IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Mastering CTD Submissions in the MENA Region

25 May 27
+ 25 November 27

This one-day course will provide you with an in depth understanding of the technical and regulatory requirements of CTD submissions in different countries in the MENA region.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Overview

Unlock a deeper understanding of the technical and regulatory landscape for generic CTD submissions across the MENA region in this focused, one-day course.

Led by a regional expert, this training dives into the specific documentation and study requirements essential for successful submissions. You'll also explore the most common reviewer inquiries, and how to proactively address them to prevent delays in your registration process.

Gain valuable insights into how MENA requirements compare and contrast with those in the USA and EU, helping you align your global regulatory strategies more effectively. Whether you're new to the region or looking to fine-tune your submission process, this is a unique opportunity to navigate complexities with expert guidance and improve your chances of a smooth, inquiry-free approval.

Benefits of attending

- **Become** more familiar with the regulatory environment and framework in the MENA region, giving you the confidence to navigate regional requirements with ease
- **Understand** how to compile effective CTD submissions that meet technical and regulatory expectations
- **Be aware** of the specific requirements to consider when submitting registration dossiers in key MENA countries, helping to streamline your submission strategy
- **Learn** the most common deficiencies and inquiries raised by reviewers, so you can avoid delays and strengthen the quality of your submissions

Who should attend

This course is specifically designed for pharmaceutical industry professionals who are currently involved in, or planning to engage with, the development of regulatory submissions to MENA regions using CTD/eCTD formats.

It is particularly well-suited to project team members seeking a practical understanding of regional regulations, essential tools, and submission processes.

Ideal for professionals working in, but not limited to:

- Regulatory Affairs
- Export drug regulatory affairs
- R&D
- Documentation Teams
- Quality Control
- Quality Assurance
- Anyone interested in understanding the regulatory environment and requirements in MENA region

Programme

Overview of the Pharmaceutical Market in the MENA Region

Format Used by Different MENA Countries (Traditional Registration Dossiers, CTC or eCTD)

Module 1 - Regional Requirements

- Pharmacovigilance requirements
- Product information requirements (Labelling, SPC & PIL)

Module 3 - Quality - CMC (Important Considerations for Specific Sections in Module 3)

- 3.2.S (S-part) and different options for submission
- Data requirements for 3.2.P (P-part)
- 3.2.R regional requirements
- Analytical procedures
- Analytical method validation
- Impurities
- Stability testing requirements

Programme

Life cycle management (Variations)

Summary of Module 3 (Product Overall Summary) and Different Formats of Submitting Module 2

Module 5 - Clinical

- Bioequivalence/Biowaiver requirements

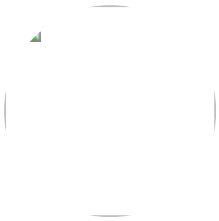
eCTD Required Technical Specifications

Regulatory Framework Examples (Egypt & GCC; Saudi Arabia & UAE as role models)

- New submissions, variations and renewals

Similarities and Differences Between CTD Requirements in MENA Region, USA & EU

Presenter



Mohammad Fat'hy Elnadi

Mohammad has a unique blend of both technical and regulatory experience and qualifications gained from his more than 18 years of experience in the pharmaceutical industry. After graduating in pharmaceutical science from the University of Cairo, he has held posts in the fields of R&D and production of pharmaceutical dosage forms, and as a contract manufacturing coordinator. After completing a postgraduate certificate in management from the American University in Cairo (AUC), he has held senior management roles in business development in the pharmaceutical industry, including opening new markets in local and export markets, which allowed him to deal with different regulatory health authorities and business environments.

He successfully led his team in cooperation with colleagues from other departments within various companies in numerous market access projects in many African countries, ASEAN, GCC and other Middle East Countries.

He has also been responsible for the establishment of supply chain departments in many pharmaceutical companies. Leading planning, local and foreign purchasing, and warehouse functions.

Mohammad is now a regulatory consultant for many pharmaceutical companies. He is an international speaker, providing courses and webinars worldwide in regulatory affairs and supply chain topics related to the pharmaceutical industry.

Course dates

25 May 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17195*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 30 Mar**
25 November 27	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 17521*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 30 Sep**

How to book

Online:
ipi.academy/2688

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 objective was to gain an understanding of the regulatory area within the MENA regulatory domain, and the webinar proved to be a valuable source of critical information. The speaker was kind enough to address [all] my queries..

Estefania del Castillo Fernandez
RA Spec
inke
Jul 1 2025

★★★★★

Speaker was very clear and knowledgeable, delivering a well structured course, with good slides to accompany it. I found it highly valuable and it gave me a good introduction into the MENA region. 5/5.

Jenny Lakin
Head of Product Registration
Torbay Pharmaceuticals
Jul 1 2025

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.

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 our training advisers:



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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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