AFRICA HEALTH ExCon

Your Gate To Innovation and Trade

Hall 1 | C

Session 1 | 25 June

10:00 am-11:30 am

Dr. Tamer El Hossieny

Egyptian Drug Authority

Vice Chairman

A distinguished leader in the pharmaceutical industry and current **Vice Chairman** of the **Egyptian Drug Authority** since Jan 2025 , **Dr. Tamer El Hossieny** has a strong track record of success in Egypt and the Gulf region.

From 1998 he held many Managerial positions roles at **Schering AG** then he has **joined Bayer HealthCare (Saudi Arabia)**, serving as Business Unit Head for Specialty Medicine and Primary Care, and Market Access Manager. By 2013, he has moved to **NovoNordisk** company as a Business Unit Director for Biopharm in the Gulf countries and Saudi Arabia. He Has appointed as a General Manager of the GCC Cluster in 2019 for Astellas then he moved back to Egypt In 2022 as a CEO of ADCO / Arab Drug Company, where he has achieved remarkable achievements in terms of sales, profits and share price.

Dr. El Hossieny is a pharmacist graduated from Cairo University, he has got many add-on training in his career including Fundamentals of Pharmaceutical Marketing diploma, strategic management , mini MBA, sustainability in business and Executive leadership from Harvard Business School in 2019.

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Abebe Genetu Bayih, PhD

Local Manufacturing Coordinator
African Centers for Diseases Control and Prevention (Africa CDC)

Abebe Genetu Bayih is the **coordinator of local manufacturing of health commodities at Africa CDC**. Prior to joining Africa CDC, he was **the Africa Engagement Lead at Coalition for Epidemic Preparedness Innovations (CEPI)**.

Abebe was also the **Director General of the Armauer Hansen Research Institute (AHRI)**, **Ethiopia**. AHRI is the biomedical and clinical research agency of the Ministry of Health of Ethiopia. In addition, Abebe was **Associate Professor of Medical Parasitology at the University of Gondar**, **Ethiopia**.

He did his **PhD on Molecular Microbiology at the University of Calgary, Canada**. His PhD research project focused on vaccine discovery. He also did postdoctoral research on antimalarial drug discovery. Abebe is a **fellow of the London School of Hygiene and Tropical Medicine Global Health Leadership Programme**.

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Dr. Gamal El-Leithy

Chairman of the Pharmaceutical Industry, Cosmetics and Medical Supplies Chamber

Chairman & Managing Director of Future Pharmaceutical industries "FPi" from January 2009 till now

Logistic Director & Board Member in Global Napi Pharmaceuticals from January 2000 to December 2008

Area Sales Manager with El-Lilly from February 1988 to March 1990

Production Supervisor with PFIZER Egypt, at their plant in Cairo, From 1978 to 1979 worked in the major four production areas: Sterile, liquid, solid and packaging areas.

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Prof. Fathy Ibrahim

Chairman & Managing Director
of Future Pharmaceutical Industries
"FPi" & Chairman of "**ACDIMA**"
International Trading

Prof. Fathy Ibrahim is a **Professor at Faculty of Pharmacy, Al-Azhar University**.

Prof. Fathy Ibrahim was the **Chairman of the board and CEO of Acdima International Trading company (AIT)**, Cairo, Egypt, since April 2023 till now.

Chairman of the board and CEO, of the International Center for Bioavailability, Pharmaceutical and Clinical Research, (ICBR), Cairo, Egypt, since November 2017 till March 2023.

Former Chairman of the board and CEO, Egyptian Research and Development Company (ERDC), Cairo, Egypt, since June 2013 till Sep. 2017.

Prof. Fathy Ibrahim is a member of scientific committees offering technical consultancy to the Central Administration for Pharmaceutical Products (CAPA) at the Egyptian Drug Authority (EDA).

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Dr. Ashraf Elkhouly

CEO & Managing Director **Holding Company for Pharmaceuticals**

CEO & Managing Director of Drug Holding Company (Holdi) with 9 production subsidiaries. (from March 2021 till today)

Chairman of the Egyptian Society of Pharmaceutical Research (ESPR). PhRMA association of Egypt. (ESPR is representing 22 research-based companies) “from 2009 to 2021” General Manager of Bayer Pharmaceuticals for Egypt, Libya, Sudan & Yemen from April 2007 to Feb. 2013.

Nearly 37 years of experience constantly in Biopharmaceuticals with a track record in most of the Middle Eastern markets.

Vice-chair of Industrial Chamber of Pharmaceuticals, Cosmetics and Appliances. Till today

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Session 2 | 25 June

11:30 am-01:30 pm

Dr. Rasha Ziada

Assistant EDA Chairman for technical development and capacity building affairs

Dr. Rasha Ziada is currently the **Assistant to the Chairman of the Egyptian Drug Authority (EDA) for Technical Development and Capacity Building Affairs**. She is pursuing a **Doctorate in Quality Management** and holds a **Master's degree in health economics from Cairo University** (2018), a **Clinical Pharmacy Diploma from Ain Shams University** (2010), and a **Bachelor of Pharmacy from Cairo University**.

With over **24 years** of diverse experience in **drug regulation and health policy and systems**. Dr. Ziada has worked across various positions within Egyptian health and drug authorities. Since 2020, she has led cross-regulatory and cross-divisional projects aimed at reforming the processes of the Egyptian drug regulatory authority and achieving WHO ML3 in vaccines 2022 .playing a significant leadership roles in formulating laws and regulations containing establishment of EDA law 2019 .

Dr. Ziada is the founder and supervisor of the **Continuing Professional Development (CPD)** Center at the EDA, a significant milestone that highlights EDA's pivotal role in building capacity for both regulators and industry professionals nationally and regionally. Previously, she served as the Head of the Central Administration for Pharmaceutical Affairs (CAPA) at the Ministry of Health and Population, and as director General for Planning and Pharmaceutical Policy. She also held the position of Head of the Pricing administration at CAPA (MOHP) contributing as **Consultant in WHO GUIDELINES ON COUNTRY PHARMACEUTICAL PRICING POLICIES** 2016 .

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Dr. Mona Maarouf

Pharmaceutical focal point WHO country office Egypt

Dr. Mona Maarouf is a seasoned pharmaceutical and public health professional with over 15 years of experience spanning regulatory affairs, pharmacovigilance, and international health systems. She currently serves as **Pharmaceutical Coordinator and Focal Point at the World Health Organization (WHO)** Country Office in Egypt, where she leads efforts to strengthen national medicines regulation, advance pharmacovigilance systems, and support local vaccine and pharmaceutical production.

Dr. Maarouf has been instrumental in shaping Egypt's pharmaceutical landscape. Her strategic guidance contributed to Egypt becoming the first African country to attain **WHO Maturity Level 3** for **medicines** and **vaccine** regulation. She works closely with the Egyptian Drug Authority, the Ministry of Health, and global partners to align regulatory frameworks with international standards.

Holding a **Master's in International Health from Université Senghor** and a **Bachelor's** in **Pharmaceutical Sciences from Alexandria** University, she has held pivotal roles in both multinational pharmaceutical firms like Bayer and major public health organizations, including the WHO Regional Office for the Eastern Mediterranean.

Fluent in Arabic, English, and French, Dr. Maarouf is recognized for her ability to foster cross-cultural collaboration and regional integration. Her work directly supports **Africa Health ExCon**'s mission of promoting innovation, excellence, and cooperation in healthcare across Africa and the Middle East.

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Dr. Dalia abouHussein

QA General Manager at EDA
WHO Temporary Advisor/ Consultanta

Ass Prof Dalia Abou Hussein, **QA General Manager at the Egyptian Drug Authority (EDA),** holds a **Master's and PhD in Pharmaceutics from Cairo University**.

She has over 23 years of regulatory experience. Starting her career in **NODCAR** as a quality control analyst, she also served as a member in committees for evaluation of stability studies, CTD quality module, clinical trials and pricing.

She has supervised the establishment of an EDA integrated quality management system and led EDA certification and accreditation according to ISO 9001:2015, ISO/IEC 17025:2017, ISO/IEC 17043:2010 and WHO GBT ML3 in both vaccines and medicine.

She is a member of WHO`s WLA-TAG, the AMRH steering committee and the **AMQF QMS** subcommittee. She has supported the **WHO Regulatory System Strengthening (RSS)** as Technical Advisor and consultant since 2022. Dalia has published 18 peer-reviewed articles.

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Hamada Sherif

General Director for the General Administration for Registration of Human Pharmaceutical Drugs at the Egyptian Drug Authority (EDA),

Hamada Sherif, a pivotal figure in Egypt's pharmaceutical regulatory landscape. As the **General Director for the General Administration for Registration of Human Pharmaceutical Drugs at the Egyptian Drug Authority (EDA),** Hamada holds a critical role.

He's directly responsible for the **market authorization processes for both new and re-registered human pharmaceutical drugs**, ensuring their safety and efficacy within Egypt. This function is vital for both public health and the growth of the pharmaceutical industry across the region.

Hamada brings nearly 17 years of dedicated experience to his role. A distinguished graduate of **Cairo University's Faculty of Pharmacy**, he began his career as a Quality Control Analyst. He progressively advanced into key regulatory positions, including serving as the **General Manager for Technical Support in the Quality Control Laboratories** at the EDA. His leadership journey has culminated in his current esteemed directorship, where his extensive expertise and commitment are shaping the pharmaceutical future in Egypt and contributing to healthcare advancements across Africa.

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Ms. Chimwemwe Chamdimba

Head of the African Medicines Regulatory Harmonization Programme (AMRH) - NEPAD

Chimwemwe Chamdimba leads the African Medicines Regulatory Harmonization Initiative at the African Union Development Agency (AUDA-NEPAD).
She is responsible for managing the African Medicines Regulatory Harmonization (AMRH) Programme and providing technical support for the operationalization of the African Medicines Agency (AMA). She leads policy reforms that link regulatory system strengthening to procurement, supporting the local manufacturing of medical products and technologies. As a health policy specialist, she has spearheaded health policy and regulatory reforms, regional harmonization and partner coordination. Chimwemwe has contributed to key continental policy processes including the African Union Model Law on Medical Product Regulation; the Treaty for the establishment of the African Medicines Agency (AMA); the AU Private Sector Engagement in Health Framework; the Science, Technology and Innovation Strategy for Africa (STISA-2024); and African Union Health Strategy.

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Mr. David Mukanga

Representing the Gates Foundation

Dr. David Mukanga is Deputy Director Africa Regulatory Systems at the Gates Foundation, where he leads the foundation's Africa regulatory systems optimization portfolio, and the linkage between regulatory systems and health care services. In this role, David supports the development of harmonized, transparent, and predictable regulatory systems covering the lifecycle of medical products in Africa across the national, regional, and continental levels of the ecosystem. His work also involves support for regulatory emergency preparedness.

In this role he works side by side with partners on the African continent to facilitate development of and access to medical products.

David served as the **1st Chair of the African Medicines Regulatory Harmonization Partners'** platform, a partner collective of more than 30 funders, technical and advocacy partners working to support Africa advance its regulatory capabilities. David serves as advisor to a number of global initiatives and seats on the Board of the **Drug Information Association (DIA)**.

Dr. Mukanga has a combined 27 years of experience spanning regulatory affairs, health systems development, academia, clinical research, and product development. Prior to joining the Gates Foundation in 2013, David was the founding CEO of the African Field Epidemiology Network (AFENET) and served on faculty at Makerere University. David received his professional training in Pharmacy and Public Health at Makerere University, epidemiology from the Johns Hopkins School of Public Health, and a PhD in International Health from the Karolinska Institute.

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Session 3 | 26 June

01:30 pm - 03:00 pm

Dr. Miriam Boles

Head of Central administration of medical devices, EDA

Dr. Miriam Boles Kostandy is the **Head of the Central Administration of Medical Devices**, responsible for evaluating and registering medical supplies, devices, and diagnostic reagents, whether locally produced or imported. Her role ensures the approval and circulation of these products, guaranteeing compliance with the technical standards set by the relevant authority. This responsibility includes verifying their quality, efficacy, and safety, as well as overseeing the release of medical devices, spare parts, sterile and non-sterile supplies, laboratory reagents, and dental equipment.

She also **develops and implements strategic plans for the regulation of medical devices and in vitro diagnostic (IVD) products**, helping to advance the mission of the Egyptian Drug Authority (EDA) in ensuring the safety and effectiveness of medical devices. She holds a **Bachelor's degree in Pharmacy from Ain Shams University** and a degree in **Business Administration with a focus on Supply Chain from the Arab Academy for Science, Technology & Maritime Transport (AASTMT)**.

With nearly two decades of experience in the medical device regulatory sector, Dr. Kostandy's career path has seen her evolve from a **Medical Device Registration Reviewer to Senior Reviewer, Director of the Medical Device Unit**, and, since November 2020, as the **Head of the Central Administration**. She is passionate about teamwork, positivity, and task-driven motivation, with a deep interest in global medical device and IVD regulation, data analysis, and problem-solving.

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Session 3 | 26 June

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Ms. Pauline Wairimu

Head of the African Medical Supplies Forum, **AMDF**

Paulyne Wairimu currently leads **the Medical Devices and Diagnostics section at the Pharmacy and Poisons Board**, which is the regulatory authority for Kenya. Her experience in regulatory framework development spans over 10 years. In addition, She has the honor of serving as **the Chair of the African Medical Devices Forum**, which is a key continental technical committee operating under the African Union.

A significant part of her work has involved championing and advocating for the adoption of international standards across the African continent, particularly through the International Medical Device Regulators Forum (IMDRF). Through these efforts, they have successfully increased the membership of affiliate members from the African region to 10 National Regulatory Authorities (NRAs). Her expertise lies in policy development, and she has a strong advocate for the harmonization of regulatory systems throughout Africa to ensure consistent quality standards.

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Dr. Mohamed Elsaid

Head of the General Division of Medical Supplies

Mohamed Elsaid Youssef, Ph.D. **Chairman of Chamber of Medical Device Industry, Federation of Egyptian industries**.

Founder and General Manager of Vitro Scient Company.

Fellow of Clinical Chemistry, Poison Control Center, Ain Shams University.

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Eng. Mostafa Elwakil

CEO of Bio business

Mostafa Elwakeel is an **expert in medical-device development, electronics, automatic control, circuit design, and equipment standards and safety**, with more than 20 years of experience. He earned his **B.Sc. in Biomedical Engineering from Cairo University** in 2006. Recognizing that healthcare innovation often lags behind IT and communications—largely due to the high cost of medical equipment—he founded BioBusiness in 2009 to drive affordable and localization solutions.

Founder & CEO, BioBusiness for Electronic Medical Devices (the first startup of its kind in the Middle East and Africa)

20 years of hands-on R&D experience in medical devices.

Proven **leader of multidisciplinary research and development teams.**

Creator of multiple internationally deployed medical devices, including patient monitors, ECG machines, infant incubators, phototherapy, infant warmer, Neonatal Cpap , Noninvasive ventilator , and hemodynamic monitors.

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Dr. Ahmed Moustafa

Regulatory Affairs Director
AMECO

Dr. Ahmed Moustafa is the **Regulatory Affairs Director and PRRC at AMECO**, bringing over 27 years of experience in the medical device industry, with more than 15 years dedicated to regulatory affairs management. In his current role, he **leads the regulatory framework for one of the MENA region's leading medical device manufacturers**. Dr. Moustafa has a proven track record of securing successful medical device registrations and certifications from global health authorities and notified bodies.

He is **highly skilled in navigating the complexities of EC certifications for Class IIa, IIb, and III medical devices, with expertise in both MDD and MDR compliance**. Additionally, he is **adept at managing FDA 510(k) submissions and approvals**. His strategic leadership has facilitated market access for products across more than 40 countries, ensuring alignment with diverse international regulatory requirements.