10th Edition

# GCCRA

REGULATORY AFFAIRS
PHARMA SUMMIT 2025

A Decade of Excellence


## 17 - 21 February 2025

Mövenpick Grand Al Bustan - Dubai, UAE

GCC
REGULATORY AFFAIRS
PHARMA SUMMIT

17 - 18 February 2025

GCCPV
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TRAINING

19 - 20 February 2025

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# Founders' Message 2025

## Dr.Mona Al Moussli

**Chairman of GCC Regulatory Affairs Pharma Summit**

### A Decade of Knowledge & Collaboration

**Ten** years ago, the GCC Regulatory Affairs Pharma Summit began with a vision: to unite regulatory professionals in shaping the future of healthcare.Today, it stands as a pillar of progress, fostering collaboration, innovation, and patient safety.
This summit has been a catalyst for meaningful dialogue and industry growth, empowering leaders to navigate an evolving pharmaceutical landscape.
As we celebrate this milestone, I am grateful for our community's dedication and proud of our shared achievements.

The future holds limitless possibilities. Together, we will continue driving regulatory excellence and advancing healthcare in the GCC.

## Dr.Najiba Al Shezawy

**Co- Chairman of the GCC Regulatory Affairs Pharma Summit**

### Commitment to Compliance & Patient Safety

**Regulatory** compliance is not just a requirement—it is a responsibility that safeguards patient well-being and strengthens the integrity of the pharmaceutical industry. Over the past decade, the GCC Regulatory Affairs Pharma Summit has played a pivotal role in guiding, educating, and aligning industry professionals with the highest regulatory standards.

Strict adherence to regulations ensures that medicines reaching the market are safe, effective, and of the highest quality. It builds trust between healthcare providers, regulators, and patients, reinforcing the credibility of the entire system. Compliance is not about restrictions; it is about accountability, ethical commitment, and a shared goal of excellence.

As we celebrate 10 years of regulatory advancements, we reaffirm our dedication to supporting the industry, driving innovation within compliance frameworks, and continuously raising the bar for pharmaceutical regulations in the GCC. Our journey continues, with a clear mission—to uphold the highest standards and ensure that regulatory excellence remains at the heart of everything we do.

# We Are SPIMACO

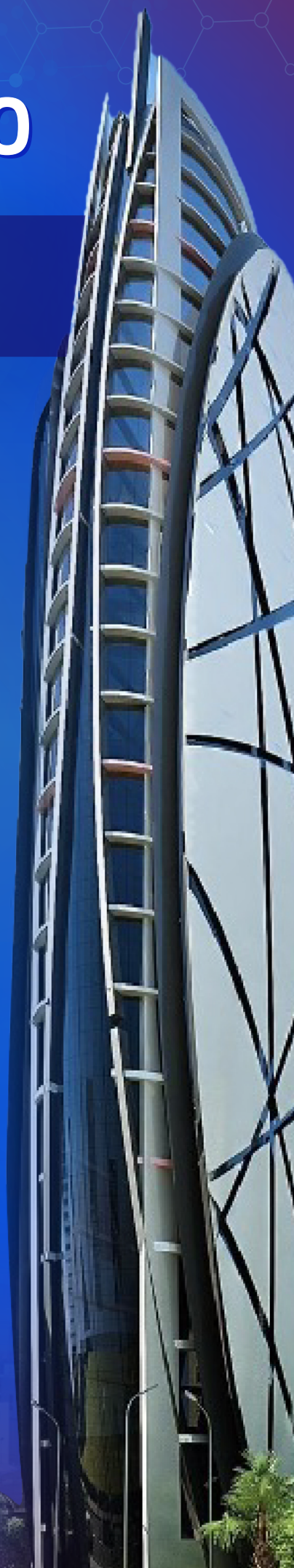
**SPIMACO** is the leading vertically-integrated pharmaceutical manufacturer in Saudi Arabia.

With **five manufacturing plants** and a network of regional affiliates and multinational partnerships, SPIMACO has created an unrivalled footprint across the MENA Region.

We offer an extensive portfolio of pharmaceutical products, covering a wide range of therapeutic areas, including **oral, injectable medicines, sterile products, high potent medications & Biosimilars.**

SPIMACO is **committed** to increasing access to healthcare, improving the quality of life of patients, and supporting the communities where it operates.

- **No.1 Private Market Leader** in Saudi Arabia
- **High-Potent** Manufacturing Facility
- Over **1,200** Employees
- Over **2 Billion** Units Manufaturing Capacity Per Annum
- **5 Manufacturing** Facilities
- Presence in **16 Countries**
- **Active Pharmaceutical Ingredient (API)** Manufacturing Facility
- **State-of-the-art Research & Development** for complex products development



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# 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**

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# AGENDA

## DAY 1: 17 February

**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

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Fellow (FRAPS)
RAPS Convergence Speaker

**GRANT GRIFFIN**
Individual Member
Fellow (FRAPS)
Education Committee
Membership Committee
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# AGENDA

## DAY 1: 17 February

**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**

# AGENDA DAY 1: 17 February

| | |
|---|---|
| 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

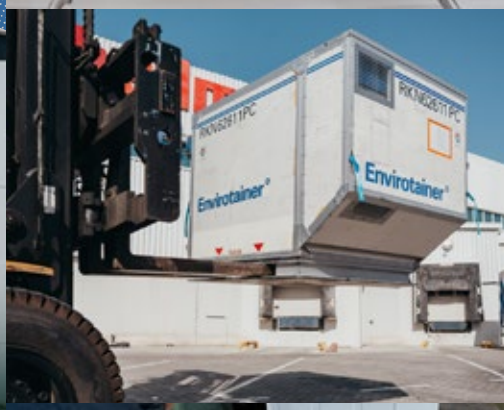
- **Navigating Barriers: Overcoming the Challenges of Biosimilars Localization**

**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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Empowering

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employees

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Leading through **innovation,**
**caring** with compassion


## Our Values

To become a leading pharmaceutical company, internationally recognized for innovation

**Leadership, Collaboration, Compassion, Integrity, Respect, Innovation**

# AGENDA DAY 1: 17 February

**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**

# AGENDA DAY 1: 17 February

## 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**

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# 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**

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# 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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At Biocon Biologics, **'Enabling Equitable Access to Biosimilars Across the World'** is more than just a goal—it's a core commitment that embodies our values as a company. As a fully integrated global leader in biosimilars, we harness our 'lab-to-market' expertise to meet the increasing demand for affordable, high-quality biosimilars in over 120 countries.

By staying true to our promise of accessibility, affordability, availability, and assurance, Biocon Biologics is not only transforming healthcare, but also positively impacting the lives of millions of patients worldwide.

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|---|---|---|---|---|
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- Facilitate rapid recalls
- Prevent sales of expired medicine

traqpharma is not just a tracking solution; it's our commitment to a future where every dose is secure, every chain is transparent, and every patient is well protected.

Discover more at www.evoteq.com

## Contact us:

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# AGENDA DAY 2: 18 February

**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**

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# 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

Inspire Pharma is a dynamic pharmaceutical consultancy dedicated to helping businesses succeed in a complex and highly regulated industry. We deliver tailored solutions that address the unique needs of each client, ensuring global regulatory compliance while maximizing operational efficiency. Our team brings extensive experience working with pharmaceutical companies across APAC, EMEA, and the USA, providing invaluable global expertise and strategic support to drive your business forward.

## Services Overview

We offer a wide range of pharmaceutical consulting services designed to meet the diverse needs of our clients.

Ensuring patient safety and product efficacy through dedicated pharmacovigilance services by actively monitoring and assessing safety data throughout the product life cycle.

## Our key services include:

- Safety Reports Management
- Clinical Trials Safety Management
- Clinical Trial Plans Writing
- Literature Monitoring
- PSUR/DSUR Writing
- Risk Management Plan Development
- PV System Gap Analysis
- Regulatory compliance
- Quality Assurance
- Training & Mentorship

## Contact Us

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- e-Prescription
- Hospital Information System
- Personal Health Record
- Population Health Management
- Healthcare Interoperability
- Health Information Exchange
- AI & Analytics

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# 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**