

10th
Edition

www.pramagcc.com | #GCCPharmaSummit

   #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 Speaker TBC	Director of Drug Department • EDE Chairman • GCC Summit 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 - 11:00	Session 2: Futuristic Horizons for Regulatory Affairs	Moderated by: TBC	
	Cell and Gene therapy as advanced medical therapeutic products Fostering Research and Innovation: A Regulatory Perspective Navigating MEA Regulatory Readiness: ATMPs, CAR T Cells, and Gene Therapy Panel Discussion	Speaker TBC Dr. Nadia Younes Dr. Fatima Zaid Abu Zanat	DOH (TBC) Consultant, Drug Regulations and Medical Products • DOH Regional Director of Regulatory Affairs & Scientific Office (META) • Ipsen SFDA
11:00 - 11:30	Coffee & Networking break		
11:30 - 12:30	Session 3: Empowering Local Production: Driving Growth in GCC's Pharmaceutical Manufacturing	Moderated by: TBC	
	Topic TBC Topic TBC Panel Discussion	Speaker TBC Speaker TBC	Spimaco Julphar

12:30 - 13:45	Session 4: Self-Care Products: Navigating Compliance in a Growing Industry	Moderated by: TBC	
	Topic TBC Topic TBC Panel Discussion	Speaker TBC Speaker TBC	Haleon Opella.
13:45 -14:45	Conference Photo, Lunch & Networking		
14:45 - 15:15	Session 5: KSA's Evolving Pharma Regulations: Insights for a Progressive Future	Moderated by: TBC	
		Speaker TBC	Saudi Food and Drug Authority (SFDA)
15:15 - 16:00	Session 6: Ensuring Integrity: The Role of Track & Trace and Serialization in Middle East Pharma	Moderated by: Khaled Rozza	Gulf Regulatory Affairs Lead • Acino
	Topic TBC Fireside Chat AI in Data Analytics for Track & Trace Systems	Görkem Aydin Speaker TBC Mr. Mete Caraca	Marketing Manager • Visiott Evoteq Executive Director • Tiga Healthcare
16:00 - 16:30	Coffee and Networking		
16:30 - 17:15	Session 7: National Regulatory Updates	Moderated by: TBC	
	Kuwait Regulatory Updates Oman Regulatory Updates Bahrain Regulatory Updates	Speaker TBC Dr. Muna Humaid Al Saidi Ms. Samar Salem	MOH Kuwait Head of Registration Section of Human Medicine • Ministry of Health Oman (MoH) Head of Narcotic Drugs & Precursors Control Section • NHRA Bahrain
17:15 - 17:30	Wrap up Day 1 Remarks - Opella.		
17:30	Country Specific Round Table Discussions		
	UAE Oman Bahrain Kuwait Jordan Tunisia EDA Iraq		

10th
Edition

www.pramagcc.com | #GCCPharmaSummit

   #GCCRegulatoryAffairsPharmaSummit



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

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 Speaker TBC Dr. Afrah Husam Hussein	EDA DMP Tunisia Head of registration department • KMCA (Kurdistan)
10:30 - 11:15	Session 2: Pharma Reliance in the GCC: Balancing Imports, Local Production and Future Growth	Moderator TBC	
11:15 - 11:45	Coffee & Networking break		
11:45 - 12:45	Session 3: Clinical Trials Regulations and vision in GCC Cinical trials in Bahrain Regulatory vision and the impact of advanced technologies and resources for Assessing Clinical Studies of Pharmacological Drugs and Medical Devices Topic TBC Cinical trials Regulations in Oman and SQUs Implementation Q&A	Moderated by: TBC Ph. Sumaya Husein Dr. Anees Puthan Veettil Dr. Ahmed AL Khalidi Ph. Hanan Al Habsi	Clinical Trials Regulations Psecialist • NHRA Bahrain Head - Evaluation Unit of Pharmaceutical Studies • EDE (UAE) Director of clinical, efficacy and safety department • SFDA Senior Speciliast Clinical Pharmacist, Head of Clinical Pharmacy and Inpatient Services • Sultan Qaboos Hospital, Oman

12:45 - 13:30	Session 4: Vaccines in Focus: Regulatory Pathways and Access Strategies	Moderated by: TBC	
	Topic TBC	Speaker TBC	Coalition for Epidemic Preparedness Innovations (CEPI)
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	
	Strategy for the Life Cycle Management of Generics	Dr. Safa' H. Abu Gharbiah	Senior Director Regulatory Affairs • Hikma Pharmaceuticals
	Value Added Medicines: New Pathway to Innovation	Mr. Ramzi Sarraj	Regulatory Affairs & PV Director MEA • Société Arabe des Industries Pharmaceutiques (SAIPH)
15:15 - 16:15	Session 6: Revolutionizing Pharma: AI-Driven Digitization and E-Health Advancements	Moderated by: TBC	
	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
	Panel Discussion: Track & Trace: Enhancing Compliance and Visibility in Pharma with AI-Powered Electronic Leaflets		
16:15 - 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			