Medical Device Regulatory Convergence Project (MDRC)
Good Regulatory Practices & Technical Competencies
Pharmacy and Poisons Board & Regulated Sector
Day 1

Date: 22 August 2023
Time: 9:00 – 18:00 Nairobi, Kenya (2:00-11:00 ET)
Language: English
Platform: Hybrid (In-person: Four Points by Sheraton Hurlingham, Nairobi, Kenya)

Time	Topic
8:30 – 9:00	**Participants Registration**
9:00 – 9:05	**Welcome and Opening Remarks** Sandra Ligia González, Medical Devices Lead - MDRC
9:05 – 9:15	**Opening Remarks** Dr. Fred M. Siyoi, Chief Executive Officer, PPB
9:15 – 9:20	**Opening Remarks** John Kuehnle, Health Population and Nutrition Director, USAID
9:20 – 9:30	**Welcome Message, Training Objectives and Overview** Paulyne Wairimu, Pharmacy and Poisons Board, Kenya
9:30 – 9:40	**MDRC Project Overview** David Wang'ombe, MDRC Africa Liaison / Sandra Ligia González, MDRC
9:40 – 10:30	**Overview of Medical Devices and IVDs** Paulyne Wairimu, PPB (40 min) Q&A: 10 min
10:30 – 10:50	**Morning Tea Break**
10:50 – 11:30	**International Benchmarks for Medical Device Regulatory Frameworks and Authorities: Health References & Recommendations** Moderator: Paulyne Wairimu, Pharmacy and Poisons Board, Kenya ● WHO Global Model Regulatory Framework for Medical Devices and IVDs ● WHO Good Regulatory Practices Agnes Kijo, World Health Organization (WHO), Virtual (30 min) Q&A: 10 min
11:30 – 12:30	**Introduction and Overview on Good Regulatory Practices (GRPs): Global and Domestic** ● **Global: WTO, OECD** Marina Carvalho, MDRC (30 min) ● **Domestic:** o **Statutory Instruments Act, 2013:** Public Consultations & Regulatory Impact Assessment, Maureen Njeri Muiruri (15 min) o **Guideline for Development, Review and Approval of Regulatory Instruments** Kibet Kisorio**,** Legal Department, PPB (20 min) Q&A: 10 min
12:30 – 13:30	**Implementation of Good Regulatory Practices by National Regulatory Authorities – Part I: US FDA** Kristan Callahan, US FDA, Virtual (50 min) Q&A 10 min

13:30 – 14:30	**Lunch**
14:30 – 15:30	**Implementation of Good Regulatory Practices by National Regulatory Authorities – Part II** Moderated by Eric Kitangala Rama Sethuraman, Health Sciences Authority (HSA) (50 min) Q&A 10 min
15:30 – 16:30	**Implementation of a Quality Management System for the regulatory processes of a National Regulatory Authority** Nancy Braier, US FDA, Virtual (50 min) Q&A 10 min
16:30 – 16:50	**Afternoon Tea Break**
16:50 – 17:50	**Implementation of a Quality Management System for the regulatory processes of a National Regulatory Authority – Fireside conversation** Rama Sethuraman, Health Sciences Authority (HSA) (50 min) Q&A 10 min
17:50 – 18:00	**Closing Remarks** Paulyne Wairimu, PPB and Sandra Ligia González, MDRC
18:30 – 20:00	**Reception for in-person participants** Rooftop – Four Points by Sheraton, Hurlingham, Nairobi

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Day 2

Date: 23 August 2023
Time: 9:00 – 18:00 Nairobi, Kenya (2:00-11:00 ET)
Language: English
Platform: Hybrid (In-person: Four Points by Sheraton Hurlingham, Nairobi, Kenya)

Time	Topic
8:30 – 9:00	**Participants Registration**
9:00 – 9:05	**Welcome and Opening Remarks** Sandra Ligia González, MDRC
9:05 – 10:05	Moderated by Eugene Odame-PPB **Overview of Medical Devices and IVDs** ● **Overview MDs** - Fatemeh Razjouyan & Steve Kipkoti (30 min) ● **IVDs** - Asmaa Awad, Roche Diagnostics (15 min) Q&A 15 min
10:05 – 11:00	**Risk Classification of Medical Devices and IVDs – International References – Part I: Medical Devices** **IMDRF References** Rama Sethuraman, Health Sciences Authority (HSA) (45 min) Q&A 10 min
11:00 – 11:20	**Morning Tea Break**
11:20 – 12:35	**Risk Classification of Medical Devices and IVDs – International References – Part II: IVDs** **IMDRF References** Rama Sethuraman, Health Sciences Authority (HSA) (45 min) **Risk Classification of Medical Devices and IVDs – Domestic Regulation** **PPB Guidelines** Solomon Koech, PPB (20 min) Q&A 10 min
12:35 – 13:00	**Panel Discussion on the impact of misalignment on Risk Classification (20 min)** Moderator: Tammy Steuerwald, Roche Diagnostics Rama Sethuraman, HSA Paulyne Wairimu, PPB Fatemeh Razjouyan, Medtronic Asmaa Awad, Roche Diagnostics Christopher Odero, Roche Diagnostics Q&A 5 min
13:00 – 14:00	**Lunch**
14:00 – 15:50	**Essential Principles of Safety and Performance – Part I** **IMDRF References** Moderated by Dr Dominic Munyoroku Augusto Geyer, Anvisa - Virtual (95 min)

	Q&A 15 min
15:50 – 16:10	**Afternoon Tea Break**
16:10 – 17:50	**Essential Principles of Safety and Performance – Part II** **Panel Discussion NRA's and Regulated Sector Perspectives** Moderator: Sandra Ligia González, MDRC Augusto Geyer, Anvisa - Virtual Paulyne Wairimu, PPB David Karenye, Medak, BBraun Fatemeh Razjouyan, Medtronic Tammy Steuerwald, Roche Diagnostics Q&A 15 min
17:50 – 18:00	**Closing Remarks** Paulyne Wairimu, PPB and Sandra Ligia González, MDRC

Medical Device Regulatory Convergence Project (MDRC)
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Day 3

Date: 24 August 2023
Time: 9:00 – 18:00 Nairobi, Kenya (2:00-11:00 ET)
Language: English
Platform: Hybrid (In-person: Four Points by Sheraton Hurlingham, Nairobi, Kenya)

Time	Topic
8:30 – 9:00	**Participants Registration**
9:00 – 9:05	**Welcome and Opening Remarks** Sandra Ligia González, MDRC
9:05 – 10:05	**International Standards. Its role in the Regulation of Medical Devices & IVDs** **Moderated by Julius Kalwai-PPB Kenya** Amanda Benedict, AAMI (25 min) Reuben Gisore, ARSO (25 min) Q&A 10 min
10:05 – 11:00	**Reliance applied to Medical Devices & IVDs – International References and Experience of National Regulatory Authorities – Part I** ● **WHO Guidance on Medical Devices –** Sunday Kisoma, WHO, Virtual (15 min) ● **Health Science Authority of Singapore –** Wong Woei Jiuang, HSA (30 min) ○ **Self – utilization** ○ **Thailand FDA - HSA Singapore Regulatory Reliance** Q&A 10 min
11:00 – 11:20	**Morning Tea Break**
11:20 –12:30	**Reliance applied to Medical Devices & IVDs – International References and Experience of National Regulatory Authorities** ● **ANVISA –** Augusto Geyer - Virtual ○ New Regulation on GRelP (15 min) ○ MDSAP – A success story of Reliance (15 min) ● **Therapeutic Goods Administration (TGA) –** John Jamieson, Virtual (15 min) ● **PPB –** Paulyne Wairimu (15 min) Q&A 10 min
12:30 – 13:30	**Lunch**

13:30 – 14:00	**Reliance applied to Medical Devices NRA's and Regulated Sector Perspectives – Panel discussion** Moderator: Alex Mutai-PPB ● John Jamieson, TGA - Virtual ● Augusto Geyer, ANVISA - Virtual ● Paulyne Wairimu, PPB ● Wong Woei Jiuang, HSA ● Tammy Steuerwald, Roche diagnostics ● Fatemeh Razjouyan, Medtronic Q&A 10 min
14:00 – 15:10	**International Standards Practical Application by National Regulatory Authorities and Manufacturers** **US FDA, S-CAP** – Scott Colburn/Terry Woods, Virtual (40 min) **Local Manufacturer's Perspective** – Roneek R. Vora, Revital (10 min) **Global Manufacturers' Perspective** - Jeffrey Eggleston, Medtronic, Virtual (10 min) Q&A 10 min
15:10 – 15:50	**Conformity Assessment** Gordon Gillerman, National Institute of Standards and Technology, NIST, Virtual (30 min) Q&A 10 min
15:50 – 16:10	**Afternoon Tea Break**
16:10 – 16:50	**Kenyan Standards and Conformity Assessment for Medical Devices** Lucy Ikonya KEBS (30 min) Q&A 10 min
16:50 – 17:00	**Closing Remarks** Paulyne Wairimu, PPB and Sandra L. González, MDRC