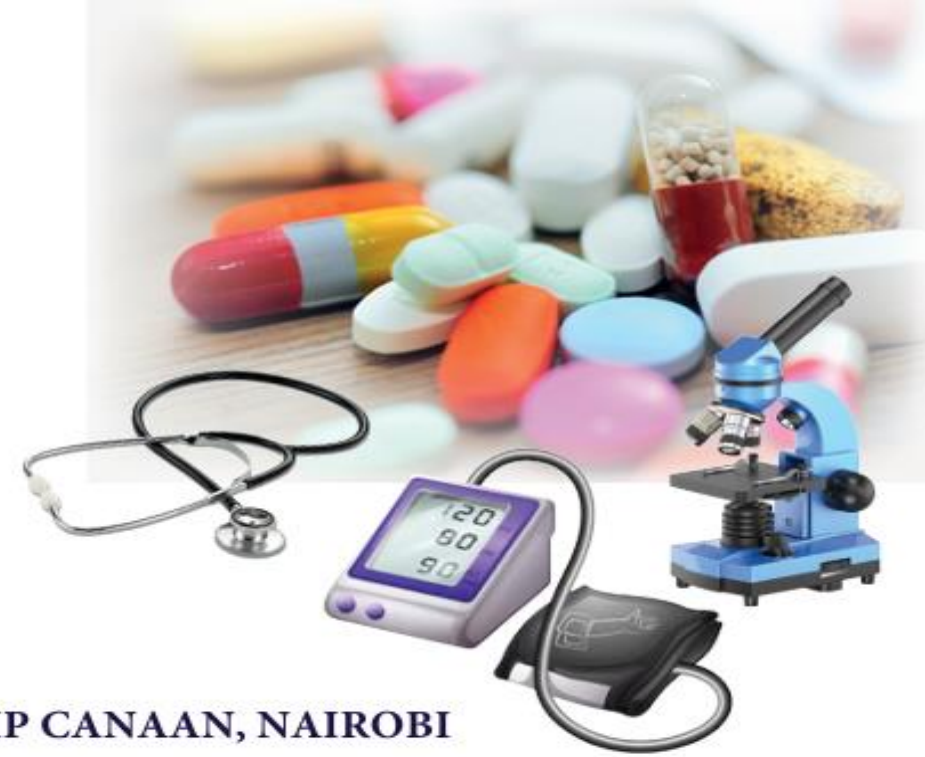
REGULATORY RELIANCE WORKSHOP



MARCH 20, 2025 **ROYAL TULIP CANAAN, NAIROBI**

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Dr. John Mwangi.

Head, Regulatory Affairs East & West Central Africa Region (Bayer East Africa)

John currently works at Bayer as Regulatory Policy & Science Lead as well as Head, Regulatory Affairs responsible for East & West Central Africa Region based in Kenya. He has previously held different roles in Pharmacovigilance and Quality Control within the Pharmaceutical Industry. He has been an active member of several industry associations including KAPI (Kenya Association of Pharmaceutical Industry) where he continues to serve in in various committees within KAPI and as a Board Member.

John is passionate about supporting the streamline of Pharmaceutical Regulatory Systems & Policy and is currently a member of the Africa Regulatory Network (ARN) within the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) where he is the past co-chair. He is currently serving as the chairman of the board for the Regulatory Professionals Society of Kenya (RAPSK) in Kenya.

John is also currently serving as Adjunct Faculty at Strathmore University.

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Radwa El Gamil is the Unit Manager of the Administration of Regulatory Affairs for Human Pharmaceuticals at the Egyptian Drug Authority. She serves as the Marketing Authorization Function Focal Point in the International Recognition of WHO through the Global Benchmarking Tool at the Egyptian Drug Authority. Further, she specializes in revising and updating policies to address emerging challenges and enhance policy effectiveness.

Radwa is actively involved in the development and implementation of programs, including the eCTD implementation in Egypt, to ensure continuous organizational improvement and alignment with international standards.

Additionally, she oversees the execution of strategic plans and organizational decisions, ensuring compliance with regulations and laws, and reports progress to senior management. They are dedicated to enhancing the efficiency of employees in the Administration of Regulatory Affairs for Human Pharmaceuticals through comprehensive training plans and integrating new tasks to stay abreast of global developments.

Radwa El Gamil

Unit Manager , Administration of Regulatory Affairs for Human Pharmaceuticals - Egyptian Drug Authority

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Dr. Reem Eltanahy
Manager of Biologics variation unit – Egyptian Drug Authority

Dr. Reem Eltanahy is the Manager of Biologics Variation Unit at the Egyptian Drug Authority (EDA). With over 13 years of experience in the pharmaceutical and biologics industry, she has held various positions within the regulatory sector.

Dr. Eltanahy earned her Bachelor of Science in Pharmaceutical Sciences from Cairo University and a Master of Business Administration from the Arab Academy for Science, Technology, and Maritime Transport.

At the EDA, she leads her team in regulating post-approval changes to registered biological products. Notably, she played a key role in establishing "the guidelines for regulating post-approval changes to a registered bio-therapeutic product in Egypt."

Furthermore, Dr. Eltanahy was part of the team that successfully achieved WHO GBT ML3 for vaccines at the EDA.

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Arit Onwusah.
Head, Regulatory Affairs Anglophone West and East Africa (Novartis)

Arit Onwusah is the Head of Regulatory Affairs for Anglophone West and East Africa for Novartis. She is a Regulatory Affairs Professional with experience working in the Pharmaceutical and FMCG sectors. During her career she has successfully registered pharmaceutical and consumer healthcare products including new chemical entities across different categories (pain, respiratory, vaccines, antibiotics, oncology, HIV).

She works with global and regional teams on regulatory strategy development, planning, coordination and implementation of innovation projects at country level. She has successfully implemented efficient regulatory processes that have reduced submission and approval timelines across countries in West Africa.

Arit holds degree in Pharmacy from Sechenov Moscow Medical Academy in Russia and a Master of Science in Public Health from the University of Liverpool in the United Kingdom.

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Inas Chehimi

Executive Director

Head of Regulatory and Policy Affairs, Middle East and Africa at Novartis

Inas Chehimi holds a distinguished academic background with a Pharmacy diploma and a Master's degree in EU and International Regulations and Healthcare Laws from Paris V University. With an impressive career spanning two decades, she brings extensive expertise in regulatory affairs across European and emerging markets.

Inas has contributed to various multinational corporations and is currently leading the Regulatory and Policy departments for the MEA region at Novartis. Her professional pursuits are deeply rooted in healthcare reforms, legislative advancements, and policy shaping, all with the paramount aim of accelerating patient access to innovative medicines.

Inas has chaired EFPIA and PhRMA association groups for six consecutive years and is presently the chair of the PHARMEA Working Group. Her influence extends to the global stage, where she frequently shares her insights as a speaker at both regional and international conferences.

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Rana Chalhoub.
Regulatory Affairs Director (Mecomed)

Rana Chalhoub is an experienced Regulatory Affairs Professional with a demonstrated history of working in leading multinational medical devices companies such as Medtronic, Johnson & Johnson and Hospira Pfizer. During her career, Rana has managed to take over regulatory roles of increased responsibilities with an extended area coverage where she has built extensive knowledge of the regulations across MEA Region.

Rana holds a Medical Laboratory Sciences degree along with a Regulatory Affairs Certification (RAC) from RAPS, and a certificate in "Regulation: Theory, Strategy & Practice" from London School of Economics & Political Sciences (LSE). In her current role as Regulatory Affairs Director at Mecomed, Rana is responsible for managing Regulatory Affairs-related responsibilities in MECOMED, the Medical Technology Association in Middle East and Africa, and works closely with the different MedTech stakeholders such as Ministry of Health officials and Regulatory agencies to advance the Medical Technology Regulations in the region.

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Angelika Joos.
Executive Director, Science & Regulatory Policy(MSD)

Angelika Joos is a trained pharmacist. She is responsible for Science & Regulatory Policy issues within MSD's Global Regulatory Affairs and Clinical Safety department.

This role includes identifying policy priorities that align with MSD's business priorities, leading cross-functional networks to define policy positions, and informing MSD's development strategy with a focus on international clinical research policy. Angelika represents MSD in various international trade association working groups such as efpia, BIO and PhRMA.

She is a member of the IFPMA Africa Regulatory Network and was one of the IFPMA delegates on the ICH Management Committee & Assembly from 2020-2024.

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Dr. Francesca Mangia.
Associate Regulatory Program Director (F.Hoffmann-La Roche Ltd)

Dr. Francesca Mangia joined the Regulatory Affairs department at F. Hoffmann-La Roche after earning her Doctoral Degree in Structural Biology and Biophysics from the University of Basel.

Currently, she serves as an Associate Regulatory Program Director within the CMC Regulatory Policy & International Operations group at F. Hoffmann-La Roche. In her role, Francesca leads filing strategies for International Markets, integrating Reliance approaches, and actively promotes and advocates for regulatory convergence and harmonization.

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Yasha Huang.
Head Regulatory Policy Asia Pacific Global Regulatory Policy & Intelligence (Roche Diagnostics)

Yasha Huang is currently the Head of Regulatory Policy Asia Pacific within the Global Regulatory Policy & Intelligence team at Roche Diagnostics. Prior to Roche, Yasha was most recently the Regulatory Affairs Director at APACMed, the region's first and only MedTech industry association. Her main role was driving the regulatory initiatives for patients' better access to medical technologies by partnering with key stakeholders including government agencies, local associations, regulatory harmonization and convergence platforms.

Prior to that, she was working at the China Food and Drug Administration, where she was actively involved in global governance and stakeholder engagement, collaborating with international organizations, government agencies, NGOs, etc.

Yasha holds a Master's Degree in Public Health from Dartmouth College in U.S. She is currently the Vice Chair of Regulatory Affairs Committee (600+ members) with APACMed, providing strategic leadership to various market-based and project-based initiatives.

Asmaa Awad.
Global Regulatory Policy Lead EEMEA (Roche Diagnostics)

Asma is deeply committed to utilizing her expertise and collaborating with various stakeholders to champion the field of regulatory science and to drive positive change in the healthcare ecosystem to ensure patients have access to safe and innovative products.

In her current position, Asma collaborates closely with various external stakeholders, including the World Health Organization (WHO), International Medical Device Forum (IMDRF), the Global Harmonization Working Party (GHWP), the Medical Device Regulatory Capacity Building (MDRC) project team, Mecomed, and national regulatory authorities.

Her specialized expertise in medical devices and in vitro diagnostics (IVDs) centers on developing and influencing regulatory policies and frameworks that enhance product access and ensure patient safety. Her efforts contribute significantly to improving health outcomes and reducing the operational burden on healthcare systems across diverse regions.

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