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 — 7:30 PM

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

Session Chair(s)

Sara Torgal, MPharm

Senior Manager, Scientific Programs
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 Younes

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

Amira is the Global Regulatory Policy Director for Eastern Europe, Middle East, and Africa at MSD. With over 15 years in Regulatory Science and Policy, she's a thought leader in reliance, work sharing, and regional harmonization. She's built a network to advance regulatory science in the region. She chairs the EFPIA Middle East Regulatory Network (MERN) and is an active member of several trade associations including IFPMA ,PhRMA, and an industry network for Southeast Europe. She regularly presents at DIA conferences and has

contributed to publications on regulatory topics. She 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

Hamza Salem Ali Benisa

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

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

Invited Speaker

Switzerland

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
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

Pharmacovigilance Consultant and PVQA Auditor - EMEA
Pharma Quality Europe, 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

Speaker(s)

Yasmine Fekry

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

Nadjat LOUMI-MEDEDJEL

Directrice Générale
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.

Lebanon Updates: The journey of publishing of the Good Pharmacovigilance Practices Guideline for Lebanon LGVP and Updates

Rita Karam

Import-Export Department
Ministry of Health, Lebanon

10:45 AM — 11:15 AM

Coffee Break

11:15 AM — 12:45 PM

Session 2: International Collaboration, Harmonisation & Convergence

Topics addressed in this session include: Innovative pathways, Regional harmonisation initiatives, WHO benchmarking tool, opportunities and challenges for regional collaboration, updates from ICH Assembly.

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

General Manager, Biological and Innovative Products and Clinical Studies
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)

Panel Discussion with Q&A

Representative Invited

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

Representative Invited

African Union Development Agency-NEPAD

Chimwemwe Chamdimba heads the African Medicines Regulatory Harmonization Initiative at AUDA-NEPAD. She manages the AMRH Programme, supports AMA operationalization, and drives policy reforms connecting regulatory strengthening to local medical product manufacturing. A health policy expert, she leads reforms, harmonization, and partner coordination, contributing to vital continental policies including the AU Model Law on Medical Product Regulation; the Treaty for the establishment of the African Medicines Agency (AMA); and the AU Private Sector Engagement in Health Framework.

ICH - Updates from the last ICH Assembly & Experiences of the Path from Observer to Member

Representative Invited

Representative Invited

Representative Invited

12:45 PM — 2:00 PM

Lunch Break

2:00 PM — 3:30 PM

Session 3: Reliance

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.

Speaker(s)

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

Regulatory Consultant with the Pharmaceuticals & Biologics Branch
Health Sciences Authority Singapore, Singapore

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)

Representative Invited

Switzerland

5:00 PM — 5:30 PM

Highlights & Closing of Day1

Session Chair(s)

Sara Torgal, MPharm

Senior Manager, Scientific Programs
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.

5:30 PM — 7:45 PM

[INVITATION-ONLY] C-Suite & Senior Executives Programme: Executive Forum

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

Senior Manager, Scientific Programs
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

Bringing changes through global Health Authority systems can be a complex lengthy process and can take up to several years, impacting timely access to medicine and important patient information. This session will focus on recent update regarding modernization of regulatory framework to facilitate the timely approval of PAC (post approval change), including EU variation guideline update, EDA' s experience in reliance implementation to variation 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 optimize LCM framework by leveraging the lessons learnt from case studies, opportunity to harmonization with international guideline and include PACMP to 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

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)

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, being currently Global Head International Regulatory Policy in Roche. M.Sci. in Analytical Chemistry and PhD in Biophysical Chemistry, Susanne is 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. Currently, she is the Vice Chair of the EFPIA IREG, member of EFPIA Middle East network and several IFPMA expert groups.

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

Ibrahim Tlili, PharmD, MPH, MSc

Senior Scientist, International CMC
MSD, Switzerland

8:45 AM — 10:15 AM

Parallel Session 5B: Rare Diseases

Topics addressed in this session include: Orphan Drugs' regulations in the region, national plans for rare diseases, best practices from Europe and other regions.

Session Chair(s)

Yazeed AlRuthia

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

Niveen Osman, MBA

Regulatory Affairs Director
Amgen Inc., United Arab Emirates

Speaker(s)

Panel Discussion with Q&A

Marco Rafael, PharmD, MBA, RPh

Regulatory Policy Lead
Roche, Switzerland

Marco is currently International Regulatory Policy Lead at Roche where he focuses on Modernizing Regulatory Frameworks across regions, being an active member of EFPIA MERN. After starting his career as a consultant, he joined the EU RA team at Teva before moving to Switzerland and joining Roche. To this, followed a variety of roles of increased responsibility in regulatory and international acceleration at Biogen and Alexion, before re-joining Roche in late 2022 for his current role. He holds a PharmD from University of Coimbra as well as an executive MBA focused on Innov Management from EPF Lausanne. In addition, he furthered his education with Public and Health Policy studies at the London School of Economics and Political Science.

Panel Discussion with Q&A

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.

9:00 AM — 9:10 AM

Opening of Day 2 & Welcome

10:15 AM — 10:45 AM

Coffee Break

10:45 AM — 12:15 PM

Parallel Session 6A: The Evolution of Digital Submissions

Session Chair(s)

Dalia Fouad

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

10:45 AM — 12:15 PM

Parallel Session 6B: Clinical Trials

Topics addressed in this session include: Continental Clinical Trials in Africa, ICH E6 revision, LMIC CTs, WHO's Clinical Trials Resolution.

Session Chair(s)

Representative Invited

Switzerland

Speaker(s)

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.

12:15 PM — 1:15 PM

Lunch Break

1:15 PM — 2:45 PM

Parallel Session 7A: eLabelling

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

Session Chair(s)

Catherine Al Ashram

Executive Director Regulatory Affairs & PV Lead, EEMEA
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.

Representative Invited

Jordan Food & Drug Administration (JFDA), Jordan

Speaker(s)

Status of the ePI Implementation Across the MENA region

Imane Hattami

Regulatory Operations Director
Abbvie Biopharmaceuticals Gmbh, Morocco

Status of the ePI Implementation Across the MENA region

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.

EU status

Elizabeth Scanlan, PhD, MSc

ePI Product Owner
European Medicines Agency, Netherlands

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

Most recent ePI Regulations and Roadmap

Talita Soares

Technician – Coordinator in Reg And Health Surveillance
Anvisa, Brazil

Panel Discussion with Q&A

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.

1:15 PM — 2:45 PM

Parallel Session 7B: Advanced Therapies

This session explore 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.

Representative Invited

Egyptian Drug Authority, 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

Director - Regulatory Policy
AstraZeneca, United Kingdom

Anna Litsiou is a Regulatory Policy and Intelligence Director with focus on International and China in AstraZeneca with more than 15-year experience in International Regulatory Affairs in different roles of strategy across therapeutic areas. Anna holds a PhD in Development Developmental Neurobiology from King's College, London and an Executive MBA from Columbia Business School, London School Business and Hong Kong Business School.

2:45 PM — 3:15 PM

Coffee Break

3:15 PM — 4:45 PM

Parallel Session 8A: Supply 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 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. Joerg received a PhD in biochemistry from the University of Hannover/Max-Planck-Institute of Biochemistry, Germany.

Representative Invited

Egyptian Drug Authority, Egypt

Speaker(s)

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

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 Q&A

Agnes Chan

Regulatory Consultant with the Pharmaceuticals & Biologics Branch
Health Sciences Authority Singapore, Singapore

3:15 PM — 4:45 PM

Parallel Session 8B: AI in Medicines Development: Exploring Applications and Considerations

Topics addressed in this session include: use of AI for regulatory efficiencies, lessons learned from EMA's experience, AI for innovative R&D.

Session Chair(s)

Inas Chehimi

Head RA Middle East & North Africa
Novartis Pharma Services AG, United Arab Emirates

Holder of Pharmacy diploma, and Master in EU and International Regulation and Healthcare Laws. Currently heading the regulatory department for MENA region in Novartis. She has 15 years' experience and expertise in the European and Emergent markets regulations; worked for various MNCs. Inas is an active member in the EFPIA Middle East Regulatory Network group, and of the Programme Committee of the MERC and DIA Middle East since 2008. She has participated as a speaker in several international and regional conferences. Inas is a member in the MEA Regulatory Working Group, under the PhARMA association umbrella. Her focus and interest is the healthcare reforms and legislations to accelerate patient access to innovative medicines.

Speaker(s)

EMA AI tool for assessors, DARWIN EU and the European Health Data Space (EHDS)

Florian Lasch

Biostatistics Specialist, Data Analytics and Methods Task Force
European Medicines Agency, Netherlands

Florian is a Biostatistician with a degree in mathematics and a PhD from Hannover Medical School. Florian works as a Biostatistics Specialist at the European Medicines Agency, providing scientific support to development and evaluation throughout all stages of marketing authorisation assessments of medicinal products, and leads the ACT EU Priority Action on Clinical Trial Methodologies.

4:45 PM — 5:00 PM

Conclusions, Highlights and Wrap-up

5:00 PM — 5:00 PM

END OF CONFERENCE