISOhealthSA
RUDOLPH-SHORTT Consultancy CC
also t/a ISOhealthSA, PeonyCo & Compliance Projects

Simone Rudolph-Shortt (Dip pharm) LA ISO9001/13485 Dip Production Management (PMI)
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Online Training
ISO13485 The 8 Clauses

Presenter
Simone Rudolph-Shortt

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

Simone is a member of MDMSA, SAMED, SAFHE, SAAPI and sits on the SABS technical committees and SANAS technical expert group for medical devices. Simone recently provided a medical textile market evaluation to expand textile medical devices for the SA Cotton Cluster.

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.

www.r-sc.co.za www.r-sctraining.co.za www.complianceprojects.co.za.

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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, Act 101 and regulations for regulating medical devices. Understanding the contents of the standard is paramount to a successful development, implementation and certification of the QMS

The International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). This International Standard can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of the International Standard are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by the International Standard that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization’s quality management system by monitoring, maintaining, and controlling the processes.

Who should take this course?

Regulatory Affairs Pharmacists, Quality Assurance Pharmacists, Responsible Pharmacists, and Authorized Representatives

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Course Content:

This course will be presented on the Microsoft Teams Platform.

CANDIDATES MUST HAVE A COPY OF ISO13485

**Evening before reading – ISO13485 Clause 0 - 6

DAY 1: Thursday 27th May 2021 (9am – 1pm)

1. ISO 13485 Introduction Clause 0, Scope clause 1
2. Clause 2 Normative references, 3 Definitions
3 Clause 4 Quality Management System
4. Clause 5 Resource Requirements
5. Clause 6 Resource Management

**Evening before reading – Clause 7 & 8

DAY 2: Friday 28th May 2021 (9am – 1pm)

6. Clause 7 Product (service) realisation
7. Clause 8 Measurement, Analysis and Improvement
10. Summary Overview

Course Outcomes:

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

1. Contents, requirements and interpretation of ISO13485