Medical Device Regulatory Convergence Project (MDRC)
Africa Medical Devices Forum (AMDF) / FDA Workshop Agenda
Nairobi, Kenya
November 6-10, 2023

Meeting location:
Radisson Blu Hotel, Nairobi Upper Hill, Kilimanjaro 3 Room
Elgon Rd
Nairobi, Kenya
Registration for in-person or virtual participation click here.

Purpose:
This workshop will provide an exchange of information and capacity building between the AMDF, its member NRAs and partner reference NRAs including the USFDA, TGA, HSA, ANVISA, also the Africa CDC and industry covering the core international references for medical device regulatory frameworks including the following core topics: IMDRF, international standards including ISO 13485 and ISO 14971, conformity assessment, MDSAP, Post-Market Activities, Good Reliance Practices, Proper Legal Foundations for Rulemaking including Good Regulatory Practices (GRP) and Technical Barriers to Trade (TBT), USFDA Regulation of Medical Devices, Reference NRA experiences, and other related topics. The workshop objective is to support and advance the AMDF 2023 Workplan and Training Plan in furtherance of the AMDF 5-year strategic plan accelerating African MD NRA capacities, to support the AMDF application as a Regional Harmonization Initiative (RHI) of the IMDRF, to strengthen the soft infrastructure of medical device regulatory frameworks on the continent 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. The workshop will also support acceleration of diagnostics access in Africa in collaboration with the Africa CDC support to AMDF medical device work through the Diagnostic Advisory Committee (DAC).

WORKSHOP AGENDA

Monday, November 6, 2023 – Day 1

8:00 am – 9:00 am	Registration
9:00 am – 9:05 am	Welcome Remarks Paulyne Wairimu, Head, Medical Devices and In-Vitro Diagnostics Health Products and Technologies, Pharmacy and Poisons Board (PPB)
9:05 am – 9:30 am	Opening Remarks • DR Fred Siyoi, Chief Executive Officer, Kenya Pharmacy & Poisons Board (PPB)

	• Alex Juma, Programme Officer, Regulatory Systems Strengthening, AUDA-NEPAD (Virtual) • Noah T. Fongwen, Diagnostics Access Coordinator at Africa Centers for Disease Control and Prevention (Africa CDC) • Daniel Vázquez, Sr. Standards Specialist & Textile and Apparel Industry Lead, U.S. Agency for international Development (USAID) • Leslie McDermott, Senior Director International Development, American National Standards Institute (ANSI) • Scott Colburn, USFDA: Director - Division of All Hazards Response, Science and Strategic Partnerships (DARSS), Center for Devices and Radiological Health (CDRH), Office of Strategic Partnership and Technology Innovation (OST) • Paulyne Wairimu, Chair AMDF
9:30 am – 9:45 am	Goals for the week • Sandra Ligia González – MDRC Tier 2 (Medical Technology) Project Lead
9:45 am – 10:15 am	Overview of FDA Regulation of Medical Devices (FDA 101) • Michelle Noonan, International Policy Analyst, USFDA/CDRH
10:15 am – 10:30 am	Break
10:30 am – 11:30 am	Overview of FDA Regulation of Medical Devices (FDA 101) / IMDRF and international harmonization • Michelle Noonan, USFDA/CDRH
11:30 am – 12:30 pm	Lunch Break
12:30 -pm – 2:45 pm	ISO 13485/14971 - What is 14971 and how is it incorporated into 13485? How is it used in standards? • Scott Colburn, USFDA/CDRH
2:45 pm – 3:00 pm	Break
3:00 pm – 4:30 pm	ISO 13485 • Melissa Torres, Associate Director for International Affairs, Office of the Center Director (OCD), Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (USFDA) (Virtual)
4:30 pm – 5:00 pm	Wrap up for the day – summarize and plan for next day - What are the priorities for regulators? - What are they hoping to focus on and get out of this week? • Dimakatso Mathibe – AMDF Vice Chair / South African Health Products Regulatory Authority (SAPHRA)
5:00 pm – 7:00 pm	Reception for in-person participants

Tuesday, November 7, 2023 – Day 2

8:00 am – 9:00 am	Registration
9:00 am – 9:30 am	Summarize Day 1 Work - Overview of Goals for the Day • Paulyne Wairimu – AMDF / PPB
9:30 am – 10:30 am	Breaking down the role of voluntary consensus standards • Joe Lewelling, Vice President Industry, Association for the Advancement of Medical Instrumentation (AAMI) / ANSI
10:30 am – 10:45 am	Break
10:45 am – 12:00 pm	Standards for regulatory use: 'putting standards to work' • Scott Colburn, USFDA: Director - Division of All Hazards Response, Science and Strategic Partnerships (DARSS), Center for Devices and Radiological Health (CDRH), Office of Strategic Partnership and Technology Innovation (OST) • Terry Woods, USFDA: CDRH/OST/DARSS – Acting Director, Standards and Conformity Assessment Program (SCAP)
12:00 pm – 1:00 pm	Lunch Break
1:00 pm – 2:15 pm	Conformity assessment: building regulators' confidence in device safety and performance • Scott Colburn, USFDA: DARSS/CDRH/OST – Standards and Conformity Assessment Program (SCAP) • Terry Woods, USFDA: CDRH/OST/DARSS – Standards and Conformity Assessment Program (SCAP)
2:15 pm – 2:30 pm	Break
2:30 pm – 3:30 pm	Optimizing standards for regulatory purposes • Scott Colburn, USFDA: DARSS/CDRH/OST – Standards and Conformity Assessment Program (SCAP) • Terry Woods, USFDA: CDRH/OST/DARSS – Standards and Conformity Assessment Program (SCAP) • Joe Lewelling, Association for the Advancement of Medical Instrumentation (AAMI) / ANSI
3:30 pm – 4:30 pm	Panel Discussion • Scott Colburn, USFDA: DARSS/CDRH/OST – Standards and Conformity Assessment Program (SCAP) • Terry Woods, USFDA: CDRH/OST/DARSS – Standards and Conformity Assessment Program (SCAP) • Joe Lewelling, Association for the Advancement of Medical Instrumentation (AAMI) / ANSI
4:30 pm – 5:00 pm	Wrap up for the day – summarize and plan for next day • Dimakatso Mathibe – AMDF / SAPHRA

Wednesday, November 8, 2023 – Day 3

8:00am – 9:00 am	Registration
9:00 am – 9:30 am	Summarize Day 2 Work – Overview of Goals for the Day • Paulyne Wairimu – AMDF / PPB
9:30 am – 10:30 am	Overview of MDSAP • Neil Mafnas, Senior Program Management Officer, International Affairs, Office of the Director, USFDA/CDRH
10:30 am – 10:45 am	Break
10:45 am – 11:30 am	Overview of MDSAP Audit Report & Certificate • Neil Mafnas, USFDA/CDRH • Linda Moon & Ajith John, British Standards Institution (Virtual)
11:30 am – 12:30 pm	MDSAP Audit Approach • Neil Mafnas, USFDA/CDRH • Linda Moon & Ajith John, BSI (Virtual) • Amy Nelson, Chapter Lead QMS, Quality Operations, Roche Diagnostics (Virtual)
12:30 pm – 1:30 pm	Lunch Break
1:30 pm – 2:30 pm	MDSAP Assessment Program • Neil Mafnas, USFDA/CDRH • Linda Moon & Ajith John, BSI (Virtual) • Amy Nelson, Roche Diagnostics (Virtual)
2:30 pm – 2:45 pm	Break
2:45 pm – 3:15 pm	MDSAP State of the Program • Neil Mafnas, USFDA/CDRH

3:15 pm – 4:45 pm	Post-Market Activities
	• Overview
	• Reporting and Actions
	  • Michelle Noonan, USFDA/CDRH
	  • Tammy Steuerwald, Global Head of Regulatory Policy, Foundational Principles & Supranational Organizations, Roche Diagnostics

4:45 pm – 5:00 pm	Wrap up for the day – summarize and plan for next day • Dimakatso Mathibe – AMDF / SAPHRA

Thursday, November 9, 2023 – Day 4

7:30 am – 8:30 am	Registration
8:30 am – 8:45 am	Summarize Day 3 Work – Overview of Goals for the Day • Paulyne Wairimu – AMDF / PPB
8:45am – 9:30 am	Good Reliance Practices • Tracey Duffy, First Assistant Secretary, Medical Devices & Product Quality Division, Health Products Regulation Group, Australian Therapeutic Good Administration (TGA) (Virtual)
9:30 am – 10:15 am	Good Reliance Practices • Rama Sethuraman, Director, Medical Devices, Medical Devices Cluster, Health Product Regulation Group, Singapore Health Sciences Authority (HSA) (Virtual)
10:15 am – 10:30 am	Break
10:30 am – 11:30 am	Good Regulatory Practices: A Regulator's Perspective • Kristan Callahan, Senior Public Health Advisor, Office of Trade and Global Partnerships, USFDA
11:30 am – 12:15 pm	World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT) and What It Means for Health Regulatory Authorities • Kristan Callahan, USFDA, Office of Trade and Global Partnerships • Marina Carvalho, MDRC Tier 1 Lead
12:15 am – 1:15 pm	Lunch Break
1:15 pm – 2:45 pm	IVDs – A Regional Overview • Africa Center for Disease Control – Diagnostics Advisory Committee Overview (20 min) ○ Noah T. Fongwen – Africa CDC • Elevating Diagnostics Availability (20 min) ○ Asmaa Awad, Global Regulatory Policy Network Lead EEMEA, & Christopher Odero, Regulatory Policy & Intelligence Manager, Roche Diagnostics Open Discussion (50 min)
2:45 pm – 3:15 pm	Break
3:15pm – 4:00 pm	Good Reliance Practices • Augusto Geyer, General Manager, Brazilian National Health Regulatory Agency – Health Products Division (ANVISA-GGTPS)
4:00 pm – 4:15 pm	Wrap up for the day – summarize and plan for next day Dimakatso Mathibe – AMDF / SAPHRA
4:15 pm – 4:45 pm	Closing Remarks/Wrap Up Meeting - Discuss next steps, timeframes, location/dates for possible next workshop • Paulyne Wairimu – AMDF / PPB • Daniel Vázquez - USAID

Friday, November 10, 2023 – Day 5

	Track 1 (G2G Meetings) (Closed Session) Chui (Leopard) Room	Track 2 (Standards and Conformity Assessment Workshops with KEBS) Kifaru (Rhino) Room
8:00 am – 9:00 am	US FDA - SAPHRA	Examination of MD Conformity Assessment Case Studies (reference separate agenda)
9:00 am – 10:00	US FDA – AUDA-NEPAD – MDRC meeting	
10:00 am – 10:45 am	Break	
10:45 am – 11:30 am	US FDA - EFDA	
11:30 am – 12:15 pm	US FDA - NAFDAC	
12:15 pm – 1:15 pm	Lunch Break	Lunch Break
1:15 pm – 2:15 pm	US FDA - PPB	International Standardization - Deeper Dive (please reference separate agenda)
12:15pm – 3:00 pm	US FDA – FDA Ghana	
3:00 pm – 3:15 pm	Break	Break
3:15 pm – 4:00 pm	US FDA – Africa CDC	Overview of the IECEE CB Scheme (please reference separate agenda)