Book before 10 May 2019
and SAVE £200/€280

Common Technical Document

To book online go to: management-forum.co.uk/2182 W

Dates and venue

3-4 July 2019 **Ref: 10473**
4-5 December 2019 **Ref: 10475**

The Rembrandt Hotel
11 Thurloe Place, London SW7 2RS
Tel: +44 (0)20 7589 8100

Programme schedule

Registration and refreshments: 09.00

	Day one	Day two
Start	09.30	09.30
Close	17.00	16.30

Accommodation

We have arranged a preferential rate for accommodation at the venue. To take advantage of this, please contact the hotel on the email below and state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment.

Email: reservations_rembrandt@sarova.co.uk
Web: www.sarova-rembrandthotel.com

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

In-house TRAINING

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.

With over 600 trainers, 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.

To get a **FREE** consultation and to find out how we can work with you call **Aleksandra**, our in-house training expert, on **+44 (0) 20 7749 4730** or email ***inhouse@management-forum.co.uk***

To find out more, please visit: ***management-forum.co.uk***

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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Book Before 10 May 2019 and SAVE £200/€280

Includes: Interactive discussion sessions

MANAGEMENT forum

Common Technical Document

A comprehensive review of the regulations and technical requirements for chemistry, manufacturing and control (CMC) management of your application

3-4 July 2019 • 4-5 December 2019 London

Skills you will gain include:

- Effective compilation of the Common Technical Document (CTD) and critical review of documentation
- Quality by design (QbD), critical attributes and developing new product using the CQA pyramid model
- Compiling and submitting Module 3 (CTD) of your registration dossier
- Identifying the extent of content expected by EU and US regulators
- Achieving the quickest turnaround of your submission
- Managing the pharmaceutical and quality aspects of your developments and registration dossier in Europe and the US
- Ensuring right-first-time development
- Meeting the legal framework and guidelines for the CMC/quality part of the dossier and links to GMP

Expert trainer

Andrew Willis BSc (Hons), MTOPRA – Independent Consultant in Advanced Regulatory Affairs and Pharmaceutical Development

'Very lively presentation and interactive. The exercises kept the course interesting.'
Natacha Gonzalez, Ares Trading S.A.

'Very clear speaker and presentation.'
Sonia Bchir Kassassi , GUERBET

CPD CERTIFIED

Common Technical Document

3-4 July 2019 • 4-5 December 2019, London

Introduction

This two-day course will provide you with a clear understanding of the regulatory and technical requirements for CMC management of your full and generic application in major markets of the EU and USA. Furthermore, the course examines the requirements for global roll-out of the dossier to ROW regions including LATAM, ASEAN, MENA and CIS territories.

You will increase your ability to manage all aspects of development of the CMC applications after two days of intensive lectures, group work and discussion sessions, covering everything you need to know about compiling the chemistry and pharmacy section of your generic dossier.

Who should attend?

- Senior analytical chemists
- Formulation chemists
- Technical services chemists
- Registration staff (all levels)
- Quality managers
- Quality control directors
- R&D project managers

In-house training

This seminar is also available as an in-house course and can be tailored to your specific needs.

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To find out more, please visit: **management-forum.co.uk**

Expert trainer

Andrew Willis currently works as an independent consultant providing expert advice and training on global regulatory solutions and pharmaceutical development. Previously, Andrew worked for Catalent Pharma Solutions as VP Regulatory Affairs & Consulting Services. Catalent is the world's leading contract manufacturer and distributor of pharmaceuticals, and Andrew was head of a team of internal and external regulatory affairs consultants.

Andrew qualified as a chemist from the University of Glamorgan, after which he furthered his understanding of pharmaceutical development, working as a research chemist with Parke Davis. He had ten years' manufacturing and analytical experience prior to entering regulatory affairs as a Senior Executive Officer with responsibility for submission of European MAAs and project management of development programmes. Andrew currently has a total of 28 years' pharmaceutical experience with extensive knowledge in the development and manufacture of sterile, solid oral, inhalation, topical and biotech pharmaceutical products. He also has particular expertise in the areas of growth hormones and multiple cancer treatments, including development and clinical registration of the first genetically modified live bacterium for such treatment.

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

Programme

Day one

What is the CTD? The road map to Module 3 and understanding ICH
- Assessing the impact of harmonisation – ICH guidelines

Preparing the drug substance section of the application – US and EU
- Analysing the needs for the section
- How to submit information – Drug Master Files, certificates of suitability (CEP) and other methods
- European submissions, CEP and active substance master file (ASMF) requirements
- Detailed information requirements for the section
- Q11 explained – EU and US expectations of failure mode and effects analysis (FMEA)
- Development expectations and scale-up requirements
- Specific examples of EU/US format and guidance

GMP for active substances
- Examining GMP requirements and EU and US expectations, inspection timing and interactions and contractual obligations

Case study: essential information from API suppliers
- Identify and understand the essential data requirements from API suppliers for submission of generic applications

Examining the content of the sections concerning the drug product composition and development of the drug product
- Defining the formulation
- Identifying the data needs for the pharmaceutical development section, explaining QbD and FMEA requirements
- Multiple examples of Development Report content – practical for table of contents and creation of QbD pyramid

Day two

Writing the section on manufacture of the drug product and process validation
- Examining the content of the section: how much information to provide
- Defining the difference between process development and validation and looking at validation expectations in today's environment

Writing the sections on excipients and packaging components
- Control of the excipients/packaging components
- Examples of data expectations
- Examining the maintenance of these sections

Writing the sections on control of the finished product and case study
- Examining the content of the section
- Control of the drug product
- Examples of specifications for multiple product types
- Examples for Method Summaries

Writing the stability section
- Examining the content of the section
- Evaluation of stability data and the impact on shelf life

The function and content of the Quality Overall Summary (QOS)
- Overview of the current approaches
- What is the Expert Report: practical involvement of the expert
- QOS explained and compared with Expert Report
- Detailed content of the QOS

Examining global roll-out of Module 3

Examining change control – practical tips

Practical exercise in generic development
- Identifying ten-stage plan for developments

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