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
RA Functions in Medical Devices - Role of the SAHPRA Authorised Rep

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.

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The Course:

The role and function of Authorized Representatives and role of a Quality Management System Management Representatives 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.

The requirements and documentation cover 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).

It’s important to understand the roles and responsibilities of all the role players, called economic operators (EO), including Top management

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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Thursday 26th May 2022 (9am – 1pm)

1. Compliance
2. QMS
3. Economic Operators
4. MAID WO Obligations
5. Placing on the market
6. Family of products
7. Authorised Representative
8. EO definitions ISO13485
9. CAB vs NB
10. QMS Management Representative
11. Conformity assessment
12. QA Agreement
13. Outsourcing
14. Top Management & leadership
15. QMS support & experts / consultants

Course Outcomes:

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

1. Understand Economic operators (EO) in the medical device sector
2. Roles and Responsibilities of EO (includes IVDs)
3. Involvement in ISO13485
4. Relationship with Top Management
5. Understanding Conformity Assessment