

6th
Edition



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:

Presented by:

Mr. Mete Karaca

Executive Board Member,
Tiga Healthcare Technologies

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:

Presented by:

Mr. Mete Karaca

Executive Board Member,
Tiga Healthcare Technologies

Prof. Mazyanga Lucy Mazaba

Public Health Expert



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 KinyanjuiSenior 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. Purity Mutinda**Regulatory Pharmacist,
Marketing Authorization Directorate,
Pharmacy and Poisons Board (PPB), Kenya**Ms. Neema Nagu**Senior Medical Devices 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**Dr. Alex Gisagara**Regulatory Harmonization Expert
at the East African Community (EAC) Secretariat**10:35 - 11:00****COFFEE BREAK AND NETWORKING**

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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

Essential Drugs and Medicines Officer
& Technical Focal Point – Health Products
and Technologies, 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. Rowland Sefakor

Head, Medical Devices Registration Department,
Food and Drugs Authority (FDA), Ghana

Dr. Edwin Kojo Ogara

Essential Drugs and Medicines Officer
& Technical Focal Point – Health Products
and Technologies, World Health Organization

Mr. Lindsay Kipkemai

Deputy Director Enforcement,
Anti-Counterfeit Authority (ACA)

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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

Joint MedTech Europe-Mecomed Paper: EU MDR & IVDR on International Registrations

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: FDA's Approach to Reliance-based Partnerships

Dr. Edwin Kojo Ogara

Essential Drugs and Medicines Officer
& Technical Focal Point – Health Products
and Technologies, World Health Organization

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 (SAMEDI)

Dr. Marie Bouchra

Regional Manager Regulatory Affairs
and Policy MEA, Johnson & Johnson

13:00 - 14:00

LUNCH, GROUP PHOTO AND NETWORKING

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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

From Submission to Approval: How AI Is Transforming Regulatory Affairs and Regional Harmonization

Presented by:

Mr. Sebastian Neuwirth

Head of Government Solutions,
Antares Vision Group

The SaMD Evolution: Framing Regulatory Oversight for AI-Driven Medical Devices 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

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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), Morocco

Egypt Regulatory Updates

Presented by:

Dr. Nourhan ElNaggar

Scientific Evaluation Unit Manager-General
Administration of Medical Devices Marketing
authorization Egyptian Drug Authority (EDA), Egypt

16:00 - 16:30

COFFEE BREAK AND NETWORKING



AGENDA (DAY :1)

16:30 - 17:00

SESSION 8:

Panel Discussion: Risk Classification and Regional Harmonization

Moderated by:

Dr. John JumaRegulatory Affairs Specialist,
East Africa, Becton Dickinson**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**Dr. Nourhan ElNaggar**Scientific Evaluation Unit Manager-General
Administration of Medical Devices Marketing
authorization Egyptian Drug Authority (EDA), Egypt**Mr. Robert Mayama**

Managing Director, Autosterile (EA)

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

17:00 - 18:00

CLOSING REMARKS & ROUNDTABLE DISCUSSIONS



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 Registration 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



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 FaiedRegulator & Vigilance Specialist,
Egypt & Libya, Medtronic

Rwanda FDA Update on Materiovigilance Status

Presented by:

Dr. Vedaste HabyarimanaHead 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-AboladeDirector, 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**



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

GS1 Unique Device Identification (UDI)

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 ElNaggar

Scientific Evaluation Unit Manager-General Administration
of Medical Devices Marketing authorization
Egyptian Drug Authority (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 & Johnson



Mr. Prem Kumar

Sr. Director, LSpedia

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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. Rowland 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: Aligning Regulatory Priorities for Medical Device Market Access and Local Manufacturing Growth in Africa

Moderated by:

Ms. Simone Rudolph-Shortt

Chairperson, Medical Device Manufacturers
of South Africa (MDMSA)

Dr. Racha Jomaa

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

Rana Chalhoub

Regulatory Affairs Director,
MECOMED

Dr. Lucas Nyabero

Director & Superintendent Pharmacist,
Xenopia group Limited



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 WairimuHead 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 OnyangoRegulatory Affairs Manager,
Axmed**Right-Sized Clinical Evidence: Practical Strategies for Medical Device Approval and Innovation in Africa**

Presented by:

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



AGENDA (DAY :2)

16:00 - 16:40**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**

Moderated by:

Dr. Matlapeng Shabalala

Regulatory Affairs
and Quality Assurance Pharmacist,
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

Before the Inspection Begins: Inspection Readness for Regulatory Authorities

Presented by:

Mr. Monir El Azzouzi

CEO & Founder, Easy Medical Device

Questions and Answers

Closing Remarks

Dr. John M. Munyu

MBS, Chairperson,
Pharmacy and Poisons Board (PPB), Kenya