



# DIA

## Middle East Regulatory Conference

21-22 November 2017

Millennium Hotel and Convention Centre Kuwait

### OVERVIEW

DIA provides the unique platform in the Middle East of **connecting experts** in the region for **collaborative discussion**.

Every country throughout the Middle East region is formulating improved regulations for pharmaceutical and biopharmaceutical development. What can we all learn from each other?

New - read insights from the Region:

Lebanon: <http://engage.diaglobal.org/Interview-01.html>

Jordan: [http://engage.diaglobal.org/EMEA\\_ME\\_2017-05-03.html](http://engage.diaglobal.org/EMEA_ME_2017-05-03.html)

Iraq: [http://engage.diaglobal.org/EMEA\\_ME\\_2017\\_06\\_08.html](http://engage.diaglobal.org/EMEA_ME_2017_06_08.html)

Egypt: [http://engage.diaglobal.org/EMEA\\_ME\\_07\\_12.html](http://engage.diaglobal.org/EMEA_ME_07_12.html)

The 12th DIA Middle East Regulatory Conference (MERC), in partnership with the EFPIA Middle East Regulatory Network (MERN), is built on the premise that collaboration leads to more efficient regulatory system that sustains patient access. This conference, growing in scale every year, brings together health authorities and global stakeholders from across the region and Europe. The conference will discuss country-level progress and challenges, as well as opportunities for increased regional collaboration.

### ARE YOU READY TO COLLABORATE?

Top 3 Reasons to Attend the 2017 MERC:

1. Collaborate with Health Authorities from many different countries – Don't miss this chance to get exposure to the future of health policy in the region
2. Connect with 300+ participants, representing 27 countries from health authorities and pharmaceutical industry, throughout the Middle East, Europe and globally
3. Establish leading strategies and processes for getting innovative medicines to patients faster

### HEALTH AUTHORITY ADVISORS

**Dr Sarah Maqseed**, KFDC , Kuwait

**Dr Donia Al Bastaki**, KFDC , Kuwait

**Dr Hassaan Alwohaibi**, SFDA , Saudi Arabia

**Dr Ahlam Abdelaziz**, JFDA, Jordan

### MERN REPRESENTATIVES

**Greg Jordinson**

EFPIA Middle East Regulatory Network Chairperson  
Janssen R&D, United Kingdom

**Nadine Otin**

LEEM, France

**Marloes van Bruggen**

F. Hoffmann-La Roche Ltd., Switzerland

**Paul Dearden**

AbbVie, United Kingdom

**Kerstin Ahrendt-Sölter**

Biotest AG, Germany

**Hany Gamal**

Boehringer Ingelheim, United Arab Emirates

**Inas Chehimi**

Novartis Pharma Services AG, United Arab Emirates

### LOCAL NETWORK CHAIRS

**Adele Choueiry**

Regulatory Working Group Chair, Novartis, Lebanon

**Mounay Khafaja**

Iraqi Regulatory Working Group Chair, Merck, Iraq

**Haitham Al-Zuhair**

Representative of Saudi Arabia Regulatory Working Group, Janssen-Cilag, Saudi Arabia

**Samia Farhan**

Egypt Regulatory Affairs Working Group Chair  
Abbvie, Egypt

**Ihab Al-Attia**

Gulf Regulatory Affairs Working Group Chair  
Eli Lilly Suisse S.A., United Arab Emirates

**Tamara Al Rabi**

LEVANT Jordan Pharma lead  
Pfizer, Jordan



# Middle East Regulatory Conference

## WHO WILL YOU MEET?

- Regulatory agencies and ministries of health in the region, experts from international organisations
- Thought leaders, global and local stakeholders from both local and multinational pharmaceutical companies who are working in the fields of
  - Regulatory affairs, Policy, Government Affairs, Access
  - Pharmacovigilance

To get a feel for the conference [view the final programme](#) from the 2015 MERC

## KEY TOPICS

- Good Regulatory Practice
- Expedited Pathways
- Life Cycle Management
- Pharmacovigilance
- Barcoding & Serialisation
- Innovation

## HANDS-ON WORKSHOPS

- eCTD
- Pharmacovigilance
- Biosimilars

## WHO SHOULD ATTEND?

The conference offers the opportunity for key stakeholders active or interested in this diverse and changing region, including representatives from regulatory agencies, ministries of health, local and multi-national pharmaceutical companies, to meet to exchange views, discuss topics of interest and identify actions to increase patient access to new and improved medicines and therapies:

- Regulatory Affairs Heads / Officers / Directors / Managers / Specialists
- Scientific Office Managers
- Registration Managers
- Pharmacists
- Patient Safety Managers / Officers
- Drug Safety & Quality Assurance Directors / Managers
- Heads of Market Access

## FOR VISA INFORMATION:

1. Participants with European passports and GCC residents can obtain their e-Visa online [https://evisa.moi.gov.kw/evisa/home\\_e.do](https://evisa.moi.gov.kw/evisa/home_e.do) and collect it upon arrival at Kuwait Airport. 3 KWD in cash is required for the visa issuance at the airport.
2. Nationals of other countries, kindly submit the copy of your passport together with the registration form or afterwards if registered online. In order to obtain visa on time, the passport should be submitted by 15 October latest.

Kindly contact Isabelle Nguyen for questions at [isabelle.nguyen@diaglobal.org](mailto:isabelle.nguyen@diaglobal.org)

## DISCLOSURE

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.



# Middle East Regulatory Conference

## | DAY ONE | TUESDAY, 21 NOVEMBER

07:30 REGISTRATION AND WELCOME REFRESHMENTS

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08:30 OPENING OF THE CONFERENCE

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Representative of the Ministry of Health, Kuwait

**Greg Jordinson**, EFPIA MERN Chairperson, Associate Director, Global Regulatory Affairs, Janssen R&D, United Kingdom

**Inka Heikkinen**, Head of Scientific Content Development, DIA Europe, Middle East and Africa

09:00 BREAK

09:30 SESSION 1, PART 1

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### GOOD REGULATORY PRACTICE

Session Chair: **Paul Dearden**, Head of Emerging Markets, Regulatory Policy & Intelligence, AbbVie, United Kingdom

Patients are demanding faster access to new medicines, especially in areas of high unmet medical need, ineffective and inefficient regulatory systems can be a barrier to access to safe, quality medical products. This session focuses on the key principles in regulatory systems (good regulatory practices) to provide sufficient flexibility to enable innovation and ensure agencies' resources are efficiently utilised.

Speakers will describe related international guidances and regulators will share their experiences implementing good regulatory practices and optimised registration procedures. Finally, interactive panel discussions will address the question "can we do more to improve systems and align with these principles?"

#### Update on Global Developments Regarding Good Regulatory Practices and Collaborative Procedures

**Stuart Walker**, Centre for Innovative Regulatory Science, UK

#### Industry Perspective on Reliance & Expedited Pathways in Emerging Markets

**Inas Chehimi**, Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates

### OPTIMISING REVIEW PROCESSES

#### Examples from SFDA, JFDA and EDA on Verification and Abridged Registration Procedures

**Bandar Al Hammad**, Director of Benefit-Risk Assessment Department, Executive directorate of Pharmacovigilance, Drug Sector, SFDA, Saudi Arabia

**Rasha Zeyada**, President, Pharmaceutical Affairs Directorate, Egyptian Drug Authority, Egypt

**Dr Ghadeer Sheik Salem**, Regulatory Affairs Specialist, JFDA, Jordan

#### Gulf Health Council Central Registration - a new Beginning

**Hajed Hashan**, Deputy of General Director, Gulf Health Council

11:00 BREAK

11:30 SESSION 1, PART 2 - PANEL DISCUSSION

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#### Stakeholders' Experience Regarding Reliance Procedures

Panelists:

All speakers

12:15 LUNCH

13:45 SESSION 1, PART 3

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### MEETING THE UNMET NEED OF THE PATIENTS

#### A view from Europe – Successes and Challenges of Early Access Tools

**Tomas Salmonson**, EMA CHMP Chair, Senior Assessor, Swedish Medicines Agency, Sweden

14:30 SESSION 1, PART 4 - PANEL DISCUSSION

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Panelists:

**Dr. Donia Al Bastaki**, Head of Registration Department, Pharmaceutical and Herbal Medicines Registration and Control Administration, Drug and Food Control, Ministry of Health, Kuwait

**Inas Chehimi**, Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates

**Stuart Walker**, Centre for Innovative Regulatory Science, UK



# Middle East Regulatory Conference

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15:00 SESSION 2

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## LIFE CYCLE MANAGEMENT

Session Chair: **Sylvie Meillerais**, Director Global Regulatory Policy, MSD Europe, Belgium

Post-approval changes (PAC) to the registered information of authorised medicinal products are introduced routinely worldwide to enhance the robustness and efficiency of the manufacturing process; improve quality control techniques; respond to changes in regulatory requirements; and upgrade to state-of-the-art facilities. The regulatory landscape for PAC varies dramatically across health authorities globally, also within the Middle East region countries have variable regulations with regard to requirements and approval timelines for changes. Implementing simple changes globally can take up to 5 years. There is a need to globally harmonize the post approval regulations to ensure continuous supply of high quality, compliant drugs to patients globally with a flexible supply chain. ICH and WHO are taking a leading role to establish key concepts that can be leveraged globally to drive global regulatory convergence regarding regulatory requirements for PACs. The session will explore the current landscape for PACs globally and specifically in ME, the challenges being faced and recommendations for improvement.

### EFPIA Position Papers on Life Cycle Management (CMC, Safety Labelling)

**Susanne Ausborn**, EFPIA CMC Working Group member, Head Regulatory Policy & International Operations EMEA, Hoffmann-La Roche, Switzerland

### ICH Q12 Guideline

**Frank Montgomery**, ICH Working group member, Global Head, Regulatory CMC, AstraZeneca, UK

### Questions and Answers

16:15 BREAK

16:45 SESSION 3

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## RAPID FIRE SESSION - DEVELOPMENTS WITHIN THE REGION

Moderator: Dr. **Donia Al Bastaki**, Head of Registration Department, Pharmaceutical and Herbal Medicines Registration and Control Administration, Drug and Food Control, Ministry of Health, Kuwait

The session will give floor to authorities in the region to present the recent developments and updates in their country as a rapid update.

Presentations will focus on life cycle management.

### Developments in Kuwait

**Dr Donia Al Bastaki**, Head of Registration Department, Pharmaceutical and Herbal Medicines Registration and Control Administration, Drug and Food Control, Ministry of Health, Kuwait

### Developments in UAE

**Ihab Attia**, Regulatory Director - Middle East Affiliate, Eli Lilly Suisse S.A., United Arab Emirates - Gulf Regulatory Affairs Working Group (RAWG) Chair

### Developments in Jordan

**Dr Ahlam Abdelaziz**, Head of Generic Unit, Senior Registration Affairs Pharmacist, Drug Registration Department/ Drug Directorate, JFDA, Jordan

### Developments in Oman

Oman Ministry of Health representative invited

### Developments in Saudi Arabia

SFDA representative invited

17:45 NETWORKING RECEPTION

18:45 END OF DAY ONE

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# Middle East Regulatory Conference

## | DAY TWO | WEDNESDAY, 22 NOVEMBER

### *Looking into the future and laying the path forward*

08:30 REGISTRATION AND WELCOME REFRESHMENTS

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09:00 SESSION 4

#### PHARMACOVIGILANCE

Session Chair: **Magnus Ekelo**, Pharmacovigilance Officer, Uppsala Monitoring Centre, World Health Organisation

Topics to be addressed and discussed:

- The implications, differences in terms of implementation in the region
  - what are the benefits from this legislation – Health Authority perspective
  - opinion sharing on harmonisation
  - reflection on and benefits of the new Pharmacovigilance legislation – Health Authority perspective
  - Pharmacovigilance Rest of World group – overlap between systems and data

#### Common Arab guidance – updates

**Prof. Amr Saad**, Professor, Founder of The Egyptian Pharmacovigilance Center (EPVC) & Former Associate Minister of Health for Pharmaceutical Affairs, Egypt

#### Regional implementation – Trends and challenges for future

**Dr Reem Al-Essa**, Senior Pharmacy Specialist, Drug Inspection Administration, Drug and Food Control, Ministry of Health, Kuwait

#### Pharmacovigilance in the rest of the world

**Esteban Herrero-Martinez**, Director, Regulatory Policy & Intelligence, Abbvie, United Kingdom

Panel discussion

10:30 BREAK

11:00 SESSION 5

#### BARCODING/SERIALISATION

Session Chairs: **Hany Gamal**, Regional Drug Regulatory Affairs Head, Middle East, Turkey & Africa, Boehringer Ingelheim, United Arab Emirates

**Adele Choueiry**, Regulatory Affairs Head, GDD | LEVANT, Novartis Pharma Services Inc.,

The ME countries are implementing barcoding and serialisation in different ways for different reasons, why are they doing this and what do they want from such implementation?

What are the practical implications for industry, how can industry pro-actively work with regulators to converge on mutually acceptable targets. Wider impacts to payers. New regulations in almost all countries, GS1 to talk about standardization, learnings from countries who have implemented it.

#### Global standards for barcoding & serialisation

**Geraldine Lissalde Bonnet**, Director Public Policy, GS1, Belgium

#### EFPIA expert group

**Dirk Van Den Wouwer**, Serialisation Business Senior Manager, Janssen Pharmaceutical companies of J&J, Belgium

#### Example of implementation from Jordan

**Dr Ahlam Abdelaziz**, Head of Generics, Drug Registration Department/ Drug Directorate, JFDA, Jordan

#### Example of implementation from Saudi Arabia

**Dr Abdullah Fahad Al-Meshal**, Director of Drug Informatics Department, Drug Sector, SFDA, Saudi Arabia

#### Example of implementation from Egypt

**Dr Yasin Afify**, Head of Technical Office, Central Administration for Pharmaceutical Affairs, Egyptian Drug Authority, Egypt

#### Questions & Answers

All speakers

**Dr Lina Abou Mrad**, National E-health Program Director, Ministry of Health, Lebanon

12:30 LUNCH



# Middle East Regulatory Conference

13:40 SESSION 6

## PARALLEL WORKSHOPS

### WORKSHOP 1

#### eCTD

Moderators:

**Alastair Nixon**, Director, Publishing, GSK, UK  
**Dr Hajed Hashan**, Deputy of General Director, Gulf Health Council, Saudi Arabia

Workshop overview

- Benefits and pitfalls of the implementation process; problems that have arisen during the implementation.
- Validation issue and interoperability of the systems
- How to keep the life cycle ongoing (too many sequences ongoing unless aligned)

### WORKSHOP 2

#### PHARMACOVIGILANCE

Moderator:

**Dr Sarah Maqseed**, Registration and Release Superintendent, Pharmaceutical and Herbal Registration and Control Administration, Kuwait Ministry of Health

Workshop overview

The workshop will invited pharmacovigilance authorities to work together on capacity building in the region.

The workshop will touch upon:

- Experience in benefit/risk assessment
- Basis for decision making
- Data utilisation
- Use of case examples

### WORKSHOP 3

#### CASE STUDIES OF BIOSIMILARS

Moderator:

**Dr Mai Allam**, Technical Manager, National Organization for Research & Control of Biologicals, Egypt

Workshop overview

This sessions starts with a brief re-cap on how to assess biosimilar dossiers and the key steps in the development of these type of products. Thereafter, we will make it more concrete, by jointly reviewing some case examples of biosimilar applications. We will review the data packages of these 'hypothetical cases' and discuss whether or not the data presented is sufficient to conclude biosimilarity. If not, we will discuss what should be done differently, to be able to draw a conclusion on biosimilarity.

14:40 BREAK

15:15 SESSION 7

## INNOVATION IN THE PHARMACEUTICAL SECTOR

Session Moderator: **Inas Chehimi**, Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates

Topic Leads: **Nadine Otin**, Consultant for Regulatory Affairs & Market Access, LEEM, France

**Inas Chehimi**, Head DRA Middle East & North Africa, Novartis Pharma Services AG, United Arab Emirates

This session will present the value of innovation from different perspectives:

- Discuss the value of innovative medicines based on new studies done in countries around the world, including emerging market and EEMEA countries (patient quality of life, cost effectiveness, disease burden management/hospitalisation, social impact, competitiveness ).
- Present how the regulatory environment operates as a central pillar in any country's competitiveness, a critical element of success if Middle East countries want to get into the P-20 or be more competitive and successful in the healthcare sector.
- Experience from the region in the RWE ( Real Word Evidence)

### Value of Innovation

**Frank Lichtenberg**, Courtney C. Brown Professor of Business, Columbia University, United States

### Competitiveness, innovation and investment

**Jeffrey P. Kemprecos**, Executive Director Emerging Markets Public Policy, MSD, United Arab Emirates

### Panel discussion

All speakers

**Dr Hend al-Hussiany**, Head, Egyptian Drug Information Centre, Egypt

**Dr Hajed Hassan**, Deputy of General Director, Gulf Health Council, Saudi Arabia

17:00 WRAP-UP OF BREAKOUT SESSIONS AND CLOSING REMARKS

**Greg Jordinson**, EFPIA MERN Chairperson, Associate Director, Global Regulatory Affairs, Janssen R&D, United Kingdom

17:30 END OF CONFERENCE





# Middle East Regulatory Conference

## CONFERENCE VENUE

### Millennium Hotel & Convention Centre Kuwait

4th Ring Road, Salmiya, Abou Thar Al Ghafari  
St Safat 13154, Kuwait  
Kuwait 29370 Kuwait City  
Tel 00965 2205 0505

Website: [www.millenniumhotels.com/en/kuwait-city/millennium-hotel-and-convention-centre-kuwait/](http://www.millenniumhotels.com/en/kuwait-city/millennium-hotel-and-convention-centre-kuwait/)

[DIA-Europe/](#)

## CONTINUING EDUCATION

### SwAPP Credits

DIA meetings and training courses are approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) and are honoured with credits for pharmaceutical medicine. All meeting and training course participants are eligible for applicable credits.

This conference has been accredited with 12.25 credits.

## EVALUATION

We value your feedback on the content and organisation of this conference. The electronic survey will be sent to you after the conference via email.

## ACCESS PRESENTATIONS

As a benefit of your registration, presentations are made available on [www.diaglobal.org](http://www.diaglobal.org).

- Presentations are made available to full conference attendees only (Attendee, Exhibitor, Speaker, and Press badges).
- To access presentations, go to My Presentation Downloads and log in when prompted
- No paper copies of the presentations will be provided

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with their presentation. Updated versions of the slides will be made available shortly after the conference.  
NOTE: You will need to enter your DIA User ID and password to verify your status. If you have forgotten your DIA User ID and password, use our Login Reminder.

In My Presentation Downloads you will see presentation PDFs from all the DIA offerings you have attended in the past 6 months. Simply choose the presentation you would like to view or download.

## CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be provided onsite to pre-registered attendees. Those who registered onsite will receive it electronically after the conference. Please note certification requires full attendance. For more information please liaise with our DIA Contact Centre on [Basel@DIAGlobal.org](mailto:Basel@DIAGlobal.org) or call +41 61 225 51 51.

## ABOUT DIA

DIA is the global connector in the life sciences product development process. Our association of thousands of members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

SAVE THE DATE

# DIA

## 1<sup>st</sup> Regional Conference on Regulatory Harmonisation

27-28 February 2018  
Casablanca, Morocco

The aim of the conference is to bring together key stakeholders and to discuss ways of improving access to medicines and therapies for the citizens and patients in the Region.

The conference will serve as an international and neutral forum for attendees to discuss how the countries can play a leadership role in drug development.

Find out more at [www.DIAGlobal.org](http://www.DIAGlobal.org)

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