



MedDevREG AFRiSUMMIT

INNOVATED HEALTH
FOR AFRICA



5 & 6 Sept 2022

Platform OPENS @ 8:00am CENTRAL AFRICAN TIME
Meet Up at the Network Lobby
Browse the Exhibition Booths
BE VISIBLE - create your AFRiSUMMIT Business Card



AFRiSUMMIT will be DUAL language
with French & English translations

Agenda: DAY 1: 5 Sept. 2022

The Agenda is in CENTRAL AFRICAN TIME ZONE
(GMT+2)

08:00 - 09:00 Platform Opens

09:00 - 09:15	Introduction by	Dr. Mona Al Moussli, Director, PRA Consultancy
	Welcome Address	Dr. Myriam Boulos, Head of the Central Administration for Medical Supplies, Egyptian Drug Authority, EDA

09:15 - 10:00	Medical Device Classification	Moderated by: Lea Atallah, Associate Director QA/RA, Zimmerbiomet
09:15 - 09:25	The importance of Med Dev Regulations	Camilla Borrini, MDR Program Manager, Zimmer Biomet
09:25 - 10:00	Overview of Medical Device Classification	Dr. Lydia Mina, Regional RA Manager, APOC Regulatory AMTI Countries ABBOTT

10:00 - 11:45	Accelerating Medtech Innovations through regulatory agility & harmonization	Moderated by: Rana Chalhoub, RA Director, Mecomed
10:00 - 10:15	African Overview Regulation	Hella Khemiri, Project Director MENA, 1MED SA
10:15 - 10:35	AMDF Harmonization	Dimakatso Mathibe, Vice Chair, AMDF
10:35 - 10:55	USAID MDRC project MD convergence	Sandra Ligia González, MDRC Project, Tier 2 Leader
10:55 - 11:15	Strengthening Medical Device Regulations in Africa-MTaPS Rwanda Experience	Nereah Kisera, MBA, MA, Bpharm, Senior Technical Advisor Regulatory Systems Strengthening.
11:15 - 11:45	Panel Discussion	
11:45 - 12:15	Coffee Break	



12:15 - 13:30	Regulatory updates from Egypt & EU	Moderated by: Dr. Shaimaa Salah, Regulatory Affairs Associate Director Africa Cluster, Alcon
12:15 - 12:40	Regulatory updates Global Perspectives: EU	Monir El Azzouzi, CEO & Founder, Easy Medical Device
12:40 - 13:05	Regulatory updates EDA	Noha Al-Hariri, General Manager, General Administration of Registration, Department Central Medical Supplies, Egyptian Drug Authority, EDA
13:05 - 13:30	Q&A and Panel Discussion	
13:30 - 14:30	Lunch - Join the Speed Networking Session and grow your connections	



Speed Networking will take place in the Conference Room of the Networking Lobby





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Agenda: DAY 1: 5 Sept. 2022 CONTINUES

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14:30 - 15:45	Pays d'Afrique francophone	Modéré par: Nadjet MEZIANI , Head of RA - North & West Africa, Bausch Health
14:30 - 14:45	Tunis DPM Règlement sur les DIV et les dispositifs médicaux	Olfa Ben Smida, Direction de la Pharmacie et du Médicament (DPM)
14:45 - 15:00	Côte d'Ivoire	Dr. Neully Konan Kouadio, Pharmacien, AIRP, Au cœur de l'activité pharmaceutique, Côte d'Ivoire
15:00 - 15:15	Réglementation Marocaine sur les Dispositifs Médicaux	Salma Salim, RA Program Manager, North & West Africa, GE Healthcare
15:10 - 15:30	Algeria	Nadjet MEZIANI, Head of RA, North & West Africa, Bausch Health
15:30 - 15:45	Discussion en group	
15:45 - 16:00	Coffee Break	



16:00 - 16:30	QMS Evaluation and Manufacturing in Africa	Moderated by: Christine Wahba Align Tech
16:00 - 16:30	QMS Evaluation and Manufacturing in Africa	Dr. Maryam George - Director of the laboratory reagents unit in the Department of Inspection of laboratory supplies and reagents in the administration Central Operations, Egyptian Drug Authority, EDA
16:30 - 18:00	Linking Medical Device Business with Compliance	Moderated by: Len Lazarus, Director, Independent Management Consultant Import & Export Specialist
16:30 - 16:45	Medical Device Manufacturing through Africa	Simone Rudolph-Shortt Chairperson MDMSA & CEO ISOhealthSA
16:45 - 17:00	Role of the Consultant: Navigating the Regulations	Mark Banfield, Chair, MDPG Medical Device Professional Group
17:00 - 17:15	Import and export	Neville Mayhew, Global Project Manager - Import/Export Specialist, Africa Region, Oxmio
17:15 - 17:30	Storage and Distribution	Rob Van den Berg, Regional Director - OXIMIO sub-Saharan Africa
17:30 - 18:00	Q&A Panel discussion	
18:00	End of Day 1	





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Agenda: DAY 2: 6 Sept. 2022

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Platform OPENS @ 8:00am CENTRAL AFRICAN TIME

09:00 – 09:05

Welcome Address

Dr. Mona Al Moussli

09:05 – 9:30

MDSAP

Moderated by: Salma Salim, RA Program Manager, North & West Africa, GE Healthcare

Medical Device Single Audit Program

Asma Fessi, Responsable management de la qualité chez medical device, Medpoint LLC-USA

09:30 – 11:15

New Regulatory in Medical Device East Africa

Moderated by: David Karenye, Head of Regulatory Affairs, B.Braun

09:30 – 09:50

Tanzania MDR

Christian Kapinga, Drug Registration Officer, TMDA

09:50 – 10:10

Uganda Release of Medical Device Regulations

Brenda Clare Kitimbo, Manager Medical Devices, NDA Uganda

10:10 – 10:30

Rwanda

Dr Placide Muhayimana, Diagnostics and Medical Devices Registration Specialist Rwanda Food & Drugs Authority

10:50 – 11:10

Ethiopia

Daniel Takelem, Medical devices dossiers Assessor, EFDA

11:10 – 11:30

Q&A and Panel discussion

11:30 – 11:45

Coffee Break

11:45 – 13:30

Updates on Medical Device South&West Africa

Nadia Issad, Director Commercial Regulatory Affairs & Quality MEA, Smith & Nephew

11:45 – 12:10

South Africa Regulations:

Dimakatso Mathibe, Snr Manager Medical Device Unit, SAHPRA

12:10 – 12:30

Botswana Releases new Regulations

Batlegang Dallas Mosweu, Manager, Medical Devices, BOMRA

12:30 – 12:50

Zimbabwe MDR

Mr Albert Maqolo, Senior Analyst, Medical Devices & Microbiology Division, MCAZ

12:50 – 13:10

Ghana Regulatory updates

Mr. Emmanuel Nkrumah, Director, Medical Devices, Cosmetics & Household chemicals GFDA

13:10 – 13:30

Q&A

13:30 – 14:30

Lunch

14:30 – 16:00

In Vitro Diagnostics

Moderator: Sarah Cohen, Executive Officer, SALDA

14:30 – 14:50

IVD Regulatory Considerations in Africa

Dr. Michelle Bronze, SALDA, Robyn Howes, SALDA

14:50 – 15:10

Clinical Evaluation
An overview of the current landscape in SA

Loshnee Vandayar, Cepheid

15:10 – 15:30

IVD Clinical Performance Studies -
Guidance & best practices for observational studies

Michelle Bulliard, Vice President, MedTech Real World Evidence & MedTech Center of Excellence, IQVIA

15:30 – 16:00

Panel Discussion

16:00 – 16:15

Coffee Break

16:15 – 17:30

Materiovigilance

Moderated by: Ahmed Hachami, J&J

16:15 – 16:45

Evolution of Materiovigilance in Africa

Ahmed Hachami, Johnson & Johnson

16:45 – 17:15

Materiovigilance Morocco

Dr. Fedoua Khadiri, Pharmacienne au Centre Antipoison et de Pharmacovigilance Marocain

17:15 – 17:30

Q&A and Panel Discussion

17:30 – 18:00

Close of First MedDevReg and Photo op

