4th - 5th November 2025

MedDevREG AFRiSUMMIT

For A Healthier Africa

Hilton Grand Nile Hotel, Cairo - Egypt

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PHARMAREG AFRiSUMMIT

AGENDA

DAY 1: 4 November 2025

09:00 - 09:30 Coffee and Registration

09:30 - 10:00 Opening Ceremony

Dr. Najiba Al Shezawy
Co-Chairman | AfriSummit

Dr. Miriam Boles
Head of the Central Administration of Medical Devices, Egyptian Drug Authority (EDA)

10:00 - 10:45 Session 1: Advancing Medical Device RegulationThrough Continental Collaboration

Moderator:
Ms. Khatija Suleman
Board Member
South African Medical Device Industry Association (SAMED), Head of Regulatory Affairs for Africa – Becton Dickinson

From Regional Efforts to Continental Impact: Harmonization in Action

Ms Khanyisile Nkuku
Medical Device & IVD Registration Officer
South African Health Products Regulatory Authority (SAHPRA)

AMDF's Role in Shaping a Unified Regulatory Future for Medical Devices

Dr. Miriam Boles
Head of the Central Administration of Medical Devices, Egyptian Drug Authority (EDA)

Panel Discussion: Continental Unity Through Regulatory Alignment

Dr. Frank Laban
Principal Registration Officer,
Zambia Medicines Regulatory Authority (ZAMRA), Zambia

Ms Khanyisile Nkuku
Medical Device & IVD Registration Officer
South African Health Products Regulatory Authority (SAHPRA)

Dr. Miriam Boles
Head of the Central Administration of Medical Devices, Egyptian Drug Authority (EDA)

10:45 - 11:30 Session 2: NRA Medical Device Regulatory Updates – North Africa

Moderator:
Dr. Marwa Said
Regulatory Affairs Manager MENA,
Boston Scientific

Egyptian Drug Authority Medical Device Regulatory Updates

Dr. Doaa Saeed Mahrous
General Manager Medical Device Registration,
Egyptian Drug Authority (EDA), Egypt

Regulatory Update on Medical Devices in Algeria

Dr. Foughalia Saïda
Deputy Director, Directorate of Medical Device Registration, National Agency for Pharmaceutical Products (ANPP), Algeria

Medical Device Regulation in Tunisia

Dr. Khalil Chemli
Pharmacist, Medical Device Department,
National Agency for Medicines and Health Products (ANMPS),
Tunisia

11:30 - 12:00 Coffee and Networking Break

12:00 - 12:45 Session 3: Adapting Global Frameworks: Insights from MDR/IVDR for African Regulators and Industry

Moderator:
Dr. Lydia Mina
Regulatory Affairs Regional Manager,
OUS markets METAP region, Abbott

Global Standards, Local Impact: MDR/IVDR Insights for African Regulators and Industry

Ms. Clare Birmingham
Manager, International Affairs,
MedTech Europe

MDR and IVDR: Reliance and Lessons Learned

Mr. Erik Vollebregt
Partner, Axon Lawyers, Netherlands

The IFU Shift: Why Going Digital Matters for the Continent

Mr. Monir El Azzouzi
CEO & Founder, Easy Medical Device

Accurate Labelling in Paper and Digital Formats

Mr. Marc Chaillou
Head of Sales Europe
& Global Strategic Projects,
Schlafender Hase GmbH

12:45 - 13:15 Session 4: NRA Medical Device Regulatory Updates – West Africa

Moderator:
Dr. Radwa Abdelkafy
Head of Regulatory Affairs Africa,
Baxter International

Medical Devices Regulatory Updates - Nigeria

Dr. Khadijah O. Ade-Abolade
Director (Vaccines, Biologics & Medical Devices Registration & Regulatory Affairs) Directorate, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria

Update of the Regulatory Framework for Medical Devices in Senegal

Dr. Arame Mbengue
Chief Pharmacist, Head of the Unit for the Authorization of Other Health Products, Directorate of Authorization and Serialization of Medicines and Other Health Products, Senegalese Pharmaceutical Regulatory Agency (ARP), Senegal

13:15 - 14:15 Group Photo, Lunch and Networking

14:15 - 15:00 Session 5: Africa's Digital Health Boom – Regulating the Connected Future

Moderator:
Dr. Bill McMoil
Executive Director, Regulatory Affairs Professionals Society (RAPS)

The Shift to Digital Regulatory Infrastructure in Medical Devices

Dr. Noha El Hariri
Strategic Business Consultant

Digitization Transformation Enhancing the Regulatory Affairs Compliance, Data Accessibility, and Environmental Sustainability

Dr. Mirette Abskharoun
RA Associate Director Middle East Africa Region,
Johnson & Johnson

AI-Enabled Medical Devices and Africa's Evolving Regulatory Landscape

Mr. Dirk Gey van Pittius
Regulatory Senior Manager- Southern Africa,
Medtronic

Panel Discussion

Ms Khanyisile Nkuku
Medical Device & IVD Registration Officer
South African Health Products Regulatory Authority (SAHPRA)

Dr. Noha El Hariri
Strategic Business Consultant

Dr. Mirette Abskharoun
RA Associate Director Middle East Africa Region,
Johnson & Johnson

Mr. Dirk Gey van Pittius
Regulatory Senior Manager,
Southern Africa,
Medtronic

15:45 - 16:15 Coffee and Networking Break

16:15 - 17:15 Session 6: The Voice of the Industry – Medical Device Associations and Their Strategies

Moderator:
Dr. Fatma Wahdan
Regulatory Senior Manager – Egypt North & West Africa, Medtronic

Partnering for Progress: The Contribution of MedTech Associations to Safer and Smarter Patient Access

Dr. Rana Chalhoub
Regulatory Affairs Director, MECOMED

South African Medical Technology Industry Association (SAMED)

Ms. Khatija Suleman
Board Member, South African Medical Device Industry Association (SAMED) and Head of Regulatory Affairs for Africa, Becton Dickinson

Medical Device Manufacturers of South Africa (MDMSA)

Mrs. Simone Shortt
Chairperson, Medical Device Manufacturers of South Africa (MDMSA), South Africa

Empowering Kenya's Medtech Industry Collaboratively

Dr. Christopher Odero
Regulatory Policy & Intelligence Manager, Africa - Roche

17:15 - 18:15 NRA Break Out Round Table Discussions

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DAY 2: 5 November 2025

09:00 - 09:30 Coffee and Registration

09:30 - 10:30 Session 1: Authority in Action: Strengthening Medical Device Oversight Across the Continent

Moderator:
Dr. Marie Emad
Regulatory Affairs Specialist, Egypt, Becton Dickinson

AUDA-NEPAD's Role in Driving Regulatory Harmonization

Dr. Nancy Ngum
Public Health Officer,
African Union Development Agency,
New Partnership for Africa's
Development (AUDA-NEPAD)

Strengthening Regulations Through Shared Progress

Dr. Christopher Odero
Regulatory Policy
& Intelligence Manager,
Africa- Roche

Harmonization & Reliance in Africa: Strengthening Regulation of Medical Devices, Equipment & IVDs

Dr. Noha El Hariri
Strategic Business Consultant

Panel Discussion: Collaborative Pathways: Positive Strides in Africa's Medical Device Regulatory Landscape

Dr. Rachel Juliet Mujawimana
Inspector of Drugs,
National Drug Authority (NDA),
Uganda

Dr. Khadijah O. Ade-Abolade
Director (Vaccines, Biologics
& Medical Devices Registration
& Regulatory Affairs) Directorate,
National Agency for Food
and Drug Administration and Control (NAFDAC),
Nigeria

Ms Khanyisile Nkuku
Medical Device & IVD Registration Officer
South African Health Products Regulatory
Authority (SAHPRA)

10:30 - 11:15 Session 2: Diagnostics on the Rise – Regulating IVDs in Africa

Moderator:
Dr. Karim Wahba
Head of Regulatory Management & Trade compliance Middle East, Africa & Turkey, Merck Life Science

From Advocacy to Innovation: The Impact of SALDA in IVD

Ms. Sarah Cohen
Executive Officer, Southern African Laboratory Diagnostics Association (SALDA), South Africa)

Panel Discussion: Regulating Diagnostics in Africa for Growth and Impact

Dr. Frank Laban
Principal Registration Officer,
Zambia Medicines Regulatory Authority (ZAMRA), Zambia

Dr. Sara Emad Gerges
Imported IVD Listing Unit Manager,
Egyptian Drug Authority (EDA), Egypt

Mr. Thabo Bokhutlo
Medical Devices Regulatory Officer,
Botswana Medicines Regulatory Authority (BoMRA), Botswana

Dr. Khadijah O. Ade-Abolade
Director (Vaccines, Biologics & Medical Devices Registration & Regulatory Affairs) Directorate, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria

11:15 - 11:45 Coffee and Networking Break

11:15 - 12:00 Session 3: NRA Medical Device Regulatory Updates – Southern Africa

Moderator:
Darein Hassan
Senior Director Regulatory Affairs and Quality – Emerging Markets, Smith & Nephew

Medical Device Regulation in Zambia – Our Journey from 2021 to 2025

Dr. Frank Laban
Principal Registration Officer, Zambia Medicines Regulatory Authority (ZAMRA), Zambia

Medical Devices Regulatory Updates - Botswana

Mr. Thabo Bokhutlo
Medical Devices Regulatory Officer, Botswana Medicines Regulatory Authority (BoMRA), Botswana

South African Health Products Regulatory Authority (SAHPRA), South Africa

Ms. Lydia Motlogelwa
Medical Device and Clinical Trials Manager, South African Health Products Regulatory Authority (SAHPRA), South Africa

12:00 - 12:45 Session 4: Securing Africa's Medical Device Supply Chain: Tackling Counterfeits and Enhancing Traceability

Moderator:
Mr. Hilton T. Stevens
Head of Regulatory Affairs and Quality Assurance Responsible Pharmacist, Population Services International (PSI)

Enhancing Post Market Surveillance

Dr. Brayhan Kariuki
Regulatory Officer, Pharmacy and Poisons Board (PPB), Kenya

Fighting Counterfeit Medical Devices in Africa: The Role of Track and Trace Systems

Mr. Gorkem Aydın
CMO, VISIOTT TPS

Panel Discussion: Securing the Future - Collaborative Approaches to Safeguard Africa's Medical Device Supply Chain

Dr. Salah Allam
Manager of Pharmacy
and Warehouse Inspection Administration,
Egyptian Drug Authority (EDA), Egypt

Mr. Thabo Bokhutlo
Medical Devices Regulatory Officer,
Botswana Medicines Regulatory Authority (BoMRA),
Botswana

12:45 - 13:45 Lunch and Networking

13:45 - 14:30 Session 5: NRA Medical Device Regulatory Updates – East Africa

Moderator:
Dr. Maria Rafaat
Senior Regulatory Affairs, Quality & Compliance Professional- EMEA, QuidelOrtho

Updates in Medical Device Regulation in Ethiopia

Dr. Abebe Alamneh
Medicine Registration Expert, Ethiopian Food and Drug Authority (EFDA), Ethiopia

Regulatory Updates Kenya

Dr. Brayhan Kariuki
Regulatory Officer, Pharmacy and Poisons Board (PPB), Kenya

Current Updates in Uganda's Medical Device Regulatory Framework

Dr. Rachel Juliet Mujawimana
Inspector of Drugs, National Drug Authority (NDA), Uganda

14:30 - 15:15 Session 6: Made in Africa – From Importer to Medical Device Powerhouse

Moderator:
Mrs. Simone Shortt
Chairperson, Medical Device Manufacturers of South Africa (MDMSA), South Africa

Made in Africa: Egypt's Role in the Transformation from Importer to Medical Device Powerhouse

Dr. Youstina Nabil Adly Sawiros
Medical Devices Registration Senior, Egyptian Drug Authority (EDA), Egypt

Driving Local Innovation: The Future of African Medical Devices

Dr. Noha El Hariri
Strategic Business Consultant

Panel Discussion: Driving Local Innovation - The Future of African Medical Devices

Dr. Youstina Nabil Adly Sawiros
Medical Devices Registration Senior, Egyptian Drug Authority (EDA), Egypt

Dr. Noha El Hariri
Strategic Business Consultant

15:15 - 16:45 Coffee and Networking Break

16:45 - 17:30 Session 7: Standard Compliance Reliance in Africa

Moderator:
Dr. Rana Chalhoub
Regulatory Affairs Director, MECOMED

Medical Device Single Audit Program MDSAP

Dr. Marie Bouchra
Regional Manager Regulatory Affairs and Policy MEA, Johnson & Johnson MedTech

Panel Discussion: Strengthening GMP Oversight Through Reliance

Ms Khanyisile Nkuku
Medical Device & IVD Registration Officer South African Health Products Regulatory Authority (SAHPRA)

Dr. Khadijah O. Ade-Abolade
Director (Vaccines, Biologics & Medical Devices Registration & Regulatory Affairs) Directorate, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria

Dr. Marie Bouchra
Regional Manager Regulatory Affairs and Policy MEA, Johnson & Johnson MedTech