IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Clinical Overview and Clinical Summary: Creating Effective Marketing Authorisation Applications

3-4 March 27
+ 29-30 September 27

This course 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).

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

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

Presenter



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).

Course dates

3-4 March 27	**Live online** 13:30-17:15 **UK (London)** (UTC+00) *Course code 17054*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 06 Jan**
29-30 September 27	**Live online** 13:30-17:15 **UK (London)** (UTC+01) *Course code 17373*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 04 Aug**

How to book

Online:
ipi.academy/1701

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

★★★★☆

John is clearly an expert in the elaboration of these documents and made some really interesting remarks regarding the critical analysis he applies.

Sara Braga
Scientific and Medical Writing & CTD Process Responsible Person
Tecnimede
Sep 30 2026

★★★★☆

I was hoping to gain a basic understanding of the MAA process. The slides were well structured and covered basics before addressing more detailed areas. I thoroughly enjoyed the training course

Sabrina Solomon
Scientist
Ipsen
Mar 16 2026

★★★★☆

During the 2 days-training the Clinical Overview and the Clinical Summary were described with a focus on the safety sections, which was exactly what I was looking for. Speaker was attentive to our questions and tried to make the training as interactive as possible. I liked the last part with practical examples.

Anna Blanco
Senior Scientific Specialist PV
Ipsen Biopharma Ltd
Mar 16 2026

★★★★☆

Very good. [Speaker was] very experienced.

Celine Anselmetti Dayer
Director, Regulatory Affairs
Debiopharm Research & Manufacturing SA
Feb 5 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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