MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

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 Devises 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 Devises Registration
Egyptian Drug Authority
Eda

Q & A Discussion Panel

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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

Presneted by
Dr. Hamoud Alsahli
Regulatory Affairs Team Leader
MRG (KSA & UAE)

Presneted 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 Amon
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

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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 Natalis Kapinga
Drug Registration Officer
Tanzania Medicines and Medical Devices Authority
TMDA

Rawanda

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)

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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 Alamneh 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

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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 Authorit
EDA

Hosted by
Dr. Noha El Hariri
General Director
General Administration of Medical Devises 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 Foughalia Fridi
Deputy Director of Scientific Documentary Evaluation of Medical Devices the National Agency for Pharmaceutical Products
ANPP

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AGENDA

DAY 2: 11 October 2023

TIME ZONE: GMT +3

9:00 - 9:30

Morning Welcome Address

Good regulatory practices an enabler for market access

Ms. Rana Chalhoub
Regulatory Affairs Director
Mecomed

9:30 - 10:30

Medical Device Regulatory Updates: SOUTHERN AFRICA

Moderated by
Ms. Avanthi Govender Bester
Member of the Board
past Chair and Vice Chairperson
SAMED

South Africa
Ms. Khanyisile Nkuku
Medical Device Registration Officer

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

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

Zimbabwe
Mr. Richard Tendayi Rukwata
Director General
Medicines Control Authority of Zimbabwe
MCAZ

10:30 - 11:30

Digital Tools and Green Submissions - PRESNETATION & PANEL DISCUSSION

Moderated by
Dr. Marwa Said
Regulatory Affairs Manager
Boston Scientific

Global Perspective of Digitisation
Ahmed Hachami
Regulatory Affairs Specialist
Johnson & Johnson MedTech

Impact of Digitization on Regulatory Framework
Dr. Rania Soliman
General Manager
General Administration of Market Authorization of Medical Devices
Egyptian Drug Authority
Eda

Electronic IFU
Dr. Carol Attieh
Growth Emerging Markets - GEM
Regulatory Lead
Boston Scientific Middle East
FZ LLC

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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

Pesented 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 Sabry
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 Authorit
EDA

13:30 - 14:30 Lunch

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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 Devises Registration
Egyptian Drug Authority (Eda)

Mr. Christian Natalis Kapinga
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 Doc Evaluation of Medical Devices
The National Agency for Pharmaceutical Products
ANPP

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

Mr. Monir El Azzouzi
CEO & Founder
Easy Medical Device

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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