Conrad Cairo Hotel

Nov 25, 2024 6:00 PM - Nov 27, 2024 6:00 PM

1191 Nile Corniche, Cairo, 11221, Egypt

Middle East and North Africa Conference (MENA)

This two-day conference is designed for the industry's regulatory professionals to explore the evolving pharmaceutical landscape in the MENA region and address its unique challenges, with all regional regulators present.

Print Agenda

Day 1 Nov 25, 2024

6:30 PM — 10:00 PM

Opening Ceremony & Gala Dinner - Manial Palace (Prince Mohamed Ali Palace), Cairo

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.

Day 2 Nov 26, 2024

8:00 AM — 9:00 AM

Registration & Welcome Coffee

9:00 AM — 9:10 AM

Welcome Remarks

9:10 AM — 10:45 AM

Session 1: Middle East & North Africa Townhall

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, Europe, Middle East & Africa (EMEA) 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.

Nevena Miletic

IFPMA ARN Chair Advisor and Regulatory Policy & Science Chapter Leader
F. Hoffmann-La Roche Ltd, Switzerland

Nevena Miletic is a pharmacist, with postgraduate studies in parmacoeconomics, Reg Affairs and QA, with more than 18 years of experience in pharma industry. Currently she works in Global Regulatory Policy at F. Hoffmann-La Roche and for the last five years, she is co-chairing IFPMA Africa Regulatory Network and CPP Network. She is also a member of IFPMA Regulatory Science and Africa Engagement Committees, DIA MEA Advisory Board, EFPIA ERAO PI WG, IATF etc., being involved in numerous projects with regulators and cross-industry collaborative platforms (e.g. Pre-ICDRA, ICDRA, IMI, SCoMRA etc.). Nevena is a strong advocate for regulatory convergence and harmonisation, with main interest in innovative approaches in drug development and review.

Speaker(s)

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

Sumaya Husain

Clinical Trials Regulations Specialist
National Health Regulatory Authority (NHRA), Bahrain

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

Aiman S. El-Khatib

Vice President
Egyptian Drug Authority (EDA), Egypt

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

Zahraa Abdulsattar

Pharmacist, Registration Department, Technical Affairs Directorate
Ministry of Health, Iraq

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

Rana Malkawi

Drug Directorate Director
Jordan Food and Drug Administration (JFDA), Jordan

Dr Rana is an experienced pharmacist with more than 15 years of experience in Regulatory affairs, holding a master degree in pharmaceutical quality assurance. She joined JFDA in 2008 and held various positions, including head of new drugs registration section, head of biological and vaccine registration section. She was the Project lead for the installation of the eCTD system at JFDA and collaborated in the preparation and review of the “Guidance for Registration of Biosimilars in Jordan” from May 2015. Currently, Dr Rana is the head of Clinical Studies Department at JFDA, a member of the Clinical studies and of the national stem cells committee and the MOH clinical trials and access to innovation committee.

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

Hamza Salem Benisa

Head of Items Registration, Pharmacy Department
Ministry of Health, Libya, Libya

Dr.Hamza Benisa currently is the Head of Items Registration,in Ministry of Health libya. He is an assistant lecturer at Faculty of pharmacy, Elmirgib University2015-2019,Farmer head of regulatory affairs section in MOH2016-2017, member of medical waste committee, member of High committee of medical gases.

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

Donia Albastaki

Acting Director, Pharmaceutical and Herbal Medicine Registration & Control Admin
Ministry of Health, State of Kuwait, Kuwait

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

Mariem Kadri

Pharmacist assessor
Directorate of Pharmacy and Medicine, 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

Representative Invited

9:30 AM — 6:00 PM

DIA MENA Pharmacovigilance Workshop

Session Chair(s)

Mohammed Ebrahim Fouda, PharmD, RPh

Head of Signal Detection Department
Saudi Food and Drug Authority (SFDA), Saudi Arabia

Dr. Mohammed Serve as Head of signal detection section at Saudi food and drug authority. In this role, he has several initiatives to enhance the drug safety regulation in the kingdom of Saudi Arabia. In 2008 Dr. Fouda received his bachelor's degree in pharmaceutical sciences from king Saud university he also awarded his doctor of pharmacy degree in 2014 from Massachusetts College of Pharmacy and Health Sciences University. Dr. Fouda is currently a member of several international reference groups.

Shahinaz Badr, PharmD

Pharmacovigilance Consultant and PVQA Auditor - EMEA
Independent Consultant, United Arab Emirates

Shahinaz, a pharmacist with over 20 years in pharmacy and the pharmaceutical industry, is a Pharmacovigilance Consultant and Lead Auditor across the EMEA region. She began as a clinical pharmacist at Cairo University Medical School and advanced to an internal auditor role. Transitioning to the pharmaceutical industry, she worked in Regulatory Affairs before specializing in Pharmacovigilance as a regional QPPV and later as a PVQA Lead Auditor. Shahinaz is active in the ISOP Special Interest Group, contributing to global pharmacovigilance certifications, and frequently speaks at international conferences on patient and drug safety

Raghda Mohamed

Patient Safety & Pharmacovigilance Cluster Lead - West Gulf, East Gulf and Leva
Takeda, United Arab Emirates

Claudia Ferreira

Scientific Programs Manager
DIA, Switzerland

Aya Eliskandarany

Patient Safety Manager | Gulf & Pakistan
Astrazeneca, United Arab Emirates

Yasmine Fekry

Patient safety and Pharmacovigilance – Greater Gulf
Sanofi, United Arab Emirates

Speaker(s)

Egypt Updates: PV Inspections and Audits

Maha Mohamed Ahmed

Acting Director of the general department of pharmacovigilance
Egyptian Drug Authority (EDA), Egypt

Dr. Maha Mohammed holds a BSc. Pharm. 2009, Master in Pharmacology, and toxicology Azhar University. 2018. She is the General Manager of Pharmaceutical Vigilance– Egyptian Drug Authority (EDA). Previously, she was a team leader of Cairo regional pharmacovigilance centre & Senior PV specialist. Maha Mohammed is has fourteen years of experience working in regulatory authority. Dr Maha specializes in pharmacovigilance and is responsible of Supervising the Egyptian Pharmceutical Vigilance Center, including ICSRs management unit, Signal detection unit, emerging safety issues unit, follow up unit and PRBER Unit, PV system, PV inspections ..etc.

Muhanad Hassan Alharbi, MPharm

Head of datacapture
Saudi Food and Drug Authority (SFDA), Saudi Arabia

Muhanad H. Alharbi is currently working as head of data capture section at the National Pharmacovigilance Center, in the Saudi Food and Drug Authority (SFDA) since 2019. He awarded his master degree in pharmacology from Aston University UK. He is the project manager of pharmacovigilance regional offices. He also has trained in several courses in drug safety and pharmacovigilance and he has participated in a number of pharmacovigilance activities.

Algeria Updates

Nadjat LOUMI-MEDEDJEL

Responsible for Training of Healthcare Professionals and Staff
Centre National De Pharmacovigilance et De Matériovigilance (CNPM), Algeria

A doctor graduated from the University of Algiers, holding a Diploma of Advanced Studies from the Faculty of Medicine of Paris (France), a university degree in pharmacovigilance from the university Claude Bernard of Lyon and a doctoral thesis in clinical pharmacology at the Faculty of Medicine of Besançon. She took part in the creation of the CNPM with its founder Professor A Helali in 1998. Since 2016, she has introduced the concept of Phytovigilance, Réactovigilance, Cosmetovigilance, in addition to the vigilance of the drug, the medical device and the vaccine already established. Teacher at the Faculty of Medicine of Algiers. Editor of the independent Medical journal "la Revue Prescrire" since 2007.

AI Initiatives in Egypt that Support Pharmacovigilance Efforts

Doaa Mohamed Soliman Ibrahim

Manager of Accreditation and Development administration
Egyptian Drug Authority, Egypt

Doaa Soliman holds a B.Sc. in Pharmaceutical Science, an Egyptian Board of Healthcare Management certification, and a Master's in Healthcare Quality Management. With 10 years of experience in the healthcare sector, she has worked as an inpatient and community pharmacist, as well as in supply chain management, specializing in pharmacovigilance (PV). As an Administrative Manager, she oversees three units: PV Training, PV Inspection, and Pharmacovigilance System Master File (PSMF) Assessment. She has contributed to the Egyptian Drug Authority's (EDA) global benchmarking program with the World Health Organization (WHO) and led PV inspections across Egypt, ensuring compliance with safety standards.

Using AI Models to Reduce Patient Risk in Drug Development

Rania Shosha

ICH expert, Manager of protocols and clinical studies follow up &GCP inspector
Egyptian Drug Authority (EDA), Egypt

Rania Shousha specializes in clinical studies regulation at the Egyptian Regulatory Authority, with over 7 years of experience. She oversees clinical trial protocols, participant safety, and data integrity, ensuring compliance with regulatory standards. She also advises pharmaceutical companies on study design, data collection, and analysis. Rania earned a Master's in Clinical Pharmacy with honors from the University of Tanta and completed a clinical

pharmacy residency at a government hospital. She is currently pursuing a PhD in Pharmacology and Toxicology at Cairo University.Rania represents the Egyptian Drug Authority (EDA) at the International Council for Harmonization (ICH) as a member of the ICH M15 Expert Working Group.

10:45 AM — 11:15 AM

Coffee Break

11:15 AM — 12:45 PM

Session 2: International Collaboration, Harmonisation & Convergence

This session will cover a range of pivotal topics that are shaping the future of healthcare in the MENA region. We will explore innovative initiatives that are driving change, discuss the impact and progress of regional harmonisation initiatives, and examine the practical application of the WHO benchmarking tool. The session will also provide a platform to discuss the opportunities and challenges that come with regional collaboration, offering insights into best practices and potential solutions. Additionally, we will share the latest updates from the ICH Assembly to keep you informed of the latest global healthcare regulatory developments.

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.

Asmaa Fouad

Head Central Adm. of Biological, Innov. Products & Clinical Trials
Egyptian Drug Authority, Egypt

Ms. Asmaa Fouad Ismail is currently General Manager of the Biological Products General Administration, the Central Administration of Biological and Innovative Products and Clinical Trials at EDA managing marketing authorization, lot release and laboratory evaluation, and analysis of biological products. Ms. Fouad is also delegate of EDA in ICH & IPRP since December,2021. She is also a member of the Emergency Committee at EDA and has participated in the formulation of many national guidelines in Egypt. She worked in the COVID-19 Vaccines Global Review team with the WHO. She has 20 years of biological products regulatory experience.

Speaker(s)

The Importance of International Collaboration for Fostering Harmonization and Convergence

Sondos Moshtohry

Manager of the Administration for Cooperation with International Organizations
Egyptian Drug Authority (EDA), Egypt

Sondos Moshtohry, Head of the Administration for Cooperation with International Organizations, Office of the Chairman of the Egyptian Drug Authority (EDA). EDA, Egypt's ICH Coordinator, IPRP Management Committee Member. Dr. Moshtohry has over a decade of experience in Regulatory and Public Affairs, representing Egypt internationally and leading projects in regulatory harmonization and market access. She is EDA, Egypt's IMDRF Representative, ICCR Observer, and a former Team Lead at the Central Administration of Pharmaceutical Policies. She holds a Master's in International Development and Policy from AUC, a Bachelor's in Pharmaceutical Sciences from Ain Shams University, and is a Microsoft Certified Educator.

Regional Harmonisation Initiatives: The North African Medicines Reguatory Harmonisation (NA-MRH) Initiative -Challenges & Opportunities

Dalia Abou Hussein

QA General Manager
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.

International: ICH and IPRP - Updates from the last Assembly & Experiences of the Path from ICH Observer to Member

Neil McAuslane, PhD, MSc

Scientific Director
Centre for Innovation in Regulatory Science (CIRS), United Kingdom

Neil McAuslane PhD, Scientific Director of the Center for Innovation in Regulatory Science (CIRS) overseeing the scientific content of both CIRS regulatory and HTA programmes. Key research areas of work include regulatory strategy and strengthening, building quality into regulatory processes, the utilization of decision frameworks and the development of multistakeholder workshops which bring companies, patients, and agencies (Regulatory and HTA) together to discuss major areas of interest.He is currently involved in specific research on how best to measure the performance of agencies, risk-based approaches in the assessment of new medicines, building quality into the review process, decision making and HTA and regulatory alignment.

International: ICH and IPRP - Updates from the last Assembly & Experiences of the Path from ICH Observer to Member

Rana Malkawi

Drug Directorate Director
Jordan Food and Drug Administration (JFDA), Jordan

Dr Rana is an experienced pharmacist with more than 15 years of experience in Regulatory affairs, holding a master degree in pharmaceutical quality assurance. She joined JFDA in 2008 and held various positions, including head of new drugs registration section, head of biological and vaccine registration section. She was the Project lead for the installation of the eCTD system at JFDA and collaborated in the preparation and review of the “Guidance for Registration of Biosimilars in Jordan” from May 2015. Currently, Dr Rana is the head of Clinical Studies Department at JFDA, a member of the Clinical studies and of the national stem cells committee and the MOH clinical trials and access to innovation committee.

Panel Discussion with QandA, with the additional participation of:

Sarah Ibrahim, PharmD, PhD

Associate Director for Stakeholder and Global Engagement, Office of Generic Drug
FDA, United States

Sarah Ibrahim is the Associate Director for Stakeholder and Global Engagement in the OGD/ CDER at the U.S. Food and Drug Administration (FDA). Dr. Ibrahim develops OGD strategies to address identified and emerging regulatory challenges in relation to the international nature of the generic drug industry. She established OGD’s current global affairs program, the generic drug cluster which is the first generic drug forum that involves the word leading regulatory agencies. In collaboration with other CDER and FDA offices, she supports stakeholder engagement concerning issues related to globalization of the generic pharmaceutical supply and harmonization of regulatory approaches for generic drugs.

Panel Discussion with QandA, with the additional participation of:

Victoria Palmi-Reig

International Affairs
European Medicines Agency, Netherlands

Victoria Palmi, Senior International Affairs officer, has over 20 years of experience at the European Medicines Agency (EMA). She supports international collaboration programs and reliance as part of her role in the International Affairs office. Previously, Victoria worked as Product Lead in different therapeutic areas within the Evaluation of Medicines department. During this time, she led initiatives that accelerated assessment and early access to priority medications.

Panel Discussion with QandA, with the additional participation of:

Mariem Kadri

Pharmacist assessor
Directorate of Pharmacy and Medicine, 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

Panel Discussion with QandA, with the additional participation of:

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.

Panel Discussion with QandA, with the additional participation of:

Heba Nabil

Chair-Egypt Regulatory Affairs WG & Regulatory Affairs Senior Manager
Pfizer, Egypt

12:45 PM — 2:00 PM

Lunch Break

2:00 PM — 3:30 PM

Session 3: Reliance

Harmonisation of requirements towards global standards, convergence of regulatory processes and frameworks that allow the sharing of confidential information are foundational to support agencies' collaboration across countries and regions. In addition, the speed of technology innovation is accelerating, and regulatory workload is increasing. To cope with this demand, regulators are implementing reliance pathways for different regulatory activities, such as initial applications, inspections, lab testing, post-approval changes and pharmacovigilance. Regulatory reliance has become a 21st-century regulatory science tool for more efficient decision-making and smarter use of regulatory resources. In this session, we will explore current global Reliance initiatives and how it is being implemented in the MENA region.

Session Chair(s)

Fadila Lakkis

Regulatory Affairs, Intelligence & Communications Manager, Gulf
GSK, United Arab Emirates

Fadilla has over 12 years of experience in Pharma Industry transitioning from Sales, to Global Policy and Intelligence till reaching Regional Regulatory Affairs. She is the Vice Chair of EFPIA Middle East Regulatory Network (MERN) since end 2021 and an active member in PhRMA Gulf Regulatory Affairs Working Group (RAWG). She holds bachelor's degree of Pharmacy from the Lebanese International University & MBA degree from the American University of Science & Technology in Lebanon.

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.

Speaker(s)

WHO Reliance Efforts

Luther Gwaza, PhD

Team Lead-Pharmaceuticals Norms & Standards, Depart of Health Products Policy
World Health Organization (WHO), Switzerland

Luther Gwaza holds a Bachelor of Pharmacy (honours), a Master of Philosophy (MPhil) in pharmacology, and a PhD in Pharmaceutical Policy and Regulation. He is currently a Technical Officer in the Regulatory Systems Strengthening (RSS) Team in the World Health Organization (WHO), Geneva. His responsibilities include all aspects related to the Collaborative Registration Procedure and other facilitated registration mechanisms. Previously, he worked as a consultant regulatory officer for the national medicines regulatory authority (NRA) in Zimbabwe. He has consulted for various international organizations such on systems strengthening, harmonization, collaboration and cooperation in medicines regulation in Africa and Asia.

Relying and being a Reference Agency as a Strategy to Bring Innovation - Good practices in making Reliance happen both ways to optimise resources

Agnes Chan

Director, Therapeutic Products Branch
Health Sciences Authority, Singapore, Singapore

EMA Reliance Focus Group and EMA OPEN – regulators and industry perspective

Victoria Palmi-Reig

International Affairs
European Medicines Agency, Netherlands

Victoria Palmi, Senior International Affairs officer, has over 20 years of experience at the European Medicines Agency (EMA). She supports international collaboration programs and reliance as part of her role in the International Affairs office. Previously, Victoria worked as Product Lead in different therapeutic areas within the Evaluation of Medicines department. During this time, she led initiatives that accelerated assessment and early access to priority medications.

EMA Reliance Focus Group and EMA OPEN – regulators and industry perspective

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.

Continental Reliance Framework - AMA Pilot Initiative & Evaluation Guidelines

Chimwemwe Chamdimba

Principal Programme Officer-African Medicines Regulatory Harmonisation Program
African Union Development Agency-NEPAD, South Africa

Chimwemwe Chamdimba leads the African Medicines Regulatory Harmonization (AMRH) Initiative at AUDA-NEPAD, overseeing the programme and supporting the operationalisation of the African Medicines Agency (AMA). A health policy specialist, she drives regulatory reforms that strengthen systems, align with procurement, and boost local manufacturing. She has contributed to key AU policy frameworks, including the Model Law on Medical Product Regulation, the AMA Treaty, the AU Health Strategy, the Private Sector Engagement Framework, and STISA-2024.

Reliance is not a “one size fits all”. How is the principle being implemented?

Rana Malkawi

Drug Directorate Director
Jordan Food and Drug Administration (JFDA), Jordan

Dr Rana is an experienced pharmacist with more than 15 years of experience in Regulatory affairs, holding a master degree in pharmaceutical quality assurance. She joined JFDA in 2008 and held various positions, including head of new drugs registration section, head of biological and vaccine registration section. She was the Project lead for the installation of the eCTD system at JFDA and collaborated in the preparation and review of the “Guidance for Registration of Biosimilars in Jordan” from May 2015. Currently, Dr Rana is the head of Clinical Studies Department at JFDA, a member of the Clinical studies and of the national stem cells committee and the MOH clinical trials and access to innovation committee.

Panel Discussion with QandA, with the additional participation of:

Jacqueline Acquah

Regulatory Affairs _ Middle-East and Africa
CEPI (Coalition for Epidemic Preparedness Innovations), Ghana

Panel Discussion with QandA, with the additional participation of:

Donia Albastaki

Acting Director, Pharmaceutical and Herbal Medicine Registration & Control Admin

Ministry of Health, State of Kuwait, Kuwait

3:30 PM — 4:00 PM

Coffee Break

4:00 PM — 5:00 PM

Session 4: Egypt Townhall

In this session hosted by the Egyptian Drug Authority (EDA), Egyptian authorities will present the vision for 2030, opportunities and latest developments in the country.

Session Chair(s)

Dalia Abou Hussein

QA General Manager
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.

Speaker(s)

EDA's Establishment and Efforts towards Alignment with International Standards

Aiman S. El-Khatib

Vice President
Egyptian Drug Authority (EDA), Egypt

EDA Efforts on Investment and Localization within the regulatory framework

Yasin Ragaey

Chairman Assistant for Media affairs & Investment Support in the Pharma Sector
Egyptian Drug Authority (EDA), Egypt

EDA’s path towards International Standards

Asmaa Fouad

Head Central Adm. of Biological, Innov. Products & Clinical Trials
Egyptian Drug Authority, Egypt

Ms. Asmaa Fouad Ismail is currently General Manager of the Biological Products General Administration, the Central Administration of Biological and Innovative Products and Clinical Trials at EDA managing marketing authorization, lot release and laboratory evaluation, and analysis of biological products. Ms. Fouad is also delegate of EDA in ICH & IPRP since December,2021. She is also a member of the Emergency Committee at EDA and has participated in the formulation of many national guidelines in Egypt. She worked in the COVID-19 Vaccines Global Review team with the WHO. She has 20 years of biological products regulatory experience.

Medhat Al-Ghobashy

Former EDA Advisor for Regulatory & Reference Labs
Egyptian Drug Authority (EDA), Egypt

EDA’s collaborative initiatives

Riad Armanious

Vice chairman, Chamber of Pharmaceutical Industry & CEO,
EVA Pharma, Egypt

EDA’s collaborative initiatives

Representative Invited

EFRP, Egypt

5:00 PM — 5:30 PM

Networking Reception Sponsored by US Pharmacopeia (USP) including Highlights & Closing of Day 1

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.

7:30 PM — 9:00 PM

Exclusive Networking Apero & End of the Executive Forum

Day 3 Nov 27, 2024

8:00 AM — 8:30 AM

Welcome Coffee

8:30 AM — 8:45 AM

Opening of Day 2 & Welcome

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.

8:45 AM — 10:15 AM

Parallel Session 5A: Modernising the Regulatory Framework to Enable Efficient Lifecycle Management

This session will focus on recent updates regarding the modernisation of the regulatory framework to facilitate the timely approval of PACs (Post-Approval Changes), including EDA' s experience in reliance implementation to the variations' system. In addition, two case studies from industry will be shared regarding how to enhance the use of reliance and PACMP (Post Approval Change Management Protocol) to accelerate PAC approval. Regulators and industry will discuss how to optimise the LCM framework by leveraging the lessons learnt from case studies, opportunities for harmonisation with international guideline and including PACMP in the local guideline, with the ultimate goal of enabling fast approval of PACs and securing supply of medicines 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.

May Shawky Mohamed

Regional Manager Regulatory Affairs MEAR
Merck Group, United Arab Emirates

May is working at Merck Group as the Regional Regulatory Affairs Manager for the Middle East, Africa, Turkey, Russia, and CIS (MEAR) region. With over 14 years of experience in the pharmaceutical sector, she has held progressively senior roles in R&D and Regulatory Affairs with a diverse experience within EU and International Markets. She is leading strategic regulatory initiatives, regulatory intelligence, and advocacy efforts in MEAR region, and chairs the EFPIA MERN Safety Label Updates Optimization Taskforce. May holds a bachelor's degree in pharmaceutical sciences from Cairo University.

Speaker(s)

EDA’s Experience - Reliance for Post-Approval Changes

Hebatullah Ibrahim

General Manager of biological Products General Administration
Egyptian Drug Authority (EDA), Egypt

Hebatallah Ibrahim Abdel-Salam, General Manager of Biological Products and Head of Marketing Authorization at EDA, holds a bachelor’s in pharmaceutical science and an MBA in project management. She is an external evaluator at the African Union Development Agency-NEPAD and represents EDA in the AMRH Technical Committee, chairing its Vaccines Oversight Subcommittee. A former head of Post-Approval Changes, she contributed to WHO COVID-19 vaccine assessments, biosimilar registration updates, and reliance pathways for biological products.

Case Study: Outcome of PAC Reliance Pilot with 48 countries

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.

Case Study: Reliance and PACMPs to Accelerate a Major PAC Approval

Ibrahim Tlili, PharmD, MPH, MSc

Senior Scientist, International CMC EU/EEMEA
MSD, Switzerland

Dr Ibrahim Tlili is an industrial Pharmacist holding a Doctor of Pharmacy and a Master degrees in Oncology from the University of the Mediterranean in Marseille, France. Ibrahim have 12 years of experience in Regulatory Affairs, started his career in the French Health Authority before moving to pharmaceutical industry in local, regional and global roles in France, Switzerland and the United Arab Emirates in different companies such as Sanofi, AbbVie, Bayer and is currently working with MSD in Zurich, Switzerland.

Panel Discussion with Q and A, with the additional participation of:

Sumaya Husain

Clinical Trials Regulations Specialist
National Health Regulatory Authority (NHRA), Bahrain

Panel Discussion with Q and A, with the additional participation of:

Donia Albastaki

Acting Director, Pharmaceutical and Herbal Medicine Registration & Control Admin
Ministry of Health, State of Kuwait, Kuwait

8:45 AM — 10:15 AM

Parallel Session 5B: Rare Diseases

The regulation and treatment of rare diseases have become a growing priority in the MENA region, where limited access to orphan drugs can create challenges for patient access. This session will focus on advancing regulatory and strategic plans for rare diseases and orphan drugs in the MENA region, with key insights from the Saudi FDA, experiences from national health systems, and international best practices.

Session Chair(s)

Yazeed AlRuthia

Professor, Department of Clinical Pharmacy
King Saud University, College of Pharmacy, Saudi Arabia

Niveen Osman, MBA

Regulatory Affairs Director Middle East & Africa
Amgen Inc., United Arab Emirates

Speaker(s)

Patient Access to Orphan Drugs in European National Health Systems: Learned Lessons

Virginie Hivert, PharmD, PhD

Therapeutic Development Director
Eurordis-Rare Diseases Europe, France

Virginie Hivert joined EURORDIS in 2014 as Therapeutic Development Director.Virginie is responsible for following the development of orphan drugs as an observer on the Committee for Orphan Medicinal Products at the European Medicines Agency.She coordinates the group of high-level EURORDIS representatives/volunteers who sit on the various scientific committees/working parties at the EMA, known as the Therapeutic Action Group (TAG).

Patient-Centric Care for Rare Diseases

Eric Obscherning

Director, Health & Life Sciences
Access Partnership, United States

Maurille Feudjo Tepie

VP & Head, GLobal RWE and Digital Sciences
UCB, United Kingdom

Panel Discussion with QandA

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.

Panel Discussion with QandA

Kristina Larsson, MS

Head of Orphan Medicines, Division for Human Medicines Evidence Generation
European Medicines Agency, Netherlands

Kristina Larsson joined the orphan team of the EMA as the Head of Office in July 2014. Before that she spent 8 years as a scientific officer in the scientific advice team of the EMA in charge of the Scientific Advice Working Party secretariat. Before joining the agency she worked three years in clinical research for AstraZeneca in Mölndal, Sweden. Kristina has a master of Medicine in Pharmaceutical Bioscience from the University of Gothenburg.

Panel Discussion with QandA

Abeer Elbehairy

General Manager - Drug Utilization & Pharmacy Practice G.A
Egyptian Drug Authority (EDA), Egypt

10:15 AM — 10:45 AM

Coffee Break

10:45 AM — 12:15 PM

Parallel Session 6A: eLabelling

Topics addressed in this session include: ePI, shared packs, eLabelling regional initiatives.

Session Chair(s)

Catherine Al Ashram

VP Regulatory Affairs & PV, Latin America MEA and Russia
Organon, Jordan

Catherine is a Medical Doctor holding an MBBS degree followed by several Post graduate Diplomas and trainings in Reg. Affairs, PV, Clinical Research, Compliance, Medical Aff., and Reg. Policy, with 20 years of experience in these fields and in different countries and clusters within the region. Currently she is leading EEMEA Regulatory Affairs and Pharmacovigilance operation in over 70 countries in Eastern Europe, Middle East and Africa at Organon. She is an active member in several Policy Advisory Committees for DIA and previously EFPIA Regulatory Networks in the Middle East region, as well in Pharma Executive Committee. She is a strong advocate to Health Care reforms that aim at enhancing regulatory environment and access to innovation.

Ronnie Harprit Mundair

Regional Labelling Head - AfME, 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)

Status of the ePI Implementation Across the MENA region

Imane Hattami

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

eLabelling Flexibility & ePI Shared Packs

Shereen M. Abdelgawad

Head of central administration of Pharmaceutical Care
Egyptian Drug Authority (EDA), Egypt

Shereen Abdelgawad is the Head of the Central Administration of Pharmaceutical Care at the Egyptian Drug Authority (EDA), with over 15 years of experience in pharmaceutical regulatory affairs and public policy. She holds master's degrees in Pharmaceutics & Industrial Pharmacy and Public Policy. Shereen focuses on improving pharmaceutical care practices, patient safety, and policies. She has spearheaded initiatives like e-labeling for accessible medical information and leads key committees on antimicrobial rational use and national guidelines. Her strategic leadership continues to drive advancements in pharmaceutical care and regulatory policy.

eLabelling Flexibility & ePI Shared Packs

Ohoud Thanebat

Director of Institutional Performance Development Directorate
Jordan Food & Drug Administration (JFDA), Jordan

Most recent ePI Regulations and Roadmap

Talita Soares

Technician – Coordinator in Reg And Health Surveillance
Anvisa, Brazil

EU status

Elizabeth Scanlan, PhD, MSc

ePI Product Owner
European Medicines Agency, Netherlands

Elizabeth Scanlan is Product Owner for electronic product information (ePI) at the European Medicines Agency. Prior to joining EMA in 2016, she worked in communication roles in the biotechnology industry and not-for-profit sector. She holds a PhD in molecular biology from Trinity College Dublin.

Panel Discussion with QandA

Pavle Zelic

International Cooperation, European Integrations and Public Relations
Medicines and Medical Devices Agency of Serbia (ALIMS), Serbia

Master of Science in Pharmacy, communicator, and certified diplomat. Manager for International Cooperation, European Integrations, and Communications at ALIMS for 15+ years. Recognized worldwide as Serbia's leading public health official and international expert, project leader, and communicator with thousands of media reports to his name and many lectures across the globe. Leader on several major EU, WHO, and Council of Europe projects and official in many groups and bodies. 2021/22 US State Department Hubert H. Humphrey Fellow at Emory University in Atlanta, Georgia, US and CDC. Valedictorian of the Diplomatic Academy of Ministry of Foreign Affairs of Serbia 2010/11. Accomplished writer and scriptwriter too.

Panel Discussion with QandA

Rana Malkawi

Drug Directorate Director
Jordan Food and Drug Administration (JFDA), Jordan

Dr Rana is an experienced pharmacist with more than 15 years of experience in Regulatory affairs, holding a master degree in pharmaceutical quality assurance. She joined JFDA in 2008 and held various positions, including head of new drugs registration section, head of biological and vaccine registration section. She was the Project lead for the installation of the eCTD system at JFDA and collaborated in the preparation and review of the "Guidance for Registration of Biosimilars in Jordan" from May 2015. Currently, Dr Rana is the head of Clinical Studies Department at JFDA, a member of the Clinical studies and of the national stem cells committee and the MOH clinical trials and access to innovation committee.

10:45 AM — 12:15 PM

Parallel Session 6B: Clinical Trials

This session will discuss the evolution of the continental clinical trials landscape in Africa through AVAREF, provide insights into the revised ICH E6(R3) guidelines that is going to be adopted by end of 2024 and Clinical research opportunities in the Kingdom of Saudi Arabia. We will also host a panel discussion to hear more how the clinical trial frameworks are evolving in Egypt and Bahrain as well as some reflections from the pharmaceutical Industry.

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.

Speaker(s)

Continental Clinical Trials

Rhanda Adechina

Consultant AVAREF Secretariat
World Health Organization (WHO), Switzerland

ICH E6/E8 revision update

Rebecca Stanbrook, RPh

EFPIA ICH E6(R3) Expert Working Group Member
Switzerland

Rebecca Stanbrook has worked in the pharmaceutical industry, as a regulator at the MHRA and at various pharmaceutical companies for over 30 years. Her main areas of interest are clinical trials and pharmacovigilance. She is a pharmacist by profession and holds a Diploma in Research Quality Assurance. Rebecca is thrilled to be a member of the ICH E6(R3) Expert Working Group. Currently Rebecca works as GCP Strategic Lead in Process & Risk Surveillance, in the Strategy, Portfolio and Programme Operations Group of Development in Novartis Pharma AG. She is based in Basel.

The Experience from Saudi NIH

Halah Alenizi

Clinical Trials Expert
Saudi National Institute of Health (Saudi NIH), Saudi Arabia

The Experience from Saudi NIH

Abdulhadi M. Alqahtani

Sr. Clinical Trial Specialist
Saudi National Institute of Health (Saudi NIH), Saudi Arabia

Panel Discussion with QandA, with the additional participation of

Heba Khalil

Head of GA of Clinical Trials
Egyptian Drug Authority (EDA), Egypt

Panel Discussion with QandA, with the additional participation of

Sumaya Husain

Clinical Trials Regulations Specialist
National Health Regulatory Authority (NHRA), Bahrain

Panel Discussion with QandA, with the additional participation of

Mohei-Eldeen Hesham

Evidence Generation Manager
AbbVie, Saudi Arabia

Mohei has over 8+ years' experience in Conducting, Managing and Monitoring Clinical Trials through CROs and Pharmaceutical industries in the MENA region. He is currently Medical Operations and Evidence Generation Specialist at AbbVie Saudi Arabia. He is fully engaged with all clinical trial management phases from Site Selection to Initiation, Monitoring and Close out. He worked in different therapeutic indications on early phase multinational clinical trials. He holds a bachelor's degree in pharmaceutical sciences and a diploma in Total Quality Management for Healthcare.

12:15 PM — 1:15 PM

Lunch Break

1:15 PM — 2:45 PM

Parallel Session 7A: The Evolution of Digital Submissions

In this session, we will navigate through the lesson' learned from the implementation of eCTD in the Middle East region, while exploring the future of regulatory submission through digital transformation. From the new Continental IMS in Africa to the transition to cloud technology, this session promises to be an exciting moment to look into the future and how to support all stakeholders in their digital transformation efforts.

Session Chair(s)

Dalia Fouad

Middle East Region Head - Global Regulatory Affairs
Sanofi Aventis, United Arab Emirates

Dalia Fouad, head of regulatory and policy at Sanofi, is a seasoned professional with over 15 years of expertise in pharmaceutical regulation and policy development. With a strong background in Pharmacy, she has demonstrated exceptional leadership, strategic thinking, and a deep understanding of regulatory frameworks. Dalia has successfully driven regulatory compliance, shaped impactful policies, and fostered collaboration to enhance access to medications. Her visionary approach and commitment to ethical standards have been instrumental in advocating patient-centric healthcare solutions and steering Sanofi toward regulatory excellence and improved health outcomes worldwide.

Speaker(s)

A Vision for Digitalisation in the MENA region

Ralph Lee

SM Lead: Türkiye & CauCAR Clusters
Pfizer , United Kingdom

Over 20 years of experience in regulatory operations across multiple regions including EU and GCC. 14 years of eCTD experience including eCTD implementation in multiple markets. Chair of EFPIA MERN eCTD Task Force. Currently leading submissions portfolio for Turkiye and CauCAR markets.

Regional Deep-Dive: Where are we now?

Ralph Lee

SM Lead: Türkiye & CauCAR Clusters
Pfizer , United Kingdom

Over 20 years of experience in regulatory operations across multiple regions including EU and GCC. 14 years of eCTD experience including eCTD implementation in multiple markets. Chair of EFPIA MERN eCTD Task Force. Currently leading submissions portfolio for Turkiye and CauCAR markets.

Regional Deep-Dive: Where are we now?

Assmaa Yousry

PPMA Quality Assurance Unit Manager & Senior Pharmacist - PPMA
Egyptian Drug Authority (EDA), Egypt

Assmaa Yousry is a pharmacist and the Quality Assurance Unit Manager at the Central Administration of Pharmaceutical Policies and Market Access (PPMA), Egyptian Drug Authority (EDA). She collaborates with the Pharmaceutical Information Systems Administration (PIS) to support EDA's digitalization and regulatory business analysis. With over 20 years of experience in Regulatory Affairs across various product categories, including Human, Biologicals, and Dietary Supplements, she also brings 10+ years of quality assurance expertise, bolstered by a TQM Diploma from the American University in Cairo (AUC).

Regional Deep-Dive: Where are we now?

Sana Dabbech

Pharmacist - LNCM/ ANMPS
Ministry of Public Health, Tunisia

New Continental IMS Working Group Africa – How is the system being set? How are learnings from other regions being utilised?

Chimwemwe Chamdimba

Principal Programme Officer-African Medicines Regulatory Harmonisation Program
African Union Development Agency-NEPAD, South Africa

Chimwemwe Chamdimba leads the African Medicines Regulatory Harmonization (AMRH) Initiative at AUDA-NEPAD, overseeing the programme and supporting the operationalisation of the African Medicines Agency (AMA). A health policy specialist, she drives regulatory reforms that strengthen systems, align with procurement, and boost local manufacturing. She has contributed to key AU policy frameworks, including the Model Law on Medical Product Regulation, the AMA Treaty, the AU Health Strategy, the Private Sector Engagement Framework, and STISA-2024.

Update on ICH M4Q/R2

Sara Magdy

Head of Technical Support administration, General Admin of Biological Products
Egyptian Drug Authority (EDA), Egypt

Dr. Sara Magdy, PhD, is Head of Technical Support Administration at the General Administration of Biological Products, EDA/BIO-INN. She leads regulatory development and collaborates on harmonizing guidelines. As EDA's Topic Lead, she contributes to the ICH Expert Working Group updating the M4Q(R2) guideline. Previously, she headed the Marketing Authorization Department at Egypt's National Organization for Research and Control of Biologicals, overseeing the technical assessment of biological product applications.

Regulatory Innovation: Strengthening collaboration through cloud-based platforms to accelerate medicines to patients

Fabio Bisordi, MSc

Global Head International Regulatory Policy
F. Hoffmann-La Roche Ltd, Switzerland

Fabio is Head of the International Regulatory Policy group at Roche. He has over 18 years' experience of working within Global Regulatory Affairs. Fabio started his regulatory career at Cyton Biosciences Ltd., and then joined Chiron Vaccines as Senior Regulatory Affairs Manager. He joined Roche in 2005 where he led the Global Regulatory activities for biologics, before joining the Biologic Strategy Team as Global Biosimilar Regulatory Franchise Head. He has contributed and managed global regulatory projects and has engaged in a variety of interactions with Health Authorities globally. He represents Roche in various EFPIA, IFPMA and EBE-biotech working groups. He is currently Vice-chair of the EBE Biotherapeutics Working group.

1:15 PM — 2:45 PM

Parallel Session 7B: Advanced Therapies

This session explores the trend of Cell & Gene Therapies (CGT) development and the harmonisation work of CGT regulatory frameworks at a global level, namely at WHO and ICH. We will discuss the opportunity of leveraging ongoing harmonisation work and innovative pathways to facilitate the CGT approval in the MENA region and what is in the horizon for ATMPs.

Session Chair(s)

Kowid Ho, PharmD

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

Kowid Ho has been working at F. Hoffmann-La Roche Ltd.'s Global Pharma Technical (CMC) Regulatory Policy in Basel, Switzerland for >10 years. He was previously a quality assessor for biological products at Agence nationale de sécurité du médicament et des produits santé (ANSM, formely AFSSaPS) for 13 years. He has authored many European assessment reports and scientific advices on biotech, vaccines, blood and advanced therapy products, and has participated to several product related inspections. He was a member of

European Medicines Agency (EMA) Biologics Working Party (BWP), Biosimilar Working Party (BMWP), and PAT/QbD team.

Asmaa Ahmed

Researcher and Head of Biotech lab
Egyptian Drug Authority (EDA), Egypt

Speaker(s)

Convergence of CGT regulations – Trends in CGT Development, Best Practices in Regulating CGT and Regulatory Pathways for CGT in the US, EU & Japan

Anna Litsiou, PhD, MBA, MSc

Regulatory Policy & Intelligence Director
AstraZeneca, United Kingdom

Anna Litsiou is an accomplished International Policy & Intelligence Director at AstraZeneca, specializing in China and International markets with 20 years of regulatory affairs experience. Her expertise spans developing regulatory strategies across diverse therapeutic areas including oncology, respiratory, neurodegenerative diseases, and advanced therapy medicinal products. She has spearheaded groundbreaking initiatives like AstraZeneca's participation in the International ACS Workshare for biologics and accelerated approvals through FDA's Project Orbis.

SFDA's experience with CGTs approval

Speaker Invited

China

2:45 PM — 3:15 PM

Coffee Break

3:15 PM — 4:45 PM

Session 8: Suppy Chain & Sample Management

This Session will explore the global trend of using a Reliance-based waiver for in-country testing. Regulators will share their practical experiences with risk-based surveillance testing to replace import/registration testing. The goal of this session is to support regulators in the MENA region in optimising their testing systems to avoid waste of resources and ensure no delay of drug supply to patients.

Session Chair(s)

Joerg Garbe, PhD, MSc

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.

Doaa Rady

Lot Release administration manager
Egyptian Drug Authority (EDA), Egypt

Speaker(s)

WHO - Reliance for Sample Testing

Rutendo Kuwana, RPh

Team Lead, Incidents and Substandard/Falsified Medical Products
World Health Organization (WHO), Switzerland

Rutendo leads the WHO Incidents and Substandard/Falsified (ISF) Medical Products team in Geneva, a role he has held since June 2021. Part of the WHO Access to Medicines and Health Products division, the team supports global coordination to help regulatory authorities prevent, detect, and respond to substandard and falsified medical products. Since joining WHO in 2009, Rutendo has contributed to prequalification of medicines quality control labs, technical assistance, and capacity building for labs, manufacturers, and regulatory authorities. With 30 years of experience, he specializes in reviewing quality data, GMP inspections, and benchmarking regulatory authorities for market control and surveillance

Regional Perspective on In-Country Testing

Rania Elafifi

Regulatory Affairs Lead - Egypt
Roche, Egypt

Risk-based Surveillance Testing in Serbia and How it Complements Anti-Counterfeit Activities in Serbia

Pavle Zelic

International Cooperation, European Integrations and Public Relations
Medicines and Medical Devices Agency of Serbia (ALIMS), Serbia

Master of Science in Pharmacy, communicator, and certified diplomat. Manager for International Cooperation, European Integrations, and Communications at ALIMS for 15+ years. Recognized worldwide as Serbia's leading public health official and international expert, project leader, and communicator with thousands of media reports to his name and many lectures across the globe. Leader on several major EU, WHO, and Council of Europe projects and official in many groups and bodies. 2021/22 US State Department Hubert H. Humphrey Fellow at Emory University in Atlanta, Georgia, US and CDC. Valedictorian of the Diplomatic Academy of Ministry of Foreign Affairs of Serbia 2010/11. Accomplished writer and scriptwriter too.

Panel Discussion with QandA, with the additional participation of:

Rana Malkawi

Drug Directorate Director
Jordan Food and Drug Administration (JFDA), Jordan

Dr Rana is an experienced pharmacist with more than 15 years of experience in Regulatory affairs, holding a master degree in pharmaceutical quality assurance. She joined JFDA in 2008 and held various positions, including head of new drugs registration section, head of biological and vaccine registration section. She was the Project lead for the installation of the eCTD system at JFDA and collaborated in the preparation and review of the "Guidance for Registration of Biosimilars in Jordan" from May 2015. Currently, Dr Rana is the head of Clinical Studies Department at JFDA, a member of the Clinical studies and of the national stem cells committee and the MOH clinical trials and access to innovation committee.

Panel Discussion with QandA, with the additional participation of:

Agnes Chan

Director, Therapeutic Products Branch
Health Sciences Authority, Singapore, Singapore

4:45 PM — 5:00 PM

Conclusions, Highlights and Wrap-up

5:00 PM — 5:00 PM

END OF CONFERENCE