

AGENDA



DAY 1: 10 October 2023

TIME ZONE: GMT +3

8:00 - 9:00

BREAKFAST REGISTRATION

8:00 - 9:15

AfriSummit Opening



Introduction by

Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy



AfriSummit Official Opening

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

9:15 - 9:45

National Regulatory Authority Medical Device Updates - Egypt



Moderated by

Ms. Shaimaa Salah
Regulatory Affairs Associate
Director North Africa & Middle East Clusters
Alcon



EDA Egypt

Dr. Noha El Hariri
General Director
General Administration of Medical Devices Registration
Egyptian Drug Authority
Eda

9:45 - 10:30

EU Regulatory updates and MDR Status



Moderated by

Dr. Nariman Hussein Fahmy
Senior RA Specialist Gulf & Levant
Johnson & Johnson Medtech



EU MDR Extension Impact

Mr. Monir El Azzouzi
CEO & Founder
Easy Medical Device



EU Manufacturer's Template

Mr. Dario Belluomini
Manager International Affairs
Medtech Europe



Impact of EU MDR on African Regulators

Dr. Noha El Hariri
General Director
General Administration of Medical Devices Registration
Egyptian Drug Authority
Eda

Q & A Discussion Panel





10:30 - 11:00

National Regulatory Authority Medical Device Updates - Algeria



Moderated by
Dr. Hassiba Chemli
Regulatory Affairs Manager
Regional Vigilance officer
Lohmann & Rauscher - MENA



Regulations governing the approval of medical devices in Algeria
Réglementation régissant de l'homologation des dispositifs médicaux en Algérie

Dr. Saida Foughalia Fridi
Deputy Director of Scientific Documentary Evaluation of Medical Devices
The National Agency for Pharmaceutical Products
ANPP

11:00 - 11:30

National Regulatory Authority Medical Device Updates - Morocco



Moderated by
Ms. Majda Mghimimi
Senior Regulatory Affairs Specialist
French Speaking Africa
Medtronic



Presented by
Mr. Morad Ajan
Head of Medical Device Unit
Directorate of Medicine and Pharmacy
Morocco

11:30 - 12:00

Coffee and Networking Break

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12:00 - 12:30

Medical Device Regulatory Updates - Saudi- Arabia



Moderated by
Ms. Alaa Okasha
Regional Senior Regulatory Affairs Associate
GETM & GCC
STADA MENA



Presented by
Dr. Hamoud Alsahl
Regulatory Affairs Team Leader
MRG (KSA & UAE)



Presented by
Dr. Abdelrahman Abdellatif
Regulatory Affairs Team Leader
MRG (Egypt)

12:30 - 13:15

NRA Medical Device Updates - West Africa



Moderated by
Ms. Loshnee Vandayar
Senior Manager
International Regulatory Affairs
(Middle East and Africa) - Cepheid



Regulations to Assess Quality and Safety to ensure performance of Medical Device in Nigeria
Mr. Emmanuel Armon
Deputy-Director
Head of Biologics
Vaccine and Medical Devices Division
Nafdac



Ghana FDA
Mr. Emmanuel Nkrumah
Director For The Medical Device
Cosmetics And Household Chemicals Directorate
The Food And Drugs Authority
Fda
Ghana

Q & A Discussion Panel



13:15 - 13:30

Conference Photo and Competition announcement

13:30 - 14:30

Lunch and Networking Break

14:30 - 15:00

Medical Device Manufacturing in Africa



SADAC Countries
Ms. Simone Rudolph-shortt
Chairperson
MDMSA



15:00 - 16:00

Status updates on New Regulatory in Medical Device - EAST AFRICA



Moderated by
Dr. Mary Kinyanjui
Senior Regulatory Affairs Specialist
Cepheid



Regulatory Requirements & how to navigate registration process in Tanzania
Mr. Christian Natais Kapinga
Drug Registration Officer
Tanzania Medicines and Medical Devices Authority
TMDA



Rwanda
Dr. Emil Ivan Mwikarago
Department of Human Medicine and Device assessment & Registration
Division of Human Medicine
Assessment and Registration
Rwanda FDA



Ethiopia
Mr. Abebe Alamneh Kassahun
Medicine Registration Expert
Ethiopian Food and Drug Authority (EFDA)
Vice Chairman
East African regulatory Affairs Professionals Association (EARAPA)

We are a leading name in medical device consultancy, assisting you with services and working closely with various Regulatory Authorities all over MENA and Asian regions.

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16:00 - 17:00

Transition to the IVDR



Moderated by
Ms. Sarah Cohen
Executive Officer at Southern African Laboratory Diagnostics Association SALDA



EU IVDR Transitions
Dr. Lydia Mina
Regulatory Affairs Regional Manager for The Region: Metap & Uk (Middle East, Turkey, Africa & Pakistan & Uk) Abbott



Impact of IVDR Transition on African regulations
Ms. Loshnee Vandayar
Senior Manager
International Regulatory Affairs (Middle East and Africa)
Cepheid

Q & A Discussion Panel



Tanzania
Drug Registration Officer
Tanzania Medicines & Medical Devices Authority



Ghana
Mr. Emmanuel Nkrumah
Director for The Medical Device Cosmetics And Household Chemicals Directorate at the Food And Drugs Authority (Fda) – Ghana



Ethiopia
Mr. Abebe Alammeh Kassahun
Medicine Registration Expert
Ethiopian Food and Drug Authority (EFDA)
Vice Chairman
East African regulatory Affairs Professionals Association (EARAPA)



SOUTH AFRICA
Ms. Khanyisile Nkuku
Medical Device Registration Officer
SAHPRA

17:00 - 17:15

Wrap up day 1



Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy



17:15 - 18:00

Coffee and Networking Break

17:15 - 18:00

Round Table Break out Discussions

EDA



Hosted by
Dr. Miriam Boles
Medical Devices - Egyptian Drug Authority
EDA



Hosted by
Dr. Noha El Hariri
General Director
General Administration of Medical Devices Registration
Egyptian Drug Authority (Eda)

NAFDAC

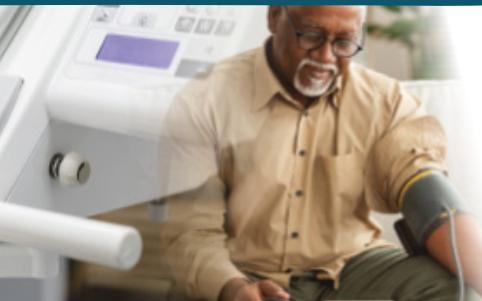


Mr. Emmanuel Armon
Deputy-Director
Head of Biologics
Vaccine and Medical Devices Division
Nafdac

ANPP



Hosted by
Dr. Saida Foughalha Fridi
Deputy Director of Scientific Documentary Evaluation of
Medical Devices the National Agency for Pharmaceutical Products
ANPP



10&11 OCTOBER 2023

11:30 - 12:00

Coffee and Networking Break

12:00 - 12:30

Digitalization of Medical Device Applications



Moderated by
Mr. Charle Leibbrandt
Partner
VECTOR Life Sciences (Pty) Ltd



Presented by
Mr. Kent Briggs
Director
VECTOR Life Sciences

12:30 - 13:30

UDI initiatives



Moderated by
Dr. Rami Mansour
Regulatory Affairs Manager
Egypt – Becton Dickinson



UDI implementation in Egypt
Dr. Haythem Saby
Head of Regulatory Solutions
Gs1



UDI SFDA
Dr. Abdelrahman Abdellatif
Regulatory Affairs Team Leader
MRG (Egypt)

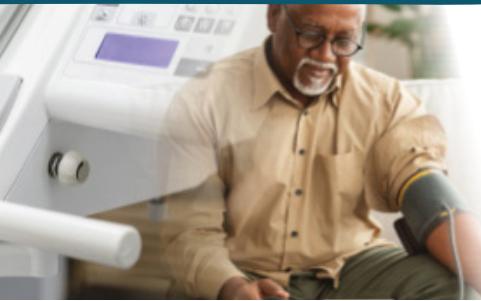
Panel discussion UDI initiatives and regulations in the region



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

13:30 - 14:30

Lunch



10&11 OCTOBER 2023

14:30 - 15:45

Reliance and Regulatory Convergence of Medical Technology



Moderated by
Dr. Asma Awad
Global Regulatory Policy
Lead E E M E A
Roche Diagnostics



GMTA Paper on Reliance
Dr. Asma Awad
Global Regulatory Policy
Lead E E M E A
Roche Diagnostics

Panel discussion Industry



Ms. Rana Chalhoub
Regulatory Affairs Director
Mecomed



Mr. Dario Belluomini
Manager International Affairs
Medtech Europe



Dr. Fatma Wahdan
Regulatory Affairs and Quality
Assurance Manager Medtronic
Egypt & Libya Cluster

Capacity Building and NRA Support needed



Dr. Noha El Hariri
General Director
General Administration of
Medical Devices Registration
Egyptian Drug Authority (Eda)



Mr. Christian Natalis Kapanga
Drug Registration Officer
Tanzania Medicines &
Medical Devices Authority
TMDA



Ms. Khanyisile Nkuku
Medical Device Registration Officer

15:45 - 16:45

Materiovigilance and Post marketing Surveillance



Moderated by
Ms. Salma Salim
Senior Regulatory Affairs Manager
GE HealthCare



Dr. Rima Nsheiwat
Regulatory Access and Market intelligence
Strategist and Consultant
B.V. Amsterdam Medical & Scientific Alliance

Panel discussion



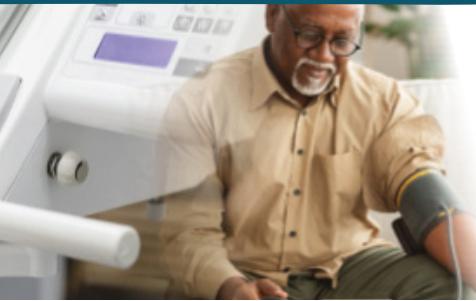
Dr. Saida Foughalia Fridi
Deputy Director of Scientific Documentation
Evaluation of Medical Devices
The National Agency for
Pharmaceutical Products
ANPP



Mr. Christian Natalis Kapanga
Drug Registration Officer
Tanzania Medicines &
Medical Devices Authority
TMDA



Mr. Monir El Azzouzi
CEO & Founder
Easy Medical Device



16:45 - 17:00

Wrap up and conclusion



Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy

17:00- 18:00

Round Table Break out Discussions



Ms. Kesego Moalosi
Medical Devices Regulatory Officer
Botswana Medicines Regulatory Authority
BoMRA



Dr. Frank N Laban
Principal Registration Officer
Zambia Medicines Regulatory Authority
ZAMRA



Mr. Christian Natalis Kapinga
Drug Registration Officer
Tanzania Medicines &
Medical Devices Authority
TMDA

17:15 - 18:00

Coffee and Networking Break