

10th
Edition

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   #GCCRegulatoryAffairsPharmaSummit



17 - 18 February 2025
Mövenpick Grand Al Bustan - Dubai, UAE

Day 1

08:30 - 09:00 Coffee & Registration

09:00 - 09:30 Opening Ceremony - 10th GCC Regulatory Affairs Pharma Summit

Keynote speaker
Welcome to 10th GCC Regulatory Affairs Pharma Summit
Welcome Remarks - Principal Sponsor

Dr. Ruqaya AlBastaki
Dr. Mona Al Moussli
Mr. Fokion Sinis

Director of Drug Department • EDE
Chairman • GCC Summit
Head of International Business • Spimaco

09:30 - 10:00 Session 1: Pioneering Progress: Emirates Drug Establishment's Role in Shaping UAE Pharma Regulations

Moderated by: TBC

Highlights on Emirates Drug Establishment
Q&A

Dr. Hanady Yousef Shourrab

Senior Pharmacist • Emirates Drug Establishment (EDE)

10:00 - 10:45 Session 2: Futuristic Horizons for Regulatory Affairs

Moderated by: TBC

Fostering Research and Innovation: A Regulatory Perspective
Navigating MEA Regulatory Readiness: ATMPs, CAR T Cells, and Gene Therapy
Panel Discussion

Dr. Nadia Younes
Dr. Fatima Zaid Abu Zanat

Consultant, Drug Regulations and Medical Products • DOH
Regional Director of Regulatory Affairs & Scientific Office (META) • Ipsen
SFDA

10:45 - 11:15 Coffee & Networking break

11:15 - 12:00 Session 3: Panel Discussion: Joining GCC Efforts for a Sustainable Near-shoring of Generics and Biosimilars

Moderated by:
Mr. Mohamed Larbi Jelassi
TBC

Panelists

Head of Market Access International • Spimaco

12:00 - 12:30 Session 4: Empowering Local Production: Driving Growth in GCC's Pharmaceutical Manufacturing

Moderated by: TBC

Topic TBC

Julphar

12:30 - 13:15	<p>Session 5: Self Care Evolution in the GCC and Beyond</p> <p>Presenter</p> <p>Panelist</p> <p>Panelists: EDE, Oman MoH, Kuwait MoH</p>	<p>Moderated by: TBC</p> <p>Mr. Ramez Sawiris</p> <p>Dr. Reem Fada</p>	<p>Head of R&D, MEA • Haleon</p> <p>Director Regulatory Affairs Gulf & Near East • Haleon</p>
13:15 - 14:15	Conference Photo, Lunch & Networking		
14:15 - 14:45	<p>Session 6: KSA's Evolving Pharma Regulations: Insights for a Progressive Future</p>	<p>Moderated by: TBC</p> <p>Speaker TBC</p>	<p>Saudi Food and Drug Authority (SFDA)</p>
14:45 - 16:00	<p>Session 7: Ensuring Integrity: The Role of Track & Trace and Serialization in Middle East Pharma</p> <p>Topic TBC</p> <p>Fireside Chat: Governance and Operational Perspectives on Tatmeen Compliance</p> <p>AI in Data Analytics for Track & Trace Systems</p> <p>Panel Discussion: Beyond Compliance: Transforming Track & Trace and Serialization for a Smarter Supply Chain</p> <p>Panelist</p> <p>Panelists: JFDA, EDA, Kuwait MoH</p>	<p>Moderated by: TBC</p> <p>Mr. Görkem Aydin</p> <p>Mr. Jihad Tayara</p> <p>Mr. Zeeshan Ahmed</p> <p>Mr. Mete Karaca</p> <p>Ms. Anna Mansurova</p>	<p>Marketing Manager • Visiott</p> <p>CEO • Evoteq</p> <p>Founder & CEO • Cosmotrace</p> <p>Executive Director • Tiga Healthcare</p> <p>Managing Director - Hellmann Calipar Healthcare Logistics</p>
16:00 - 16:30	Coffee and Networking		
16:30 - 17:15	<p>Session 7: National Regulatory Updates</p> <p>Kuwait Regulatory Updates</p> <p>Oman Regulatory Updates</p> <p>Bahrain Regulatory Updates</p>	<p>Moderated by: TBC</p> <p>Speaker TBC</p> <p>Dr. Muna Humaid Al Saidi</p> <p>Ms. Samar Salem</p>	<p>MOH Kuwait</p> <p>Head of Registration Section of Human Medicine • Ministry of Health Oman (MoH)</p> <p>Head of Narcotic Drugs & Precursors Control Section • NHRA Bahrain</p>
17:15 - 17:30	Wrap up Day 1 Remarks - Julphar		
17:30	Country Specific Round Table Discussions		
	<p>UAE</p> <p>Oman</p> <p>Bahrain</p> <p>Kuwait</p> <p>Jordan</p> <p>Tunisia</p> <p>EDA</p> <p>Iraq</p>		

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REGULATORY AFFAIRS
PHARMA SUMMIT 2025
A Decade of Excellence



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Day 2

08:30 - 09:30 Coffee & Networking

09:30 - 09:45 Day 2 Opening Remarks

Welcome back

Speaker TBC

Haleon

09:45 - 10:30 Session 1: National Regulatory Updates

Egypt Regulatory Updates

Tunisia Regulatory Updates

Kurdistan Medical Control Agency Regulatory Updates

Q&A

Moderated by: TBC

Speaker TBC

EDA

Speaker TBC

DMP Tunisia

Dr. Afrah Husam Hussein

Head of Registration Department • KMCA
(Kurdistan)

10:30 - 11:15 Session 2: Biologics & Biosimilars: Redefining Regulatory Pathways and Advancing Access

Moderated by: TBC

11:15 - 11:45 Coffee & Networking break

11:45 - 12:30 Session 3: Clinical Trials Regulations and vision in GCC

Regulatory vision and the impact of advanced technologies and resources for Assessing Clinical Studies of Pharmacological Drugs and Medical Devices

Clinical trials Regulations in Oman and SQUs Implementation

Q&A

Moderated by: TBC

Dr. Anees Puthan Veettil

Head - Evaluation Unit of Pharmaceutical Studies
• EDE (UAE)

Ph. Hanan Al Habsi

Senior Specialist Clinical Pharmacist, Head of
Clinical Pharmacy and Inpatient Services • Sultan
Qaboos Hospital, Oman

12:30 - 13:30	Session 4: Strengthening Global Health Systems: Strategies for Regulatory Preparedness and Vaccine Innovation	Moderated by: Dr. Jacqueline Acquah	Senior Regulatory Affairs Lead - Middle East & Africa • Coalition for Epidemic Preparedness Innovations (CEPI)
	Presenter	Mr. Alessandro Lazdins	Regulatory Policy and Intelligence Manager • Coalition for Epidemic Preparedness and Innovations (CEPI)
	Panel Discussion: EDE, EDA, JFDA		
13:30 - 14:30 Lunch & Networking			
14:30 - 15:15	Session 5: Charting the Path: Regulatory Frameworks for Generics in the GCC	Moderated by: Dr. Shaimaa Elmeligy	Pharmaceutical Affairs Director Middle East, North Africa and Turkey • Aspen Pharma
	Strategy for the Life Cycle Management of Generics	Dr. Abba Hijazi	Associate Director - Regulatory Affairs MENA • Hikma Pharmaceuticals
	Value Added Medicines: New Pathway to Innovation	Dr. Farah Arar	Regulatory Affairs Senior Manager • Hikma Pharmaceuticals
	Panel Discussion	Mr. Ramzi Sarraj	Regulatory Affairs & PV Director MEA • Société Arabe des Industries Pharmaceutiques (SAIPH)
15:15 - 16:30	Session 6: Revolutionizing Pharma: AI-Driven Digitization and E-Health Advancements	Moderated by: Dr. Dalia Fouad	Head of Regulatory and Policy • Sanofi
	The Role of Generative AI in Shaping the Pharmaceutical Sector	Mr. Nusaibah Al Jaloudi	Founder & CEO • Pi Pharma Intelligence
	Revolutionizing Compliance: AI-Powered e-Labeling in the Era of Digital Transformation	Dr. Shatha Safi	Labelling Supervisor • Hikma Pharmaceuticals
	Topic TBC	Mr. Michael Faust	Business Consultant • Extedo
	Strengthening Pharma Regulations: Leveraging e-Prescriptions for Industry Advancement	Mr. Mete Karaca	Executive Director • Tiga Healthcare
16:30 - 16:45 Coffee and Networking			
16:45 - 17:30	Session 7: National Regulatory Updates	Moderated by: Dr. Safa' H. Abu Gharbiah	Senior Director Regulatory Affairs • Hikma Pharmaceuticals
	Iraq Regulatory Updates	Speaker TBC	Ministry of Health, Iraq
	Jordan Regulatory Updates	Speaker TBC	Jordan Food & Drug Administration (JFDA)
	Q&A		
17:30	Wrap Up 10th GCC Regulatory Affairs Summit	Visiott	
Gala Dinner to follow at 8pm onwards			