

Pharmaceutical Regulatory Affairs in the Middle East

29-30 Jun 2022, Live webinar

+ 1 more date - see back page for full schedule



Covering Bahrain, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya, Oman, Palestine, Qatar, Saudi Arabia, Sudan, Syria, UAE and Yemen

Programme at a glance:

- ✓ Introduction to Regulatory Affairs in the Middle East
- ✓ Economic overview of the Middle East
- ✓ Saudi Arabia
- ✓ Harmonisation and recent developments
- ✓ Bahrain
- ✓ Qatar
- ✓ Oman
- ✓ Kuwait
- ✓ Yemen
- ✓ UAE
- ✓ Egypt
- ✓ Sudan
- ✓ Libya
- ✓ Syria
- ✓ Lebanon
- ✓ Jordan
- ✓ Iran
- ✓ Iraq
- ✓ Palestine
- ✓ Israel
- ✓ Local trade associations
- ✓ MERC

Full programme inside

★★★★★ "I wanted to learn more about regulations in the middle east and the content was definitely very informative. The speakers had a lot of knowledge, there were a few technical issues however these were quickly resolved."

Hafsa Khan, Regulatory Associate, Gilead Sciences International Ltd

★★★★★ "Overall it was a good informative webinar. Content was detailed."

Tarak Patel, Regulatory Affairs Manager, Syri Limited

★★★★★ "Speakers are definitely experts in their area and have a depth of knowledge. Well worth it if you need an update on product registration issues / processes in the region."

Zul Mamon, Senior Consultant, Responsible Person and Pharmacist, Pharma Experts Limited

Pharmaceutical Regulatory Affairs in the Middle East

29-30 Jun 2022, Live webinar

+ 1 more date - see back page for full schedule

Course overview

This seminar will provide you with an essential overview of the key areas of pharmaceutical regulatory affairs in the Middle East. This two-day course will focus on practical aspects and will cover the regulatory requirements and developments in the individual countries as well as discuss harmonisation in the region.

Benefits of attending:

- **Gain** an overview of the regulatory environment in the Middle East
- **Understand** the economic and cultural background to the markets
- **Clarify** procedures for company and product registration
- **Discuss** harmonisation and recent developments in the region

Who should attend?

This seminar will be of particular interest to:

- Personnel involved in pharmaceutical regulatory affairs in the Middle East
- Anyone new to the region
- All those interested in an update on recent developments

Programme

Economic overview of the Middle East

- Population and GDP per capita
- Unemployment rate
- GDP real growth rate
- Inflation rate
- Healthcare spend per capita

The pharmaceutical regulatory environment in the Middle East – with individual presentations on:

- Bahrain
- Egypt
- Iran
- Iraq
- Israel
- Jordan
- Kuwait
- Lebanon
- Libya
- Oman
- Palestine
- Qatar
- Saudi Arabia
- Sudan
- Syria
- UAE
- Yemen

Harmonisation and recent developments

- Centralised registration in the Gulf
 - Gulf Central Committee for Drug Registration (GCC-DR)
 - SGH Tender
- Middle East Regulatory Conference (MERC)
- MERC follow-up activities
- Industry regulatory groups and activities
- Local trade associations

Final discussion and objectives review

★★★★★ *"Speakers of a very high quality. EXCELLENT."*

Marianne Serritzlev, Senior Regulatory Affairs Specialist, PHARMANOVIA A/S

★★★★★ *"Simply one of the best courses I have ever attended! It is so obvious that the speakers are highly experienced and have a huge knowledge regarding the region."*

Nermin Ipek, Global Regulatory Affairs Manager, Ferring Pharmaceuticals Inc

★★★★★ *"Great speakers – it was possible to ask every question. Great country-specific knowledge regarding the guidelines (all up to date)."*

Sabrina Waitz, International Drug Regulatory Affairs Manager, Octapharma Pharmazeutika Prod.Ges.m.b.H.

Expert trainers

Ilona Putz

Ilona Putz is the founder and General Manager of PULONA Emerging Markets based in the UAE since 2008. Her company is dedicated to creating and developing tailor-made business concepts including regulatory consultancy for international manufacturers in the healthcare sector across the Middle East. Ilona has worked in the Pharmaceutical Industry since 1988 for companies like MSD, SmithKline Beecham, Karl Engelhard, HEXAL and Sandoz where she was the Regional Head, Middle East, for Sandoz International, Germany, responsible for all commercial and business development activities. She also consults for RegAff, Emergo and Dr. Regenold GmbH for the Middle East. Ilona spoke during the DIA Europe Meeting on "Clinical Trials in the Middle East" and at the Global Pharmaceutical Regulatory Affairs Summit 2021.

Heba Hashem

Heba has been working with Regulatory Affairs in the Middle East for more than 25 years. She has a Pharmaceutical and Business background being a graduate of the Faculty of Pharmacy (Cairo University), RAC certified in addition to an MBA at Maastricht School of Business. For the past 20 years Heba held the position of Middle East & Africa Regulatory and Quality Head at different Pharmaceutical and Medical Device companies; Gambro, Bayer and Novo Nordisk.

Heba is now the Middle East and Africa Associate Director at PPD where she is providing regulatory consulting services and training to Health Care companies.

Introduction to Regulatory Affairs in the Middle East

General overview on the following topics:

- Markets and culture
- Healthcare
- Business culture
- Regulatory environment and characteristics
- General regulatory requirements
- Company and product registration
- Variations and renewals
- Pharmacovigilance
- Regulatory summary

Economic overview of the Middle East

- Population and GDP per capita
- Unemployment rate
- GDP real growth rate
- Inflation rate
- Healthcare spend per capita

Saudi Arabia

Harmonisation and recent developments

- Centralised registration in the Gulf
 - Gulf Central Committee for Drug Registration (GCC-DR)
 - SGH Tender
- Middle East Regulatory Conference (MERC)
- MERC follow-up activities
- Industry regulatory groups and activities
- Local trade associations

Bahrain

Qatar

Oman

Kuwait

Yemen

UAE

Egypt

Sudan

Libya

Syria

Lebanon

Jordan

Iran

Iraq

Palestine

Israel

Local trade associations

MERC

📍 Run this programme in-house for your whole team

Coming to Management Forum for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through

to feedback and follow-up after the programme. With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of

designing and delivering the appropriate solution for each client. For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact **Yesim Nurko** on +44 (0)20 7749 4730 or email inhouse@management-forum.co.uk



Receive a
Free
in-house
consultation

Pharmaceutical Regulatory Affairs in the Middle East

Schedule and prices

Three ways to book:

 **Online**
management-
forum.co.uk/1634

 **Email**
bookings@management-
forum.co.uk

 **Telephone**
+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
11671	29-30 Jun 2022	Live webinar	GBP 1,299 + VAT = 1,558.80 EUR 1,859 + VAT = 2,230.80 USD 2,098 + VAT = 2,517.60	GBP 1,099 + VAT = 1,318.80 EUR 1,579 + VAT = 1,894.80 USD 1,786 + VAT = 2,143.20	25 May
11958	14-15 Dec 2022	Live webinar	GBP 1,299 + VAT = 1,558.80 EUR 1,859 + VAT = 2,230.80 USD 2,098 + VAT = 2,517.60	GBP 1,099 + VAT = 1,318.80 EUR 1,579 + VAT = 1,894.80 USD 1,786 + VAT = 2,143.20	9 Nov

 **Your choice of date & location**

We can present this course on an in-house basis, tailored to your requirements, at your location and/or online. Contact us at inhouse@management-forum.co.uk or see inside the brochure for more details of how this can be a more cost-effective approach.

 **Multiple booking discounts**

Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

* Note the early booking discount cannot be combined with any other offers or promotional code

The 'Small Print'

FEE

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

PLEASE NOTE

Falconbury Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Falconbury will refund the registration fee and disclaim any further liability.

TERMS AND CONDITIONS

The rest of the 'Small Print', the event cancellation policy and the terms and conditions are on our website, please visit management-forum.co.uk/content/terms-and-conditions



@mfconferences



www.linkedin.com/company/management-forum-ltd