10th Edition

GCCRA REGULATORY AFFAIRS PHARMA SUMMIT 2025
A Decade of Excellence

10th Edition

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

AGENDA DAY 1: 17 February

08:30 - 09:00 **Opening Ceremony - 10th GCC Regulatory Affairs Pharma Summit**

09:00 - 09:30 **Introduction**

- **Welcome to the 10th GCC Regulatory Affairs Pharma Summit**

  Dr. Mona Al Moussli
  Chairman of GCC Regulatory Affairs Pharma Summit

- **Keynote speaker**

  Dr. Ruqaya Al Bastaki
  Emirates Drug Establishment (EDE)

- **Welcome Remarks - Principal Sponsor**

  Dr. Fokion Sinis
  Head of International Business - SPIMACO

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

Moderated By: **Dr. Ihab Attia**
Regulatory & Strategic Business Partner Director - META HUB
ELI Lilly and Company

- **Highlights on Emirates Drug Establishment**

  Dr. Hanady Yousef Shourrab
  Senior Pharmacist, Drug Department
  Emirates Drug Establishment
  (EDE), UAE

- **Q&A**

AGENDA

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

Moderated By: **Mr. Brian Savoie**
Senior Vice President, Education & International Programs
Regulatory Affairs Professionals Society (RAPS)

- **Fostering Research and Innovation: A Regulatory Perspective**

  Dr. Nadia Younis
  Consultant, Drugs and Medical Products Regulations
  Department of Health Abu Dhabi (DOH)

- **Navigating MEA Regulatory Readiness for Advanced Medicinal Products**

  Dr. Fatima Zaid Abu Zanat
  Regional Director of Regulatory Affairs & Scientific Office
  Middle East, Turkey & Africa – Ipsen

- **Q&A**

10:45 - 11:15 **Coffee & Networking break**

11:15 - 11:50 **Session 3: Panel Discussion: Joining GCC Efforts for a Sustainable Near-shoring of Generics and Biosimilars**

Moderated By: **Dr. Mohamed Larbi Jelassi**
Head of Market Access International – SPIMACO

Panel Discussion:

Dr. Hamada Sherif
Chairman Associate - Egyptian Drug Authority (EDA)

Ph. Muna Al Saidi
Section Head of Registration Section of Human Medicine
Ministry of Health, Oman

Dr. Mohammad Yousuf
MSc Clinical Pharmacy, Pharmacy Department - Sheikh Shakhbout Medical City

AGENDA

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11:50 - 12:30 — **Session 4: Beyond Compliance: Advancing Regulatory-Driven Supply Chains with Digital Transformation and End-to-End Visibility**

Moderated By: **Dr. Supriya Shetty**
Senior Manager Regulatory Affairs

- **From Simple Codes to Smart Supply Chains: The Future of Traceability**

  Mr. Görkem Aydın
  International marketing officer – VISIOTT | TPS

- **Presener**

  Ms. Anna Mansurova
  Managing Director of Hellmann Calipar Healthcare Logistics

Panel Discussion:

Dr. Wael El Sisi
Manager of Pharmaceutical Information Systems Department
Egyptian Drug Authority (EDA)

12:30- 13:15 — **Session 5: Self Care Evolution in the GCC and Beyond**

- **Presenter**

  Mr. Ramez Sawiris
  Head of R&D, MEA - Haleon

Panel Discussion:

Dr. Reem Fada
Director Regulatory Affairs, Gulf & Near East - Haleon GNE

Ph. Noha Allawati
Regulatory Affairs Expert, Drug Control Department, Variation Section
Ministry of Health, Oman

13:15- 13:30 — **Exclusive Industry Insight by - Julphar**

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13:30- 14:30	**Conference Photo, Lunch & Networking**
14:30- 15:15	**Session 6: Empowering Local Production: Driving Growth inGCC's Pharmaceutical Manufacturing**

Moderated By: Dr. Rima Nsheiwat
Regulatory Access and Market Intelligence Consultant

- **Navigating Barriers: Overcoming the Challenges of Biosimilars Localization**

Dr. Rawya Kredly
Director of Medical & Regulatory Affairs - Julphar

Panel Discussion:

Dr. Sawsan Shahin
Regulatory Affairs Specialist, Drug Directorate
Jordan Food and Drug Administration

Dr. Hanan Sboul
Secretary General of the Jordanian Association of Pharmaceutical Manufacturers (JAPM)

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15:15- 16:15 **Session 7: Ensuring Integrity: The Role of Track & Trace and Serialization in Middle East Pharma**

Moderated By: Dr. Marielouise Abi Hanna
Founder and Executive Director - Creaiviti

- **Egyptian Pharmaceutical Track and Trace Project**

  Dr. Wael El Sisi
  Manager of Pharmaceutical Information Systems
  Department Egyptian Drug Authority (EDA)

- **Fireside Chat - Securing Traceability and Transparency: The Application of Traqpharma in Supporting Compliance**

  Mr. Jihad Tayara
  Chief Executive Officer of EVOTEQ

- **Achieving Serialization Excellence in the UAE: A Collaborative Approach to Operational Challenges**

  Mr. Zeeshan Ahmed
  Founder and CEO of CosmoTrace

- **AI in Data Analytics for Track & Trace Systems**

  Mr. Mete Karaca
  executive director
  Tiga Healthcare Technologies

16:15- 16:45 **Coffee and Networking break**

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16:45 - 17:30 Session 8: National Regulatory Updates

Moderated By: **Safa' Abu Gharbiah, PhD.**
Senior Director Regulatory Affairs, MENA
Hikma Pharmaceuticals

- **Jordan Regulatory Updates**

  Dr. Manal Khader
  Senior Regulatory Affairs Specialist
  Jordan Food and Drug Administration

  Dr. Sawsan Shahin
  Regulatory Affairs Specialist, Drug Directorate
  Jordan Food and Drug Administration

- **Kurdistan Regulatory Updates**

  Dr. Afrah Husam Kakai
  Head of Registration Department
  Kurdistan Medical Control Agency (KMCA)

17:30 Country Specific Round Table Discussions

- **UAE**
- **Bahrain**
- **Egypt**
- **Track & Trace and Serialization Exclusive Round Table Discussion**
- **Oman**
- **Jordan**
- **Kurdistan**
- **Self Care Evolution Round Table Discussion**

End of Day 1

AGENDA DAY 2: 18 February

08:30 - 09:15 **Coffee & Networking**

09:15 - 09:30 **Day 2 Opening Remarks**

- **Welcome back**

  Mr. Arda Arat
  General Manager - Haleon GNE

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

Moderated By: **Dr. Fatima Zaid Abu Zanat**
Regional Director of Regulatory Affairs & Scientific Office
Middle East, Turkey & Africa – Ipsen

- **Oman Regulatory Updates**

  Dr. Muna Al Saidi
  Section Head of Registration Section of Human Medicine
  Ministry of Health, Oman

- **Bahrain Regulatory Updates**

  Dr. Shima Altaher
  Pharmacist & Regulatory Affairs Specialist
  National Health Regulatory Authority (NHRA)
  Bahrain

AGENDA DAY 2: 18 February

10:10 - 11:10 **Session 2: 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)

- **Advancing Global Health: CEPI's Role in Regulatory Preparedness and Vaccine R&D Innovation**

  Dr. Alessandro Lazdins
  Regulatory Policy and Intelligence Manager
  Coalition for Epidemic Preparedness Innovations (CEPI)

Panel Discussion:

Dr. Anees Puthan Veettil
Head of Evaluation Unit of Pharmaceutical Studies,
Drug Department - Emirates Drug Establishment (EDE), UAE

Dr. Abeer Althiban
Scientific Evaluation Expert - Infectious and Immunity Section
Saudi Food & Drug Authority (SFDA)

Dr. Rawan I. Aloufi
Laboratory Expert, Vaccines Lab Department, Biologics Executive Department
Saudi Food & Drug Authority (SFDA)

Dr. Reem Mahmoud Eltanahy
Head of Variation Unit for Biological Products – Egyptian Drug Authority (EDA)

11:10 - 11:30 **Coffee and Networking break**

AGENDA DAY 2: 18 February

11:30 - 12:00 Session 3: National Regulatory Updates

Moderated By: Dr. Inas Chehimi
Executive Director, Head of Regulatory and Policy
MEA Region – Novartis

- **Egypt Regulatory Updates**

  Dr. Hamada Sherif
  Head of Variation Unit for Biological Products
  Egyptian Drug Authority (EDA)

- **Q&A**

12:00 - 13:00 Session 4: Biologics & Biosimilars: Redefining Regulatory Pathways and Advancing Access

Moderated By: Dr. Rasha El Masry
Head Of Regulatory Affairs for Gulf - Merck

- **Biologics regulations in the Egyptian Drug Authority**

  Dr. Reem Mahmoud Eltanahy
  Head of Variation Unit for Biological Products
  Egyptian Drug Authority (EDA)

- **Streamlining Biosimilar Development and Approval**

  Mr. Varma Bhupathiraju
  Associate Vice President - Regulatory Affairs
  Biocon Biologics

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Panel Discussion:

Navigating Regulatory Challenges in Life Cycle Management - A Global Approach to Product Harmonization

Ms. Shruthi Shankar
Senior Manager, Global Regulatory Affairs - Biocon Biologics

13:00 - 14:00 **Lunch & Networking**

14:00 - 14:40 **Session 5: Clinical Trials Regulations and Vision in GCC**

Moderated By: Dr. Rima Nsheiwat
Regulatory Access and Market I ntelligence Consultant

- **Regulatory Vision and Role of EDE in Clinical Trials**

  Dr. Anees Puthan Veettil
  Head of Evaluation Unit of Pharmaceutical Studies,
  Drug Department - Emirates Drug Establishment (EDE), UAE

- **Cinical trials Regulations in Oman and SQUs Implementation**

  Ph. Hanan Salim Al-Habsi
  Senior Speciliast Clinical Pharmacist, Head of Clinical Pharmacy and Inpatient Services

- **Q&A**

AGENDA DAY 2: 18 February

14:40 - 15:15 **Session 6: 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

- **Generics: From Regulatory Challenges to Market Barriers**

  Dr. Abla M. Hijazi
  Associate Director, Regulatory Affairs, MENA
  Hikma Pharmaceuticals

Panel Discussion:

Dr. Sawsan Shahin
Regulatory Affairs Specialist, Drug Directorate
Jordan Food and Drug Administration

15:14 - 15:45 **Coffee and Networking**

AGENDA DAY 2: 18 February

15:45 - 17:00 **Session 7: Revolutionizing Pharma: AI-Driven Digitization and E-Health Advancements**

Moderated By: **Dr. Deema Musa**
Regional Regulatory Affairs Manager - META, Acino

- **The Role of Generative AI in Shaping the Pharmaceutical Sector**

  Eng. Nusaibah Aljaloudi
  Founder & CEO of Pi Pharma Intelligence

- **Fast, Smart, Compliant: The Future of Global Drug Regulation**

  Mr. Michael Faust
  RCC Business Consultant - EXTEDO

- **Strengthening Pharma Regulations: Leveraging e-Prescriptions for Industry Advancement**

  Mr. Mete Karaca
  Executive Director
  Tiga Healthcare Technologies

- **Revolutionizing Compliance: Digital transformation in Labeling**

  Dr. Shatha Safi
  RA Planning and Labelling Manager
  Hikma Pharmaceuticals

AGENDA DAY 2: 18 February

17:00 - 17:40 **Session 8: Revolutionizing Compliance: Digital transformation in Labeling**

Moderated By: **Dr. Mohamed Salem**
Manager - Regulatory Affairs
International Region, Sanofi

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

  Dr. Dalia Fouad
  Head of Regulatory Affairs, Greater Gulf
  Global Regulatory Affairs - Sanofi

- **Revolutionizing the Pharmaceutical Industry: The Impact of Smart Portals on Metadata Sharing, Automation, and Efficiency**

  MS. Madelein Terblanche
  Senior Operations Consultant
  VECTOR Life Sciences

- **Q&A**

17:45 **Wrap Up 10th GCC Reguatory Affairs Summit** **Visiott**