MedDevREG AFRiSUMMIT

Grand Nile Tower, Cairo - Egypt

5 & 6 November 2024

AGENDA

DAY 1: November 5th

9:00 - 9:30

COFFEE & REGISTRATION

9:30 - 10:00

Introduction

Welcome Address

Dr. Mona Al Moussli
Chairman of
AfriSummit

Opening Remarks

Dr. Miriam Boles
Head of Central Administration
of Medical Devices - Egyptian
Drug Authority (EDA)

10:00 - 11:00

Session 1: Reliance and Regulatory Convergence of Medical Technology

Moderated by:
Dr. Fatma Wahdan
Regulatory and Quality Lead – Medtronic Egypt, North & West Africa

Benefits and Challenges from Industry Perspective

Mr. Christopher Odero
Pan-Africa Regulatory Policy & Intelligence
Partner - Roche Diagnostics

Realiance from Regulator Perspective

Dr. Noha El Hariri
General Manager of General Administration
of Medical Device Registration & Supervisor
of Investment Support & Localization of
Medical Devices Medical Equipment & IVDs
Egyptian Drug Authority (EDA)

Panel Discussion:

AUDA-NEPAD

Dr. Nancy Ngum
Public Health Officer- AUDA-NEPAD

South Africa

Ms. Khanyisile Nkuku
Medical Device & IVD Regulatory Expert

PPB (Kenya)

Dr. Shellan Omondi
Regulatory Officer - Pharmacy and
Poisons Board (PPB), Kenya

AGENDA

DAY 1: November 5th

11:00 - 11:45

Session 2: NRA Medical Device Updates - North Africa

Moderated by:
Dr. Alaa Okasha
Regional Senior Regulatory Affairs Associate - STADA, MENA

Egypt Medical Device Regulatory Updates

Dr. Noha El Hariri
General Manager of General Administration of Medical Device Registration & Supervisor of Investment Support & Localization of Medical Devices, Medical Equipment & IVDs
Egyptian Drug Authority (EDA)

Tunisia Medical Device Regulatory Updates

Dr. Rafik Khazri
Pharmacist • National Agency of Medicines and Health Products in Tunisia

Morocco Medical Device Regulatory Updates Q&A

Dr. Saadia Abatour
Chief of Medical Devices Unit - Directorate of medicines and pharmacy (DMP) Morocco

Q&A Panel Discussion

11:45 - 12:15

COFFEE AND NETWORKING BREAK

AGENDA

DAY 1: November 5th

12:15 - 13:15 **Session 3: Assessing the Impact of EU MDR/IVDR Amendments on Africa**

Moderated by:
Dr. Rana Chalhoub
Regulatory Affairs Director - Mecomed

Update on EU MDR/IVDR implementation

Mr. Dario Belluomini
Manager International Affairs - MedTech Europe

The Impact of EU MDR Updates on Africa's Medical Technology Regulatory Landscape

Dr. Shaimaa Salah
Associate Director Regulatory Affairs
North Africa & Regulatory Advocacy
Middle East & Africa - Alcon

Q&A Panel Discussion

Dr. Miriam Boles
Head of Central Administration of Medical Devices - Egyptian Drug Authority (EDA)

Dr. Asmaa Awad
Global Head of Eastern Europe, Middle East, and Africa Regulatory Policy - Roche Diagnostics

13:15 - 14:15 **CONFERENCE PHOTO, LUNCH & NETWORKING**

AGENDA

DAY 1: November 5th

14:15 - 15:15

Session 4: Enhancing Patient Safety: Materiovigilance in Medical Devices

Moderated by:
Dr. Dalia Safwat
Quality Assurance Manager for Africa & ME - Alcon

Egyptian Medical Devices Vigilance Requirements in Pre-market and Post-market

Dr. Lamiaa Attia
Manager of Medical Devices Vigilance Unit
Egyptian Drug Authority (EDA)

Why Build New? Leveraging EU PMS for MEA's Success

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

Q&A Panel Discussion:

15:15 - 15:45

Session 5: NRA Medical Device Updates - West Africa

Moderated by:

Mr. Hilton T. Stevens
Head of Regulatory Affairs and Quality Assurance
Responsible Pharmacist
Population Services International, South Africa

Ghana Medical Device Regulatory Updates

Mr. Rowland Sefakor
Head Medical Devices Department
Food and Drugs Authority, Ghana

Ivory Coast Medical Device Regulatory Updates

Dr. Kone Dahafolo
Deputy Director of Approval of Medicines and Other Pharmaceutical Products - Ivorian Pharmaceutical Regulation Authority (AIRP)

Q&A Panel Discussion

MedDevREG AFRiSUMMIT

Grand Nile Tower, Cairo - Egypt

5 & 6 November 2024

AGENDA

DAY 1: November 5th

15:45 - 16:15 — **COFFEE AND NETWORKING BREAK**

~~16:15 - 17:15~~ — **~~Session 6: Advancing Standards: Regulatory Insights into Medical Device Manufacturing in Africa~~**

Moderated by:
Dr. Abdelrahman Abdellatif
Regulatory Affairs & Quality Team Leader – MRG

Enhancing Quality Control: Best Practices in African Medical Device Production

Mrs. Simone Rudolph-Shortt
Chairperson at MDMSA

New Guidelines from South Africa on Local Manufacturing

Ms. Khanyisile Nkuku
Medical Device & IVD Regulatory Expert

Regional Manufacturing Updates - Egypt

Dr. Noha El Hariri
General Manager of General Administration of Medical Device Registration & Supervisor of Investment Support & Localization of Medical Devices, Medical Equipment & IVDs
Egyptian Drug Authority (EDA)

Q&A Panel Discussion

PPB (Kenya)
Dr. Shellan Omondi
Regulatory Officer - Pharmacy and Poisons Board (PPB), Kenya

17:15 — **Round Table Break out Discussions**

Egypt
Dr. Noha El Hariri
General Manager of General Administration of Medical Device Registration & Supervisor of Investment Support & Localization of Medical Devices, Medical Equipment & IVDs
Egyptian Drug Authority (EDA)

Tunisia
Dr. Rafik Khazri
Pharmacist • National Agency of Medicines and Health Products in Tunisia

Ivory Coast
Dr. Kone Dahafolo
Deputy Director of Approval of Medicines and Other Pharmaceutical Products - Ivorian Pharmaceutical Regulation Authority (AIRP)

Morocco
Dr. Saadia Abatour
Chief of Medical Devices Unit - Directorate of medicines and pharmacy (DMP) Morocco

Ghana
Mr. Rowland Sefakor
Head Medical Devices Department
Food and Drugs Authority, Ghana

AGENDA

DAY 2: November 6th

09:00 - 09:30 COFFEE & REGISTRATION

09:30 - 10:15 Session 1: Medical Device Regulatory Updates: Southern Africa

Moderated by:
Dr. Madelein Terblanche
Senior Operations Consultant - VECTOR Life Sciences

South Africa Medical Device Regulatory Updates

Ms. Khanyisile Nkuku
Medical Device & IVD Regulatory Expert

Botswana Medical Device Regulatory Updates

Mr. Thabo Bryan Bokhutlo
Regulatory Officer Medical Devices
Botswana Medicines Regulatory Authority (BoMRA)

Zambia Medical Device Regulatory Updates

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

Q&A Panel Discussion



AGENDA

DAY 2: November 6th

10:15 - 11:00

Session 2: Digital Documentation: Regulatory Guidelines on Electronic Instructions for Use (IFU)

Moderated by:
Dr. Rana Chalhoub
Regulatory Affairs Director - Mecomed

Global Perspective of Digitisation

Mr. Dirk Gey Van Pittius
RAQA Southern Africa Leader – Medtronic, Africa

Impact of Digitization on Regulatory Framework

Dr. Mirette Abskharoun
RA Associate Director Middle East
Africa Region - Johnson & Johnson

Q&A Panel Discussion

Egyptian Drug Authority (EDA)

Dr. Noha El Hariri
General Manager of General Administration of Medical Device Registration & Supervisor of Investment Support & Localization of Medical Devices, Medical Equipment & IVDs
Egyptian Drug Authority (EDA)

Food and Drugs Authority, Ghana

Mr. Rowland Sefakor
Head Medical Devices Department
Food and Drugs Authority, Ghana

11:00 - 11:30

COFFEE AND NETWORKING BREAK

AGENDA

DAY 2: November 6th

11:30 - 12:15

Session 3: Innovating Compliance for IVD

Moderated by:
Ms. Sarah Cohen
Executive Officer – Southern African Laboratory Diagnostics Association (SALDA)

Streamlining Regulatory Approvals for Cutting-Edge Diagnostics

Ms. Loshnee Vandayar
Senior Manager, Regulatory Affairs, EEMEA - Cepheid

Panel Discussion: Shaping the Future of IVD Regulations: Key Challenges and Emerging Opportunities

Panel Moderator:

Dr. Maha Zahran
Owner of Uniclue for Consultation Services

Egyptian Drug Authority (EDA)

Dr. Heba Ahmed Sadiq
Manager of Administration of In Vitro
Diagnostic (IVD) Listing - Egyptian Drug Authority (EDA)

Industry Perspective:

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

Mr. Karim Wahba
Head of Regulatory Affairs
and Trade Compliance
Middle East & Africa - Merck Life Science

Ms. Loshnee Vandayar
Senior Manager, Regulatory Affairs
EEMEA
Cepheid

AGENDA

DAY 2: November 6th

12:15 - 13:15

Session 4: Securing the Supply Chain: Combating Counterfeits in Medical Devices in Africa

Moderated by:
Mr. Brian Savoie
Sr. Vice President, Education & International Programs
Regulatory Affairs Professionals Society (RAPS)

Recommendations for Effective UDI Implementation

Dr. Noha El Hariri
General Manager of General Administration of Medical Device Registration & Supervisor of Investment Support & Localization of Medical Devices, Medical Equipment & IVDs
Egyptian Drug Authority (EDA)

Counterfeits

Mr. Görkem Aydın
International Marketing Manager – VISIOTT

Supply Chain

Dr. Hisham Stait
Vice Chairman, Unified Procurement Authority - Egypt

Q&A Panel Discussion

13:15 - 14:15

LUNCH AND NETWORKING BREAK

AGENDA

DAY 2: November 6th

14:15 - 15:15

Session 5: Ensuring Compliance in Africa: MDSAP Audits and Site Inspections for Medical Devices

Moderated by:
Dr. Marwa Said
Regulatory Affairs Manager, Africa – Boston Scientific

Presenter

Dr. Marie Bouchra
Manager Regulatory Affairs & Policy
MEA, Gulf, Levant & Iraq - Johnson & Johnson MedTech

Panelist

Ms. Khatija Suleman
Head Regulatory Affairs Africa – Becton Dickinson
& Vice Chairperson SAMED Regulatory Committee

Panelist

Dr. Shellan Omondi
Regulatory Officer - Pharmacy and
Poisons Board (PPB), Kenya

Panelist

Mr. Dario Belluomini
Manager International Affairs - MedTech Europe

AGENDA

DAY 2: November 6th

15:15 - 16:00 **Session 6: Status Updates on New Regulations in Medical Device - East Africa**

Moderated by:
Steve Kiptoki
Regulatory Sr. Specialist – English Speaking
Africa & VES • Medtronic

Rwanda Medical Device Regulatory Updates
Dr. Emil Ivan Mwikarago
Technical Analyst, Assessment of Medical Devices
In Vitro Diagnostics (IVDs), Vaccines, & Biologicals
Rwanda Food and Drugs - Authority (Rwanda FDA)

Kenya Medical Device Regulatory Updates
Dr. Solomon Koech
Regulatory Officer, Medical Devices and In-Vitro
Diagnostics Evaluation & Registration
Pharmacy and Poisons Board (PPB), Kenya

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

Uganda Medical Device Regulatory Updates
Dr. Marvin Turinaiwe
Regulatory Officer
National Drug Authority (NDA), Uganda

Tanzania Medical Device Regulatory Updates
Mr. James Tanguye
Medical Device Officer
Tanzania Medicines & Medical Devices Authority (TMDA)

Q&A Panel Discussion





AGENDA

DAY 2: November 6th

16:00 **Round Table Break out Discussions**

South Africa
Ms. Khanyisile Nkuku
Medical Device & IVD Regulatory Expert

Tanzania
Mr. James Tanguye
Medical Device Officer
Tanzania Medicines & Medical Devices Authority (TMDA)

Kenya
Dr. Shellan Omondi
Regulatory Officer - Pharmacy and Poisons Board (PPB), Kenya

Kenya
Dr. Solomon Koech
Regulatory Officer, Medical Devices and In-Vitro Diagnostics Evaluation & Registration
Pharmacy and Poisons Board (PPB), Kenya

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

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

Uganda
Dr. Marvin Turinaiwe
Regulatory Officer
National Drug Authority (NDA), Uganda

16:00 **COFFEE BREAK**