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
Medical Device post market surveillance, Recall and Adverse Incident

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, 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.

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 Medical Device post market surveillance and adverse Incident requirements.

It’s important to understand the terminology, requirements and processes for Medical Device post market surveillance and adverse Incident in regards to Vigilance to sustain your business operations and regulatory compliance

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.

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Topics

1. Terminology
2. SAHPRA guideline
3. ISO13485
4. Vigilance
5. Reportable adverse event
6. Exemption
7. Timeframes
8. Reporting
9. Access to device
10. Decision tree
11. IMDRF terminology
12. Class & Type
13. Post Market Surveillance
14. Vigilance plan

Course Outcomes:

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

1. How navigate Vigilance
2. Understand the regulations
3. Conduct adverse event reporting and Post market surveillance
4. Understand recall requirements