6th Edition

MedDevREG AFRiSUMMIT | AFRiSUMMIT

1 - 2 OCTOBER 2026

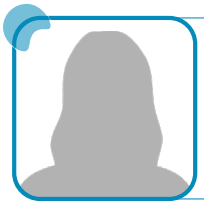
EMARA OLE-SERENI HOTEL, **NAIROBI - KENYA**

WWW.PHARMAREGAFRISUMMIT.COM

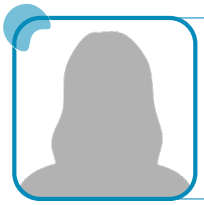
AGENDA (DAY :1)

07:45 - 08:15 REGISTRATION AND WELCOME RECEPTION

08:15 - 09:00 OPENING CEREMONY



Dr. Mona Al Moussli
Chairman of AfriSummit



Dr. Janki Chauhan
Chairperson,
Medical Technology Industry Association of Kenya (MEDAK)

Dr. Ali Arale
Ag Director Health Products and Technologies Pharmacy and Poisons Board (PPB), Kenya

09:00 - 09:20 SESSION 1: Driving Regulatory Convergence in Africa: AMDF's Vision for Medical Devices

Moderator By:

Mr. Marc Chaillou
Head of Sales Europe & Global Strategic Projects, Schlafender Hase

Presented by:

Dr. Paulyne Wairimu
Chair of AMDF and Chair, African Medical Devices Forum and Head for Medical Devices and In-Vitro Diagnostics, Health Products and Technologies, Pharmacy and Poisons Board (PPB), Kenya

09:20 - 09:35 SESSION 2: The Critical Role of IVDs in Strengthening Diagnostics, Disease Surveillance & Health Security Across Africa

Moderator by:

Mr. Marc Chaillou
Head of Sales Europe & Global Strategic Projects, Schlafender Hase

Presented by:

Dr. Lucy Mazyanga Mazaba Liwewe
Regional Director,
Africa CDC Eastern Africa RCC

6th Edition

MedDevREG AFRiSUMMIT | AFRiSUMMIT

1 - 2 OCTOBER 2026

EMARA OLE-SERENI HOTEL, **NAIROBI - KENYA**

WWW.PHARMAREGAFRISUMMIT.COM

AGENDA (DAY :1)

09:35 - 10:35 SESSION 3: East Africa Regulatory Landscape: Medical Devices, IVDs & Software as Medical Devices (SaMD)

Moderator by:

Dr. Mary Kinyanjui
Senior Specialist, Commercial Regulatory Affairs,
Cepheid Diagnostics

Presentation: Key National Updates from Kenya, Tanzania, Uganda, Rwanda, Ethiopia, and the EAC

Panel Discussion: Advancing Medical Device Regulation for the EAC: Strengthening Systems for Safety, and Access

Dr. Solomon Koech
Senior Regulatory Officer, Department of Product Evaluation and Registration, Medical Devices and In-vitro Diagnostics Unit, Pharmacy and Poisons Board (PPB),
Kenya

Ms. Neema Nagu
Senior Drug Registration Officer,
Tanzania Medicines and Medical Devices Authority (TMDA),
Tanzania

Dr. Rachel Juliet Mujawimana
Inspector of Drugs, National Drug Authority (NDA),
Uganda

Dr. Vedaste Habyarimana
Head of Drugs Department,
Food and Drug Authority (FDA),
Rwanda

Mr. Nathan Seyoum
External Medicine Dossier Assessor,
Ethiopian Food and Drug Authority (EFDA),Ethiopia

Mr. Alex Gisagara
Regulatory Harmonization Expert at the East African Community (EAC) Secretariat

10:35 - 11:00 COFFEE BREAK AND NETWORKING

AGENDA (DAY :1)

11:00 - 12:00 | **SESSION 4: Combating Counterfeit and Substandard Medical Devices in Africa: Regulatory and Digital Solutions**

Moderator by:

Dr. John Paul Omollo
Policy and Government Affairs Partner, Africa, Roche

Leveraging WHO Guidelines and Regional Networks to Safeguard Medical Device Integrity

Presented by:

Dr. Edwin Kojo Ogara
Technical Officer for Essential Drugs and Medicines, World Health Organization

Fighting Counterfeit Medical Devices in Africa: The Role of Track and Trace Systems

Presented by:

Mr. Wilfrid Sewade
Marketing Specialist, VISIOTT TPS

Panel Discussion: Strategies for Securing Device Integrity

Mr. Roland Sefakor
Head, Medical Devices Registration Department, Food and Drugs Authority (FDA), Ghana

Mr. Lindsay Kipkemoi
Deputy Director Enforcement, Anti-Counterfeit Authority (ACA))

6th Edition

MedDevREG AFRiSUMMIT | AFRiSUMMIT

1 - 2 OCTOBER 2026

EMARA OLE-SERENI HOTEL, **NAIROBI - KENYA**

WWW.PHARMAREGAFRISUMMIT.COM

AGENDA (DAY :1)

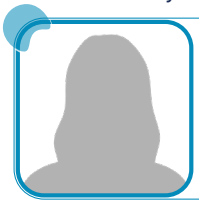
12:00 - 13:00 SESSION 5: Regulatory Reliance and Convergence in Practice: Leveraging Global Decisions for Faster Access in Africa

Moderated by:

Mr. Steve Kipkoti
Senior Regulatory Affairs Specialist, Medtronic

Advancing IVD Regulatory Excellence in Africa: Reliance, Harmonisation & Capacity Building

Presented by:



Ms. Nataliya Deych
Chair, MedTech Europe Middle East and Africa Working Group, Vice President, Regulatory Affairs EMEACLA, Edwards Lifesciences

FDA's Approach to International Partnerships for African Regulators

Presented by:

Mr. Ravi Bharwani
Deputy Director, Office of Global Policy and Strategy, United States Food and Drug Administration

Panel Discussion: The Future of Continental Regulatory Alingment

Dr. Edwin Kojo Ogara
Essential Drugs and Medicines Officer & Technical Focal Point – Health Products and Technologies, World Health Organiza

Ms. Nataliya Deych
Chair, MedTech Europe Middle East and Africa Working Group, Vice President, Regulatory Affairs EMEACLA, Edwards Lifesciences

Dr. Tanya Vogt
Executive Officer, South African Medical Technology Industry Association (SAMED)

Dr. Marie Bouchra
Regional Manager Regulatory Affairs and Policy MEA, Johnson & Johnson

13:00 - 14:00 LUNCH, GROUP PHOTO AND NETWORKING

6th Edition

MedDevREG AFRiSUMMIT | AFRiSUMMIT

1 - 2 OCTOBER 2026

EMARA OLE-SERENI HOTEL, **NAIROBI - KENYA**

WWW.PHARMAREGAFRISUMMIT.COM

AGENDA (DAY :1)

14:00 - 15:00 SESSION 6: Regulatory Oversight for AI-Driven Medical Devices

Moderated by:

Dr. Vinod Guptan
Board Director and Board Lead of the Supply Chain Committee, Kenya Healthcare Federation

AI-Powered Regulatory Affairs: Transforming Registration and Accelerating Approvals

Presented by:

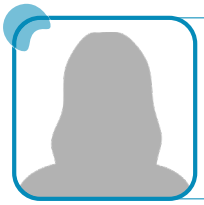
Mr. Sebastian Neuwirth
Head of Government Solutions, Antares Vision Group

From SaMD to AI: Building the Digital Regulatory Backbone for Lifecycle Oversight in Africa

Presented by:

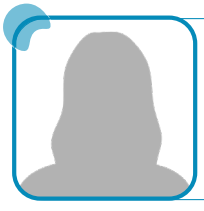
Mr. Chacha Sammy Nyanswi
Project Manager and IRIMS Implementation Team Lead, SoftClans Technologies Limited

Panel Discussion: Co-Creating SaMD Regulation and Africa's Pathway Forward



Dr. Paulyne Wairimu
Head for Medical Devices and In-Vitro Diagnostics, Health Products and Technologies, Pharmacy and Poisons Board (PPB), Kenya

Mr. Sebastian Neuwirth
Head of Government Solutions, Antares Vision Group



Ms. Sarah Cohen
Strategic Executive Officer, Southern African Laboratory Diagnostics Association (SALDA)

Mr. Monir El Azzouzi
CEO & Founder, Easy Medical Device

AGENDA (DAY :1)

15:00 - 16:00 SESSION 7: Navigating the New Era of MedTech in North Africa

Moderated by:

Dr. Karim Wahba
Head of Regulatory Affairs and Trade Compliance for Middle East & Africa, Merck Life Science

Tunisia Regulatory Updates

Dr. Racha Jomaa
Regulatory Affairs Pharmacist & Medical Device Specialist, National Agency for Medicines and Health Products (ANMPS), Tunisia

Morocco Regulatory Updates

Presented by:

Dr. Fadoua Oudrhiri
Head of Evaluation and Authorization Division for Health Products Agency for Medicines and Health Products (AMMPS)

Egypt Regulatory Updates

Presented by:

Dr. Nourhan Mohsen Mohammed AbdelKader ElNaggar
Scientific Evaluation Unit Manager-General Administration of Medical Devices Marketing authorizationm Egyptian Drug Authority (EDA), Egypt

16:00 - 16:30 COFFEE BREAK AND NETWORKING

6th Edition

MedDevREG AFRiSUMMIT

AFRiSUMMIT

1 - 2 OCTOBER 2026

EMARA OLE-SERENI HOTEL, **NAIROBI - KENYA**

WWW.PHARMAREGAFRISUMMIT.COM

AGENDA (DAY :1)

16:30 - 17:00 SESSION 8:

Panel Discussion: Risk Classification and Regional Harmonization

Moderated by:

John Juma
Regulatory Affairs Specialist,
East Africa,
Becton Dickinson

Dr. Nourhan Mohsen Mohammed AbdelKader ElNaggar
Scientific Evaluation Unit
Manager-General Administration
of Medical Devices Marketing
authorizationm Egyptian Drug Authority
(EDA), Egypt

Dr. Avanthi Govender Bester
Chairperson, The South African Medical
Technology Industry Association (SAMED)

Dr. Solomon Koech
Senior Regulatory Officer, Department
of Product Evaluation and Registration,
Medical Devices and In-vitro Diagnostics Unit,
Pharmacy and Poisons Board (PPB),
Kenya

Mr. Robert Mayama
Managing Director,
Autosterile (EA)

17:00 - 18:00 CLOSING REMARKS & ROUNDTABLE DISCUSSIONS

6th Edition

MedDevREG AFRISUMMIT | AFRISUMMIT

1 - 2 OCTOBER 2026

EMARA OLE-SERENI HOTEL, **NAIROBI - KENYA**

WWW.PHARMAREGAFRISUMMIT.COM

AGENDA (DAY :2)

08:00 - 08:20	**REGISTRATION AND WELCOME RECEPTION**
08:20 - 08:30	**OPENING CEREMONY**
08:30 - 09:30	**SESSION 1: The Future of Medical Device & IVD Regulation in Southern Africa: Implementation, Reliance & Regional Harmonisation**

Moderated by:

Dr. Avanthi Govender Bester
Chairperson, The South African Medical Technology Industry Association (SAMED)

Zimbabwe Regulatory Updates

Presented by:

Dr. Zivanai Antony Makoni
Head of the Evaluations and Registrat on Division, Medicines Control Authority of Zimbabwe (MCAZ)

SAHPRA - Medical Device Including IVDs South Africa

Presented by:

Ms. Lydia Motlogelwa
Medical Device and Clinical Trials Manager, South African Health Products Regulatory Authority (SAHPRA), South Africa

Zambia Regulatory Updates

Presented by:

Mr Lyoko Nyambe
Director Marketing Authorisation, Zambia Medicines Regulatory Authority (ZAMRA), Zambia

6th Edition

MedDevREG AFRiSUMMIT | AFRiSUMMIT

1 - 2 OCTOBER 2026

EMARA OLE-SERENI HOTEL, **NAIROBI - KENYA**

WWW.PHARMAREGAFRISUMMIT.COM

AGENDA (DAY :2)

09:30 - 10:45 SESSION 2: Strengthening Materiovigilance From Approval to Oversight

Moderated by:

Mr. Monir El Azzouzi
CEO & Founder,
Easy Medical Device

Materiovigilance: From Approval to Oversight

Presented by:

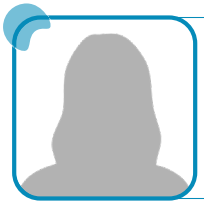
Dr. Mai Faied
Regulator & Vigilance Specialist,
Egypt & Libya,
Medtronic

Rwanda's Strategy for Device Vigilance Integration

Presented by:

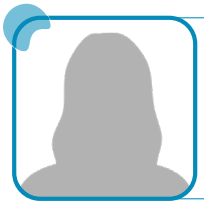
Dr. Vedaste Habyarimana
Head of Drugs Department,
Food and Drug Authority (FDA),
Rwanda

Panel Discussion: Making Post-Market Surveillance Work: Aligning Regulators, Industry, and Systems in Africa



Dr. Khadijah O. Ade-Abolade
Director, Vaccines, Biologics & Medical Devices Registration and Regulatory Affairs, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria

Dr. Vedaste Habyarimana
Head of Drugs Department,
Food and Drug Authority (FDA),
Rwanda



Dr. Mai Faied
Regulator & Vigilance Specialist,
Egypt & Libya
Medtronic

Ms. Nataliya Deych
Chair, MedTech Europe Middle East and Africa Working Group, Vice President, Regulatory Affairs EMEACLA, Edwards Lifesciences

10:45 - 11:15 COFFEE BREAK AND NETWORKING

6th Edition

MedDevREG AFRiSUMMIT | AFRiSUMMIT

1 - 2 OCTOBER 2026

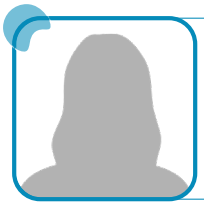
EMARA OLE-SERENI HOTEL, **NAIROBI - KENYA**

WWW.PHARMAREGAFRISUMMIT.COM

AGENDA (DAY :2)

11:15 - 12:15 SESSION 3: Medical Device Nomenclature and Traceability: Building Safer Device Ecosystems in Africa

Moderated by:



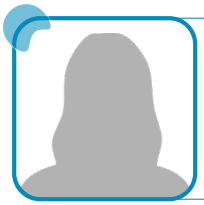
Dr. Catherine Maina
Regulatory Affairs Expert

UDI Adoption and Traceability Frameworks

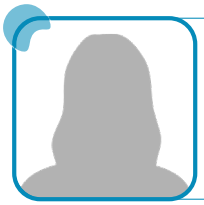
Presented by:

Mr. Joseph Oloo
Software and Data Management Team Lead,
GS1 Kenya

Panel Discussion: From Egypt's Blueprint to Kenya's Scale to Africa's Device Traceability Future



Dr. Nourhan Mohsen Mohammed AbdelKader ElNaggar
Scientific Evaluation Unit Manager-General Administration of Medical Devices Marketing Authorization (EDA),
Egypt



Dr. Paulyne Wairimu
Head for Medical Devices and In-Vitro Diagnostics, Health Products and Technologies, Pharmacy and Poisons Board (PPB),
Kenya

Mr. Joseph Oloo
Software and Data Management Team Lead,
GS1 Kenya

Dr. Mirette Abskharoun
Regulatory Affairs Associate Director Middle East Africa Region,
Johnson & Johnso

Mr. Prem Kumar
Sr. Director,
LSpedia

AGENDA (DAY :2)

12:15 - 13:15 SESSION 4: West Africa Regulatory Updates

Moderated by:

Dr. Eric Konan
Head of the Regulatory Affairs, Subsaharan Africa, ETHICA

Ivory Coast Regulatory Updates

Presented:

Dr. Gnamon Achy Christian Martial
Registration Department for Innovative Products, Vaccines and Medical Devices, Ivorian Pharmaceutical Regulatory Authority (AIRP), Ivory Coast

Senegal Regulatory Updates

Presented:

Dr. Arame Mbengue
Pharmacist Inspector, Head, Department for the Approval of Drugs and Other Health Products at the Directorate for the Approval and Serialization of Drugs and Other Health Products (DIHS), Senegalese Pharmaceutical Regulatory Agency (ARP)

Medical Device Regulatory Updates - Nigeria

Presented by:

Dr. Khadijah O. Ade-Abolade
Director, Vaccines, Biologics & Medical Devices Registration and Regulatory Affairs, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria

AGENDA (DAY :2)

Update on the Ghana Medical Device Regulatory Space

Presented by:

Mr. Roland Sefakor
Head, Medical Devices Registration Department, Food and Drugs Authority (FDA), Ghana

Questions and Answers - Democratic Republic of the Congo

Adv. Olivia Esiso Ngomosi
Chief Executive Officer & Managing Director, LIVY SARLU

13:15 - 14:15	**LUNCH, GROUP PHOTO AND NETWORKING**
14:15 - 15:00	**SESSION 5:**

Panel Discussion: Industry on Medical Devices in Africa & Aligning Priorities for Growth and Accesss

Moderated by:

Ms. Simone Rudolph-Shortt
Chairperson, Medical Device Manufacturers of South Africa (MDMSA)

Rana Chalhoub
Regulatory Affairs Director, MECOMED

Dr. Racha Jomaa
Regulatory Affairs Pharmacist & Medical Device Specialist, National Agency for Medicines and Health Products (ANMPS), Tunisia

Dr. Lucas Nyabero
Director & Superintendent Pharmacist, Xenopia group Limited

6th Edition

MedDevREG AFRiSUMMIT | AFRiSUMMIT

1 - 2 OCTOBER 2026

EMARA OLE-SERENI HOTEL, **NAIROBI - KENYA**

WWW.PHARMAREGAFRISUMMIT.COM

AGENDA (DAY :2)

15:00 - 15:30 SESSION 6:

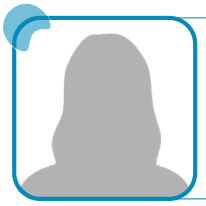
Panel Discussion: Enabling Decentralised Diagnostics: Regulatory Approaches for POCT Expansion

Moderated by:

Dr. Mona Al Moussli
MSc,
Chairman of the AfriSummit

Dr. Paulyne Wairimu
Head for Medical Devices and In-Vitro Diagnostics, Health Products and Technologies, Pharmacy and Poisons Board (PPB), Kenya

Ms. Sarah Cohen
Strategic Executive Officer, Southern African Laboratory Diagnostics Association (SALDA)



Ms. Kim Stephenson
Clinical and Regulatory Affairs Associate, AI Diagnostics

15:30 - 15:45 COFFEE BREAK AND NETWORKING

15:45 - 16:00 SESSION 7: Clinical Evidence for MD: Balancing Innovation and Regulatory Requirements

Moderated by:

Dr. Michael Onyango
Regulatory Affairs Manager, Axmed

Right-Sized Clinical Evidence: Practical Strategies for Medical Device Approval and Innovation in Africa

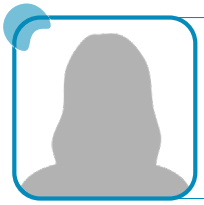
Presented by:

Mr. Hilton Tommy Stevens
Head of Regulatory Affairs and Quality Assurance, Viya Health

AGENDA (DAY :2)

13:30 - 14:15 SESSION 8: Ensuring Quality in Medical Devices and IVDs

Moderated by:



Ms. Catherine Kokeno
Supervisor, Regulatory Affairs and Local Compliance Officer, Beta Healthcare

Role of Rapid Micro Methods in Medical Devices

Presented by:

Mr. Priyank Modi
Senior Manager, Quality Control, Sahjanand Medical Technology

Dr. Prafulla K. Chitnis
Senior Director of Business Development for the Middle East, India and Bangladesh, Charles River Laboratories Microbial

Building Quality Ecosystems That Enable Access and Innovation

Presented by:

Ms. Simone Rudolph-Shortt
Chairperson, Medical Device Manufacturers of South Africa (MDMSA)

16:40 - 17:30 SESSION 9: Audit and Inspection Readiness

Presented by:

Dr. Matlapeng Shabalala
Regulatory Affairs and Quality Assurance Manager, Viya Health

AGENDA (DAY :2)

Inspection Readiness in Rwanda and the Evolving Regulatory Expectations for Manufacturers

Presented by:

Dr. Vedaste Habyarimana
Head of Drugs Department,
Food and Drug Authority (FDA),
Rwanda

Building Audit Readiness in African Medical Device and IVD Manufacturing

Presented by:

Mr. Monir El Azzouzi
CEO & Founder,
Easy Medical Device

Questions and Answers

Closing Remarks

Ms. Mary Muthoni
Principal Secretary, State Department for Public Health and Professional Standards, Ministry of Health (MOH), Kenya

17:30 - 18:30 | **ROUNDTABLE DISCUSSIONS**