Medical Device Regulatory Aspects and Device Documentation

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, SAMED, SAFHE, SAAPHI 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.

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.

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 know if a products is a Medical Device (or IVD), what the rule for risk Classification is in relation to the intended use, consideration for Borderline cases, routes and requirements for Conformity Assessment, Documentation required and Common Specification, Safety & Performance Principles, Clinical considerations and Risk Benefits Report, and the Adverse event process and reporting to enable regulatory approval and market access.

Who should take this course?

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

Course Content:

1. Medical Device and associated definitions
2. Classification rules
3. Borderline Considerations
4. Conformity Assessment routes and requirements
5. Documentation
6. Common Specification requirements
7. Safety & Performance Principles
8. Clinical Evidence requirements and process
9. Risk Benefits Report
10. Adverse event

Course Outcomes:

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

1. The medical device documentation requirements and conformity assessment, clinical evidence and adverse event expectations.