IPI Academy

MANAGEMENT forum

Presented by
Management Forum

The Common Technical Document (CTD) Submission in the MENA Region

10 July 2024
+ 28 November 2024

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

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 regarding generic submissions.

Attendees will receive a detailed explanation of the specific requirements for documents and studies required in generic submissions, with the most common inquiries raised by reviewers to consider. This in turn will assist in avoiding a long list of inquiries that may delay your registration process.

Similarities and differences between the requirements in MENA regions, USA and EU will be discussed.

This is an excellent opportunity to discuss the complexities involved with an expert in this geographic region.

Benefits of Attending

- **Become more familiar** with the regulatory environment and framework in the MENA region
- **Understand** how to compile effective CTD submissions
- **Be aware** of the specific requirements that should be considered when submitting registration dossiers in major countries in the MENA region
- **Learn** the most common deficiencies and inquiries raised by the reviewers

Who Should Attend

This course has been designed for professionals of the pharmaceutical industry who are currently, or planning to become involved in the development of regulatory submissions to MENA regions using CTD/eCTD. The programme is particularly suitable for project team members interested in gaining a practical understanding of regulations, tools, and required submission processes. This includes 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

Welcome and Introduction

Overview of the Pharmaceuctical 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 (Labeling, SPC & PIL)

Module 3 - Quality - CMC

- 3.2.S (S-part) and different options for submission
- Data requirements for 3.2.P (P-part)
- 3.2.R regional requirements

Important Considerations for Specific Sections in Module 3

- Analytical procedures
- Analytical method validation
- Impurities
- Stability testing requirements

Programme

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

Module 5 - Clinical

- Bioequivalence requirements

eCTD Required Technical Specifications

Regulatory Framework Examples (GCC & Egypt)

- New submissions, variations and renewals

Smilarities 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

10 July 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 14196*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 05 Jun**
28 November 2024	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 14197*	GBP **549** ~~649~~ EUR **789** ~~929~~ USD **893** ~~1,049~~ **Until 24 Oct**

How to book

Online:
ipi.academy/2688

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% 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

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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