MANAGEMENT forum

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Clinical Overview and Clinical Summary: Creating Effective Marketing Authorisation Application

30 Mar 2022, Live webinar
+ 1 more date - see back page for full schedule

This seminar looks at the latest guidance on how to prepare a clinical overview and summary in accordance with regulatory expectations and to comply with the requirements of the Common Technical Document (CTD)

Programme at a glance:

- The CTD Guideline
- Planning content of the clinical overview
- Content of the written summary – practical considerations including a workshop
- Meeting regulators' expectations

Full programme inside

★★★★ *"It was a very interesting and useful webinar. I would definitely recommend it."*

Fernando Bergantinos, Manager. Drug Safety Scientist, Daiichi Sankyo Europe GmbH

★★★★ *"It was a very nice webinar and met my expectations. The slides were well structured and the content nicely presented. It was great to profit from John´s huge experience."*

Katharina Broeker, Scientific Expert, Department of Medical Affairs, Medac GmbH

★★★★ *"Presentation was clearly structured and there was a good interaction with the speaker. "*

Sofie Stalmans, Regulatory Affairs, PhaRA BVBA

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Course Overview

The Common Technical Document (CTD) Guideline is the obligatory format in the EU and most territories worldwide for registration applications. The clinical overview and clinical summaries in Module 2 provide a critical analysis of the clinical data within the CTD.

This interactive course will present the regulatory guidelines and requirements of Module 2 and discuss practical approaches to developing the content and preparation of the clinical overview and clinical summaries. The programme will provide a review of the latest information and potential future developments and cover associated documents, such as the RMP and SmPC. A practical workshop session will simulate real situations and highlight the key issues to consider when preparing the content of the written summary.

Benefits of attending:

- **Gain** practical advice on writing clinical documents for global submissions
- **Review** the latest guidance to ensure you meet regulatory expectations
- **Understand** how to prepare separate integrated summaries of efficacy and safety for FDA
- **Clarify** the content of orphan drug applications, over-the-counter (OTC) switches, line extensions and safety-related labelling updates
- **Ensure** your risk management plan (RMP) is consistent with the Common Technical Document (CTD)
- **Discuss** the place of the clinical overview and summary in life cycle knowledge from initial IB to PSUR, and how they support the changing summary of product characteristics (SmPC)

Who should attend?

- Senior R&D managers
- Members of medical science clinical trial departments
- Medical writers
- Regulatory affairs personnel
- All those interested in the CTD document, clinical overview and summary and its place in the evolving clinical, safety and regulatory processes

★★★★ *"Clear, manage of the knowledge, practice, orientated."*

Diego Silva Vasquez, Regulatory Affairs Coordinator, Eurodrug Laboratories B.V.

★★★★ *"The course was informative and all topics on the agenda were addressed. There were also plenty of opportunities to ask questions and have discussions due to the small group size."*

Rasielle Gonzales, R&D Project Manager, Disphar International B.V.

★★★★★ *"Overall, I felt the course content was excellent; it contained a lot of relevant and useful information that was well-organised. The course was presented at a pace that kept the audience's attention and involved them throughout. The speaker was very experienced in the topic, open to answering questions in a calm and professional way, being sure to clarify that he understood what was being asked."*

Lynne Isaac, Medical Writer, Pharmaceutical Company

Expert trainer

John Price

Dr John Price is a physician consultant in pharmacovigilance and regulatory affairs, working with several small biotechnology companies in North East USA planning submissions for marketing approval of oncology, haematology, renal and orphan drugs.
He was previously Vice President and Head of Global Pharmacovigilance and Drug Safety at Alexion Pharmaceuticals, USA. Until 2014 he was VP and Head of Medical, Clinical and Regulatory Operations at Johnson and Johnson Consumer Health, USA and previously VP of Medical Documentation, Labelling and Submissions Management, Worldwide Safety and Regulatory Operations, Pfizer Inc, USA. In these roles he has led and participated in the preparation of multiple clinical overviews and summaries for MAAs, variations, renewals and labelling updates globally.
He is a physician trained also in clinical pharmacology who has worked in the pharmaceutical industry since 1998, including working as a consultant providing medical writing support to pharmaceutical companies and service providers. Prior to joining Pfizer he spent 7 years as medical assessor and head of the Clinical Evaluation Unit of the Post Licensing Division at the Medicines Control Agency (now the Medicines and Healthcare products Regulatory Agency).

The CTD Guideline

- CTD modules, structure and content
- An effective clinical overview
- The role of the written summary
- Agency validation

Planning content of the clinical overview

- Data sources
- Presenting efficacy and safety data
- Risk management
- Expressing benefit/risk
- Comparative effectiveness
- Avoiding pitfalls

Content of the written summary – practical considerations including a workshop

- The document writing process
  - Templates
  - Style
  - Timelines
  - Efficiency
- The writing team
- Engaging and working with external writers
- Getting started, and reviewing and interpreting data
- Document review: avoiding rework
- Achieving quality
- Document review and approval

Meeting regulators' expectations

- The CTD in a global company: regional and country requirements
- Is a separate ISS or ISE necessary for an application to FDA?
- Writing for NCEs, orphan drugs, over-the-counter switches, MA renewal, generic products and line extensions
- Recent developments and their effect on producing future CTDs
  - The RMP and risk evaluation and mitigation strategy (REMS)
- Writing an overview and summary to support the SmPC and labelling changes

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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.

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For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact **Yesim Nurko** on +44 (0)20 7749 4730 or email inhouse@management-forum.co.uk

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Schedule and prices

Three ways to book:

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management-forum.co.uk/1701	bookings@management-forum.co.uk	+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
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Your choice of date & location

We can present this course on an in-house basis, tailored to your requirements, at your location and/or online. Contact us at inhouse@management-forum.co.uk or see inside the brochure for more details of how this can be a more cost-effective approach.

Multiple booking discounts

Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

* Note the early booking discount cannot be combined with any other offers or promotional code

The 'Small Print'

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

Falconbury 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, Falconbury will refund the registration fee and disclaim any further liability.

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The rest of the 'Small Print', the event cancellation policy and the terms and conditions are on our website, please visit management-forum.co.uk/content/terms-and-conditions