



# 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

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

|                      |                                           |                                                                            |
|----------------------|-------------------------------------------|----------------------------------------------------------------------------|
| <b>09:15 - 10:00</b> | <b>Medical Device Classification</b>      | <b>Moderated by: Lea Atallah, Associate Director QA/RA, Zimmerbiomet</b>   |
| 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 |

|                      |                                                                                        |                                                                                            |
|----------------------|----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| <b>10:00 - 11:45</b> | <b>Accelerating Medtech Innovations through regulatory agility &amp; harmonization</b> | <b>Moderated by: Rana Chalhoub, RA Director, Mecomed</b>                                   |
| 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                                                                           |                                                                                            |



|                      |                                                                     |                                                                                                                                            |
|----------------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| <b>12:15 - 13:30</b> | <b>Regulatory updates from Egypt &amp; EU</b>                       | <b>Moderated by: Dr. Shaimaa Salah, Regulatory Affairs Associate Director Africa Cluster, Alcon</b>                                        |
| 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

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

**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

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



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