

Online Training

Non conformance Corrective action Preventive action 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, 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.

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) including Corrective Action and Preventive Actions as a means for Improvement & PICGMP covers management of deviations— Requirements, Act 101 and regulations

Improvement is crucial in operations management because it enables businesses to prevent problems and unsafe nonperforming products entering the market as well as enhancing efficiency, reduced costs, improved quality, confidence in products on the market and adapt to changing market conditions.

It's important to understand the management process for nonconformities or deviations in association to risk management to enable regulatory compliance.

Who should take this course?

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

Course Content:

This course will be presented on the Microsoft Teams Platform.

AGENDA

Non conformance Corrective action Preventive action for Medical Devices short course

Date: 12 November 09:00am-13:00pm

08:30 – 09:00 Registration

09:00 – 09:10 Welcome

1. Why Improve
2. Definitions
3. PROBLEM
4. SOLUTION

Tea break 10:30am

5. IMPROVEMENT
6. TOOLS
7. PREVENTIVE ACTION
8. 6. Validation process

12:45 – 13:00pm Q & A

Course Outcomes:

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

1. conformity & deviation process, aspects and activities
2. Understanding the tools and opportunities for improvement