For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

EGYPTIAN DRUG AUTHORITY
EDA
هيئة الدواء المصرية

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

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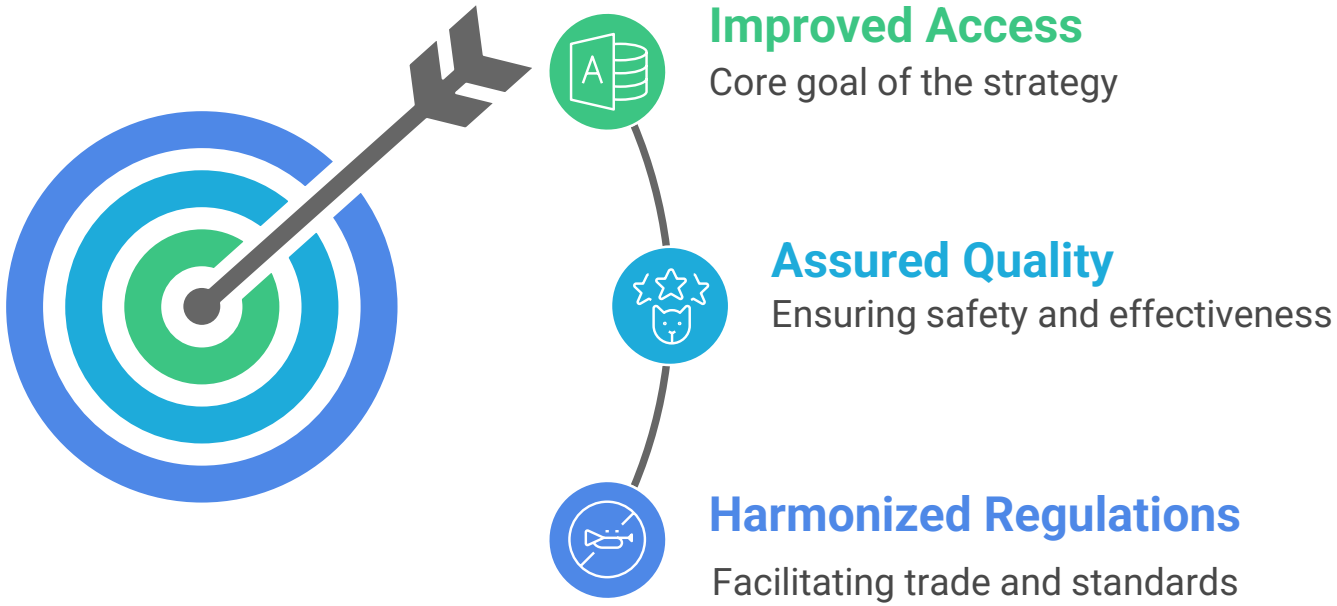
Agenda

- Introduction & AMDF Role 01
- Egypt’s Election & Leadership 02
- Guidelines Implementation 03
- EDA at the 4th MDA-TC Meeting 04
- Capacity Building & MDA-TC Progress 05
- EOIs for Selection for Assessors and auditors 06

African Medical Devices Forum (AMDF) Overview

- A technical committee under the African Medicines Regulatory Harmonization (AMRH) Programme, jointly hosted by AUDA-NEPAD (African union development agency) and WHO.



Egypt’s Leadership in AMDF

- In April 2025, Kenya (Pharmacy and Poison Board) was elected as chair of AMDF,and Egypt (Egyptian Drug Authority) was elected Vice-Chair of the AMDF for a three-year term (2025-2028).
- Reflects continental confidence in Egypt’s regulatory leadership.
- Reinforces commitment to advancing medical device regulation across Africa.

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IMDRF-Aligned Regulatory Guidelines

Labelling Requirements

Guidelines for labelling medical devices, including Invitro diagnostics.

Emergency Authorization

Procedures for authorizing in vitro diagnostic medical devices during public health emergencies.

Registration and Listing

Registration of manufacturers and listing of medical devices.

Field Safety Actions

Procedure for field safety corrective actions for medical devices.

Egyptian Drug Authority at the 4th MDA-TC Meeting

- Reviewed **3** applications for **Mpox molecular diagnostic tests** (RT-PCR).
- **Approved** additional data requirements and technical references for the QMS Audit Working Group.
- **Adopted** joint technical recommendations, reference documents, and assessment tools.
- Advanced Agenda 2063 through coordinated regional and continental initiatives.

Regulatory Convergence through Capacity Building

- Capacity building on **strengthening oversight of medical devices and IVDs** for **120+ regulators** across Africa .

Expressions of Interest (EOI)for Selection of Technical File Assessors and ISO13485 Based QMS Auditors

In September 2025 ,The African Medicines Regulatory Harmonization (AMRH) Initiative, under AUDA-NEPAD, invited qualified experts from African Union Member States to express interest in serving as continental assessors and auditors. These experts will support the Medical Device Assessment Technical Committee (MDA-TC) in strengthening regulatory oversight for medical devices and in-vitro diagnostics (IVDs) across Africa.

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