IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Pharmaceutical Regulatory Affairs in the Middle East and North Africa

7-9 June 27

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

Format:
Live online

CPD:
18 hours for your records

Certificate of completion

Course overview

The course will equip participants with practical understanding and essential insights into the latest regulatory requirements and developments specific to individual countries within the Middle East and North Africa.

Additionally, this course will explore regional initiatives aligned with global trends, including Common Technical Documents (CTD), and electronic Common Technical Documents (eCTD) submissions, and regional harmonisation efforts. With a strong emphasis on real-world application, this course aims to provide valuable knowledge for navigating the evolving regulatory landscape in one of the world's most dynamic pharmaceutical markets.

Benefits of attending

- **Gain** an overview of the regulatory environment in the Middle East and North Africa
- **Understand** the economic and cultural background to the markets
- **Obtain** insights regarding procedures for company and product registration
- **Receive** information about Dossier format in each country (CTD, eCTD or other)
- **Examine** harmonisation and recent developments in the region

Who should attend

This course will be of particular interest to:

- Personnel involved in pharmaceutical regulatory affairs in the Middle East and North Africa
- Anyone new to the region e.g. Regulatory Affairs, Pharmacovigilance, Market Access and Business Development leads
- All those interested in an update on recent developments

Programme

Day 1

Introduction to Regulatory Affairs in the Middle East and North Africa

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 and North Africa

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

Saudi Arabia

GCC-DR

- 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

Real case examples

Day 2

UAE

Yemen

Sudan

Egypt

Libya

Lebanon

Jordan

Syria

Iraq

Day 3

Algeria

Morocco

Tunisia

Palestine

Israel

Iran

Local trade associations

MENA Regulatory Conference

Case studies for practical application

Presenters



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.

Course date

7-9 June 27	**Live online** 09:00-17:30 **UK (London)** (UTC+01) *Course code 17208*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 12 Apr**

How to book

Online:
ipi.academy/3291

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

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
IPI Academy (and our training partners) 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, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★☆

The speakers were highly knowledgeable and demonstrated strong expertise in their respective areas. They were also very approachable, inclusive, and genuinely engaged with the participants. I appreciated their willingness to answer questions and share their experience openly throughout the course.

Walaa Jallaw
Senior RA Specialist
Afyx Therapeutics A/S
Oct 20 2026

Run this programme in-house for your whole team

Coming to IPI Academy 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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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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