Virtual

Oct 13, 2025 9:30 AM - Oct 15, 2025 4:00 PM

(W. Europe Standard Time)

Middle East & Africa Conference (MEA)

Dive into three impactful days of knowledge-sharing, innovation, and collaboration at the virtual MEA conference from 13–15 October.

Print Agenda

Day 1 Oct 13, 2025

10:00 AM — 10:20 AM

Welcome Remarks & Official Opening

Welcome Remarks & Official Opening

Session Chair(s)

Ghanim Ali M A Al Mannai

Assistant Undersecretary for Healthcare Regulatory Affairs
Ministry of Public Health (MOPH), Qatar

Omneya Darwish

General Manager, Middle East & Africa
DIA, Switzerland

10:20 AM — 11:30 AM

SESSION 1: Middle East & North Africa Townhall

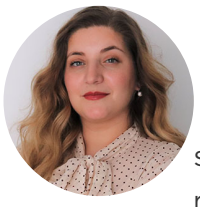
Overview: In this session, a representative from each Health Authority in the MENA region will share updates, developments and future plans, followed by an interactive Panel Discussion.

Session Chair(s)

Amira Deia Younes

Director-Eastern Europe, Middle East & Africa (EEMEA) Global Regulatory Policy
MSD, United Arab Emirates

Amira is the Global Regulatory Policy Director for Europe, Middle East, and Africa at MSD, with over 14 years of experience in regulatory science and policy. She is recognized as a thought leader in reliance, work sharing, and regional harmonization. Amira has built a strong network of colleagues to enhance regulatory practices in the region. She chairs the EFPIA Middle East Regulatory Network and actively participates in various trade associations, including the EMA Reliance focus group, IFPMA and PhRMA networks. She has been a regular speaker and session leader at conferences and has numerous publications on regulatory topics. Amira holds a Bachelor's degree in Pharmacy and Biotechnology from the German University in Cairo.



Sara Torgal, MPharm

Global Regulatory Policy Lead
DIA, Switzerland

Sara is currently Senior Manager, Scientific Programmes at DIA. In the EMEA region, she is responsible for engaging with external stakeholders and advancing the scientific content strategy by creating opportunities to integrate scientific and regulatory changes of interest in DIA initiatives. Additionally, she is responsible for the regional patient engagement and learning design initiatives, being the liason for the Middle East and SEE regions. Previously, she was Public Health Promotion Projects Manager at the Portuguese Pharmaceutical Society. Sara is a Master of Pharmacy since 2015 and a Soft skills Trainer since 2012, having delivered over 300h of Training internationally primarily focused on creating impactful interactions.

Speaker(s)

Reflections from the Health Authorities in the MENA region on their Recent Biggest Achievements and Key Priorities for the Future

Aisha Al Ansari

Director, Pharmacy and Drug Control Department
Ministry of Public Health, Qatar, Qatar

Dr. Aisha Al-Ansari is Director of the Pharmacy & Drug Control Department, Ministry of Public Health, Qatar. She holds degrees in Pharmaceutical Sciences (University of Jordan) and Pharmaceutical Services & Medicines Control (University of Bradford, UK). Since 2001, she has led national drug policy, pharmacy laws, and regulatory oversight. She chairs committees on drug registration, pricing, and safety, and represents Qatar in GCC, WHO, and Arab Union for Pharmacists forums. Dr. Aisha has advanced initiatives under Qatar National Vision 2030 and National Health Strategies, including the Community Pharmacy Strategy, Qatar National Formulary, National Drug Coding System, and the proposed Qatar e-Pedigree Pharmaceutical Track & Trace System.

Reflections from the Health Authorities in the MENA region on their Recent Biggest Achievements and Key Priorities for the Future

Donia Al Bastaki

Head of Registration Department, Pharmaceutical & Herbal Medicines Registration
Ministry of Health, Drug and Food Control, Kuwait

Head of drug registration department in Pharmaceutical and Herbal Medicines Registration and Control Administration, Ministry of Health, Kuwait. She is responsible of registration and approval of pharmaceutical products including human medicines, herbal medicines, veterinary medicines and medical devices. In addition to monitoring pharmacovigilance activities in Kuwait, she is a member of Kuwait Pharmaceutical Association and member of GCC Central Registration Committee and participated in setting the GCC Guidelines for Drug Registration as well as Stability, Bioequivalence and PIL GCC guidelines and others. She is assigned as Kuwait focal point with the League of Arab states in the field of Pharmacy and drugs.

Reflections from the Health Authorities in the MENA region on their Recent Biggest Achievements and Key Priorities for the Future

Tamer El-Hossieny

Vice Chairman
Egyptian Drug Authority (EDA), Egypt

Dr. Tamer Mohamed El-Husseini is the Vice Chairman of the Egyptian Drug Authority (EDA), a role he has held since January 2025. He earned his Bachelor's degree in Pharmaceutical Sciences from Cairo University in 1997. Before joining the EDA, he served as CEO of the Arab Drug & Chemical Industries Company (ADCO) & was a board member representing Holdi Pharma. His previous leadership roles include General Manager at Astellas Pharma (UAE & Saudi Arabia), Business Unit Director at Novo Nordisk (Gulf & Saudi Arabia), Market Access Director at Bayer Pharmaceuticals, & Franchise Head for Oncology & Multiple Sclerosis at Schering AG.

Reflections from the Health Authorities in the MENA region on their Recent Biggest Achievements and Key Priorities for the Future

Shatha Ziad Al-Quraan

Head - Chemical Drug Registration Department
Jordan Food and Drug Administration (JFDA), Jordan

Pharmacist Shatha Ziad Al-Quraan holds a Master's degree in Pharmaceutical Sciences & serves as Head of the Chemical Drug Registration Department at the Jordan Food & Drug Administration (JFDA). With over a decade of experience in pharmaceutical & medical device regulatory affairs, she has previously led the Medical Devices & Supplies Registration Department & the Scientific Advice Division. Shatha represents the JFDA in several international regulatory bodies, including the ICH, where she actively contributes to technical committees & guideline development. For the past four years, she has served as Topic Leader for the ICH Working Group revising the Extractables & Leachables guideline (ICH Q3E).

Reflections from the Health Authorities in the MENA region on their Recent Biggest Achievements and Key Priorities for the Future

Nancy Yang Ngum

Public Health Officer (Public Health Expert)
African Union Development Agency (AUDA-NEPAD), South Africa

Dr. Nancy Ngum is a Public Health Expert at the African Union Development Agency (AUDA-NEPAD), working under the African Medicines Regulatory Harmonization (AMRH) initiative. She supports the operationalization of the African Medicines Agency (AMA) & leads the development of the Regulatory Information Management System (RIMS) & Regulatory Information Sharing Platform (RISP) for Africa. Passionate about improving patient access to safe, quality & effective medical products, Dr. Ngum conducts research on Regulatory Review Systems. She holds a Ph.D. in Regulatory Sciences from the University of Hertfordshire, UK, & is the author of a book on the AMA's regional initiatives

DIA

Panel Discussion with Q&A (With the additional participation of):

Speaker(s) / Representative(s) Invited

Qatar

11:30 AM — 11:50 AM

Break

11:50 AM — 1:10 PM

SESSION 2: International Collaboration & Regulatory Systems Strengthening

SESSION 2: International Collaboration & Regulatory Systems Strengthening

Session Chair(s)

Alia Seoud Abdalla

Global Regulatory Sciences Head (Africa Cluster)
Pfizer, Egypt

Alia is Pfizer's Global Regulatory Sciences Head – Africa Cluster, an energetic leader with over 20 years of blended experience in the pharmaceutical industry, including more than 14 years in Regulatory Sciences and Policy shaping, and the rest in sales and marketing at top multinational research-based organizations. Since the start of her regulatory career, Alia has been an active PhRMA network member, leading multiple task forces and workstreams across the Middle East & Africa, as well as a diverse RA team with a strong record of success in advocating patient-centric regulatory policies, building regulatory authority capabilities, and enhancing early access to medicines.

Samvel Azatyan, MD, PhD

Senior Adviser
Council for International Organizations of Medical Sciences (CIOMS), Switzerland

Dr Samvel Azatyan is a Paediatrician with a PhD in clinical pharmacology and medical products regulation. Over his more than 24 years at WHO, he has had a wide range of leadership roles associated with the regulation of medical products, including supporting regulatory collaboration, convergence and harmonization, as well as regulatory capacity building and facilitation of products introduction in the countries. Dr Azatyan has also led various projects aiming at development of national regulatory systems, as well as the development and implementation of the concept of reliance in regulation of medical products. Dr Azatyan is currently leading the Regulatory Convergence and Networks Team at the WHO's Headquarters in Geneva, Switzerland.

Speaker(s)

Strengthening Regulatory Systems, EDA's Milestone towards WHO GBT Maturity Level 3

Dalia Abou Hussein

Quality Assurance (QA) General Director
Egyptian Drug Authority (EDA), Egypt

Asst. Prof. Dalia Abouhussein, QA General Manager at the Egyptian Drug Authority, holds a Master's and PhD in Pharmaceutics from Cairo University and has over 23 years of regulatory experience. Starting her career at NODCAR, she has served on committees for stability studies, CTD quality files, clinical trials, and pricing. She is a member of WHO's TAG-WLA, the AMRH Steering Committee, and the AMQF QMS subcommittee. Since 2022, she has supported WHO's Regulatory System Strengthening (RSS) team and joined the International Pharmacopoeia consultant roster in 2023. Dalia has published 17 peer-reviewed articles.

Saudi FDA's ML4 & WLA Journey

Bandar Al Hammad, MPharm

Chief Pharmacist & Director of Veterinary Preparations Department
Saudi Food and Drug Authority (SFDA), Saudi Arabia

Dr Bandar is Chief Pharmacist at the Executive Department of Regulatory Affairs in Saudi FDA since October 2018. Before this, he was in charge of clinical assessment at SFDA, working as Director of Risk-Benefit Assessment Department from Jan 2015 - Oct 2018. He joined Saudi FDA in 2005 as a pharmacist and worked on the establishment of the Pharmacovigilance Center, later working as a Clinical Assessor, at the National Drug Information Center at SFDA 2009-2015. He got his Master's degree in clinical pharmacy from Curtin University, Western Australia in 2009. His bachelor's from King Saud university in 2004.

Tunisia's experience with Reliance and role in North Africa Harmonisation initiative

Sonia Sebai Ben Amor

Head - National Control Laboratory National Regulatory Authority
Tunisian Medicines Agency (AEMPS), Tunisia

Convergence and Harmonisation in Africa: AMA operationalisation progress, AMA continental pilot, Africa Continental Reliance Framework and North Africa Harmonisation initiative

Nancy Yang Ngum

Public Health Officer (Public Health Expert)
African Union Development Agency (AUDA-NEPAD), South Africa

Dr. Nancy Ngum is a Public Health Expert at the African Union Development Agency (AUDA-NEPAD), working under the African Medicines Regulatory Harmonization (AMRH) initiative. She supports the operationalization of the African Medicines Agency (AMA) & leads the development of the Regulatory Information Management System (RIMS) & Regulatory Information Sharing Platform (RISP) for Africa. Passionate about improving patient access to safe, quality & effective medical products, Dr. Ngum conducts research on Regulatory Review Systems. She holds a Ph.D. in Regulatory Sciences from the University of Hertfordshire, UK, & is the author of a book on the AMA's regional initiatives

Reliance Pilots - Industry experience with AMA continental pilot

Christine Ledimo

Senior Director: Regulatory Affcairs SSA
MSD , South Africa

Reliance Pilots - Industry experience with AMA continental pilot

Charlene Roopnarain

Regulatory Affairs Cluster Head - South Africa, Nigeria and East Africa
Merck Serono, South Africa

Panel Discussion with Q&A (With the additional participation of):

Enas Hijjih

Head of Bioequivalence Division- Registration department
Jordan Food and Drug Administration (JFDA), Jordan

1:10 PM — 1:30 PM

Break

1:30 PM — 2:40 PM

SESSION 3: Optimising LCM in ME: Leveraging Regulatory Tools to Secure Medicine Supply for Patients in the MEA Region

Overview: In this Session, we will explore opportunities to optimise Lifecycle Management (LCM) in the Middle East & Africa regions by expanding the use of modern regulatory tools (e.g. risk-based approach, ICH Q12, Reliance), with the overall objective of securing supply to patients.

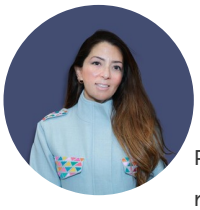
Session Chair(s)

Melly Lin, MS

CMC Regulatory Policy Lead, Pharma Technical Regulatory
F. Hoffmann-La Roche Ltd, Switzerland

Melly Lin is working at F. Hoffmann-La Roche Ltd. as CMC Regulatory Policy Lead. She is responsible for identifying policy priorities and supporting regulatory policy advocacy efforts for South East Europe, Central Asia and Egypt. She has over 20 years of experience in Regulatory Affairs, within that 13 years in CMC Regulatory Policy. She joined Roche China in 2004. There she held different positions with increasing experience and responsibility in regulatory filing. She took the responsibility as China Policy

Lead from 2011 to 2019. She is now taking an active role in the middle east region by leading the EFPIA MERN LCM team. She is also chairing an industry network for South East Europe.



Patricia Salami

Senior Director, Regional RA Head - MEAR (Middle East_Africa_Turkey_Russia_CIS)
Merck, United Arab Emirates

Patricia is a Pharm D from 'Universite Saint Joseph', Beirut with 21 years of experience mainly in regulatory affairs. She is currently heading the Regulatory Affairs of Merck (Healthcare Sector) in the MEAR region (Middle East, Africa, Turkey, Russia & CIS countries), handling a diverse team of RA professionals. Since the beginning of her RA Career, Patricia has been an active contributing member in the industry via IFPMA/EFPIA/PhRMA. During the last 2 years; she acted as Regional Coordinator of the PhRMA MEA RA Group enabling, with the support of esteemed peers, the design and implementation of multiple capability building programs for key Authorities, contributing to re-shaped policies/regulations; enhancing medicines access to patients.

Speaker(s)

EU New Variations Guideline

Marie Kirman

EFPIA MQEG & CMC Regulatory Affairs Director
Astrazeneca, United Kingdom

Marie is a CMC Regulatory Affairs Director at AstraZeneca, specializing in CMC regional strategy, regulatory intelligence, knowledge management, and advocacy. With over 20 years of regulatory experience across generic and innovator products, Marie has spent the past 13 years in CMC roles. She is a member of the EFPIA MQEG CMC LCM Team, contributing to EU variations framework updates and leading the EFPIA CMC LCM PAC Reliance sub-team.

Benchmarking of PAC within Middle East Region

Tala Habib

Chair-Jordan Regulatory WG & Associate Director, Regulatory Affairs (Levant)
MSD , Jordan

Tala holds the position of Regulatory Affairs Associate Director at MSD responsible for driving regulatory strategies for oncology and diabetes portfolio in Levant. Bringing over 15 years of experience in the regulatory field, Tala joined MSD in 2021 armed with strong knowledge and expertise in the regulatory and pharmacovigilance domains within the Middle East region. Tala is currently chairing the local pharma regulatory working group (MPG) in Jordan since Jan 2025 and is passionate about strengthening partnerships and fostering collaboration with health authorities. Tala holds a Bachelor of science degree in pharmacy from the University of Jordan, Amman.

Turkish Health Authority’s Experience in Implementing Reliance in LCM

Kubra Ekinci

Pharmacist at the Coordination Department
Turkish Medicines and Medical Devices Agency (TITCK), Turkey

Kübra Ekinci, PhD, Pharmacist at the Coordination Department, TITCK, Turkey Kübra Ekinci is a biotechnology specialist currently working at the Coordination Department of the Turkish Medicines and Medical Devices Agency

(TITCK). She completed her PhD in Biotechnology and Pharmaceutical Sciences at Ankara University and King's College London. She previously worked for two years at TITCK as a regulatory affairs specialist and for three years as a biological and biotechnological products expert, focusing on regulatory assessment and oversight of biological and biotechnological product development.

Simplifying Lifecycle Management -Summary of PAC Reliance Pilots supported by EMA

Susanne Ausborn, PhD

Global Head International Regulatory Policy
Roche, Switzerland

Susanne Ausborn has more than 20 years of experience in technical regulatory affairs and regulatory policy. She joined Roche in December 2001 and since then held different positions with increased responsibilities in PTR. She gained extensive experience with global filings of new drug submissions, clinical trial applications as well as post-approval changes. Knowing the challenges of operating globally she is now a strong advocate for global convergence of regulatory requirements and has been engaged in many international conferences, workshops and meetings with regulators from various emerging markets around the world over the last decade.

Panel Discussion with Q&A (With the additional participation of):

Hussah Albehaijan

Head of Innovative Pharmaceuticals and Investigational Drugs Section
Saudi Food and Drug Authority (SFDA), Saudi Arabia

Hussah Albehaijan is the Head of Innovative Pharmaceuticals and Investigational Drugs Section at the Saudi Food and Drug Authority (SFDA). She is a quality expert with more than 12 years of experience in quality evaluation, regulatory initiatives, accreditation, standards setting, and building institutional capacities. Hussah holds an MBA from Al Faisal University, a Master of Pharmacy from the University of Nottingham, and a Master of Polymer Science and Engineering from KFUPM. She leads efforts advancing regulatory science and pharmaceutical innovation.

Panel Discussion with Q&A (With the additional participation of):

Mariam Maged

Manager - Human pharmaceuticals Variations Administration
Egyptian Drug Authority (EDA), Egypt

Mariam Maged is the Manager of human pharmaceuticals Variations Administration at the Egyptian Drug Authority (EDA), where being responsible for all types of post market changes for human pharmaceutical drugs. She started her career almost 11 years ago in the central administration of pharmaceutical affairs (CAPA) after graduation from faculty of pharmacy Future university with grade excellent with honor, in 2012 started the new career path as a registration specialist in CAPA .In 2020 with establishment of EDA Started a new career as manager of evaluation unit of specification and composition variation until 2021 where promoted to the current title in EDA as Manager of human pharmaceuticals Variations Administration.

Panel Discussion with Q&A (With the additional participation of):

Panellist(s) Invited

Qatar

2:40 PM — 3:00 PM

Break

3:00 PM — 4:00 PM

SESSION 4: Sample Management

Overview: This session will explore challenges associated with sample provision for Post-Approval Changes and promote best practices in Sample Management, leveraging Reliance pathways. The session will also highlight the development of a unified laboratory framework for sample testing through the Network of African Reliance Laboratories (NARL), the growing importance of post-marketing surveillance, share effective risk management strategies for product release post-importation and emphasise capacity building for local laboratories to detect substandard and falsified medicines.

Session Chair(s)

Neveen Kamel

Regulatory Affairs Head North Africa, Egypt & French-speaking Africa
Merck Group, Egypt

Neveen holds degree of Bachelor of Pharmacy – Faculty of Pharmacy – Cairo University, She is currently Head of Regulatory Affairs North Africa ,Egypt & Africa Developing Markets at Merck, supporting regulatory policy advocacy efforts for the region. She has over 20 years of experience in industry and 16 years of them as Regulatory Affairs, Prior to Regulatory Affairs she worked in several Multinational companies in different roles Commercial ,Quality, Pharmacovigilance ,Market Access & pricing . Neveen is also an active member of several trade associations including IFPMA Africa Regulatory Network (ARN); PhRMA Egypt Regulatory working Group; She participated in writing the Position paper for Registration Sampling & QC testing (IFPMA ARN)

Zainab Aziz, MSc, RPh

IFPMA ARN Co-Chair & Associate Director, Regulatory Policy Middle East & Africa
Novartis, South Africa

Zainab is a pharmacist with an MSc in Medicine (Pharmaceutical Affairs) from the University of the Witwatersrand and over 15 years of regulatory affairs experience. She is currently Associate Director, Global Regulatory Affairs Policy at Novartis, supporting regulatory policy across the Middle East and Africa. She co-chairs the IFPMA Africa Regulatory Network and is a member of the EFPIA Middle

East Regulatory Network. Zainab has led key initiatives in regulatory harmonisation, clinical trial oversight, capability building, and digital transformation, and actively supports the Africa Medicines Agency Treaty Alliance.

Speaker(s)

Reliance Frees up Capacity for Efficient Post-Marketing Surveillance of Medicines

Joerg Garbe, PhD, MSc

IFPMA In-Country Testing Taskforce Lead; Global Quality Manager & Policy Lead
F. Hoffmann-La Roche Ltd, Switzerland

Joerg has 20 years of extensive experience in the pharmaceutical industry within different functions in the quality field for development and commercial products. He serves as Global Quality Manager in Roche Pharma Global Technical Operations overseeing Roche's global in-country testing activities. Joerg has been a contributing member in the industry via IFPMA/EFPIA. As global Policy Lead, he co-/authored several publications and industry positions on in-country testing and Advanced Therapy Medicinal Products (ATMPs) and functions as scientific reviewer for several journals. He is engaged as conference speaker and in numerous workshops/capability buildings with regulators from around the globe.

Sample Management in the Context of Reliance for NDA and PACs

Neven Ahmed

Reliance team leader
Egyptian Drug Authority (EDA), Egypt

Neven Ahmed, Ph.D. is the Reliance team leader in Egyptian Drug Authority (EDA). A Quality assessor with 18 years of experience in the field of quality. well-versed in international quality standards. Specialized in research, drug control and local regulations. Currently overseeing quality assurance for registration and reliance drug products in Egyptian Drug Authority.

Sample Management overview – Qatar Experience

Noha Mohamed Reda Arram

Head of Drug Quality Control Laboratory - Pharmacy & Drug Control Department
Ministry of Public Health (MOPH), Qatar, Qatar

Dr. Noha Mohamed Reda Arram is Head of the Drug Quality Control Laboratory (DQCL) at the Ministry of Public Health, Qatar. With over three decades in pharmaceutical quality control, regulatory compliance, and laboratory management, she has been central to strengthening drug standards and aligning laboratory practices with international regulations. She began her career at Egypt's National Authority of Drug Research & Control before joining Qatar's Ministry of Public Health in 2000, where she became Head of the DQCL in 2003. Dr. Arram also contributes to national health initiatives, represents Qatar at WHO forums, and has advanced training in leadership, lab management, and regulatory systems.

Panel Discussion with Q&A (With the additional participation of):

Assane Coulibaly

CEO / Director General
Autorité Ivoirienne de Régulation Pharmaceutique (AIRP) / Ivorian Pharm RA, Côte d'Ivoire

Dr. Assane Coulibaly, an industrial pharmacist since 1991, brings over 30 years of experience in the pharmaceutical industry. Formerly Deputy General Manager with experience in community pharmacy, he now leads the Ivorian Pharmaceutical Regulatory Authority (AIRP). His career blends expertise in industry & distribution, strengthened by leadership roles as President of APPCI (2012–2019) & Vice-President of WAPMA (2012–2016), where he remains a permanent executive committee member for ECOWAS. As Principal Coordinator at UNIDO (2015–2019), he advanced Good Pharmaceutical Practices, championed the fight against counterfeit medicines, & continues to promote regional integration & access to safe, quality medicines across West Africa.

4:00 PM — 4:15 PM

Wrap-up & Highlights

4:15 PM — 4:15 PM

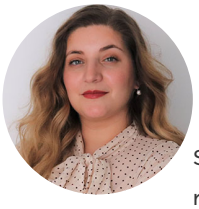
END of Day 1

Day 2 Oct 14, 2025

10:00 AM — 10:10 AM

Welcome & Introduction to Day 2

Session Chair(s)



Sara Torgal, MPharm

Global Regulatory Policy Lead
DIA, Switzerland

Sara is currently Senior Manager, Scientific Programmes at DIA. In the EMEA region, she is responsible for engaging with external stakeholders and advancing the scientific content strategy by creating opportunities to integrate scientific and regulatory changes of interest in DIA initiatives. Additionally, she is responsible for the regional patient engagement and learning design initiatives, being the liason for the Middle East and SEE regions. Previously, she was Public Health Promotion Projects Manager at the

Portuguese Pharmaceutical Society. Sara is a Master of Pharmacy since 2015 and a Soft skills Trainer since 2012, having delivered over 300h of Training internationally primarily focused on creating impactful interactions.

10:10 AM — 11:20 AM

SESSION 5: Qatar Townhall

Overview: In this session, hosted by the Ministry of Public Health of the State of Qatar, Qatari authorities will present the vision and strategy for the future, as well as opportunities and the latest developments in the country.

Session Chair(s)

Ahmed Awaisu

Professor and Head of the Department of Clinical Pharmacy and Practice
Qatar University - College of Pharmacy, Qatar

Prof. Ahmed Awaisu is Professor and Head of Clinical Pharmacy and Practice at Qatar University's College of Pharmacy. With 25+ years of international experience, he is recognized for his work in medication safety, pharmacoepidemiology, and pharmacy education. He has over 250 publications, including in The Lancet, with 8,000+ citations. He has led training in research, deprescribing, medication reconciliation, and diabetes management across the Middle East, Africa, and Asia, and has served as WHO Lead Consultant in Malaysia, Chair of Qatar University's Institutional Review Board, and on editorial boards of leading pharmacy journals.

Mohamed Izham Mohamed Ibrahim

Professor of Social & Administrative Pharmacy
Qatar University College of Pharmacy, Qatar

Professor Mohamed Izham Mohamed Ibrahim is a Professor of Social & Administrative Pharmacy at Qatar University's College of Pharmacy. With over 3 decades of academic experience, his research spans pharmaceutical policy and supply management in low- and middle-income countries, pharmaceutical economics, pharmacoepidemiology, socio-behavioral aspects of pharmacy and health, and quality of life studies. He has supervised research for more than 100 undergraduate, MSc, and PhD students and published approximately 300 journal articles, books, and chapters. His interests include writing, travel, and engaging in conversations over coffee. Professor Izham is recognized for advancing pharmacy education and research in developing nations.

Speaker(s)

Pharmacy Practice and Digital Transformation in Qatar

Ameena Jesaimani

Executive Director of Pharmacy
Hamad Medical Corporation (HMC), Qatar

Dr. Ameena Jesaimani is the Executive Director of Pharmacy at Hamad Medical Corporation (HMC), leading the strategic direction of pharmacy services across Qatar's largest healthcare provider. With over 20 years of experience, she has advanced pharmacy practice, clinical excellence & patient safety through research-driven

innovation. She holds a Ph.D. in Clinical Pharmacology, Toxicology & e-Health from the University of Geneva & a B.Sc. in Pharmacy from King Saud University. Dr. Jesaimani established HMC's Ambulance Service Pharmacy Department & strengthened regulatory compliance, operational efficiency & workforce development. An active researcher, she publishes widely on medication safety, pharmacovigilance & digital health innovation.

Digitalisation of Regulatory Services: Qatar Experience

Mohammed Abdelaal

Supervisor - Drug Registration & Pricing Section, Pharmacy & Drug Depart.
Ministry of Public Health (MOPH), Qatar, Qatar

Mohammed Abdelaal is a pharmacist with over 15 years of experience and a Master's in Pharmacoeconomics and Outcomes Research. His career spans government and private sectors, with a focus on pharmaceutical regulatory affairs, including evaluation of drug registration dossiers in CTD, NeeS, and eCTD formats, covering quality, safety, and efficacy in line with ICH and GCC guidelines. He currently serves as Supervisor in the Drug Registration and Pricing Section at Qatar's Ministry of Public Health, overseeing product registration, regulatory compliance, and strategic initiatives. He has authored three scientific publications contributing to clinical practice and pharmacoeconomics in the region.

Digitalisation of Regulatory Services: Qatar Experience

Hassan Salman Faisal

Head - Inspection & Narcotic section
Ministry of Public Health (MOPH), Qatar, Qatar

A pharmacist specialist, he worked in the pharmaceutical industry (1997–2004) and served as Supervisor of the Drug Preparation Unit (2005–2011) and Inspection Supervisor (2011–2015) at the Ministry of Public Health (MOPH). Since 2015, he has been Head of the Inspection & Narcotic Section, representing MOPH in meetings with the Ministry of Interior and serving on committees for registration of supplements, herbal products, medical cosmetics, hazardous materials, narcotics, and institutional performance evaluation.

Standardising Pharmacy Services in Qatar – QNDC and QNF

Emad Eldin Munsour

Head - Drug Release Section, Pharmacy and Drug Control Depart.
Ministry of Public Healh (MOPH), Qatar, Qatar

Standardising Pharmacy Services in Qatar – QNDC and QNF

Ibrahim Assaf

Head of IT Department & GS1 Healthcare Project Manager
GS1, Qatar

Ibrahim Assaf is the Head of IT Department and GS1 Healthcare Project Manager at GS1 Qatar, with over 17+ years of experience in global standards, digital transformation, and supply chain innovation. He has worked with GS1 Jordan, GS1 Saudi Arabia, and GS1 Qatar, leading projects in healthcare, traceability, and national product cataloging. At GS1 Qatar, Ibrahim has supported initiatives such as the Qatar Pharmaceutical Track & Trace System (QPTTS) by providing technical expertise and guidance to align stakeholders with global GS1 standards. His work focuses on

enabling patient safety, regulatory compliance, and digitalization across industries, with a strong emphasis on healthcare engagement.

Exchange Hub: An Experience from Qatar – EPN Integrated in NHI

Juliet Ibrahim

Director, Electronic Health (e-health) Department
Ministry of Public Health (MOPH), Qatar, Qatar

Dr. Juliet Ibrahim is Director of eHealth at the Ministry of Public Health, Qatar, leading national health information systems, including the health information exchange and central data repository. With over 15 years in Qatar's government healthcare system, she has held leadership roles in planning, strategy, and policy, contributing to the National Health Strategy (2011–2016 and 2018–2022). A physician by training, Dr. Ibrahim completed Family Medicine Specialty Training at Georgetown University, followed by fellowships in Health Center Director Development and Health Systems Administration. She combines clinical expertise with strategic leadership to advance digital health and integrated healthcare in Qatar.

Overview of the Clinical Trial Unit

Abdul Rouf Palli Valapila, PhD

Director of Operations for Clinical Trial Unit
Hamad Medical Corporation (HMC), Qatar

Dr. Abdul Rouf, PhD is Director of Operations for the Clinical Trial Unit at Hamad Medical Corporation (HMC), overseeing clinical trials across the institution. He previously served as Assistant Director of Pharmacy, Drug Information Supervisor, and Head of Pharmacy Practice Research. His expertise includes medication safety, pharmacovigilance, adverse drug reactions, and clinical guideline development, with a focus on obstetrics and gynecology. Dr. Rouf has authored 90+ publications, served on national committees, and presented at international conferences. He holds an MPharm from India, an MSc in Clinical Pharmacology, and a PhD from the University of Aberdeen, UK.

Q&A

Panellist(s) Invited

Qatar

11:20 AM — 11:40 AM

Break

11:40 AM — 12:55 PM

SESSION 6: Digital Transformation of the Regulatory Systems

Overview This Session aims to familiarise the audience with the cutting-edge developments in the digitalisation of regulatory submissions and global collaboration. As the pharmaceutical landscape rapidly evolves, understanding and adapting to new digital tools and harmonised standards is paramount for efficient development and patient access. We will delve into key initiatives transforming the regulatory ecosystem: the next generation of eCTD, ICH M4Q revision, Structured Product Quality Submissions, and ICH PQKM.

Session Chair(s)

Geoffrey Williams

Director of Regulatory Information Management
Gilead Sciences, United Kingdom

Speaker(s)

eCTD 4.0: Cornerstone for Digitalisation and Future Structured Product Quality Submissio

Hrishikesh Dhongade, MS

Associate Director - Regulatory Affairs, Submission Standards and Strategy
Novartis Healthcare Pvt. Ltd., India

ICH M4Q Update

Sara Shatat

Head - General Administration of Innovative Products
Egyptian Drug Authority (EDA), Egypt

Dr. Sara Shatat serves as Head of the General Administration of Innovative Products at the Egyptian Drug Authority (EDA), providing leadership & oversight for the assessment of innovative products submitted for marketing authorization in Egypt. Internationally, she represents EDA as Topic Lead in the ICH M4Q(R2) Expert Working Group. Previously, she led the Biologicals Technical Support Administration, advancing regulatory harmonization & scientific advice for manufacturers. Dr. Shatat holds a Ph.D. in Analytical Chemistry from Cairo University, specializing in recombinant therapeutic protein characterization.

ICH PQKM & Cloud-based Platforms

Hilmar Hamann, PhD

Chief Information Officer
European Medicines Agency, Netherlands

Dr Hilmar Hamann is currently the Head of Information Management at the European Medicines Agency (EMA) where he focuses on advancing EMA's vision to become an all-digital, efficient and data-driven

Agency of the future.

Artificial Intelligence Involvement in Regulatory Systems

Samya Alabdulrahim

Senior Regulatory Affairs Expert
Saudi Food and Drug Authority (SFDA), Saudi Arabia

Samya holds an Executive Master's degree in Regulatory Affairs from King Saud University & a Doctor of Pharmacy (Pharm.D.) from Princess Norah University. With a strong foundation in pharmaceutical sciences & regulatory frameworks, she navigates the complexities of the healthcare industry with expertise. At the SFDA, she has led AI-driven initiatives to enhance regulatory efficiency & streamline pharmaceutical processes. By integrating AI into workflows, she has improved decision-making, reduced time-to-market, & strengthened compliance, positioning her as a key contributor to the future of pharmaceutical regulation in Saudi Arabia.

Panel Discussion with Q&A (With the additional participation of):

Panellist(s) Invited

Qatar

12:55 PM — 1:15 PM

Break

1:15 PM — 2:15 PM

SESSION 7: ePI: Where are we?

Overview: In this session, we will hear from Industry Regulatory Experts and Regulators from the MENA region on regional insights, success stories and challenges, and how the adoption of the ePI can support the overall medicines ecosystem.

Session Chair(s)

Imane Hattami

Therapeutic Area Head and Regulatory Policy Intelligence MEAR
Abbvie Biopharmaceuticals Gmbh, Morocco

Ronnie Mundair

Regional Labelling Head - Canada and LATAM - Senior Director
Pfizer, United Kingdom

+20 years' of experience working in both the public & private sector of Regulatory Affairs (RA). Her career started at the MHRA - the UK RA & then moved into UK & EU regulatory strategy roles at both AZ & then Pfizer. In each of these roles she gained valuable experience across multidisciplinary aspects of RA ranging from Strategy, Labelling, CMC, Submissions, Artwork to Clinical Trials. In 2009, Ronnie moved into Labeling, managing diverse roles within Global & Regional functions at Pfizer. Ronnie's responsibilities have included projects spanning labeling activities across EUCANZ, EME, AfME, Canada &LATAM. Currently a key focus for Ronnie is internally & externally leading on the topics of health literacy and ePI across LATAM, AFME, EU.

Speaker(s)

EFPIA IREG Survey Results: Conclusions & Recommendations

Stefano Accorsi, MBA, MSc

Senior Director, Global Regulatory Affairs Policy, Intelligence and Affiliates
Chiesi Farmaceutici S.p.A., Italy

Stefano Accorsi holds a graduation in Chemistry at the University of Modena (Italy) and an Executive MBA at the Bologna Business School and has been working in the International Regulatory Affairs for more than twenty years. Today, he leads and develops the Company relationship with Regulatory Authorities world-wide, in collaboration with external industry associations and is responsible for the regulatory intelligence activities globally. Stefano is member of several EFPIA Regulatory Working Groups, of the IFPMA Regulatory Science Committee, the Regulatory Affairs Steering Committee at the US Biotechnology Innovation Organization (BIO) and of the EU Regulatory Intelligence Group (EU RING).

How could Evolving Technology support Patients better and support the Industry and Regulators to offer much more when it comes to Product Information?

Bernhard Salb

Global Supply Chain Project Manager
Roche, Switzerland

Panel Discussion with Q&A on the Basic Adoption of ePI and Digital Roadmap for ePI Adoption (with the additional participation of):

Mohammed Abdelaal

Supervisor - Drug Registration & Pricing Section, Pharmacy & Drug Depart.
Ministry of Public Health (MOPH), Qatar, Qatar

Mohammed Abdelaal is a pharmacist with over 15 years of experience and a Master's in Pharmacoeconomics and Outcomes Research. His career spans government and private sectors, with a focus on pharmaceutical regulatory affairs, including evaluation of drug registration dossiers in CTD, NeeS, and eCTD formats, covering quality, safety, and efficacy in line with ICH and GCC guidelines. He currently serves as Supervisor in the Drug Registration and Pricing Section at Qatar's Ministry of Public Health, overseeing product registration, regulatory compliance, and strategic initiatives. He has authored three scientific publications contributing to clinical practice and pharmacoeconomics in the region.

Panel Discussion with Q&A on the Basic Adoption of ePI and Digital Roadmap for ePI Adoption (with the additional participation of):

Mohammad Rabi, PharmD

IT Specialist · Drug Directorate
Jordan Food and Drug Administration (JFDA), Jordan

Mohd Rabi works for Jordan FDA, the comprehensive consumer protection agency in Jordan that manages and regulates pharmaceutical industry. Rabi supervises IT related operations in the drug directorate. He has over 25 years of experience as full-stack developer. Artificial Intelligence (AI) and Image Processing are the main fields of interest. Rabi is currently working on the ePI project, which provides access to official, up-to-date, and approved medicinal information.

Panel Discussion with Q&A on the Basic Adoption of ePI and Digital Roadmap for ePI Adoption (with the additional participation of):

Rehab Mehriz

Manager - General Administration of Pharmaceutical References & leaflets
Egyptian Drug Authority (EDA), Egypt

Rehab Mehriz serves as Manager of the General Administration of Pharmaceutical References and Leaflets at the Egyptian Drug Authority (EDA). A board-certified Pharmacist in Pharmacotherapy, she holds a Master's in Clinical Biochemistry and Oncology and has completed advanced studies at Harvard Medical School, the University of Washington, and King's College London. With over 15 years' experience across Regulatory Affairs, Pharmacovigilance, and Clinical Pharmacy, she leads Egypt's pioneering Electronic Labelling Project, establishing the country as a regional leader in digital regulatory transformation and e-labelling implementation.

Panel Discussion with Q&A on the Basic Adoption of ePI and Digital Roadmap for ePI Adoption (with the additional participation of):

Lynsey Flitton

Director, Strategic Global Labeling, Europe
AbbVie, United Kingdom

2:15 PM — 2:35 PM

Break

2:35 PM — 3:35 PM

SESSION 8: Serialisation and Track & Trace

Overview: This Session will provide an overview of Track & Trace implementation around the world, share experiences in the implementation of serialisation and T&T, and support countries in the MEA region that currently don't have a roadmap for T&T.

Session Chair(s)

Heba Nabil

Chair-Egypt RWG EFPR & Regulatory Sciences Director- Egypt & Sudan
Pfizer, Egypt

Heba Nabil is Regulatory Sciences Director- Egypt &Sudan- Pfizer and the Chair of the regulatory working group (RWG) of the Egyptian foundation for pharmaceutical research (EFPR) She worked in the academic field, for more than 10 years, in pharmaceutical technology department, Faculty of Pharmacy, Misr International University (MIU). Then she moved to the regulatory affairs field joining the Registration General Directorate in the Ministry of Health and Population of Egypt. she worked as the Rapporteur of The Technical Committee for Drug Control then she became the Head of Human Pharmaceutical Drug products Registration Directorate before moving to her current role

Anthony B. Kapeta

Legal Officer
AUDA-NEPAD(African Union Development Agency), South Africa

Anthony B. Kapeta is a Legal Officer at AUDA-NEPAD (African Union Development Agency), supporting health programs & leading the Technical Committee on Medicines Policy & Regulatory Reforms under the African Medicines Regulatory Harmonization Programme (AMRH). He coordinates interventions against substandard & falsified medical products, serving as the focal point for the Continental Plan on SF medical products. Anthony also provides expertise on pooled procurement mechanisms & supports country-level legislative development on medicines, including SF legislation. Previously, he worked as Legal Advisor for MSF Canada in Cameroon, Legal Associate at the African Union Commission in Ethiopia, & is a Registered Lawyer at the Kinshasa Bar, DRC.

Speaker(s)

GS1 - Roadmap for the implementation of serialisation

Chiara Bernini

Senior Manager Public Policy Healthcare - presso

GS1, Belgium

Chiara Bernini has been part of the GS1 Healthcare team since 2020 as Senior Manager, Public Policy Healthcare, managing the GS1 Global Healthcare Public Policy Work Team. She oversees & drives the global strategy for harmonised use of GS1 standards to support healthcare-related regulatory & procurement requirements for pharmaceuticals & medical devices. Chiara has extensive experience engaging with decision-makers globally, providing guidance on implementing GS1 standards in healthcare. She is passionate about GS1's work to enhance patient safety, improve medical outcomes, & increase supply chain efficiency across the healthcare sector.

Global Standards for Local Impact: The GS1 Qatar Story

Ibrahim Assaf

Head of IT Department & GS1 Healthcare Project Manager
GS1, Qatar

Ibrahim Assaf is the Head of IT Department and GS1 Healthcare Project Manager at GS1 Qatar, with over 17+ years of experience in global standards, digital transformation, and supply chain innovation. He has worked with GS1 Jordan, GS1 Saudi Arabia, and GS1 Qatar, leading projects in healthcare, traceability, and national product cataloging. At GS1 Qatar, Ibrahim has supported initiatives such as the Qatar Pharmaceutical Track & Trace System (QPTTS) by providing technical expertise and guidance to align stakeholders with global GS1 standards. His work focuses on enabling patient safety, regulatory compliance, and digitalization across industries, with a strong emphasis on healthcare engagement.

How Track and Trace helps combat against product crime

Pius Waldmeier, PhD

Head of Supply Chain Projects Mgt; Head of GRACC, Pharma Global Technical Ops
F. Hoffmann-La Roche, Ltd., Switzerland

Dr. Pius Waldmeier is a trained chemist and has been working for Hoffmann-La Roche Switzerland in various areas for over 30 years. Currently he is responsible with his team for defining the global strategy to detect and prevent counterfeits, falsified and diverted products and for initiating corresponding investigations. Roche invests a lot of effort to protect patients and products against counterfeiters and product crime.

Securing the Supply Chain: Egyptian Track & Trace Project Update

Nourhan Yasser El Manzalawy

Head-Follow-up & Decision Support Unit, Central Admin-Pharma policies & Market
Egyptian Drug Authority (EDA), Egypt

Dr. Nourhan El-Manzalawy is the Head of the Follow-up and Decision Support Unit at the Central Administration of Pharmaceutical Policies and Market Access, Egyptian Drug Authority (EDA). She is a member of Egypt's National Track and Trace Committee and holds a Master's degree in Public Policy from the American University in Cairo. Her work focuses on regulatory policy development, data-driven decision support, and advancing digital transformation within Egypt's pharmaceutical sector.

Panel Discussion with Q&A (With the additional participation of):

Emad Eldin Munsour

Head - Drug Release Section, Pharmacy and Drug Control Depart.
Ministry of Public Health (MOPH), Qatar, Qatar

Panel Discussion with Q&A (With the additional participation of):

Panellist(s) Invited

Qatar

3:35 PM — 3:40 PM

Wrap-up & Highlights

3:40 PM — 3:40 PM

END of Day 2

Day 3 Oct 15, 2025

10:00 AM — 10:05 AM

Welcome & Introduction to Day 3

Session Chair(s)

Sara Torgal, MPharm

Global Regulatory Policy Lead
DIA, Switzerland

Sara is currently Senior Manager, Scientific Programmes at DIA. In the EMEA region, she is responsible for engaging with external stakeholders and advancing the scientific content strategy by creating opportunities to integrate scientific and regulatory changes of interest in DIA initiatives. Additionally, she is responsible for the regional patient engagement and learning design initiatives, being the liason for the Middle East and SEE regions. Previously, she was Public Health Promotion Projects Manager at the Portuguese Pharmaceutical Society. Sara is a Master of Pharmacy since 2015 and a Soft skills Trainer since 2012, having delivered over 300h of Training internationally primarily focused on creating impactful interactions.

10:05 AM — 11:15 AM

SESSION 9: Bringing Innovation to the MEA Region

Overview: In this Session, we will identify and highlight different tools and initiatives across the Middle and North Africa to bring innovation to the Region, including Pharma Industry advances, IP, groundbreaking research, advanced technologies, and transformative regulatory pathways. That all ensures continuous commitment to innovation, to drive scientific and economic value, to evolve the regional healthcare systems, and faster patient access to innovative medications. Furthermore, we will dive into different tools and new pathways that help attract and bring innovation to the region, and what we could do more or differently to keep focusing on innovation.

Session Chair(s)

Dina Fathy, MPharm, AHIP

Senior Director, Regulatory Affairs Middle East Subregional Lead
MSD UAE, United Arab Emirates

Bachelor of Pharmacy – Faculty of Pharmacy – Cairo University, MBA Maastricht school University- The Netherlands. Extensive knowledge and experience in Pharma industry and Health sector, regulatory affairs, governmental affairs for 23 years. 10 years working with Ministry of Health in Egypt. Also as a government official working with various HA, Ministries e.g. ministry of foreign affairs, associations across different countries in ME, Africa. Heading regulatory operations in Egypt, Libya, SAU, year 2015- MSD. In 2016 until date Heading Gulf region Regulatory operations -MSD Gulf. Local Chair for the Regulatory Working group in Gulf Region. An active member in Regulatory working group for Pharma Middle East & Africa.

Abdulrahim Alyahya

SaudiArabia Regulatory WG; Director-Regulatory Policy, Governmental Affair & TSO
Biogen, Saudi Arabia

Speaker(s)

The IP Ecosystem in GCC: Building confidence for Innovation and Access

Ahmad Saleh

Partner, Head of Innovation, Patents, Industrial Property, & AI
Tamimi & Co., United Arab Emirates

Accelerating Access for Innovation: The SFDA experience

Ahmad Al Menea

Head - Pharmaceutical Products Registration Section (Drug Sector)
Saudi Food and Drug Authority (SFDA), Saudi Arabia

EDA Regulatory Perspectives for Innovative Medicinal Products

Sara Shatat

Head - General Administration of Innovative Products
Egyptian Drug Authority (EDA), Egypt

Dr. Sara Shatat serves as Head of the General Administration of Innovative Products at the Egyptian Drug Authority (EDA), providing leadership & oversight for the assessment of innovative products submitted for marketing authorization in Egypt. Internationally, she represents EDA as Topic Lead in the ICH M4Q(R2) Expert Working Group. Previously, she led the Biologicals Technical Support Administration, advancing regulatory harmonization & scientific advice for manufacturers. Dr. Shatat holds a Ph.D. in Analytical Chemistry from Cairo University, specializing in recombinant therapeutic protein characterization.

Panel Discussion with Q&A (With the additional participation of):

Panellist(s) Invited

Qatar

11:15 AM — 11:35 AM

Break

11:35 AM — 12:35 PM

SESSION 10: Making the ME(N)A region a Clinical Trials hub

Overview This Session will highlight global, regional and local efforts to enhance the Clinical Trials environment. WHO will share how regulatory ecosystem optimisation can be a driver for trial activity, followed by AVAREF exploring cross-country collaboration between regulators and ethics committees. Regulators from Saudi Arabia, Tunisia, Egypt, and the UAE will share national initiatives to strengthen the CTs infrastructure and streamline approvals. The session will close with insights on data quality, patient recruitment, and health literacy in line with ICH and ethical guidelines.

Session Chair(s)

Angelika Joos, MPharm

Executive Director, Science & Regulatory Policy
MSD, Belgium

Angelika Joos is a trained pharmacist. She is responsible for Regulatory Policy issues within MSD's Global Regulatory Affairs and Clinical Safety department. This role includes identifying regulatory policy priorities that align with MSD's business priorities, leading cross-functional networks to define policy positions, and informing MSD's regulatory strategy development. Angelika represents MSD in the IFPMA Regulatory Science Committee and is one of IFPMA's delegates to the ICH Management Committee. She is also involved in international policy activities though efpia as well as BIO and PhRMA international Committees. She served on the DIA Board of Directors from 2013-2020.

Marco Rafael, PharmD, MBA, RPh

Regulatory Policy Leader
Roche, Switzerland

Marco Rafael, a PharmD graduate from the University of Coimbra, transitioned from consulting to the pharmaceutical industry, building an international career in the UK and Switzerland. Over nine years, he held key roles at Teva, Roche, Biogen, and Alexion, complemented by an MBA from EPFL and specialization in Health Policy at the London School of Economics. As Regulatory Policy Leader at Roche's Global Headquarters in Basel, Marco develops policies driving medical innovation, leads strategic foresight initiatives, and contributes to EFPIA's Clinical Research Expert Group, Clinical Trial Strategy, and other global regulatory networks.

Speaker(s)

National Initiatives for Ecosystem Strengthening, Regulatory Approval Predictability, Collaboration with Ethics Review Boards, Capacity Building and Infrastructure Investment

Marwa Al Abbas

Senior Clinical Trial Expert
Saudi Food and Drug Authority (SFDA), Saudi Arabia

National Initiatives for Ecosystem Strengthening, Regulatory Approval Predictability, Collaboration with

Ethics Review Boards, Capacity Building and Infrastructure Investment

Rania Ibrahim

General Manager of The General Administration of Clinical Trials
Egyptian Drug Authority (EDA), Egypt

National Initiatives for Ecosystem Strengthening, Regulatory Approval Predictability, Collaboration with Ethics Review Boards, Capacity Building and Infrastructure Investment

Shaikha Almazrouei

Director of the Reference National Laboratory – Drug Department
Emirates Drug Establishment (EDE), United Arab Emirates

Strengthening Technical Collaboration between Regulators and Ethics Committees across countries under the AMA Framework

Rhanda Adechina Adehan

Technical Officer - Consultant AVAREF Secretariat
World Health Organization (WHO), Switzerland

Panel Discussion with Q&A (with the additional participation of):

Abdul Rouf Palli Valapila, PhD

Director of Operations for Clinical Trial Unit
Hamad Medical Corporation (HMC), Qatar

Dr. Abdul Rouf, PhD is Director of Operations for the Clinical Trial Unit at Hamad Medical Corporation (HMC), overseeing clinical trials across the institution. He previously served as Assistant Director of Pharmacy, Drug Information Supervisor, and Head of Pharmacy Practice Research. His expertise includes medication safety, pharmacovigilance, adverse drug reactions, and clinical guideline development, with a focus on obstetrics and gynecology. Dr. Rouf has authored 90+ publications, served on national committees, and presented at international conferences. He holds an MPharm from India, an MSc in Clinical Pharmacology, and a PhD from the University of Aberdeen, UK.

Panel Discussion with Q&A (with the additional participation of):

Mariem Kadri

Pharmacist - Directorate of Pharmacy and Medicine
ANMPS (Agence Nationale Du Médicaments et des Produits de la santé), Tunisia

Mariem Kadri is a Doctor in pharmacy . A Team lead in the National Agency for Medicines and Health Products . She is in charge mainly of clinical trials. Mariem is the focal point regarding the function : clinical trial supervision in the GBT of WHO . She is working on the different agency projects like digitalization and e-CTD implementation

12:35 PM — 12:55 PM

Break

12:55 PM — 1:55 PM

SESSION 11: Biosimilars

SESSION 10: Biosimilars

Session Chair(s)

Ali AlSamil

Head of Biotech and Biosimilar Products Department
Saudi Food and Drug Authority (SFDA), Saudi Arabia

Speaker(s)

Global Perspectives - Evolution of the Regulatory Framework for Biosimilars, Experiences and Lessons Learned

Sarah Yim, MD

Director, Office of Therapeutic Biologics and Biosimilars, OND, CDER
FDA, United States

Sarah Yim, M.D. has been the Director of the Office of Therapeutic Biologics and Biosimilars, in CDER's Office of New Drugs (OND), FDA since 2019. Prior to that, she spent 2 years as Director of the Division of Clinical Review in the Office of Generic Drugs, and 11 years in various roles in rheumatology drug review in OND. She received her undergraduate degree from Stanford University, her Doctor of Medicine degree from the Uniformed Services University of Health Sciences, and completed a postdoctoral fellowship in rheumatology at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), at the National Institutes of Health.

Global Perspectives - Evolution of the Regulatory Framework for Biosimilars, Experiences and Lessons Learned

Mohammed H. Aldosari, PhD

Director of Biological Products Directorete
Saudi Food and Drug Authority (SFDA), Saudi Arabia

Dr. Mohammed Aldosari is a scientific assessment expert of biological medicinal products at Saudi FDA (Saudi Arabia) since 2008. Mohammed is a pharmacist by education and gained the master degree in biotechnology from Macquarie University (Australia) and doctoral degree in biopharmaceutical biotechnology from Utrecht University (Netherlands). He has been involved in the development of investigational biological drugs (Novel/Biosimilar). Mohammed has over 10 years of regulatory experience in CMC assessment for different biological medicinal products such as monoclonal antibodies, recombinant hormones/enzymes, vaccines and biosimilars. He published several scientific papers related to development and regulation of biological orphan drugs.

Global Perspectives - Evolution of the Regulatory Framework for Biosimilars, Experiences and Lessons Learned

Anne Cook

Expert Quality Assessor (Biologicals) Healthcare, Quality and Access group
Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Global Perspectives - Evolution of the Regulatory Framework for Biosimilars, Experiences and Lessons Learned

Andrea Laslop, MD

Former Head of Scientific Office, AGES & Regulatory expert, lecturer
Malta Medicines Authority, University of Innsbruck, Austria

Andrea Laslop retired from her role as Head of the Scientific Office at the Austrian Medicines and Medical Devices Agency, part of the Austrian Agency for Health and Food Safety, at the end of 2024. Her work focused on centralized European procedures in drug development, marketing authorization, and life-cycle management. From 2003 to 2024, she was a member of the EMA's Scientific Advice Working Party and served as a delegate on the Committee for Medicinal Products for Human Use (2007–2022). Previously a professor of pharmacology and toxicology at the Medical University of Innsbruck, she now teaches and conducts regulatory evaluations

Industry Perspective

Virginia Acha, PhD, MSc

AVP, Global Regulatory Policy
Merck Sharpe & Dohme LLC , United States

Virginia (Ginny) has worked in industry and academia throughout her career, combining interests in science policy research and innovation performance within and across organizations. She joined MSD in 2017 to lead

regulatory policy efforts ex-US for innovation that leads to better treatment for patients globally. Since 2020 this scope has expanded, as Ginny now leads the talented and experienced Global Regulatory Policy and Intelligence team for MSD. Her work has regularly focused on policy shocks that challenge innovation and access to novel therapies for patients, including global and industry-wide policy work on BREXIT, COVID-19 and now the R&D impacts of the Inflation Reduction Act.

Panel Discussion with Q&A (With the additional participation of):

Panellist(s) Invited

Qatar

1:55 PM — 2:10 PM

Break

2:10 PM — 3:10 PM

SESSION 12: Masterclass in Combination Products: The EU Landscape - Regulatory and Practical Insights

SESSION 12: Masterclass in Combination Products: The EU Landscape - Regulatory and Practical Insights

Session Chair(s)

Gert Bos, PhD, MSc

Chief Scientific Oficer, Executive Director, Partner
Qserve Group B.V., Netherlands

Gert is an expert in European regulations based on 15 years hands-on working in the field, as auditor, product reviewer, regulatory specialist, head of notified body. He led the Notified Bodies in Brussels for many years, and has strongly supported the regulatory debate with the EU Commission, EU Parliament and the EU Council of Ministers. He combines strong experience in quality, compliance and regulations with a pragmatic, result driven approach at both operational and strategic level.

Speaker(s)

The Role and Experiences of the Regulator

Christelle Bouygues, PharmD

Senior Regulatory Affairs Officer

European Medicines Agency, Netherlands

Regulatory Affairs Senior Officer at the European Medicines Agency. Joined the EMA in 2004. Responsible for providing regulatory intelligence and advice in relation to the development, evaluation and surveillance of medicinal products for the Centralised Procedure. Involved in particular with the implementation of the paediatric and pharmacovigilance legislation. Currently, amongst other projects, closely involved in the implementation of the MDR/IVDR within EMA as regard to the aspects on medical devices used in combination with medicinal products and on the repurposing pilot. Before joining the Agency, gained experience at the French Competent Authority, in the Mutual Recognition Procedures and in the Industry.

The Role of the Notified Bodies – NB Opinions

Jonathan Sutch, PhD

Principal Medicinal Technical Specialist
BSI Group, United Kingdom

Dr Jonathan Sutch is a Principal Medicinal Specialist at the Notified Body BSI Group, working with medical devices containing medicinal substances and drug/device combinations. Jon trained as a Pharmacist at the London School of Pharmacy prior to completing a PhD in Pharmaceutical Sciences at Nottingham University. He has 15 years of experience in the pharmaceutical industry as a formulation scientist and manager before moving to BSI 5 years ago.

Panel Discussion with Q&A (With the additional participation of):

Panellist(s) Invited

Qatar

3:10 PM — 3:30 PM

Wrap-up & Highlights

3:30 PM — 3:30 PM

END OF THE CONFERENCE