Medical Device Regulatory Convergence Project (MDRC)
Good Regulatory Practices & Technical Competencies
South African Health Products Regulatory Authority (SAHPRA) & Regulated Sector
Day 1

Date: 14 November 2023
Time: 9:00 – 17:30 Pretoria, South Africa (2:00 am - 10:30 ET)
Language: English
Platform: Hybrid (In-person: Southern Sun Pretoria Hotel, Cnr. Steve Biko and, Pretorius St, Arcadia, Pretoria, 0083). Please register here for virtual or in-person participation.

Purpose:
This workshop will provide an exchange of information and capacity building between the South African Health Products Regulatory Authority, SAHPRA and partner reference NRAs including the WHO, USFDA, TGA, HSA, ANVISA, covering the core international references for medical device regulatory. The workshop objective is to support and advance to strengthen the soft infrastructure of medical device regulatory framework to incorporate global lessons learned from the COVID-19 pandemic, to better prepare for future health emergencies, to prevent the implementation of unnecessary regulatory barriers to medical technologies, to improve general MD NRA public administration and general public health.

Time	Topic
8:00 – 9:00	**Participants Registration**
9:00 – 9:05	**Welcome and Housekeeping Message** Sandra Ligia González, Medical Devices Lead - MDRC
9:05 – 9:15	**Opening Remarks** Dimakatso Mathibe, SAHPRA
9:15 – 9:25	**Training Objectives and Overview** Dimakatso Mathibe, SAHPRA
9:25 – 9:35	**MDRC Project Overview** Sandra Ligia González, MDRC
9:35 – 10:00	**Overview of Medical Devices and IVDs. Where we are and where we are heading.** Dimakatso Mathibe, SAHPRA (20 min) Q&A: 5 min
10:00 – 10:40	**International Benchmarks for Medical Device Regulatory Frameworks and Authorities: Health References & Recommendations** Moderator: Khaniyisile Nkuku, SAHPRA (Virtual) • WHO Global Model Regulatory Framework for Medical Devices and IVDs • WHO Good Regulatory Practices Agnes Kijo, World Health Organization (WHO) (30 min) (Virtual) Q&A: 10 min
10:40 – 11:00	**Morning Tea Break**

11:00 – 12:10	**Introduction and Overview on Good Regulatory Practices (GRPs): Global and Domestic** Moderator: Marina Carvalho, MDRC • **Global: WTO, OECD** Marina Carvalho, MDRC (30 min) • **Domestic:** Dineo Hexana, South African Bureau of Standards (SABS), Enquiry Point, (15 min) Lydia Motlogelwa, Technical Officer, SAHPRA (15 min) Q&A: 10 min
12:10 – 12:30	**Medical Device Master Plan and the Role of regulation** Victor van Vuuren, Director Halovic
12:30 – 14:00	**Lunch**
14:00– 14:50	**Implementation of a Quality Management System for the regulatory processes of a National Regulatory Authority** Moderator: Dr Legohu Mogodi, SAHPRA Nancy Braier, US FDA, Virtual (40 min) Pre-recorded presentation
14:50 – 15:30	**Afternoon Tea Break / Open Conversation on GRPs with Marina Carvalho**
15:30 – 16:20	**Implementation of Good Regulatory Practices by National Regulatory Authorities: US FDA** Moderator: Marina Carvalho, MDRC Kristan Callahan, US FDA, Virtual (35 min) Q&A 15 min
16:20 – 16:30	**Wrap Up of the day & Closing Remarks** Dimakatso Mathibe, SAHPRA

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Day 2

Date: 15 November 2023
Time: 9:00 – 18:00 Pretoria, South Africa (2:00 – 11:00 AM ET)
Language: English
Platform: Hybrid (In-person: Southern Sun Pretoria Hotel, Cnr. Steve Biko and, Pretorius St, Arcadia, Pretoria, 0083). Please register here for virtual or in-person participation.

Time	Topic
8:00 – 9:00	**Participants Registration**
9:00 – 9:05	**Welcome and Opening Remarks** Sandra Ligia González, MDRC

9:05 – 10:05	**Overview of Medical Devices and IVDs**
	Moderator: Tanya Vogt, SAMED
	• **Overview MDs** (20 min)
	  ○ Tanya Vogt, SAMED
	  ○ Dirk Gey van Pittius & Fatemeh Razjouyan, Medtronic
	• **IVDs** (20 min)
	  ○ Sarah Cohen, SALDA
	  ○ Asmaa Awad, Roche Diagnostics (Virtual)
	Q&A 20 min

10:05 – 10:55	**Risk Classification of Medical Devices and IVDs – International References – Part I: Medical Devices** Moderator: Lydia Motlogelwa, SAHPRA **IMDRF References** Rama Sethuraman, Health Sciences Authority (HSA) (40 min) (Virtual) Q&A 10 min
10:55 – 11:15	**Morning Tea Break**
11:15 – 12:35	**Risk Classification of Medical Devices and IVDs – International References – Part II: IVDs IMDRF References** Moderator: Lydia Motlogelwa, SAHPRA Rama Sethuraman, Health Sciences Authority (HSA) (40 min) (Virtual) Q&A 10 min
12:35 – 13:00	**Risk Classification of Medical Devices and IVDs – Domestic Regulation** Moderator: Sandra Ligia González, MDRC Khanyisile Nkuku, SAHPRA (20 min) Q&A 5 min

13:00 – 14:00	**Lunch**
14:00 – 15:00	**Essential Principles of Safety and Performance – Part I** **IMDRF References** Moderator: Sandra Ligia González, MDRC Augusto Geyer, ANVISA (45 min) (Virtual) Q&A 15 min
15:00 – 16:00	**Essential Principles of Safety and Performance – Part II** **Panel Discussion NRAs and Regulated Sector Perspectives (45 min)** Moderator: Sandra Ligia González, MDRC Augusto Geyer, ANVISA (Virtual) Lydia Motlogelwa, SAHPRA Khanyisile Nkuku, SAHPRA Khatija Suleman, Becton Dickinson Sarah Cohen, SALDA Simone Rudolph-Shortt, MDMSA Fatemeh Razjouyan, Medtronic Tammy Steuerwald, Roche Diagnostics Q&A 15 min
16:00 – 16:10	**Wrap Up of the day & Closing Remarks** Dimakatso Mathibe, SAHPRA
16:10 – 18:00	**Reception for in-person participants**

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Day 3

Date: 16 November 2023
Time: 9:00 – 17:00 Pretoria, South Africa (2:00am -10:00 ET)
Language: English
Platform: Hybrid (In-person: Southern Sun Pretoria Hotel, Cnr. Steve Biko and, Pretorius St, Arcadia, Pretoria, 0083). Please register here for virtual or in-person participation.

Time	Topic
8:00 – 9:00	**Participants Registration**
9:00 – 9:05	**Welcome and Opening Remarks** Sandra Ligia González, MDRC
9:05 – 10:00	**International Standards. Its role in the Regulation of Medical Devices & IVDs** Moderator: Lydia Motlogelwa, SAHPRA Tracey Duffy, TGA (45 min) (Virtual) Q&A 10 min
10:00 – 11:00	**International Standards Management and Practical Application at a National level. The When, How and Who.** Moderator: Lydia Motlogelwa, SAHPRA Mapaseka Gumbi, Standards Writer|Natural Science: Food and Health Standards Department, South Africa Bureau of Standards, SABS (20 min) Simone Rudolph-Shortt, MDMSA (10 min) (Virtual) Global Manufacturers' Perspective – Jeff Eggleston (Fatemeh Razjouyan) – Medtronic (10 min) Q&A 20 min
11:00– 11:20	**Morning Tea Break**
11:20 – 12:20	**Reliance applied to Medical Devices & IVDs – International References and Experience of National Regulatory Authorities – Part I** Moderator: Sandra L. González, MDRC • **WHO - Good Reliance Practices –** Agnes Kijo, WHO, Virtual (20 min) (Virtual) • **Health Science Authority of Singapore –** Wong Woei Jiuang, HSA (30 min) (Virtual) ○ **Self–utilization** ○ **Thailand FDA - HSA Singapore Regulatory Reliance** Q&A 10 min
12:20 – 13:20	**Lunch**

13:20 –14:30	**Reliance applied to Medical Devices & IVDs – International References and Experience of National Regulatory Authorities**
	Moderator: Sandra L. González
	• **ANVISA –** Augusto Geyer (Virtual)
	  ○ New Regulation on GRelP (15 min)
	  ○ MDSAP – A success story of Reliance (15 min)
	• **Therapeutic Goods Administration (TGA) –** John Jamieson (15 min) (Virtual)
	• **SAHPRA** - Dimakatso Mathibe (15 min)
	Q&A 10 min

14:30 – 15:00	**Reliance applied to Medical Devices NRAs and Regulated Sector Perspectives – Panel discussion (20 min)** Moderator: Sandra Ligia González, MDRC • Tracy Duffy, TGA (Virtual) • Augusto Geyer, ANVISA (Virtual) • Dimakatso Mathibe, SAHPRA • Wong Woei Jiuang, HSA (Virtual) • Fatemeh Razjouyan, Medtronic • Tammy Steuerwald, Roche Diagnostics • Loshnee Vandayar, Cepheid, SALDA Q&A 10 min
15:00 – 15:20	**Afternoon Tea Break**
15:20 – 16:00	**Conformity Assessment** Moderator: Steven Bipes, AdvaMed Amy Phelps, National Institute of Standards and Technology, NIST (30 min) (Virtual) Q&A 10 min
16:00 – 16:40	**Conformity Assessment. The domestic perspective** Moderator: Steven Bipes, AdvaMed Tumelo Ledimo: SANAS (20 min) Q&A 20 min
16:40 – 17:00	**Closing Remarks** • Dimakatso Mathibe, SAHPRA • Andrew Fleming, Health Advisor, USAID • Sandra L. González, MDRC