
PRA CONSULTANCY
PRESENTS

# PHARMAREG AFRiSUMMIT

CONNECT REGULATORY AUTHORITIES & PEOPLE OF THE PHARMA INDUSTRY


AFRiSUMMIT will be DUAL language with French & English translations

## AGENDA

## DAY 1: 12 September 2022

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

**Platform OPENS @ 8:00am CENTRAL AFRICAN TIME**
Meet Up at the Network Lobby
Brows the Exhibition Booths

BUSINESS CARDS
Create your Business Card be visible to connect

**8:00 - 9:00** Central African Time

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

**9:00 - 9:10** Central African Time

**Inauguration and Morning Welcome**
Dr. Mona Al Moussli • Co Founder • Managing Director • PRA Consultancy

**9:10- 10:15** Central African Time

**AMA - African Medicines Agency towards a unified continental regulatory framework 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**
Bunmi Femi-Oyekan • IFPMA-African Regulatory Network Working Group

**Advancing Regulatory Systems in Africa**
Kate Kikule • Principal Technical Advisor • Pharmaceutical Regulatory Systems • USAID MTaPS Program

**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

**10:15- 11:15** Central African Time

**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

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

**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

**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** Central African Time

**Coffee and Networking Break**


CHAT ROOM
JOIN US


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## DAY 1: 12 September 2022 Continue

**11:30- 12:30**
Central African Time

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

**Moderated by**

Dr. Heba Nabil • Regulatory Affairs Senior Manager • Egypt and Sudan • Pfizer

**Pharmaceutical products Registration regulations in Egypt and its Updates**

Dr. Mona Moussa • Director of Technical Affairs Administration • Human Pharmaceutical Drugs registration GA • Central administration for Pharmaceuticals products • EDA

**Updates in Biologics Registration and Post Approval changes procedures in EDA**

Dr. Reem Mahmoud Al-Tanahy • Biologics variation unit manager • Biologics Registration Administration • GA of biological products • central Administration of biological and innovative products and clinical Studies • EDA

**Biosimilars in Egypt**

Dr. Hoda Al-Saeed • Development and advice unit manager • Technical Support administration • GA of biological products • CA of biological and innovative products and clinical studies • EDA

**12:30 - 13:30**
Central African Time

### 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

SPEED NETWORKING

Brought to you by PRA

**14:30 - 15:30**
Central African Time

### 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


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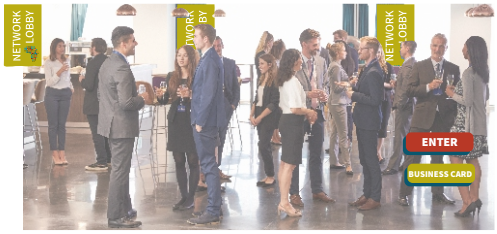
## AGENDA

## DAY 1: 12 September 2022 Continue

**15:30- 15:45** Central African Time

### 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** Central African Time

### 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**

Dr. Imène Mersni • Pharmacist • Directorate of pharmacy and medicines (DPM) • 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. Hadeer Sayed • EMEA RMC Life cycle management • Johnson & Johnson
Dr. Mona Moussa • EDA & Asmaa Fouad • General Manager • EDA

**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 Consulatants &
Aishvarya Apte • RA Consultant • PRA Consultancy
Samuel Asante-Boateng • Director, Drugs and Herbal Medicine Registration • 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 2- Dr. Samiha Toumi
3- Dr. Meriem Kadri 4- Dr. Sameh Jalleli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**8:00 - 9:00** Central African Time

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

**9:00 - 9:15** Central African Time

**Morning Welcome, Honorary Mentions and Introduction**

**Appropriate Pharmaceutical Care Key to UHC; Case for Policy and Regulatory Support**

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

**9:15 - 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** Central African Time

**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 Bagratee • 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**

CHAT ROOM
JOIN US

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

**Tanzania**

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

**Zanzibar**

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

**Rwanda**

Honore Ayinkamiye • Human Medicines Assessment and registration Specialist • 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**


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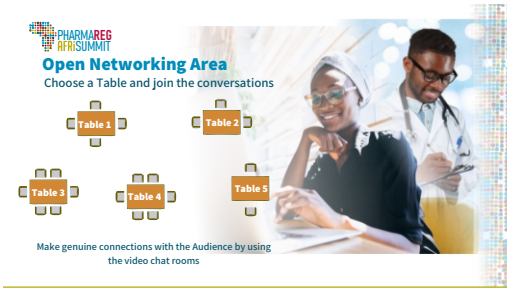
## DAY 2: 13 September 2022

**13:00 - 14:00**
Central African Time

**Lunch and Networking Break**


**14:00 - 15:00**
Central African Time

**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

**Role of e-labelling in assuring patients of the authenticity of their medicines**
Dr. Rehab Mehrez • Manager of the general Administration of Pharmaceutical References and inserts • EDA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## DAY 2: 13 September 2022

**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 Trials Strategy for African Countries**
Bicky Nyeleti Mthombeni • Clinical trial strategist • SACRA Chair

**Clinical Trial Regulations in Egypt**
Dr. Nesma Gamal Mahmoud • Clinical trials specialist & GCP Inspector manager of Herbal medicine protocols unit • Administration of protocols and studies follow up • General Administration of clinical Trials • Egyptian Drug Authority

**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

**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**

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