3rd Edition

AFRiSUMMIT

Triumph Plaza Hotel, Cairo - Egypt

8-11 OCTOBER 2023

#AfriSummit | #PharmaRegAriSummit |
#MeDevReg | #PVAfriSummit

DR. MONA SPEECH AND FOUNDER LETTER AFRISUMMIT 2023

Welcome to all esteemed participants of AfriSummit 2023,

As the Co-Founder and Managing Director of PRA Consultancy, I am honoured to address you all on this best of health and high spirits.

AfriSummit 2023 is not merely an event in our calendars; it is a manifestation of our shared vision for the future of regulatory affairs in pharma and medical device in Africa. It represents the convergence of minds, the fusion of ideas, and the collective determination to drive positive change across this beautiful continent.

Our journey began with a simple yet profound idea: that the regulatory challenges facing Africa can only be met met through a united effort. PRA Consultancy was founded on the principle of empowering individuals, organizations, and governments to navigate the complex landscape of regulatory affairs, fostering innovation worldwide.

In its third year, today, AfriSummit stands as a testament to our commitment. It is a platform for thought leaders, innovators, policymakers, and pharma and medical device influencers to come together and catalyse progress. We aim to harness the immense potential of regulations that resides within Africa's diverse cultures, industries, and sectors.

At AfriSummit 2023, we will delve deep into the regulatory landscape, exploring the opportunities and challenges that shape our continent's future. Through interactive sessions, workshops, and engaging discussions, we will dissect critical topics, exchange invaluable insights, and forge partnerships that will not only benefit our individual endeavours but also leave an indelible mark on Africa's growth trajectory.

Regulatory excellence is not a hurdle; it's a stepping stone towards progress. It is the catalyst that ensures the safety, efficacy, and quality of products and services. Innovation, on the other hand, is the driving force behind economic growth, sustainability, and improved quality of life. Together, they form the cornerstone of our mission at PRA Consultancy.

As we embark on this extraordinary journey, let us remember that our collective power is stronger than any obstacle, and our shared wisdom is more potent than any challenge. AfriSummit 2023 is not just an summit; it's a declaration of our unwavering commitment to Africa's advancement and betterment in pharmaceutical and medtech regulatory affairs.

I am truly excited about the rich tapestry of experiences, insights, and expertise that each of you brings to this gathering. Your presence will undoubtedly enrich the dialogue, broaden perspectives, and ignite innovation.

Together, let us share knowledge, connect network and be impactful, one regulatory stride and innovative leap at a time.

PRA
CONSULTANCY

Healthcare Regulations
Expert in Middle East

Agency Representation

Pharmacovigilance

Regulatory Affairs

Market Access

Storage & Logistics

Compliance (GxP)

Our Mission is YOUR Success!

www.pra-me.com

info@pra-me.com

@praconsultancy

DR. NAJIBA SPEECH AND FOUNDER LETTER AFRISUMMIT 2023

As the Co-founder and Managing Director of Hubplus Events, I proudly present our creative event management and production company, catering to clients from the MENA region.
We offer world-class, bespoke services that guarantee audience engagement and effective message delivery.As the Co-Founder and Managing Director of hubplus Events, I am honoured to address you all on this best of health and high spirits.

With years of dynamic industry experience, Hubplus Events provides unique and impactful solutions, ensuring your events become cherished and unforgettable experiences. As a progressive event company, we have successfully served numerous corporate and official clients throughout the Middle East.

Our mission is to elevate innovative event management standards, delivering immersive experiences that captivate the target audience. As a leading event management company, our commitment to excellence and continuous improvement drives us to surpass client expectations, placing 'you' at the core of our services.

We aspire to be recognized worldwide as the go-to event management company, offering robust and innovative solutions. By blending strategy, creative thinking, and technical expertise, we aim to catalyze industry growth and exceed client expectations for every event we undertake.

As an established and independent event management company, we work as your partner, transforming your concepts into impactful solutions that resonate with your target audience. Our passionate and dedicated team of experts envisions and creates events tailored to your specific requirements, focused on achieving your goals.

Hubplus Events provides one-stop solutions for all your corporate and official event management needs. From planning to promotion and production, our uniquely designed solutions leave lasting impressions on your audience. As a client-centric company, we leverage our in-depth industry knowledge, creativity, and expertise to bring your vision to life.

As the official organizers of the third edition of AfriSummit, in a hybrid format, we ensure each edition meets the high standards this summit deserves. Our creative and diligent event creatives and executors combine their expertise and talents to produce AfriSummit, ensuring professionalism and creativity are always at the forefront.

This year, we are dedicated to creating a memorable and attendee-focused summit, conceptualizing, and executing every aspect with precision. In conclusion, "It takes a creative mindset, punctuality, precision, and creativity to bring an event to life."

Powered By

hubplus events

Making Events Come Alive

@Hubplusevents

www.hubplus-events.com

VECTOR LIFE SCIENCES
Exclusive partner in Africa

&

Lorenz LIFE SCIENCES GROUP

Software solutions for electronic submission

Industry solution

Prepare & Publish submissions

Multi-format publishing: eSubmission, eCTD for all regions,(V) NeeS, and CTD (Paper)

Efficient content & lifecycle management

Shorten time to market and reduce costs

Submission status tracking

Agency solution

Review electronic submissions

Effective collaborative assessment to support market authorization processes

Enables efficient reliance and work-sharing practices

Ability to share content among NMRAs

Support with preparing to operate at WHO ML3/4

LORENZ trusted by over 1700 customers and 14 authorities around the world.

Visit us at our booth!

Contact: info@vectorls.co.za

OCTOBER 2023

AFRiSUMMIT

Triumph Plaza Hotel, Cairo - Egypt

An Initiative of PRA CONSULTANCY | In Collaboration with PIONEERS | Organized By hubplus events

AGENDA

DAY 1: 8 October 2023

TIME ZONE: GMT +3

8:00 - 9:00 — **BREAKFAST REGISTRATION**

9:00 - 9:30 — **AfriSummit Opening**

AfriSummit Welcome Address

Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy

AfriSummit Official Opening

Dr. Feirouz Ellouze
General Manager
Sanofi Consumer Health Care

9:30 - 10:30 — **Session 1: African Medicines Agency (AMA) - Towards strengthening regulatory framework in Africa**

Moderated by
Dr. Hala Abu Ghazalah
Head of Regulatory Science, Africa & Middle East
Pfizer

Status of AMA operationalization and next steps towards regulatory strengthening in Africa

Ms. Vanessa Msengezi
Officer in charge of Regulatory Policy
Reforms African Union Development
Agency-NEPAD

Role of other stakeholders in support of AMA

Ms. Susan Lin
Senior Analyst - Public
Health Advisor, Advocacy and Public Policy
PATH

Q & A Panel discussion - NRA and Industry perspective on AMA

Ms. Marlene Moonsamy
Head of Regulatory Affairs for
the African Cluster
AstraZeneca

Dr. Karim Wanga
Chief Principal Regulatory Officer
Pharmacy and Poisons Board
Ministry of Health - Kenya

Ms. Rosemary Nkemdilim Onwualu
Assistant Director
Drug Evaluation and Research
National Agency for Food & Drug
Administration and Control
NAFDAC

Ms. Silverani Padayachee
Senior Manager
Pharmaceutical Evaluation Management
SAHPRA

Mr. Samuel Asante-Boateng
Director
Drugs and Herbal Medicine Registration
Ghana FDA

Dr. Sybil Nana Ama Ossei Agyeman Yeboah
Ag. Principal Program Officer and
Head of Public Health Division
WAHO

10:30 - 11:15

Session 2: NRA Pharma Regulatory Updates North Africa

Moderated by
Dr. Neveen Kamal
Regulatory Affairs Director for Egypt
North Africa & Africa developing Markets
Merck

Post market Changes & Reliance approach for Small Molecules

Dr. Mariam Maged Moris
Manager of human pharmaceuticals
Variations Administration
Egyptian Drug Authority (EDA)

Q & A Panel discussion

Dr. Nabiha El Khaldia Boutarene
Director of Technical Monitoring
Inspection and Vigilance
The National Agency for Pharmaceutical Products
ANPP

Ms. Naoual Assam
Technical-Regulatory Deputy Director
Registration Department
The National Agency for Pharmaceutical Products
ANPP

Dr. Mariam Maged Moris
Manager of human pharmaceuticals
Variations Administration
Egyptian Drug Authority (EDA)

Dr. Samia Seleem
Scientific & Regulatory Affairs Director
AbbVie

11:15 - 11:45

Session 3: Regulatory Challenges

Moderated by
Dr. Amal Ibrahim
Regulatory Affairs and Pharmacovigilance Director
Egyptian International Pharmaceutical Industries Co. EIPICO

Critical & comparative analysis of Marketing Authorization Procedures

Safa' Abu Gharbia, PhD
Senior Director
Regulatory Affairs MENA
Hikma Pharmaceuticals

11:45 - 12:15

Coffee Break

12:15 - 13:30

Session 4: Southern African National Regulatory Updates

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

South African Health Products Regulatory Authority

Ms. Silverani Padayachee
Senior Manager
Pharmaceutical Evaluation Management
SAHPRA

Botswana Medicines Regulatory Authority

Dr. Ropafadzai Hove
Chief Regulatory Officer
Botswana Medicines Regulatory Authority
BoMRA

Zambia Medicines Regulatory Authority

Mr. Lyoko Nyambe
Assistant Director
Marketing Authorization
Zambia Medicines Regulatory Authority
ZAMRA

Medicines Control Authority of Zimbabwe

Mr. Richard Tendayi Rukwata
Director General
Medicines Control Authority of Zimbabwe
MCAZ

Q & A Panel discussion

13:30 - 14:30

Conference Photo and Competition announcement

Lunch and Networking

14:30 - 15:15

Session 5: Pharma Manufacturing

Moderated by
Dr. Winnie Ng'ang'a
Chairperson
Kenya Association of Pharmaceutical Industry
KAPI

Pharmaceutical Industry Localization and contract Manufacturing

Dr. Mona Mousa
Regulatory Affairs
Associate Director
Hikma Pharmaceuticals

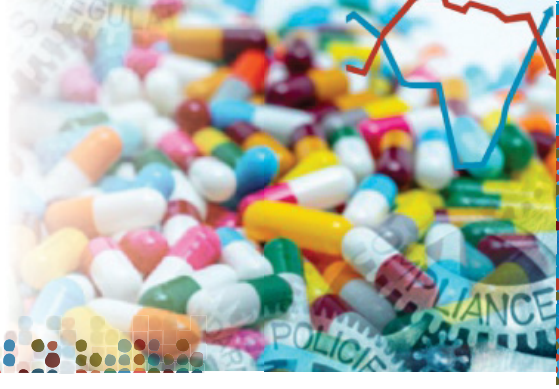
Pharma Manufacturing in Egypt: SCZone opportunities for growth

Dr. Ibrahim Mustafa
Vice President
General Authority Economic
Zone of the Suez Canal

AFRiSUMMIT

Triumph Plaza Hotel, Cairo - Egypt

An Initiative of PRA CONSULTANCY | In Collaboration with PIONEERS | Organized By hubplus events



15:15 - 16:15

Session 6: How to strengthen Supply Chain in Africa

Moderated by
Dr. Donia Fady
Regulatory Affairs Head
Takeda

Parallel importation

Dr. Winnie Ng'ang'a
Chairperson
Kenya Association of Pharmaceutical Industry
KAPI

Ensuring Quality of Medicines: Role of USP

Dr. Zakieh Ibrahim Al-Kurdi
Regulatory Affairs & Public Policy Director
EMEA Region
USP

Counterfeit Prevention

Mr. Franck Chauty
Security Head
Sanofi Consumer Health Care

OCTOBER 2023

AFRiSUMMIT

Triumph Plaza Hotel, Cairo - Egypt

An Initiative of PRA | In Collaboration with PIONEERS | Organized By hubplus events

16:15 - 17:00

Session 7: The Evolution of Biosimilars in Africa

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

The regulatory updates of biosimilar products in Egypt
Dr. Hebatallah Ibrahim Abdel-salam
Head of biological Products Marketing Authorization Administration
Egyptian Drug Authority
EDA

Biosimilars overview from the industry perspective
Dr. Ahmed Ghazala
Regulatory Affairs Manager
ELI countries
Amgen

17:00 - 18:00

Session 8: Landscape for Clinical Trials of Africa

Moderated by
Dr. Sahar Ebrahim
Regional Head of Clinical Operations
MENA
IQVIA

Optimizing the efficiency of the African Clinical Trials Ecosystem
Dr. Elvis Temfack
Senior Research Officer
Africa CDC

Review of latest resolutions and guidelines: ICH GCP R3 & WHO new draft guidance Q3
Ms. Bicky Nyeleti
Director
CRO AfriLeadTech Research (PTY) LTD
Chairperson
The South African Clinical Research Association
SACRA

Q & A Discussion Panel: Country specific capacity building and status

Dr. Rania Ibrahim Hassan
General Manager
General Administration of Clinical Trials
C.A. of Biological, Innovative Products & Clinical Studies
Egyptian Drug Authority
EDA

Ms. Rosemary Nkemdilim Onwualu
Assistant Director
Drug Evaluation and Research
National Agency for Food & Drug Administration and Control
NAFDAC

Dr. Manal El-Sayed
Director of the Clinical Research Center (MASRI-CRC)
Faculty of Medicine
Ain Shams University

AFRiSUMMIT

Triumph Plaza Hotel, Cairo - Egypt

An Initiative of PRA CONSULTANCY | In Collaboration with PIONEERS | Organized By hubplus events

18:00 NRA Break Out Round Table Discussions

Egypt
Dr. Mariam Maged Moris
Manager of human pharmaceuticals Variations Administration
Egyptian Drug Authority (EDA)

Botswana
Dr. Ropafadzai Hove
Chief Regulatory Officer
Botswana Medicines Regulatory Authority
BoMRA

Algeria
Dr. Nabiha El Khaldia Boutarene
Director of Technical Monitoring Inspection and Vigilance
The National Agency for Pharmaceutical Products
ANPP

Ms. Naoual Assam
Technical-Regulatory Deputy Director Registration Department
The National Agency for Pharmaceutical Products
ANPP

Zambia
Mr. Lyoko Nyambe
Assistant Director Marketing Authorization
Zambia Medicines Regulatory Authority
ZAMRA

Mr. Arthur Sichivula
ICT Manager
Zambia Medicines Regulatory Authority
ZAMRA

18:00 End of day Coffee Break and Networking

AFRiSUMMIT

Triumph Plaza Hotel, Cairo - Egypt

An Initiative of PRA CONSULTANCY | In Collaboration with PIONEERS | Organized By hubplus events

AGENDA

DAY 2: 9 October 2023

TIME ZONE: GMT +3

8:00 - 9:00

BREAKFAST REGISTRATION

9:00 - 9:15

Session 1: Opening Session

Opening and Welcoming
Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy

The link between regulation and public health
Why medicines regulation must align with Africa's New Public Health Order
Dr. Amit N. Thakker
President of Africa Healthcare Federation &
Executive Chairman of Africa Health Business

9:15 - 10:15

Session 2: National Regulatory Updates East Africa

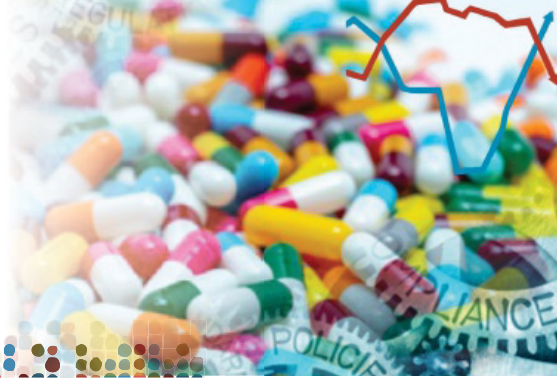
Moderated by
Dr. Mariham Gergis
Regulatory Affairs Lifecycle Manager
EMEA RMC
Janssen

Kenya
Mr. Karim Wanga (M Pharm)
Chief Principal Regulatory Officer
Pharmacy and Poisons Board Pharmacy
Poisons Board
Ministry of Health
Kenya

Uganda
Mr. Amos Mulera Atumanya
Senior Inspector of Drugs
National Drug Authority
Uganda

Ethiopia
Mr. Abebe Alamneh Kassahun
Medicine Registration Expert
Ethiopian Food and Drug Authority (EFDA)
Vice Chairman
East African regulatory Affairs Professionals
Association (EARAPA)

Q & A Panel discussion



10:15 - 11:00

Session 3: Vaccine production in Africa

Moderated by
Dr. Heba Adel
Senior Manager Regulatory Affairs
GlaxoSmithKline (GSK)

Lot release for vaccines in African countries

Dr. Doaa Rady
Lot Release administration manager
Egyptian Drug Authority
EDA

Vaccine Manufacturing and Regulatory Capacity

Ms. Silverani Padayachee
Senior Manager
Pharmaceutical Evaluation Management
SAHPRA

Q&A Panel discussion

11:00 - 11:30

Coffee Break

11:30 - 12:30

Session 4: Selfcare Regulations

Moderated by
Dr. Haidy Ahmed
Director Regulatory Affairs, North, East & West Africa
Consumer healthcare Egypt Limited
GSK (Now part of the Haleon group of companies)

Dr. Mohamed Larbi Jelassi
Africa Public Affairs Head
Sanofi Consumer Health Care

Mr. Lyoko Nyambe
Assistant Director
Marketing Authorization
Zambia Medicines Regulatory Authority
ZAMRA

Mr. Karim Wanga (M Pharm)
Chief Principal Regulatory Officer
Pharmacy & Poisons Board Pharmacy
Poisons Board
Ministry of Health
Kenya

12:30 - 13:00

Session 5: West African NRA Pharma Regulatory Updates

Moderated by
Ms. Marlene Moonsamy
Head of Regulatory Affairs for
the African Cluster
AstraZeneca

Pharmaceutical Regulatory Strengthening in Nigeria Following GMP Roadmap Implementation

Ms. Rosemary Nkemdilim Onwualu
Assistant Director
Drug Evaluation and Research
National Agency for Food & Drug
Administration and Control
NAFDAC

Ghana

Mr. Samuel Asante-Boateng
Director
Drugs and Herbal Medicine Registration
Ghana FDA

Q&A and Panel Discussion

13:00 - 14:00

Lunch and Networking

14:00 - 15:15

Session 6: Regulatory Digitization

Moderated by
Heba Nabil
Regulatory Affairs Senior Manager
Egypt & Sudan
Pfizer

Utilizing Digitization in support of Harmonization

Mr. Kent Briggs
Director
VECTOR Life Sciences

ECOWAS perspective in the utilization of eCTD

Dr. Sybil Nana Ama Ossei Agyeman Yeboah
Ag. Principal Program Officer and
Head of Public Health Division
WAHO

Digitizing labeling in Pharma: e-labeling in Egypt

Dr. Rehab Mehrez
Manager of the General Administration of
Pharmaceutical References and Leaflets
Egyptian Drug Authority
EDA

Q&A Panel discussion

15:15 - 16:15

Session 7: Track & Trace

Moderated by
Mr. Konstantine Ivanov
Co-founder & CEO
Utrace

Traceability Revolution: Transforming pharmaceutical supply chain for a healthier world

Mr. Udit Singh
CEO
ACG Inspection

End-to-End Compliance: A Practical Roadmap to Serialization Success Track and Trace the Status in Africa Panel discussion

Mr. Arif Gadzhiev
Business Development Director
Utrace

Q&A and Panel Discussion

Nigeria

Ms. Folasade Osho
Chief Regulatory Officer
National Agency for Food &
Drug Administration
Control (NAFDAC)

Zambia

Mr. Arthur Sichivula
ICT Manager
Zambia Medicines Regulatory Authority
ZAMRA

Senegal

Dr. Aliou Ndiaye
Drug Serialization Department Directorate
of Drug Approval and Serialization of Drugs
Other Health Products
Senegalese Regulatory Agency

GS1 Egypt

Dr. Haythem Sabry
Head of Regulatory Solutions
Gs1

16:15 - 17:00

Session 8: Regulatory Intelligence

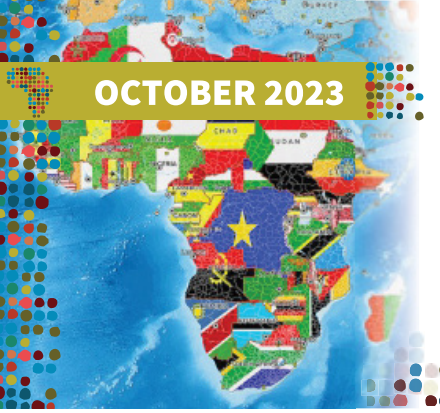
Moderated by
Dr. Amal Fathy
Africa Science Affairs Head
Sanofi Consumer Health Care

Regulatory Access and Market intelligence

Dr. Rima Nsheiwat
Regulatory Access and Market intelligence
Strategist and Consultant
B.V. Amsterdam Medical & Scientific Alliance

Regulatory Strategy and Vision

Dr. Marielouise Abi Hanna
Industry Leader in Corporate Strategy
Market Access & Founder
The Reg.Cloud



AFRiSUMMIT

Triumph Plaza Hotel, Cairo - Egypt

An Initiative of PRA CONSULTANCY | In Collaboration with PIONEERS | Organized By hubplus events

17:00 - 18:00

Session 9: Orphan Drugs Regulation in Africa

Moderated by
Dr. Fatima Zaid Abu Zanat
Regional Director of Regulatory Affairs &
Scientific Office Middle East
Turkey & Africa
Ipsen Pharma

Fighting Rare Disease and Developing Orphan Drugs to support

Dr. George Kamal
Regional Regulatory Affairs Hub
Lead MEAR
Merck Group

Market insight and development of regulations

Dr. Reham Alassily
Associate Director Regulatory Affairs NEMEA
IQVIA

Q&A and Panel Discussion

18:00

Closing Remarks End of PharmaReg AfriSummit

18:00

NRA Break Out Round Table and Networking

Ethiopia

Mr. Abebe Alamneh Kassahun
Medicine Registration Expert
Ethiopian Food and Drug Authority (EFDA)
Vice Chairman
East African regulatory Affairs Professionals
Association (EARAPA)

Nigeria

Ms. Rosemary Nkemdilim Onwualu
Assistant Director
Drug Evaluation and Research
National Agency for Food & Drug
Administration and Control
NAFDAC

Uganda

Mr. Amos Mulera Atumanya
Senior Inspector of Drugs
National Drug Authority
Uganda

Ghana

Mr. Samuel Asante-Boateng
Director
Drugs and Herbal Medicine Registration
Ghana FDA

MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

DAY 1: 10 October 2023

TIME ZONE: GMT +3

9:00 - 8:00

BREAKFAST REGISTRATION

AfriSummit Opening

Introduction by

Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy

AfriSummit Official Opening

Dr. Miriam Boles
Head of Central Administration of Medical Devices - Egyptian Drug Authority
EDA

National Regulatory Authority Medical Device Updates - Egypt

Moderated by
Ms. Shaimaa Salah
Regulatory Affairs Associate
Director North Africa & Middle East Clusters
Alcon

EDA Egypt

Dr. Noha El Hariri
General Director
General Administration of Medical Devises Registration
Egyptian Drug Authority
Eda

EU Regulatory updates and MDR Status

Moderated by
Dr. Nariman Hussein Fahmy
Senior RA Specialist Gulf & Levant
Johnson & Johnson Medtech

EU MDR Extension Impact

Mr. Monir El Azzouzi
CEO & Founder
Easy Medical Device

EU Manufacturer's Template

Mr. Dario Belluomini
Manager International Affairs
Medtech Europe

Impact of EU MDR on African Regulators

Dr. Noha El Hariri
General Director
General Administration of Medical Devises Registration
Egyptian Drug Authority
Eda

Q & A Discussion Panel

MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

10:30 - 11:00

National Regulatory Authority Medical Device Updates - Algeria

Moderated by
Dr. Hassiba Chemli
Regulatory Affairs Manager
Regional Vigilance officer
Lohmann & Rauscher - MENA

Regulations governing the approval of medical devices in Algeria
Réglementation régissant de l'homologation des dispositifs médicaux en Algérie

Dr. Saida Foughalia Fridi
Deputy Director of Scientific Documentary Evaluation of Medical Devices
The National Agency for Pharmaceutical Products
ANPP

11:00 - 11:30

National Regulatory Authority Medical Device Updates - Morocco

Moderated by
Ms. Majda Mghimimi
Senior Regulatory Affairs Specialist
French Speaking Africa
Medtronic

Presented by

Mr. Morad Ajan
Head of Medical Device Unit
Directorate of Medicine and Pharmacy
Morocco

11:30 - 12:00

Coffee and Networking Break

MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

12:00 - 12:30

Medical Device Regulatory Updates - Saudi- Arabia

Moderated by
Ms. Alaa Okasha
Regional Senior Regulatory Affairs Associate
GETM & GCC
STADA MENA

Presneted by
Dr. Hamoud Alsahli
Regulatory Affairs Team Leader
MRG (KSA & UAE)

Presneted by
Dr. Abdelrahman Abdellatif
Regulatory Affairs Team Leader
MRG (Egypt)

12:30 - 13:15

NRA Medical Device Updates - West Africa

Moderated by
Ms. Loshnee Vandayar
Senior Manager
International Regulatory Affairs
(Middle East and Africa) - Cepheid

Regulations to Assess Quality and Safety to ensure performance of Medical Device in Nigeria
Mr. Emmanuel Armon
Deputy-Director
Head of Biologics
Vaccine and Medical Devices Division
Nafdac

Ghana FDA
Mr. Emmanuel Nkrumah
Director For The Medical Device
Cosmetics And Household Chemicals Directorate
The Food And Drugs Authority
Fda
Ghana

Q & A Discussion Panel

13:15 - 13:30

Conference Photo and Competition announcement

13:30 - 14:30

Lunch and Networking Break

14:30 - 15:00

Medical Device Manufacturing in Africa

SADAC Countries
Ms. Simone Rudolph-shortt
Chairperson
MDMSA

MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

15:00 - 16:00

Status updates on New Regulatory in Medical Device - EAST AFRICA

Moderated by
Dr. Mary Kinyanjui
Senior Regulatory Affairs Specialist
Cepheid

Regulatory Requirements & how to navigate registration process in Tanzania

Mr. Christian Natalis Kapinga
Drug Registration Officer
Tanzania Medicines and Medical Devices Authority
TMDA

Rawanda

Dr. Emil Ivan Mwikarago
Department of Human Medicine and Device assessment & Registration
Division of Human Medicine
Assessment and Registration
Rwanda FDA

Ethiopia

Mr. Abebe Alamneh Kassahun
Medicine Registration Expert
Ethiopian Food and Drug Authority (EFDA)
Vice Chairman
East African regulatory Affairs Professionals Association (EARAPA)

MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

16:00 - 17:00

Transition to the IVDR

Moderated by
Ms. Sarah Cohen
Executive Officer at Southern African
Laboratory Diagnostics Association
SALDA

EU IVDR Transitions
Dr. Lydia Mina
Regulatory Affairs Regional Manager for The Region:
Metap & Uk (Middle East, Turkey , Africa & Pakistan & Uk)
Abbott

Impact of IVDR Transition on African regulations
Ms. Loshnee Vandayar
Senior Manager
International Regulatory Affairs
(Middle East and Africa)
Cepheid

Q & A Discussion Panel

Tanzania
Drug Registration Officer
Tanzania Medicines & Medical
Devices Authority

Ghana
Mr. Emmanuel Nkrumah
Director for The Medical Device
Cosmetics And Household Chemicals
Directorate at the Food And Drugs Authority
(Fda) – Ghana

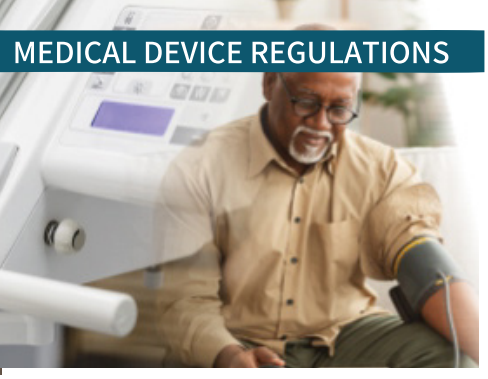
Ethiopia
Mr. Abebe Alamneh Kassahun
Medicine Registration Expert
Ethiopian Food and Drug Authority (EFDA)
Vice Chairman
East African regulatory Affairs Professionals
Association (EARAPA)

SOUTH AFRICA
Ms. Khanyisile Nkuku
Medical Device Registration Officer
SAHPRA

17:00 - 17:15

Wrap up day 1

Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy



MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

17:15 - 18:00

Coffee and Networking Break

17:15 - 18:00

Round Table Break out Discussions

EDA

Hosted by
Dr. Miriam Boles
Medical Devices - Egyptian Drug Authorit
EDA

Hosted by
Dr. Noha El Hariri
General Director
General Administration of Medical Devises Registration
Egyptian Drug Authority (Eda)

NAFDAC

Mr. Emmanuel Armon
Deputy-Director
Head of Biologics
Vaccine and Medical Devices Division
Nafdac

ANPP

Hosted by
Dr. Saida Foughalia Fridi
Deputy Director of Scientific Documentary Evaluation of Medical Devices the National Agency for Pharmaceutical Products
ANPP

MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

AGENDA

DAY 2: 11 October 2023

TIME ZONE: GMT +3

9:00 - 9:30

Morning Welcome Address

Good regulatory practices an enabler for market access

Ms. Rana Chalhoub
Regulatory Affairs Director
Mecomed

9:30 - 10:30

Medical Device Regulatory Updates: SOUTHERN AFRICA

Moderated by
Ms. Avanthi Govender Bester
Member of the Board
past Chair and Vice Chairperson
SAMED

South Africa
Ms. Khanyisile Nkuku
Medical Device Registration Officer

Botswana
Ms. Kesego Moalosi
Medical Devices Regulatory Officer
Botswana Medicines Regulatory Authority
BoMRA

Zambia
Dr. Frank N Laban
Principal Registration Officer
Zambia Medicines Regulatory Authority
ZAMRA

Zimbabwe
Mr. Richard Tendayi Rukwata
Director General
Medicines Control Authority of Zimbabwe
MCAZ

10:30 - 11:30

Digital Tools and Green Submissions - PRESNETATION & PANEL DISCUSSION

Moderated by
Dr. Marwa Said
Regulatory Affairs Manager
Boston Scientific

Global Perspective of Digitisation
Ahmed Hachami
Regulatory Affairs Specialist
Johnson & Johnson MedTech

Impact of Digitization on Regulatory Framework
Dr. Rania Soliman
General Manager
General Administration of Market Authorization of Medical Devices
Egyptian Drug Authority
Eda

Electronic IFU
Dr. Carol Attieh
Growth Emerging Markets - GEM
Regulatory Lead
Boston Scientific Middle East
FZ LLC

MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

11:30 - 12:00 Coffee and Networking Break

12:00 - 12:30 Digitalization of Medical Device Applications

Moderated by
Mr. Charle Leibbrandt
Partner
VECTOR Life Sciences (Pty) Ltd

Pesented by
Mr. Kent Briggs
Director
VECTOR Life Sciences

12:30 - 13:30 UDi initiatives

Moderated by
Dr. Rami Mansour
Regulatory Affairs Manager
Egypt – Becton Dickinson

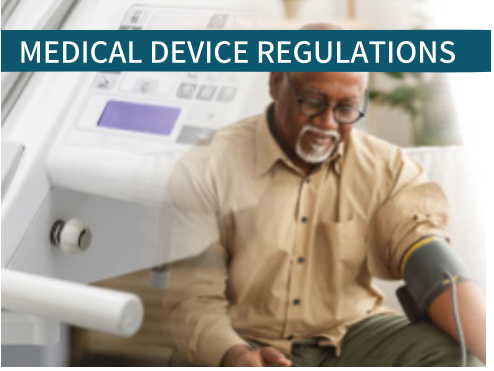
UDi implementation in Egypt
Dr. Haythem Sabry
Head of Regulatory Solutions
Gs1

UDI SFDA
Dr. Abdelrahman Abdellatif
Regulatory Affairs Team Leader
MRG (Egypt

Panel discussion UDI initiatives and regulations in the region

Dr. Miriam Boles
Head of Central Administration of
Medical Devices - Egyptian Drug Authorit
EDA

13:30 - 14:30 Lunch



MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

14:30 - 15:45

Reliance and Regulatory Convergence of Medical Technology

Moderated by
Dr. Asma Awad
Global Regulatory Policy
Lead E E M E A
Roche Diagnostics

GMTA Paper on Reliance
Dr. Asma Awad
Global Regulatory Policy
Lead E E M E A
Roche Diagnostics

Panel discussion Industry

Ms. Rana Chalhoub
Regulatory Affairs Director
Mecomed

Mr. Dario Belluomini
Manager International Affairs
Medtech Europe

Dr. Fatma Wahdan
Regulatory Affairs and Quality Assurance Manager Medtronic Egypt & Libya Cluster

Capacity Building and NRA Support needed

Dr. Noha El Hariri
General Director
General Administration of Medical Devises Registration
Egyptian Drug Authority (Eda)

Mr. Christian Natalis Kapinga
Drug Registration Officer
Tanzania Medicines & Medical Devices Authority
TMDA

Ms. Khanyisile Nkuku
Medical Device Registration Officer

15:45 - 16:45

Materiovigilance and Post marketing Surveillance

Moderated by
Ms. Salma Salim
Senior Regulatory Affairs Manager
GE HealthCare

Dr. Rima Nsheiwat
Regulatory Access and Market intelligence
Strategist and Consultant
B.V. Amsterdam Medical & Scientific Alliance

Panel discussion

Dr. Saida Foughalia Fridi
Deputy Director of Scientific Doc Evaluation of Medical Devices
The National Agency for Pharmaceutical Products
ANPP

Mr. Christian Natalis Kapinga
Drug Registration Officer
Tanzania Medicines & Medical Devices Authority
TMDA

Mr. Monir El Azzouzi
CEO & Founder
Easy Medical Device

MedDevREG AFRiSUMMIT

INNOVATED HEALTH FOR AFRICA

AN INITIATIVE BY PRA CONSULTANCY | IN COLLABORATION WITH PIONEERS | ORGANIZED BY hubplus events

16:45 - 17:00

Wrap up and conclusion

Dr. Mona Al Moussli
Co-founder and Managing Director
PRA Consultancy

17:00- 18:00

Round Table Break out Discussions

Ms. Kesego Moalosi
Medical Devices Regulatory Officer
Botswana Medicines Regulatory Authority
BoMRA

Dr. Frank N Laban
Principal Registration Officer
Zambia Medicines Regulatory Authority
ZAMRA

Mr. Christian Natalis Kapinga
Drug Registration Officer
Tanzania Medicines &
Medical Devices Authority
TMDA

17:15 - 18:00

Coffee and Networking Break


Dolls
Pharma
www.dollspharmaegy.com

Welcome

to Our State Of The Art Contract Manufacturing Facility

• At our cutting-edge contract manufacturing facility, we bring your vision to life. We understand that quality, precision, and efficiency are paramount when it comes to manufacturing your products, and we are dedicated to exceeding your expectations every step of the way

Your Manufacturing Partner

We are more than just a manufacturing facility; we are your trusted partner in turning ideas into reality. Our commitment to excellence and innovation drives us to deliver outstanding results for your business. Here's what sets us apart:

1 Advanced Technology

Our facility is equipped with the latest technology, ensuring that your products are manufactured with precision and efficiency.

2 Quality Assurance

We uphold the highest standards of quality control, from raw material sourcing to the final product, to ensure consistency & compliance with industry regulations.

3 Expert Team

Our team of experienced professionals is dedicated to bringing your concepts to life. From product design to production, we have the expertise to meet your unique requirements.

4 Flexibility

We understand that each project is unique. Our flexible manufacturing processes allow us to tailor our services to fit your specific needs.

5 Timely Delivery

We prioritize on-time delivery, ensuring that your products reach the market when you need them.

6 Cost Efficiency

Our streamlined processes and economies of scale enable us to offer competitive pricing without compromising on quality.

7 Confidentiality

We take data security and confidentiality seriously, providing a secure environment for your intellectual property.

Partner with us and you'll have a reliable ally in achieving your manufacturing goals. Our commitment to excellence and customer satisfaction drives everything we do.

Ready to take your products to the next level?
Contact us today to discuss how our contract manufacturing facility can turn your ideas into reality.

Discover Who to Meet at the afrisummit 2023

REGULATORY AFFAIRS MANAGER
REGULATORY AFFAIRS ASSOCIATE
REGULATORY MANAGEMENT ANALYST
DIRECTOR OF SUPPLY, REGULATORY, QUALITY & PV
EXPORT MANAGER
HEAD OF GLOBAL RA DEVELOPMENT AND STRATEGY
REGULATORY AFFAIRS SPECIALIST
REGULATORY SCIENCES SENIOR MANAGER
REGIONAL STRATEGIST MANAGER
REGULATORY SCIENCES MANAGER
REGULATORY SCIENCES SPECIALIST
CLUSTER LEAD - SUB
HEAD OF REGULATORY SCIENCES
SENIOR REGULATORY SCIENCES MANAGER
TECHNICAL DIRECTOR MEA
REGULATORY AFFAIRS DIRECTOR
SENIOR REGULATORY AFFAIRS ASSOCIATE
REGULATORY AFFAIRS SECTION HEAD
REGULATORY AFFAIRS MANAGER
REGULATORY AFFAIRS SENIOR SPECIALIST
REGULATORY & QUALITY DIRECTOR
SENIOR ASSOCIATE REGULATORY & AFFILIATE LABELLING COORDINATOR
REGULATORY PHARMACIST
LEAD REGULATORY PHARMACIST
QUALITY ASSURANCE MANAGER
GMP ARCHITECT
SENIOR RA ASSOCIATE
RA AFFAIRS MANAGER
SENIOR RA ASSOCIATE
HEAD OF RA
RA COMPLIANCE MANAGER
SENIOR REGULATORY ASSOCIATE
ERMC LIFECYCLE MANAGEMENT RA PROFESSIONAL
ERMC LIFECYCLE MANAGEMENT SUB-TEAM LEAD
ASSOCIATE DIRECTOR, RA POLICY AND STRATEGIC OPERATIONS
HEAD, RA POLICY AND STRATEGIC OPERATIONS
REGULATORY AFFAIRS ASSOCIATE
REGULATORY AFFAIRS MANAGER
REGULATORY AFFAIRS SPECIALIST
REGULATORY AFFAIRS MANAGER
RA SENIOR SPECIALIST
SNR REGULATORY AFFAIRS MANAGER, RESPONSIBLE PHARMACIST
SNR REGULATORY AFFAIRS PHARMACIST, DEPUTY RESPONSIBLE PHARMACIST
REGULATORY AFFAIRS PARTNER
SENIOR MANAGER REGULATORY AFFAIRS
EQUITY RESEARCH ANALYST, HEALTHCARE AND PHARMACEUTICALS
REGULATORY AFFAIRS HEAD
SALES HEAD
SOLUTION CONSULTANT
RA MANAGER
ASSOC DIR, REGULATORY AFFAIRS
PRINCIPAL, RA SPECIALIST
REGULATORY AFFAIRS ASSISTANT MANAGER
GENERAL MANAGER
COUNTRY MANAGER

REGULATORY AFFAIRS LEAD
SNR RA MANAGER / RESPONSIBLE PHARMACIST
SUPPLY CHAIN ANALYST
REGULATORY AFFAIRS SECTION HEAD
REGULATORY AFFAIRS SPECIALIST
MARKET ACCESS MANAGER
REGULATORY AFFAIRS DEPUTY MANAGER
REGULATORY AFFAIRS SPECIALIST
REGULATORY AFFAIRS SENIOR SPECIALIST
ACT AS GENERAL MANAGER R&D
FORMULATION MANAGER.
REGULATORY AFFAIRS SECTION HEAD
SPECIALIST – REGULATORY AFFAIRS, ROW
DIVISIONAL MANAGER: REGULATORY EXPORTS
CLUSTER REGULATORY AFFAIRS HEAD
SENIOR QRC SPECIALIST
REGULATORY AND QUALITY MANAGER
SENIOR REGULATORY SPECIALIST
COMPLIANCE OFFICER
REGULATORY POLICY AND INTELLIGENCE MANAGER
RA MANAGER SADC
RA & QA MANAGER EA
REGULATORY AFFAIRS EXECUTIVE
REGULATORY AFFAIRS MANAGER, META
REGULATORY AFFAIRS AND QUALITY ASSURANCE MANAGER
EMEA REGULATORY, QUALITY & COMPLIANCE SPECIALIST
SENIOR RA
QUALITY PROFESSIONAL
QA&RA MANAGER
SENIOR MANAGER, REGULATORY AFFAIRS
ASSOC DIR, REGULATORY AFFAIRS
PRINCIPAL, RA SPECIALIST, EEA
MARKET ACCESS AND POLICY AFFAIRS MANAGER
SENIOR RA MANAGER
SENIOR MANAGER, GEM REGULATORY
DEPUTY MANAGER
MARKET ACCESS DIRECTOR
QUALITY ASSURANCE AND RA MANAGER
SUPPLY CHAIN AND QA MANAGER
SR MANAGER QA MEA
SOLUTION CONSULTANT
CHIEF EXECUTIVE OFFICER/OWNER
QUALITY AND REGULATORY AFFAIRS MANAGER
GOVERNMENT AFFAIRS HEAD
DIRECTOR PUBLIC AFFAIRS
CONSULTANT
SCIENTIFIC OFFICE MANAGER
MARKET ACCESS LEAD
SENIOR REGULATORY AFFAIRS PHARMACIST, DEPUTY RESPONSIBLE PHARMACIST
REGULATORY SYSTEMS & ANALYST
REGULATORY AFFAIRS SCIENTIST
REGULATORY AFFAIRS PHARMACIST
SNR RA MANAGER
HEAD OF REGULATORY AFFAIRS: AFRICAN CLUSTER HEAD
REGULATORY AFFAIRS SENIOR OFFICER
REGULATORY AFFAIRS DEPUTY MANAGER

AFRiSUMMIT

Platinum Sponsor

sanofi

Gold Sponsor

Dolls Pharma
We Seek Engagement

Sliver Sponsors

MRG
Bridge To Your Success

UTRACE

Workshop Sponsor

VECTOR LIFE SCIENCES & Lorenz LIFE SCIENCES GROUP
exclusive partner in Africa

Session Sponsor

Cepheid
A better way.

Lunch Sponsor

ACG
Make it better.

Valued Exhibitor

EXTEDO
eRegulatory Affairs

Strategic Partner

AHB
AFRICA HEALTH BUSINESS

Knowledge Partner

GS1 Egypt

Supporting Partner

AGH
AFRICAN GLOBAL HEALTH

Supporting ORG

AdvaMed
Advanced Medical Technology Association

Education Partner

The BRITISH UNIVERSITY IN EGYPT

Association Partners

SALDA · mecomed · TOPRA · kapi · SACRA · SAMED · MDMSA · EARAPA

Media Partners

MEDICA · CNN686 MEDIA · JPRA · Journal of Medical Device Regulation · MEDIWORLD · HOSPITALS · ECHEMI · MED TECH · AXESSHEALTH · The Arab Hospital Magazine

An Initiative of PRA CONSULTANCY

In Collaboration with PIONEERS FOR EXHIBITIONS & CONFERENCES

Organized By hubplus events

hubplus

Making Events Come Alive

@Hubplusevents

www.hubplus-events.com

UPCOMING EVENTS

GCC REGULATORY AFFAIRS PHARMA SUMMIT

GCCPV PHARMACOVIGILANCE TRAINING

MIDDLE EAST MEDICAL TENDER TRAINING

ACRAS

PharmaCC Pharmacy Career Conference

PHARMAREG AFRISUMMIT PHARMACOVIGILANCE TRAINING

PHARMAREG AFRISUMMIT

MedDevREG AFRISUMMIT