SAAPI
South African Association of Pharmacists in Industry

ISOhealthSA
RUDOLPH-SHORTT Consultancy CC
also t/a ISOhealthSA, PeonyCo & Compliance Projects
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QMS vs GMP 4 medicines, devices and IVD short course

Presenter
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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.

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The Course:
The registration of medicines, 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 and GMP for medicines is published by PICS adopted by SAHPRA

Understanding Definition of each healthcare products, differences in Safety & Performance, applying QMS vs GMP, navigating the legislation, role of the Responsible Pharmacist and Authorised Representative and navigating the supply Chain,

The organisation needs to follow a risk based approach to the control of the appropriate processes needed, which includes that a technical 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 the above topics to be able to implement an effective Quality Management System and be regulatory compliant.

Who should take this course?
Individuals involved in Production, Distribution, Regulatory Affairs, Quality Assurance, Responsible Pharmacists, and Authorized Representatives for medical devices

Course Content:
1. Definitions
2. Safety & Performance
3. QMS vs GMP
4. Legislation
5. Role of the Responsible Pharmacist and Authorised Representative
6. Supply Chain navigation

Course Outcomes:
At the end of this course the attendee will have a clear understanding of:
1. What is the difference in healthcare products and the safety and performance requirements
2. Understanding and implementing an appropriate quality management system