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
Iraq: http://engage.diaglobal.org/EMEA_ME_2017_06_08.html
Egypt: 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

Sarah Maqseed, KFDA , Kuwait

Donia Al Bastaki, KFDA , Kuwait

Hassaan Alwohaibi, SFDA , Saudi Arabia

Ahlam Abdelaziz, JFDA, Jordan

MERN REPRESENTATIVES

Greg Jordinson
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,
Janssen Pharmaceutical companies of J&J, 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

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 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

Middle East Regulatory Conference

DAY ONE I TUESDAY, 21 NOVEMBER

07:30 REGISTRATION AND WELCOME REFRESHMENTS

08:30 OPENING OF THE CONFERENCE

Minister of Health Kuwait

Holger Adelmann, Senior Vice President & Managing Director, DIA EMEA

Greg Jordinson, MERN Chairperson

09:00 BREAK

09:30 SESSION 1

GOOD REGULATORY PRACTICE

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

Topic leads: **Marloes van Bruggen**, Regulatory Program Manager, F. Hoffmann-La Roche Ltd., Switzerland
Hany Gamal, Regional Drug Regulatory Affairs Head, Middle East, Turkey & Africa, Boehringer Ingelheim, United Arab Emirates

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?"

WHO Update on Good Regulatory Practices with a Focus on Collaborative Procedures
WHO Representative invited

Industry Perspective on Reliance & Expedited Pathways in Emerging Markets
Marloes van Bruggen, Regulatory Program Manager, F. Hoffmann-La Roche Ltd., Switzerland

OPTIMISING REVIEW PROCESSES

Examples from SFDA and EDA on Verification and Abridged Registration Procedures
SFDA representative invited
EDA representative invited

Future of GCC's Joint Registration Procedure – any Changes Foreseen?
Hajed Hashan, Deputy of General Director. Gulf Health Council, Gulf Health Council

11:00 REFRESHMENT BREAK

11:30 SESSION 1 CONTINUED - PANEL DISCUSSION

Panel discussion 1: Stakeholders Experience Regarding Reliance Procedures

Panelists:
All speakers
JFDA representative invited
Stuart Walker, CIRS

12:15 LUNCH

13:45 SESSION 1 CONTINUED

MEETING THE UNMET NEED OF THE PATIENTS

Patient View on the Availability of Medicinal Products and the Role of Stakeholders Involved
Local patient representative invited

A view from Europe – Successes and Challenges of Early Access Tools
Tomas Salmonson, EMA CHMP Chair, Senior Assessor, Swedish Medicines Agency, Sweden

14:30 PANEL DISCUSSION ABOUT FACILITATED REGULATORY PATHWAYS & GOOD REGULATORY PRACTICE

Panelists:
All speakers
KFDC representative invited
EFPIA representative – Marloes van Bruggen , Regulatory Program Manager, F. Hoffmann-La Roche Ltd., Switzerland

15:00 SESSION 2

LIFE CYCLE MANAGEMENT

Topic leads: **Marloes van Bruggen,** Regulatory Program Manager, F. Hoffmann-La Roche, Switzerland
Mounay Khafaja, Regulatory Affairs Director &
Regulatory Center of Excellence, Iraqi Regulatory Working Group Chair, Merck, Iraq

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, Head Regulatory Policy & International Operations EEMEA, Hoffmann-La Roche, Switzerland

WHO Draft Guideline on Post-Authorisation Change
WHO Representative invited

ICH Q12 Guideline
Frank Montgomery, Global Head, Regulatory CMC, AstraZeneca, UK

16:15 REFRESHMENT BREAK

16:45 RAPID FIRE SESSION - DEVELOPMENTS WITHIN THE REGION

Moderator: **Donia Al Bastaki**, KFDC

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.

17:45 NETWORKING RECEPTION

18:45 END OF DAY ONE

Middle East Regulatory Conference

DAY TWO | WEDNESDAY, 22 NOVEMBER

Looking into the future and laying the path forward

08:30 REGISTRATION AND WELCOME REFRESHMENTS

09:00 SESSION 4

PHARMACOVIGILANCE

Session Chair: **Raj Long**, Gates Foundation

Topic lead: **Greg Jordinson**, Regulatory Manager, Global Regulatory Affairs, Janssen R&D, United Kingdom

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
Professor Amr Saad, 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, KFDC, Kuwait

Pharmacovigilance in the rest of the world
Esteban Herrero-Martinez, Director, Regulatory Policy & Intelligence, Abbvie, United Kingdom

Panel discussion

10:30 REFRESHMENT BREAK

11:00 SESSION 5

BARCODING/SERIALISATION

Topic leads: **Hany Gamal,** Regional Drug Regulatory Affairs Head, Middle East, Turkey & Africa, Boehringer Ingelheim, United Arab Emirates
Adele Choueiry, Regional Regulatory Affairs Senior Manager - Near East, Maghreb and Africa region, Lebanese Regulatory Working Group Chair, Janssen Pharmaceutical companies of J&J, Lebanon

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
GS1 representative invited

EFPIA expert group
EFPIA Representative invited

Example of implementation from Turkey
Government representative invited

Example of implementation from Saudi Arabia
Government representative invited

Example of implementation from Iran
Government representative invited

Questions & Answers
Iranian authority invited to participate in the discussion

12:30 LUNCH

13:40 SESSION 6

PARALLEL WORKSHOPS

WORKSHOP 1

ECTD

Topic leads:
Greg Jordinson
Regulatory Manager, Global Regulatory Affairs, Janssen R&D, United Kingdom

Kerstin Ahrendt-Sölter
Senior Director Corporate Regulatory Affairs International, Biotest AG, Germany

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 (regulators only)

Topic lead:
Sarah Al Maqseed, Ministry of Health, Kuwait

Workshop overview
The workshop will invited pharmacovigilance authorities to work together on capacity building in the region. A European regulator will be invited to lead the workshop.

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

Topic lead:
Marloes van Bruggen, Regulatory Program Manager, F. Hoffmann-La Roche Ltd., Switzerland

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 REFRESHMENT BREAK

15:00 SESSION 7

INNOVATION IN THE PHARMACEUTICAL SECTOR

Topic leads: **Inas Chehimi,** Head DRA Middle East & North Africa Novartis Pharma Services AG, United Arab Emirates
Nadine Otin, LEEM, France

This session will present the future of innovative medicine and its value from different perspectives:

- The innovation in development of new therapies, real world evidence (RWE), novel endpoints (with regard to the development of oncology, neuroscience and diabetes, novel study designs) and benefits of the changes and cooperation between industry and regulators to regulate it;
- Sharing a global overview of the research pipeline and provide more insights about what will come next, highlighting clearly the critical role of an efficient regulatory environment;
- Discuss the value of innovation in the emerging market (patient quality of life, cost effectiveness, disease burden management/hospitalisation, social impact, competitiveness, etc).

Introduction to the Topic
Holger Adelmann, Senior Vice President and Managing Director, DIA EMEA

Trends in R&D – What is Coming in the Future?
Industry representative invited

Value of Innovation
Representative invited

Global Research Picture and New Medicines in the Pipeline
Industry representative invited

Panel discussion
All speakers

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

Greg Jordinson, MERN Chair

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/

A limited number of rooms are available at a special DIA rate.
Reservation cut-off date is: 19th October 2017

Standard Room	Single KD 60.500 / Double KD 70.500 (subject to 15 % service charge) Check in: 2 pm Check out: 12 pm

Above rates are inclusive of the following:
- Breakfast in Lamar Restaurant
- WIFI
- Airport Pick Up & Drop Off (sharing basis)

Payment Terms: A valid credit card is required upon check in. Payment should be settled upon arrival, any other additional charges can be settled upon departure.

No show fee will be charged equivalent to 1 room rate per night plus service charge.

No penalties for cancellations received 72 hours before arrival.

To book your room please click here: https://millenniumhotels.com/en/campaigns/mena/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.

FPM RCP Credits

DIA has been awarded with Continuing Professional Development (CPD) credits from the Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom for selected meetings and training courses. Physicians who are eligible for these credits can find more information about registering for CPD on https://www.fpm.org.uk/revalidationcpd/CPD/cpd. Already registered CPD members can claim the applicable credits directly on https://www.revalidation.fpm.org.uk/login.

EVALUATION

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

ACCESS PRESENTATIONS

As a benefit of your registration, presentations are made available on 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 sent to all attendees electronically after the conference. Please note certification requires full attendance. For more information please liaise with our DIA Contact Centre on diaeurope@diaeurope.org or call +41 61 225 51 51.

GROUP DISCOUNTS

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact Zsofia.Molnar@DIAglobal.org for a custom group rate.

LEARN MORE

Visit **www.DIAglobal.org/MERC** for programme updates or contact EMEA@DIAglobal.org with questions.

REGISTRATION FORM | ID# 17102

Middle East Regulatory Conference | 21-22 November 2017 | Kuwait City, Kuwait

DIA

Early-bird discount available for members: Register by 18th September 2017

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above.

Early-bird fee applies to industry members only. **€ 1'700.00** ❑

CATEGORY	Member *	Non-Member*
Industry	€ 1'835.00 ❑	€ 1'990.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 800.00 ❑	€ 995.00 ❑

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility. Please contact DIA EMEA for more information.
Registration fee includes: refreshments, lunches, reception and meeting materials.

*All fees are subject to the applicable VAT. Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

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Attendee email required to access presentations

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PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

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Exp. Date /

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Event ID#17102 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here**.

Date	Signature

DIA MEMBERSHIP

Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.DIAglobal.org and click on Membership for more details.

DIA offers one year complimentary membership against event registration at non-member rate

❑ **I do not want complimentary membership**

TERMS AND CONDITIONS

Cancellations

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA EMEA office of any such substitutions as soon as possible.

Photography and Video Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Center will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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