



Presented by
Management Forum

Clinical Overview and Clinical Summary: Creating Effective Marketing Authorisation Applications

16-17 March 2026

+ 30 September-1 October 2026

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).



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

Programme

Day 1

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

Day 2

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

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

16-17 March 2026

Live online

13:30-17:00 **UK (London)** (UTC+00)

Course code 16137

GBP **749**

EUR **1,049**

USD **1,199**

30 September-1 October **Live online**
2026

13:30-17:00 **UK (London)** (UTC+01)

Course code 16363

GBP **649** ~~749~~

EUR **909** ~~1,049~~

USD **1,043** ~~1,199~~

Until 26 Aug

How to book



Online:

ipi.academy/1701

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



Email:

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Phone:

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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 our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews



Very good. [Speaker was] very experienced.



Celine Anselmetti Dayer
Director, Regulatory Affairs
Debiopharm Research & Manufacturing SA
Feb 5 2025



The course was excellent for me.



Alina Valentina Covaci
QPPV
BIOFARM SA
Oct 23 2024



John Price explained all information in practical and useful way. I have been satisfied from the whole shapes of the program. For sure I will recommend it to other colleagues.



Marco Taras
Regulatory Affairs
Philogen S.p.A.
Feb 7 2024



I found the webinar very good in general. I accomplished a good understanding of the CO (in particular) and the crucial elements to take into account when structuring it. I found [the speaker] knowledgeable, clear and open to discussion.



Claudia Guida
Senior Manager Regulatory Science
Kinesys consulting
Oct 23 2024

Run this programme in-house for your whole team

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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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