







Platform OPENS @ 8:00am CENTRAL AFRICAN TIME

Meet Up at the Network Lobby

**Brows the Exhibition Booths** 



# **DAY 1: 12 September 2022**

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

8:00 - 9:00

**Breakfast Registration Meet Up at the Network Lobby** 

# **Inauguration and Morning Welcome**

Dr. Mona Al Moussli • Co Founder • Managing Director • PRA Consultancy

# AMA - African Medicines Agency towards regulatory strengthening in Africa

#### Moderated by

Dr. Hala Abu Ghazalah • Head of Regulatory Affairs • Africa & Middle East • Pfizer

## AMA ratification a milestone to be celebrated

Keynote Speaker: Dr. Michel Sidibé • Africa Union Special Envoy for The Africa Medicine Agency

## African Medicines Regulatory Harmonization (AMRH) initiative- achievements to build on

Margareth Ndomondo-Sigonda • Head of Programme • AUDA-NEPAD

# The role of Biopharmaceutical industry in regulatory strengthening

Greg Perry • Assistant Director General • IFPMA

## **Advancing Regulatory Systems in Africa**

Kate Kikule • Senior Technical Advisor • Regulatory Systems Strengthening portfolio • Africa region. The United States Agency for International Development (USAID) • Medicines Sciences for Health (MSH) Medicines • Technologies and Pharmaceutical Services (MTaPS)

# Optimizing Regulatory Processes in Africa and lessons learnt from the pandemic

Lenias Hwenda • CEO • Medicines4africa

# Panel discussion: Aspirations and hopes of (National Regulatory Authorities) NRAs under AMA

Uganda: Mr. Mwesigwa Denis • Director Inspectorate and Enforcement National Drug Authority • Uganda

# **Session 2**

# Regional Harmonizations: Joint assessment procedures - Marketing Authorizations and beyond

## Moderated by

Dr. Patricia Salami • PhRMA MEA

Regional Regulatory Affairs Head • MEAR Region (Middle East, Africa, Turkey, Russia & CIS) • Merck Group

EAC

Alex Juma Ismail • Regional Technical Officer • EAC

DRO • Tanzania Medicines & Medical Devices Authority (TMDA),

ZaZiBoNa

Farai Masekela

• Assessments Coordinator • ZAZIBONA

Collaboration & the Head of Evaluations & Registration • MCAZ • Zimbabwe

Sybil Nana Ama Ossei-Agyeman-Yeboah • Ag. Principal Professional Officer Public Health • WAHO

# **Industry Perspective**

Nevena Milisavljevic • IFPMA Africa Regulatory Network & IFPMA CPP Network Co-chair

Regulatory Policy Lead, Global Regulatory Policy • F. Hoffmann-La Roche

11:15 -11:30

# **Coffee and Networking Break**

















# **DAY 1: 12 September 2022 Continue**

11:30- 12:30

# Session 3: Regulatory Updates in the Pharma Market - Egypt

#### Moderated by

Dr. Heba Nabil • Pfizer

#### **Egypt Pharma Regulations**

Dr. Mona Moussa • Director of Administration • Technical Affairs of the Administration public sign up Human preparations • Central administration for Pharmaceuticals • Egyptian Drug Authority • EDA

## **Egypt Biologics Regulations**

Dr. Huda Al-Saeed • Director of the Development and Advice Unit • Support Department Technician • General Administration of Vital Preparations • Central Administration for biological and innovative preparations and clinical studies • Egyptian Drug Authority • EDA

#### **Egypt Biologics Post Market Approvals**

Dr. Reem Mahmoud Mahmoud Al-Tanahi • Unit Manager Variables in the Registry Department General Administration of Pharmaceuticals Vitality in the central administration for prebiotics • Innovative and studies Clinical • Egyptian Drug Authority • EDA

12:30 - 13:30

#### Session 4

## **Pharma Manufacturing and Localisation - Regulatory view**

#### Moderated by

John M. Mwangi • Head, Regulatory Affairs & Quality Assurance - East & West Central Africa • Bayer

## **Overview of African Pharma Manufacturing**

Dr. Ahmed Ogwell • Acting Director • Africa Centers for Disease Control & Prevention

# The PMPA Governance Framework: Strengthening coordination to improve efficiency and effectiveness

Dr. Janet Byaruhanga • Senior Programme Officer • Head of Health Unit • AUDA-NEPAD

# **Opportunities for Private Sector in Pharma Manufacturing**

Dr. Amit N. Thakker • Executive Chairman • Africa Healthcare Federation

## **Local Manufacturer Experience**

Stavros Nicolaou • Senior Executive • Aspen Pharmacare Group

13:30 - 14:30 Central African Time

# Lunch and Networking Break Join the Speed Networking Session

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



14:30 - 15:30

# **Session 5**

## **Access to Innovative Medicine in Africa**

# **Moderated by**

Dr. Inas Chehimi • Snr Regulatory Affairs Director • Novartis

# Presented by

Simge Sasmaz • Principal, Consulting Services • IQVIA

Harmandeep Singh • Engagement Manager • IQVIA

# **Panelist Industry Perspective**

Qutaiba Al Manaseer • Corporate Affairs Director • AstraZeneca

# **Panelists NRA Perspective**

Lorraine Danks • Backlog Clearance Programme Manager • SAHPRA











# **DAY 1: 12 September 2022 Continue**



# **Coffee and Networking Break**





**Meet Up at the Network Lobby** 

**15:45- 16:45**Central African Time

#### **Session 8:**

# **ECOWAS: Regulatory updates of ECOWAS Countries and Reliance Overview**

# **Moderated by**

Emeka Chukwurah • Regulatory Affairs • CQRAFF Solutions

## **RA Harmonization in ECOWAS**

Sybil Nana Ama Ossei-Agyeman-Yeboah • Ag. Principal Professional Officer Public Health • WAHO

# **Ghana Pharma Updates Regulations**

Samuel Asante-Boateng • Director, Drugs and Herbal Medicine Registration • Ghana FDA

# **Senegal Pharma Updates Regulations**

Rostand Sagu • Directeur Qualité et responsable des affaires règlementaires

16:45- 17:30

# Session 9: Mises à jour réglementaires sur le marché pharmaceutique

# Moderated by

Chourouk Ben Dhia • Pharm.D • Regulatory Portfolio Optimisation Executive - Emerging Markets

# Tunisia: Vaccins anti-covid 19 et processus réglementaire en Tunisie

 $\textit{Dr. Im\`ene Mersni} \bullet \textit{Pharmacist} \bullet \textit{Directorate of pharmacy and medicines (DPM)} \bullet \textit{Tunisie}$ 

## Côte d'Ivoire - Pharma Regulations

Dr. Kaul Clamougou • AIRP • Republic de Cote D'Ivoire

## Côte d'Ivoire - Biologics Update

Dr. Neully Konan Kouadio, Pharmacien, AIRP, Au cœur de l'activité pharmaceutique, Côte d'Ivoire

**17:30 - 18:00**Central African Time

# **Regulatory Round Table Discussions**

**TABLE 1: Egypt** Moderated by: Dr. Mona Al Moussli • Co Owner • Director • PRA Consultancy

Dr. Mona Moussa • EDA & Asthma Foud • General Manager • EDA

Dr. Hadeer Sayed, EMEA RMC Life cycle management, Johnson & Johnson

**TABLE 2: Ivory Coast** Moderated by: Celine Ghalieh • Hubplus-events

Dr. Kaul Clamoungou • AIRP • Republic de Cote D'Ivoire

**TABLE 3: Ghana** Moderated by: Tony Hama • Hamsventure Consultants • Aishvarya Apte • RA Consultant • PRA Consultancy

Samuel Asante-Boateng  $\bullet$  Director, Drugs and Herbal Medicine Registration  $\bullet$  Ghana FDA

TABLE 4: Tunisia Moderated by: Chourouk Ben Dhia • Pharm.D • Regulatory Portfolio Optimisation Executive - Emerging Markets

Lana Nabil • PRA Consultancy

1. Professeur Abderrazek Hedhili

razek Hedhili 2- Dr. Samiha Toumi

3- Dr. Nesrine Ghozzi

4- Dr. Sameh Jalleli



















































# **DAY 2: 13 September 2022**

#### Platform OPENS @ 8:00am CENTRAL AFRICAN TIME

Meet Up at the Network Lobby Brows the Exhibition Booths



8:00 - 9:00

Breakfast Registration Meet Up at the Network Lobby

9:00 - 9:10 Central African Time

# **Morning Welcome and Honorary Mentions**

Dr. Lucas Kimanga Nyabero • CEO • Pharmaceutical Society of Kenya

9:10 - 10:00 Central African Time

#### **Session 1**

# **Regulatory Updates in the Pharma Market - South Africa**

#### Moderated by

Susan Lin • Senior Manager: Health Policy Development I Support - Health Policy Unit • Medcheme

# **Pharma Regulatory Updates**

Kuda Kapfumvuti • Senior Manager - Health Products Authorisation • SAHPRA

## **Biologics Regulatory Updates**

Khamusi Mutoti • Biologics • SAHPRA

10:00- 10:30

# **Session 2**

# **Data Management and Data Protection: Value Beyond Compliance**

# **Moderated by**

Mitesh Patel • Data management and Data Privacy lead • Deloitte Analytics Africa

# **Topic Name**

Kiran Bagtatee • Cross functional data privacy team Head • Deloitte Africa

**10:30-11:00**Central African Time

# Coffee and Networking Break Meet Up at the Network Lobby



**11:00 - 13:00**Central African Time

## **Session 3**

# Regulatory Updates in the Pharma Market East Africa

## Moderated by

Catherine Maina • Regulatory Affairs Specialist • Glenmark

# Uganda

Agnes Kemigisha • National Drug Authority • Uganda

# Ethiopia

 $Nathan \, Seyoum \, \bullet \, Co \, Founder \, \& \, Vice \, President \, \bullet \, EARAPA \, \bullet \, External \, Medicine \, Dossier \, Assessor \, \& \, Consultant \, \bullet \, EFDA \, And \, Consultant \, EFDA \, And \, Cons$ 

## Tanzania

Alex Juma Ismail • DRO • Tanzania Medicines & Medical Devices Authority (TMDA)

## Zanzibai

Dr. Burhani Othman Simai • Executive Director • Zanzibar Food and Drug Agency

## Rwanda

 $Honore\ Ayinkamiye\ \bullet\ Human\ Medicines\ Assessment\ and\ registration\ Specialist\ \bullet\ Rwanda\ Food\ And\ Drugs\ Authority$ 

## Kenya

Dr. Peter Mbwiiri Ikamati • Acting Chief Principal Regulatory Officer • PER • Pharmacy and Poisons Board Kenya

Panel discussions and Q&A











# **DAY 2: 13 September 2022**

13:00 - 14:00 Central African Time

# **Lunch and Networking Break**







14:00 - 15:00

# Session 4:

# Track and Trace

## Moderated by

Sara AGAK • Laborex-Kenya

# **Gs1** Perspective

Nuran Idris • Healthcare Manager • Africa • Gs1

#### **Track and Trace**

Santosh Balbhadra Trivedi • Senior Product Management Lead • Honeywell

#### **NRA Panelist**

South Africa • Mokgadi Fafudi • Regulatory Compliance Manager • SAHPRA

15:00- 15:15 Central African Time

# Coffee and Networking Break Meet Up at the Network Lobby



15:15 - 16:15 Central African Time

## **Session 5**

# **Authenticity in Pharma Products in Africa**

## Moderated by

Daniella Munene • Head of Consulting • Africa Health Business

How to fight drug counterfeiters: Why packaging serialization is only a part of the answer

Arnaud Bernaert • Head Health Security Solutions • SICPA

The partnership model that helped drop poor quality malaria medicine rates from 1 in 5 to 1 in 77 in Nigeria

Ashifi Gogo • Tech Entrepreneur • Ph.D. Engineer • CEO • Sproxil

**16:15-17:30**Central African Time

# **Session 7**

# Clinical Trial Regulation in Africa - Harmonized Tools, Fast Track Submissions and Strategies

# **Moderated by**

Tshepiso Mabena • Independent Consultant

# **Clinical Trails Strategy for African Countries**

Bicky Nyeleti Mthombeni • Clinical trial strategist • SACRA Chair

# Fast track submission of infectious disease trials in Africa

Salma Kita • Director • Project Delivery Management • Icon

**Challenges to meet a growing Clinical Research Industry** 

Angela Conway • CEO • ACRO

17:30 - 18:00 Central African Time **Round Table Discussion - See next page** 











# **DAY 2: 13 September 2022**

17:30 - 18:00

# **Regulatory Round Table Discussions**

**TABLE 1: Tanzania** Moderated by: Aishvarya Apte • RA Consultant • PRA Consultancy

Alex Juma Ismail • DRO • Tanzania Medicines & Medical Devices Authority (TMDA)

**TABLE 2: Ethiopia** Moderated by: Dr. Mona Al Moussli • Co Owner • Director • PRA Consultancy

Nathan Seyoum • Co Founder & Vice President • EARAPA • External Medicine Dossier Assessor & Consultant • EFDA

**TABLE 3: Uganda** Moderated by: Lana Nabil • PRA Consultancy

Agnes Kemigisha • National Drug Authority • Uganda

**18:00** Central African Time Close of Day, End of PharmaReg AfriSummit 2022

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