

November 2024

# AFRiSUMMIT

Grand Nile Tower, Cairo - Egypt

## AGENDA

DAY 1: 3 November 2024

08:30 - 09:15

### COFFEE AND REGISTRATION

09:15 - 09:45

### Opening Ceremony



**AfriSummit Welcome Address**

Dr. Mona Al Mousli  
Chairman of  
AfriSummit



**AfriSummit Welcome Address**

Dr. Ahmed Ashour  
Chair of the Organizing  
Committee for AfriSummit  
Egypt



**AfriSummit Official Opening**

Dr. Rasha Ziada  
Chairman Assistant for Professional  
Development and Capacity Building Affairs  
Egyptian Drug Authority (EDA)



**AfriSummit Opening Remarks**

Dr. Hisham Stait  
Vice Chairman, Unified Procurement  
Authority - Egypt



**Welcome Remarks - Titanium Sponsor**

Mr. Ramez Sawiris  
R&D Lead - Haleon  
MEA

09:45 - 10:45

### Session 1: Current Landscape of Pharmaceutical Regulations in Africa - Challenges and Opportunities



**Moderated by**

Mrs. Bunmi Femi-Oyekan  
Regulatory Lead, Accord &  
Access (Snr. Director)  
Pfizer



**AMRH support to the Operationalisation of AMA**

Dr. Nancy Ngum  
Public Health Officer- AUDA  
NEPAD



**ECOWAS/WAHO**

Pharm. Mrs. Sybil Nana Ama  
Ossei Agyeman Yeboah  
Regulatory Consultant & CEO of  
SNAAP Access



**SADC MRH - ZAZIBONA**

Mrs. Sakhile Dube-Mwedzi  
Program Coordinator -  
SADC MRH  
ZAZIBONA



**IGAD**

Mr. Karim Wanga (M Pharm)  
Senior Principal Regulatory Officer  
Pharmacy & Poisons Board (PPB)  
Kenya



**IFPMA**

MS. Zainab Aziz  
Associate Director RA Policy &  
Strategic Operations, SSA  
Novartis

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10:45 - 11:30

## Session 2: Egypt National Regulatory Updates



**Moderated by**  
Dr. Inas Chehimi  
Senior Director - Head of Regulatory Affairs  
Middle East and Africa  
Novartis



**Egypt Regulatory Updates**  
Dr. Yasmine Mohamed Hisham  
Manager of The Evaluation Unit For Registration  
Files of Imported Human Pharmaceuticals in  
Central Administration of Pharmaceutical Products  
Egyptian Drug Authority  
(EDA)



**Unified Procurement Authority (UPA)**  
Dr. Hisham Stait  
Vice Chairman, Unified Procurement  
Authority - Egypt

### Q & A Panel Discussion



11:30 - 12:00

## Coffee and Networking Break

12:00 - 13:00

## Session 3: Harnessing Potential: Africa's Journey to Pharmaceutical Reliance: Panel Discussion



**Moderated by**  
Dr. Eman Wahdan  
Egypt regulatory Head for  
Opella



**Presenter**  
Dr. Hebatallah Ibrahim Abdel-Salam  
General Manager of Biological Products  
General Administration & Head of Biological  
Products Marketing Authorization Administration  
Egyptian Drug Authority  
(EDA)



**Presenter**  
Sonia Sebai Ben Amor, MD  
Head of National Control Laboratory  
National Regulatory Authority  
Tunisia



**Panelist**  
Mr. Karim Wanga (M Pharm)  
Senior Principal Regulatory Officer  
Pharmacy & Poisons Board (PPB)  
Kenya



**Panelist - Industry perspective**  
Dr. Najlala Fathy  
Regulatory Affairs Head, GDD  
Novartis

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13:00 - 14:00

## Session 4: Innovation and Accessibility: Shaping the OTC Landscape in Africa



**Moderated by**  
Pharm. Mrs. Sybil Nana Ama  
Ossei Agyeman Yeboah  
Regulatory Consultant & CEO of  
SNAAP Access



**Empowering Access: Strategic Insights into Self-Care Products in Pharma**  
Mr. Ramez Sawiris  
R&D Lead - Haleon  
MEA



**Regulatory Pathways in Self-Care: Mastering the Switch**  
Dr. Marwa Souei  
Head of Regulatory Affairs across Africa  
Middle East & Turkey  
Opella



**Panelist**  
Dr. Shereen Abdelgawad  
Head of the Central Administration of  
Pharmaceutical Care  
Egyptian Drug Authority  
(EDA)



**Panelist**  
Sonia Sebai Ben Amor, MD  
Head of National Control Laboratory  
National Regulatory Authority  
Tunisia



**Panelist**  
Dr. Haidy Ahmed  
Director Regulatory Affairs  
North Africa  
Haleon

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14:00 - 15:00

Group Photo, Lunch and Networking

15:00 - 15:45

Session 5: Attaining WHO Maturity Level and Collaboration Opportunities



**Moderated by**  
Dr. Yousra Farid  
Regulatory Affairs | Quality Assurance Director &  
Strategic Project Lead - Gulf  
Levant & Emerging Markets  
Abbott



**Presenter**  
Prof. Saleh A. Bawazir  
Prof. of Clinical Pharmacy & CEO  
of Bawazir Pharma Consulting Center



**Panelist**  
Dr. Emil Ivan Mwikarago  
Technical Analyst, Assessment  
of Medical Devices, In Vitro  
Diagnostics (IVDs), Vaccines,  
& Biologicals Rwanda Food & Drugs  
Authority (Rwanda FDA)



**Panelist**  
Dr. Zivanai Makoni  
Head of Division Evaluation &  
Registration – Medicines Control  
Authority of Zimbabwe (MCAZ)

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15:45 - 16:45

## Session 6: Empowering Local Production: Advancing Pharmaceutical Manufacturing and Localization in Africa



**Moderated by**  
Dr. Alaa Attia  
Business Development Director  
EIPICO



**Building a Sustainable Pharma Ecosystem:  
Regulatory Perspectives on Localization in Africa**  
Dr. Zakiyah Ibrahim Al-Kurdi  
Regulatory Affairs & Public Policy Director for  
EMEA Region - U.S. Pharmacopeia (USP)



**Panelist**  
Dr. Claudy Raymond Tarazy  
Chairman & Managing Director  
One Pharma Medics

## Q & A Panel Discussion :Collaborating for Sustainable and Efficient Nearshoring of Generics and Biosimilars



**Moderated by**  
Dr. Mohamed Larbi Jelassi  
Head of Market Access International  
SPIMACO



**Panelists**  
Dr. Zineb Housni  
Pharmacist Inspector, Evaluator of Marketing  
Authorization Files For Medicinal Products for  
Human - Directorate of Medicines and Pharmacy  
Morocco



**Panelists**  
Dr. Hebatallah Ibrahim Abdel-Salam  
General Manager of Biological Products  
General Administration & Head of Biological  
Products Marketing Authorization Administration  
Egyptian Drug Authority (EDA)



**Panelists**  
Dr. Ahmed El-Iekawy  
Innovative Products' Registration Manager  
Egyptian Drug Authority  
(EDA)



**Panelists**  
Mr. Karim Wanga (M Pharm)  
Senior Principal Regulatory Officer  
Pharmacy & Poisons Board (PPB)  
Kenya



**Panelists**  
Dr. Eric Konan  
Director of the Regulatory Affairs Department  
ETHICA

16:45 - 17:15

## Coffee & Networking

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17:15 - 18:00

## Session 7: Southern Africa National Regulatory Updates



**Moderated by**  
Mrs. Simone Rudolph-Shortt  
Chairperson  
MDMSA



**Botswana Regulatory Updates**  
Ms. Ntsetselele Kago  
Manager, Human Medicines Unit  
Botswana Medicines Regulatory Authority  
(BoMRA)



**Zambia Regulatory Updates**  
Mr. Lyoko Nyambe  
Director Marketing Authorisation  
Zambia Medicines Regulatory Authority  
(ZAMRA)



**Zimbabwe Regulatory Updates**  
Dr. Zivanai Makoni  
Head of Division Evaluation and Registration  
Medicines Control Authority of Zimbabwe  
(MCAZ)



**Namibia Regulatory Updates**  
Ms. Fransina Nambahu  
Registrar of Medicines at Namibia Medicines  
Regulatory Council (NMRC) of the Ministry of  
Health and Social Services  
(MoHSS)

### Q & A Panel Discussion



18:00

### End of Day 1

**tiga** Healthcare  
Technologies

*Drug Safety and Track & Trace System  
for a Safer, Healthier Africa!*



Pharmaceutical Track & Trace System



Population Health Management



e-Prescription



Healthcare Interoperability



Hospital Information System



Health Information Exchange



Personal Health Record



AI & Analytics

Let's Shape the  
Future Together!



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## AGENDA

DAY 2: 4 November 2024

09:00 - 09:30

### COFFEE AND NETWORKING

09:30 - 09:45

### Opening Remarks Day 2



Dr. Ahmed El-Kamhawy  
Country Head  
Opella

09:45 - 10:45

### Session 1: Unlocking the Future: Regulatory Pathways & Innovations in Biosimilars & Biologics



**Moderated by**  
Dr. Yara Hussein  
Director, Regional Regulatory Hub Team lead – MERAST  
Specialty Care Business Unit Lead  
Pfizer Biopharmaceutical  
GRS IRSP



**Overview of Biosimilars in MENA: Comparative Assessment of Biosimilars PAC Guidelines in MENA**  
Safa' Abu Gharbiah, PhD.  
Senior Director Regulatory Affairs, MENA  
Hikma Pharmaceuticals



**Innovating with AI in Biologics: Ethical & Regulatory Frontiers in Africa**  
Dr. Fatima Zaid Abu Zanat  
Regional Director of Regulatory Affairs & Scientific Office – Middle East  
Turkey & Africa  
Ipsen

### Q & A Panel Discussion



**EDA**  
Dr. Ahmed El-Iekawy  
Innovative Products' Registration  
Manager – Egyptian Drug Authority  
(EDA)



**EDA**  
Dr. Asmaa Ahmed Abdel-Ghaffar Mohammed  
Researcher and Head of Biotechnology Lab  
Egyptian Drug Authority (EDA)



**DMP Tunisia**  
Sonia Sebai Ben Amor, MD  
Head of National Control Laboratory  
National Regulatory Authority  
Tunisia

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10:45 - 11:30

## Session 2: National Regulatory Updates EAC



**Moderated by**  
Dr. Daniella Munene  
Head of External Affairs  
Africa Health Business



**Kenya Regulatory Updates**  
Mr. Karim Wanga (M Pharm)  
Senior Principal Regulatory Officer  
Pharmacy & Poisons Board (PPB)  
Kenya



**Ethiopia Regulatory Updates**  
Mr. Abebe Alamneh  
Vice Chairman of East African Regulatory Affairs  
Professionals Association (EARAPA) & Medicine  
Registration Expert  
Ethiopia Food and Drug Authority  
(EFDA)

### Q & A Panel Discussion



**Rwanda Regulatory Updates**  
Dr. Emil Ivan Mwikarago  
Technical Analyst, Assessment of Medical Devices,  
In Vitro Diagnostics (IVDs), Vaccines,  
& Biologicals Rwanda Food & Drugs  
Authority (Rwanda FDA)



**Uganda Regulatory Updates**  
Dr. Rachel Juliet Mujawimana  
Inspector of Drugs  
National Drug Authority (NDA)  
Uganda

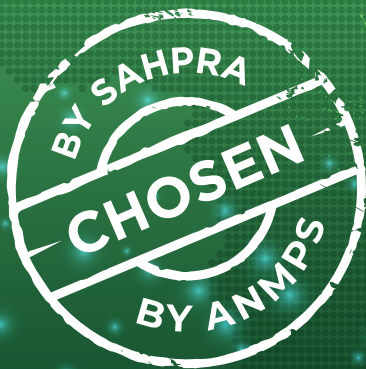


Ms. Pamela Ajwang  
Regulatory Officer  
National Drug Authority (NDA)  
Uganda



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11:30 - 12:00

12:00 - 13:00

## COFFEE AND NETWORKING BREAK

### Session 3: Vaccine Regulations in Africa: Harmonization & Access for Public Health Impact



**Moderated by**  
Dr. Mariham Gergis  
Submission Excellence Lead – Emerging Market  
EMA Regulatory Center  
Johnson and Johnson Innovative Medicine



#### Harmonizing Vaccine Regulatory Pathways in Africa : Enhancing Preparedness for Future Health Emergencies

Pharm. Jacqueline Acquah  
Senior Regulatory Affairs Strategy Lead  
MEA - Coalition for Epidemic Preparedness  
Innovations (CEPI)



#### National Network for the African Reliance Laboratories Status and Its Impact

Dr. Doaa Rady  
Lot Release Administration Manager  
Egyptian Drug Authority (EDA) &  
Chairperson for AMQF Vaccine  
Subcommittee



#### Strengthening Vaccine Manufacturing Capabilities in Africa: A Strategic Approach to Ensuring Self-Sufficiency and Resilience

Dr. Mariam Raouf Wefky Ghobrial  
Technical Specialist (Life Sciences)  
Access Health International  
(AHI)

#### Q & A Panel Discussion



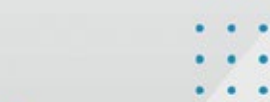
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13:00 - 14:00

## Session 4: Ensuring Safety and Compliance: Regulatory Perspectives in Track & Trace & Serialization



**Moderated by**  
Mr. Christopher Oduor  
Senior Regulatory Affairs Manager  
Middle East, Africa and CIS  
Novo Nordisk



**Complete Control: How End-to-End Traceability Creates Benefits**  
Mr. Görkem Aydın  
International Marketing Manager  
VISIOTT



**Fireside chat**  
Mr. Jihad Tayara  
Chief Executive Officer of  
EVOTEQ



Ms. Tutku Kazan  
Marketing Director  
VISIOTT

## Q & A Panel Discussion: Securing Africa's Supply Chain: Advances in Track & Trace & Serialization Technologies



**Panelists**  
Mr. Mete Karaca  
Executive Board Member  
Tiga Healthcare Technologies



**Panelists**  
Mr. Lyoko Nyambe  
Director Marketing Authorisation  
Zambia Medicines Regulatory Authority  
(ZAMRA)



**Panelists**  
Dr. Aliou Ndiaye  
Pharmacist in Drug Serialization Department  
Senegalese Pharmaceutical Regulatory Agency  
(ARP)



**Panelists**  
Ms. Nuran Idris  
Manager Healthcare Africa  
GS1 Global Office

14:00 - 15:00

## LUNCH AND NETWORKING

15:00 - 15:30

## Session 5: NRA Pharma Regulatory Updates - North Africa



**Moderated by**  
Dr. Amina Fazila Laras  
Regulatory Affairs Manager  
French Speaking Africa Cluster  
Abbott



**Tunisia Regulatory Updates**  
Dr. Mariam Aounallah  
Project Manager  
National Agency of Medicines &  
Health Products in Tunisia  
(ANMPS)



**Morocco Regulatory Updates**  
Dr. Zineb Housni  
RPharmacist Inspector, Evaluator of  
Marketing Authorization Files For Medicinal  
Products for Human  
Directorate of Medicines and Pharmacy  
Morocco

## Q & A Panel Discussion



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15:30 - 16:30

## Session 6: Digital Transformation in Pharma: Navigating e-Labeling & eCTD in Africa's Regulatory Landscape



**Moderated by**  
Dr. Yasmine Maher El-Shebiny  
Director of Regulatory Affairs  
MSD Egypt Cluster  
(Egypt, Libya, Sudan, & Yemen)



**Harmonisation: Africa becomes One through one eCTD specification**  
Dr. Madelein Terblanche  
Senior Operations Consultant  
VECTOR Life Sciences



Dr. Mariam Aounallah  
Project Manager  
National Agency of Medicines &  
Health Products in Tunisia  
(ANMPS)



**E-Labeling Presentation**  
Dr. Rehab Mehrez  
Manager of the General Administration of  
Pharmaceutical References & Leaflets  
Central Administration of Pharmaceutical Care  
Egyptian Drug Authority  
(EDA)



**Data Consistency through Production, Supply Chain & Regulatory Business Processes**  
Mr. Michael Faust  
RCC Business Consultant  
EXTEDO

### Q & A Panel Discussion



16:30 - 17:00

## COFFEE AND NETWORKING

17:00 - 17:30

## Session 7: AI Revolution: Shaping the Future of Pharmaceutical Innovations



**Moderated by**  
Dr. John M. Mwangi  
Regulatory Policy & Science Lead  
Bayer Pharmaceuticals



**AI & R&D in Pharmaceutical Industry**  
Dr. Neveen Kamel  
Director of Regulatory Affairs  
(Egypt, Maghreb Countries, Developing  
Africa Markets)  
Merck



**Enhancing Regulatory Preparedness through Digital Collaboration: CEPI's Framework for Accelerated Access during Public Health Emergencies**  
Dr. Alessandro Lazdins  
Regulatory Policy and Intelligence Manager  
Coalition for Epidemic Preparedness and  
Innovations  
(CEPI)

### Q & A Panel Discussion



November 2024

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17:30 - 18:00

## Session 8: West African NRA Pharma Regulatory Updates



**Moderated by**  
Dr. Eric Konan  
Director of the Regulatory Affairs Department  
ETHICA



**Senegal Regulatory Updates**  
Dr. Aliou Ndiaye  
Pharmacist in Drug Serialization Department  
Senegalese Pharmaceutical Regulatory Agency  
(ARP)



**Ivory Coast Regulatory Updates**  
Dr. Chantalle Affoue  
Director of Approval of Drugs and Other  
Pharmaceutical Products  
Ivorian Pharmaceutical Regulation Authority  
(AIRP)

### Q & A Panel Discussion



17:30 - 18:00

## NRA Break Out Round Table Discussions