Medical Device Regulatory Convergence Project (MDRC)
Workshop on Good Regulatory Practices and its implementation in the Medical Device Sector
Africa - MDRC Project Countries
Updated 30 Jan 23

Please use the following link to register to attend the two sessions:
https://us06web.zoom.us/webinar/register/WN_fJMuW5PhSHiPFt5mZlKkrg

Day 1

Date: 31 January 2023
Time: Nairobi: 15:00 – 17:30 UTC+3
Pretoria: 14:00 – 16:30 UTC+2
Washington DC: 7:00-9:30 ET/UTC-5
Language: English, simultaneous interpretation to Portuguese and French
Platform: Zoom

Time	Topic
15:00 – 15:10 (UTC+3)	**Welcome Message and Opening Remarks** Sandra Ligia González, MDRC Project Team
15:10 – 15:50 (UTC+3)	**Introduction and Overview on Good Regulatory Practices (GRPs)** **Renee Hancher**, Director for Regulatory Policies, Office of the United States Trade Representative (USTR) (30 min) **Q&A** (10 min)
15:50 – 16:35 (UTC+3)	**International Benchmarks for Medical Device Regulatory Frameworks and Authorities: Trade & Legal References and Obligations** Moderator: Renee Hancher, Office of the United States Trade Representative (USTR) (5 min) Panelist: **Anastasiia Kultunova**, Legal Office, World Trade Organization (WTO) (30 min) **Q&A** (10 min).
16:35 – 17:25 (UTC+3)	**African Regional Trade & GRP – Conversational Focus** Moderator: Steven Bipes – MDRC Project Lead, AdvaMed (5 min) **Kenya – Tobias Ololo,** Manager for Standards – Kenya Bureau of Standards (KEBS) and EAC/COMESA **United States – Renee Hancher**, Office of the United States Trade Representative (USTR) **Q&A** (15 min)
17:25 – 17:30 (UTC+3)	**Closing Remarks** (10 min) Steven Bipes – MDRC Project Lead, AdvaMed

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Day 2

Date: 1 February 2023
Time: Nairobi: 15:00 – 18:00 UTC+3
Pretoria: 14:00 – 17:00 UTC+2
Washington DC: 7:00-10:00 ET/UTC-5
Language: English, simultaneous interpretation to Portuguese and French
Platform: Zoom

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15:00 – 15:05 (UTC+3)	**Welcome Message and Opening Remarks** Sandra Ligia González, Medical Devices Lead - MDRC
15:05 – 15:50 (UTC+3)	**International Benchmarks for Medical Device Regulatory Frameworks and Authorities: Health References & Recommendations** Moderator: **Paulyne Wairimu**, Chair, Africa Medical Devices Forum (AMDF) (5 min) • WHO Global Model Regulatory Framework for Medical Devices and IVDs • WHO Good Regulatory Practices • WHO Good Reliance Practices **Agnes Sitta Kijo**, Technical Officer, Regulatory and Safety Unit (REG), Regulation and Prequalification Department (RPQ), World Health Organization (WHO) (30 min) **Q&A** (10 min).
15:50 – 16:10 (UTC+3)	**International References – international Medical Devices Regulators Forum (IMDRF)** **Michelle Noonan,** US Food and Drug Administration, Center for Devices and Radiological Health (FDA/CDRH) (15 min) **Q&A** (5 min)
16:10 – 16:30 (UTC+3)	**GRPs Checklist as a Tool to ensure Compliance** **Marina Carvalho**, MDRC Good Regulatory Practices Lead (15 min) **Q&A** (5 min)
16:30 – 17:40 (UTC+3)	**International Standards as a Base for Developing Regulations** Moderator: **Steven Bipes**, MDRC, AdvaMed Global Perspective, **Jessica Roop**, Senior Manager, International Development, American National Standards Institute (ANSI) (10 min) **Regional Perspectives:** **Reuben Gisore**, African Regional Standards Organization (ARSO) (10 min) **Michael Bromley**, USITA Commercial Officer – Standards Attaché – South Africa (10 min) Ghana: **Alexandre Dodoo**, Ghana Standards Authority (GSA) (10 min) Kenya: **Titus Oyoo**, Kenya Bureau of Standards (KEBS) (10 min) South Africa: **Mapaseka Gumbi**, South African Bureau of Standards (SABS) (10 min) **Q&A** (10 min).
17:40 – 17:55 (UTC+3)	**Africa Medical Device Forum – Its role to advance regulatory convergence** (15 min) **Dimakatso Mathibe**, AMDF -Vice-chair **Q&A** (5 min)
17:55 – 18:00	**Closing Remarks** **Paulyne Wairimu**, AMDF Chair and **Sandra Ligia González**, Medical Devices Lead - MDRC