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)
Cell: +27 82 871 5740 | Email: simone@isohealthsa.co.za http://www.isohealthsa.co.za/

Online Training
Validation for Medical Devices

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 together with the EU Medical Device Regulations May 2017 define the requirements and documentation for regulating medical devices as well as validation requirements.

The requirements, including validation, and documentation cover 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).

It’s important to understand the Validation and Documentation required together covering Common Specifications, Safety & Performance Principles, Clinical considerations and association to risk mangement to enable regulatory approval and market access.

Who should take this course?

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

Course Content:

This course will be presented on the Microsoft Teams Platform.

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DAY 1: Wednesday 8th February 2023 (9am – 1pm)

1. Why validate & QbD
2. Risk based approach & LifeCycle of medical devices
3. Definitions
4. Types of Validation

**Evening reading – Q8--Q9----Q10-Questions-and-Answers; ICH Quality Implementation Working Group (Q-IWG) - Points to Consider document covering topics relevant to the implementation of ICH Q8(R2), Q9, and Q10, which supplement the existing guidance Q8, Q9, and Q10 Questions & Answers

DAY 2: Thursday 9th February 2023 (9am – 1pm)

5. Validation Activities
6. Validation process
7. Validation Aspects

**Evening reading – Software validation_article; STS Consulting
Computer System Validation - It's More Than Just Testing

DAY 3: Friday 10th February 2023 (9am – 1pm)

8. Software Validation
9. Validation Standards
10. Validation QMS
11. Validation Protocol
12. Validation Report

Course Outcomes:

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

1. Validation, what it is, types, process, aspects and activities
2. How to write a Protocol and navigate a Report