Pharmaceutical Regulatory Affairs in the Middle East

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

17-18 June 2019 London

To book online go to: management-forum.co.uk/1634

Dates and venue
17-18 June 2019
The Cavendish Hotel
81 Jermyn Street, London SW1 6JF
Tel: +44 (0)20 7930 2111
(Note: Entrance via Duke Street)

Programme schedule
Registration and refreshments: 09.00
Day one Day two
Start 09.30 09.00
Close 17.00 17.00

Accommodation
When available we have arranged a preferential rate for accommodation at the venue. To take advantage of this price, please mention that you are attending the Management Forum seminar when booking your accommodation.
Email: enquiry.cavendish@the-ascott.com
Web: www.thecavendish-london.co.uk
For information on alternative accommodation, please visit our website: management-forum.co.uk/accommodation

Three ways to book
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Fees and payment

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Multiple booking discount for 2nd or subsequent delegates - 15%
£1274.15 + VAT = £1528.98 • £1784.15 + VAT = £2140.98

Payment options
1. Invoice which can be paid by bank transfer or credit/debit card
2. Online through our secure website when registering

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
  - Centralised registration in the Gulf (GCC-DR)
  - Middle East Regulatory Conference (MERC)
  - MERC follow-up activities
  - Industry regulatory groups and activities

Expert trainers:

Ilona Putz
Business Concepts in Healthcare, PULONA Emerging Markets, United Arab Emirates (UAE)

Heba Hashem
Pharmacist, MBA, RAC, Associate Director, Regulatory Affairs – Middle East & Africa, PPD

‘Simply one of the best courses I have ever attended!’
Nermin Ipek, Ferring Pharmaceuticals Inc

‘Great country-specific knowledge regarding the guidelines (all up to date)’
Sabrina Waitz, Octapharma Pharmazeutika Prod.Ges.m.b.H.
Why you should attend
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.

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

Expert trainers
Ilona Putz founded PULONA Emerging Markets based in the UAE. Her company is dedicated to creating and developing tailor-made business concepts for clients in the healthcare sector across the Middle East. She holds an MBA from George Washington University and attended a finance programme at Harvard Business School. Ilona has worked in the pharmaceutical industry since 1988 for companies like MSD, SmithKline Beecham, Karl Engelhard and HEXAL where she was responsible for regulatory affairs and, later, commercial operations for countries in the Middle East and Africa. Between 2005 and August 2008 she was Regional Head, Middle East, for Sandoz International, Germany, responsible for all commercial and business development activities. Ilona consults for RegAff for the Middle East, the only global specialist regulatory affairs company with a broad geographical coverage, and for Emergo Group, a global consultancy company for medical devices.

Heba Hashem has been working in 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 and holding an MBA from 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 now works for PPD as an Associate Director, Regulatory Affairs – Middle East and Africa, where she provides regulatory consulting services and training to healthcare companies.

Programme

- **Introduction, welcome and objectives**
- **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
  - Palestinian
  - Qatar
  - Saudi Arabia
  - Sudan
  - Syria
  - UAE
  - Yemen
- **Each regional presentation will cover:**
  - Markets and culture
  - Healthcare
  - Business culture
  - Regulatory environment and characteristics
  - General regulatory requirements
  - Company and product registration
  - Variations and renewals
  - Regulatory summary
  - Practical advice on registration in each region
- **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**

A certificate of attendance for professional development will be available to each participant who completes the course.