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

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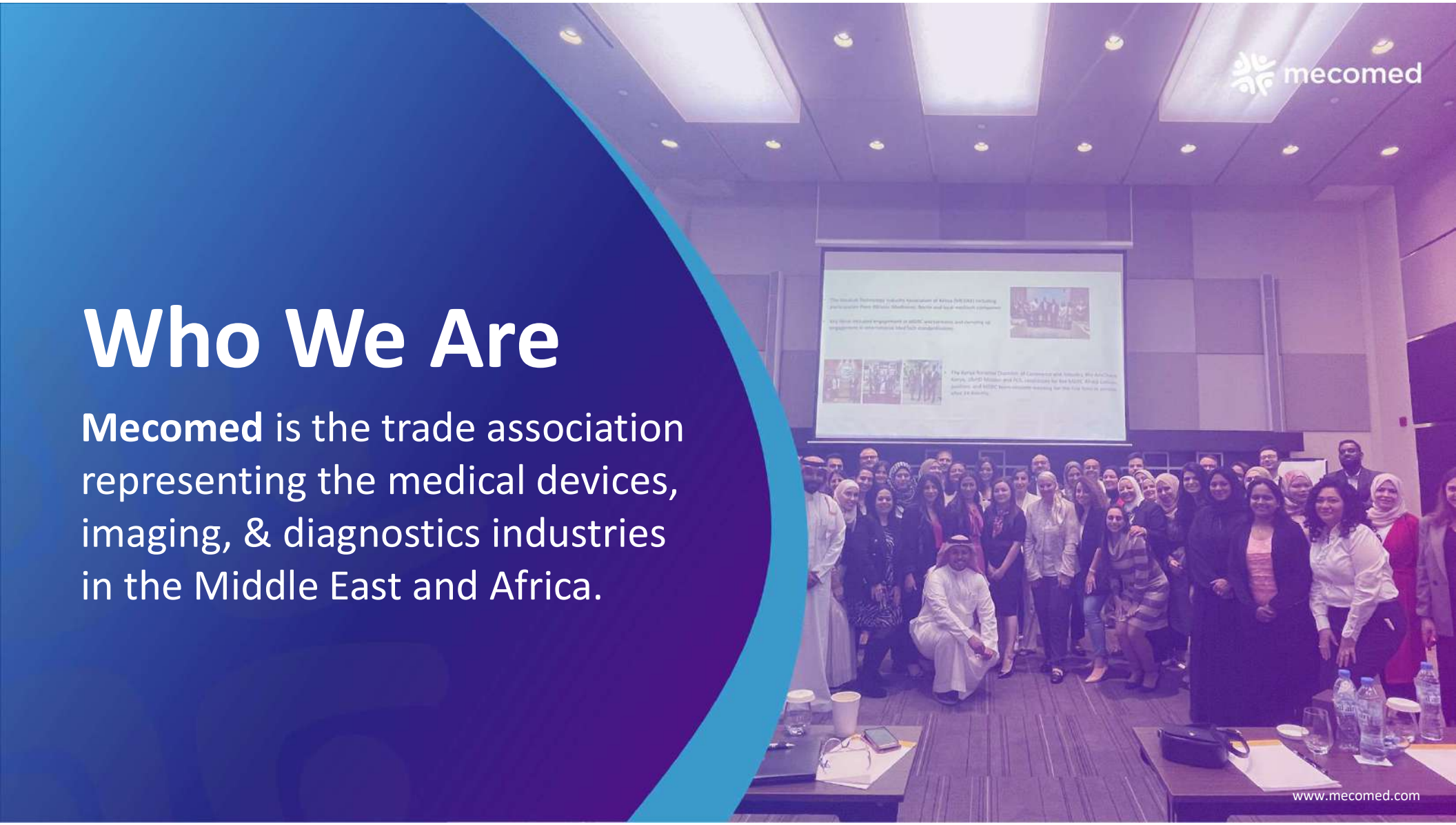
Partnering for Progress:

The contribution of MedTech Associations to Safer and Smarter Patient Access

RANA CHALHOUB
RA Director - MECOMED

Who We Are

Mecomed is the trade association representing the medical devices, imaging, & diagnostics industries in the Middle East and Africa.



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Our Mission

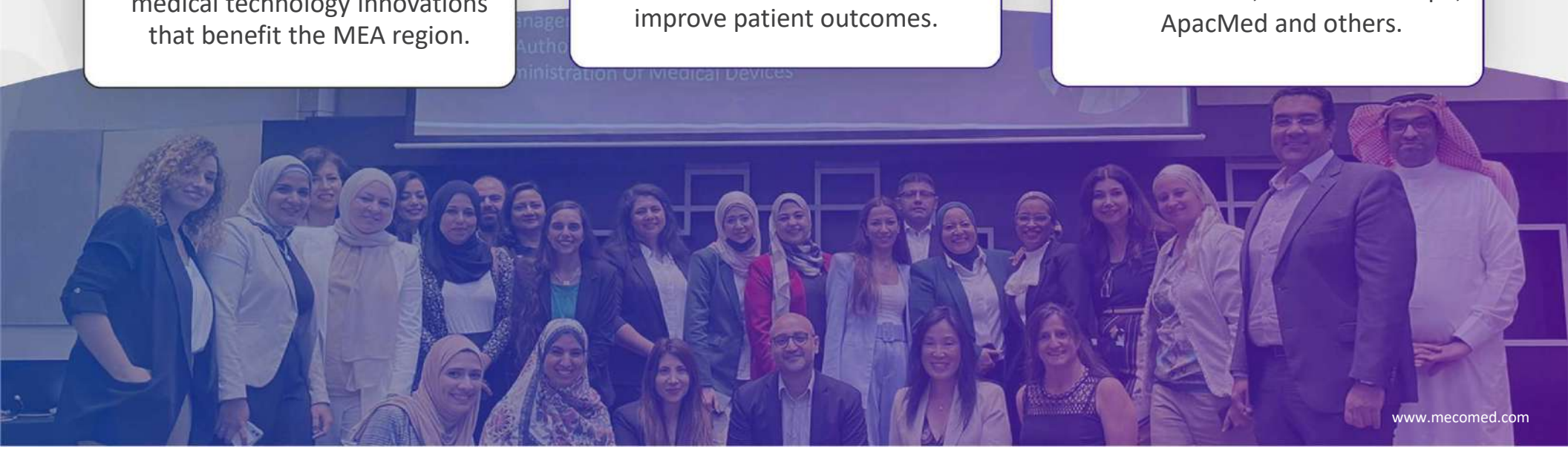
Bring together all stakeholders in healthcare to improve people's health through the timely introduction of meaningful medical technology innovations that benefit the MEA region.

Foster Good Citizenship

Collaborate with governments, regional organizations, and healthcare providers to deliver high-value solutions that improve patient outcomes.

Our Association

Mecomed is a member of Global Medical Technology Alliance, which includes other associations, like AdvaMed, MedTech Europe, ApacMed and others.



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Our Members 2025

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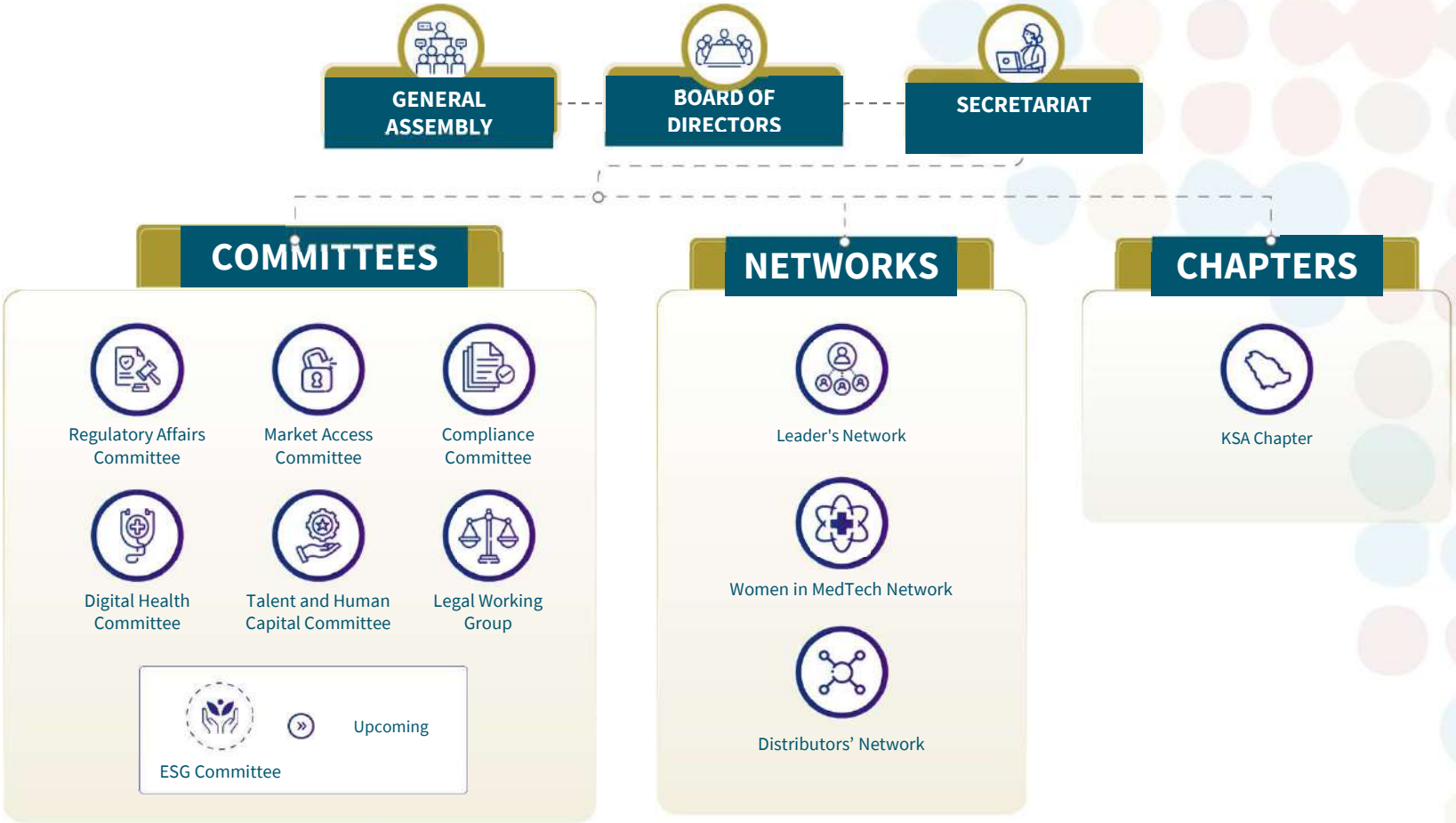
Our Associate Members 2025

Mecomed Org. Structure



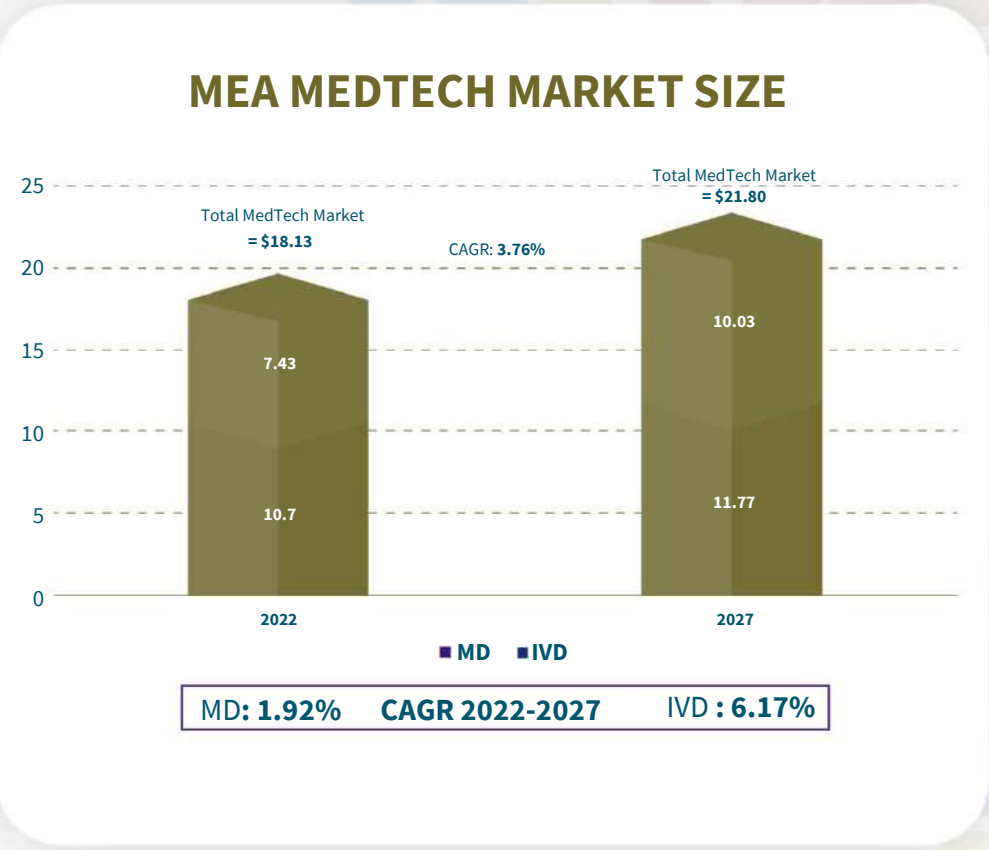
Specificity of the MEA MedTech Market & Regulatory Environment

MEA MedTech Market

1.67 Billion
Population

Country Healthcare Expenditure range:
from under $50 to over $1700 per capita

Country Healthcare Expenditure range in% of GDP in MEA: **3% to 10%**



https://data.worldbank.org
MEA IVD Market Size Worth USD 10.03 Bn By 2027 (marketdataforecast.com)
https://www.businessmarketinsights.com/reports/middle-east-and-africa-medical-devices-market

MEA Regulatory Environment

Be Informed

- Regulatory Intelligence & Updates
- Sharing Best Practices

Anticipate Change

- Capacity Building Initiatives
- Members' Training & Education

Respond with Confidence

- Solid Databank
- Engaging with Authorities & Trade Associations

Our RA Working Groups

1
UDI WG

2
E-IFU WG

3
Reliance WG

4
Databank Update WG

5
IVDR WG

6
MDR WG

7
AI Regulations WG

8
Distributors Training WG

1. Working on harmonizing UDI requirements for the region

2. Working on advocating the acceptance of E-IFU in the region

3. Working on advancing regulatory convergence in the region, with a main focus on Africa

4. Maintaining an up-to-date tracker of the regulatory framework and requirements in the region

5. Assessing the impact of IVDR on the registrations in the region and building capacity with regulators around the changes introduced

6. Assessing the impact of MDR on the registrations in the region and building capacity with regulators around the changes introduced

7. In collaboration with Digital Health Committee – Yet to be kicked off

8. Building and delivering a regulatory training curriculum for Mecomed members' distributors.

Driving Impact through Collaboration

MECOMED – GHWP Liaison Member

MECOMED endorsed as a GHWP Liaison Member

A significant milestone that was achieved by Mecomed is becoming an official Liaison Member for GHWP (Global Harmonization Working Party).

Learn more about this collaboration in our press release here:

https://bit.ly/3BnoHCp

GHWP Annual Meeting, Malaysia

Presented and shared best practices on reliance implementation in the MEA region, along with an esteemed panel of experts from WHO, industry and regulators.

1st GHWP Training Academy, Guangzhou, China

Being part of the subject matter experts at the first GHWP Training Academy program in China, sharing best regulatory practices across the different geographies, and where Regulatory Harmonization and Reliance continue to be the answer to enable access to safe and effective medical technology to the patient.

Global Engagement: A Key Driver to Amplify the Voice of Our Region

MedTech Forum

Discussing Reliance, presenting on the impact of MDR/IVDR on Registrations in the region at different MedTech Forums editions

Global Access, Ireland

Participated in a panel discussion on International Harmonization at **Global Access, Ireland**, sharing insights and bringing forward the experience from the MEA region.

ABHI, UK

Participated in the **ABHI** (UK MedTech Association) MEA Accelerator Programme providing insights into MEA Region

Life Sciences Academy, Budapest

Providing insights on the impact of MDR on the MEA Region at The 7th edition of the MedDevDay where leading experts and regulators from around Europe will explore how evolving medical device regulations are reshaping global business strategies and innovation.

Engagement across Africa

- MECOMED spearheaded, in collaboration with GMTA Members, the drafting of the GMTA Industry paper on: Exploring the Benefits of Reliance and the Medical Device Single Audit Program (MDSAP) for Maufacturing site audits.

Read GMTA MDSAP Paper Here

- MECOMED, co-chairing the GMTA Africa WG.

- Mecomed serves as a member of the Advisory Board of the U.S. Africa Health Regulatory Harmonization Network, an initiative by the Corporate Council on Africa, aiming to promote knowledge sharing, shape policy, support implementation, and enable international benchmarking to expand access to high-quality, safe, and effective healthcare products in Africa.

CORPORATE COUNCIL ON AFRICA'S
U.S.-AFRICA HEALTH SECURITY AND RESILIENCE INITIATIVE

Regional Cooperation in Africa: A Cornerstone for Success

SAMED

- Presented MEA Regulatory updates and co-chairing the GMTA Africa WG.

SALDA

- Presented on MEA Regulatory updates in their regulatory forum on May 21, 2025
- Engagement with SAPRA for an IVDR focused discussion

MEDAK

- Contributed to MEDAK Regulatory Reliance Workshop in Kenya

Nigerian Association

Our 2025 Story: Key Initiatives That Made an Impact

MEA MedTech Regulatory Summit in collaboration with RAPS

The 2025 MEA MedTech Regulatory Summit, co-hosted by Mecomed and and RAPS, brought together 135 global regulators, health authorities, and industry leaders from 25 countries.

Through insightful discussions, interactive workshops, and expert-led sessions, the summit tackled the evolving regulatory landscape in MEA, emphasizing patient safety, compliance, and innovation.

Click here for:
Presentations

Click here for:
Pictures 1 & Pictures 2

Click here for:
Highlights Video

A Flagship Initiative in 2025
Regulatory Distributors' Training Program

Led and organized by **Mecomed**, this program brought together over 400+ participants from across the region — marking another important milestone in strengthening regulatory expertise and fostering collaboration within the regional MedTech community.

Key topics covered included:
– EU & US regulatory pathways for Medical Devices and IVDs
– Good Regulatory Practice (GRP)
– Quality Management Systems and Regulatory Intelligence
– EU MDR/IVDR implementation and impact
– MEA regulatory frameworks
– Digital transformation, including UDI readiness

This marks a strong start to Mecomed's commitment to building regulatory excellence and alignment across the Middle East, Africa, and beyond.

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Women in MedTech Network

Vision:

Pioneering a MedTech ecosystem where women lead innovation, shaping a future where diversity is the cornerstone of healthcare advancements in the Middle East.

Mission:

Empower, connect, and elevate women in MedTech through mentorship, leadership development, and strategic collaboration, breaking down barriers and fostering inclusion.

Goals:

- Drive 15-20% of female representation in leadership roles across the MedTech sector by 2030
- Launch cross-industry partnerships and establish a sustainable support network for continuous professional growth
- Ensure gender equality and benefits across the industry.

The IVDR Initiative

Impact Assessment of the IVDR Changes on the registrations in MEA Region

5 Geographical Tiers:

KSA	GULF	LEVANT & PAKISTAN
EGYPT	NORTH AFRICA FRENCH SPEAKING	SUB SAHARAN AFRICA

Assessment covering the following aspects:

- Administrative & Labeling
- Technical Documentation
- Supply Chain/Economic Operators
- Notified Body/ Certificates/ Other

MECOMED Paper around IVDR Amendment

The **purpose** of the paper is to provide an overview of the European Regulation (EU) 2024/1860 of 13 June 2024, amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed (European Database on Medical Devices), information obligation in case of interruption of supply, and the transitional provisions for certain in vitro diagnostic medical devices (IVDs). It covers the following aspects:

- Which IVDs are in scope of this extension?
- What are the new deadlines?
- What are the documents proposed by the EU Commission to confirm that the IVD complies with the extended transition
- What are the conditions to meet to benefit from the deadline extension?
- Annex – Link to EU Commission Supporting Documents

Scan to Read

MECOMED-MedTech Europe Joint Webinar on IVDR & EUDAMED – April 2025

Webinar attended by **60 people** from **15 different National Regulatory Authorities,** including:

Drug Regulatory Authority of Pakistan (DRAP)	Jordan FDA	NHRA Bahrain
Egyptian Drug Authority (EDA)	Kurdistan Medical Control Agency, Iraq	Rwanda FDA
Emirates Drug Establishment (EDE)	Ministry of Public Health Lebanon	SAHPRA – South Africa
Ethiopian Food and Drug Authority	MOH Oman	Saudi Food and Drugs Authority
Food and Drugs Authority, Ghana	National Drug Authority Uganda	Zambia Medicines Regulatory Authority (ZAMRA)

Our Key Publications

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MECOMED Paper on e-IFU

Paper on E-IFU, calling for higher adoption of Electronic Instructions for Use for Professional use Medical Devices in the MEA region.

Highlighting the several benefits of this approach, for the Healthcare Professionals, the patients and the environment alike.

Paper on Electronic Instructions for Use - E-IFU:

Industry Paper on UDI Recommendations

The **purpose** of this document is to provide recommendations for the implementation of future Unique Device Identification (UDI) regulations, encouraging global harmonization aligned with IMDRF guidance. It aims to support health authorities in adopting internationally recognized UDI coding systems, standardized labeling, and consistent update triggers through a phased, risk-based, and automated approach.

These recommendations build upon existing frameworks to:

- enhance patient safety
- improve healthcare system efficiency
- streamline compliance for manufacturers.

Scan to Read

MECOMED Paper on AI In Healthcare: Building The Future Together

The **purpose** of this paper is to explore the transformative impact of Artificial Intelligence (AI) on the healthcare sector and to highlight the critical need for a robust, ethical, and globally harmonized policy framework.

It aims to provide insights and actionable recommendations to ensure that AI integration in healthcare is secure, reliable, inclusive, and sustainable.

The paper emphasizes the importance of addressing ethical, societal, and regulatory challenges while fostering innovation, safeguarding data privacy, and promoting international collaboration to shape the future of healthcare delivery.

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MECOMED Paper on the Role of Digital Health in Value Based Health Care in MEA

The **purpose** of this paper is to explore how digitally enhanced health technologies are driving the transition toward value-based healthcare by improving clinical outcomes, increasing system efficiency, and optimizing costs. It aims to highlight the critical need for medical device manufacturers to demonstrate the value of their innovations to all healthcare stakeholders and to show how digital solutions are transforming healthcare delivery in an increasingly cost-constrained environment.

Scan to Read

Mecomed Annual Report

www.mecomed.com

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It’s not the association that creates change -
It’s the collective strength and drive of the people who believe in its mission.

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THANK YOU