Common Technical Document

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

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Dates and venue

5-6 December 2017 **Ref: 9911**
4-5 July 2018 **Ref: 10187**

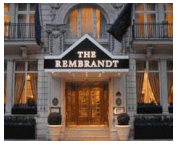
The Rembrandt Hotel
11 Thurloe Place
London
SW7 2RS
Tel: +44 (0)20 7589 8100

Programme schedule

Registration and refreshments: 09.00

	Day one	Day two
Start	09.30	09.00
Close	17.00	16.30

Accommodation



We have arranged a preferential rate for accommodation at the venue. To take advantage of this please contact **reservations_rembrandt@sarova.co.uk** and state you are a Management Forum delegate. There are limited rooms available at this rate so please book early to avoid disappointment. For information on alternative accommodation please visit our website: **management-forum.co.uk/accommodation**

Three ways to book

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

Fees and payment

EARLY BOOKING DISCOUNT Book BEFORE 2 October 2017
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2182.80

FULL PRICE Book AFTER 2 October 2017
£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

This course is also available in-house and can be tailored to your specific needs. Our experts come to you, saving you time and money. For more information contact **Customer Services** on **+44 (0)20 7749 4730** or email: **inhouse@management-forum.co.uk**

The small print

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.

HOW TO REGISTER AND PAY: A VAT invoice and booking confirmation will be sent within 7 days, please contact us if you have not heard anything after that time. Payment can be made by credit/debit card, by bank transfer (for bank account details please see payment details section on our website). VAT no GB 341232109. Any questions please contact Customer Services on +44 (0)20 7749 4730. **ALL PAYMENTS MUST BE RECEIVED IN ADVANCE OF THE EVENT.**

MULTIPLE BOOKING DISCOUNTS: This discount may not be used in conjunction with any other offer

CANCELLATIONS AND TRANSFER: Once we have received your booking the place(s) are confirmed.

Delegate	Up to 28 days before course	27 to 14 days before course	13 to 0 days before course
Cancellation	10% admin fee	100% admin fee	100% admin fee
Transfers	Free	10% admin fee	100% admin fee
Substitution	Free	Free	Free

A maximum of one transfer is allowed. After the transfer no cancellation can be accepted and the full invoiced fee will be charged. Transfers are subject to payment of the difference on higher value courses. All cancellations must be received in written form.

For event cancellation policy and T&Cs see our website

Book Before 2 October 2017 and SAVE £200/€280

MANAGEMENT forum

Common Technical Document

Project management/collection of critical documents for chemistry, manufacturing and control (CMC) for global registration (CTD) and incorporate quality by design within the CTD

5-6 December 2017 • 4-5 July 2018 London

Skills you will gain include:

- Effective compilation of CTD and critical review of documentation
- Quality by design, 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 development and quality aspects of your developments and registration dossier in Europe and 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 detailed and informative. Speaker clearly very knowledgable on experiences and delivered the content in a clear and concise manner. Excellent transfer of information'
Ini Okereke, GW Pharmaceuticals

Includes: Interactive discussion sessions

CPD CERTIFIED The CPD Certification Service

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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 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

Attendance limited - early booking recommended

This limitation, a unique feature of all **Management Forum** seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme

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 has 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 programs. Andrew currently has a total of twenty eight years pharmaceutical experience with extensive knowledge in the development and manufacture of sterile, solid oral, inhalation, topical and biotech pharmaceutical products. These experiences have allowed knowledge of many biotech products requirements with experiences 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 Understanding ICH
- Assessing the impact of the 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, other methods
- European Submissions, CEP and ASMF requirements
- Detailed information requirements for the section
- Q11 explained – EU and US expectations of FMEA analysis
- Development expectations and scale-up requirements
- Specific examples on 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
- The case study will allow participants to 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

(All module sections include example sections for writing)

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
- Examining the content of the section

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

The function and content of the Quality Overall Summary
- 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 CTD Module 3

Examining change control - practical tips

Practical exercise in generic development
- Identifying 10 – stage plan for developments

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