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Pharmaceutical Regulatory Affairs in the Middle East

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Dates and venue

17-18 June 2019 **Ref: 10441**
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

management-forum.co.uk @ info@management-forum.co.uk +44 (0)20 7749 4730

Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 10 May 2019

£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

FULL PRICE Book AFTER 10 May 2019

£1499.00 + VAT = £1798.80 • €2099.00 + VAT = €2518.80

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



Management Forum in-house training

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.

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FEE: The fee includes all meals and refreshments for the duration of the course and a complete set of course materials. If you have any particular requirements, please advise customer services when booking.

PLEASE NOTE: Management Forum 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, Management Forum will refund the registration fee and disclaim any further liability.



For event cancellation policy and T&Cs see our website

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Includes: Interactive discussion sessions



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



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



Management Forum
in-house training

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To find out how we can work with you, what you will get and for how much, please call **customer services** on **+44 (0) 20 7729 4730** or email **inhouse@management-forum.co.uk**

Please note we are also running a seminar on **Medical Device Regulations in the Middle East and North Africa** on **19-20 June 2019**. Please visit **management-forum.co.uk** for further information

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
 - Palestine
 - 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