IPI Academy

MANAGEMENT forum

*Presented by*
**Management Forum**

# Clinical Overview and Clinical Summary: Creating Effective Marketing Authorisation Application

**18-19 June 2025**
+ 1-2 October 2025

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

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|---|---|---|
| **18-19 June 2025** | **Live online**<br>13:30-17:15 **UK (London)** (UTC+01)<br>*Course code 14759* | GBP **749**<br>EUR **1,049**<br>USD **1,199** |
| **1-2 October 2025** | **Live online**<br>13:30-17:15 **UK (London)** (UTC+01)<br>*Course code 14961* | GBP **649** ~~749~~<br>EUR **909** ~~1,049~~<br>USD **1,043** ~~1,199~~<br>**Until 27 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 **15% 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

★★★★☆

**Very good. [Speaker was] very experienced.**

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

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★★★★★

**The course was excellent for me.**

**Alina Valentina Covaci**
QPPV
BIOFARM SA
Oct 23 2024

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★★★★★

**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

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★★★★☆

**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

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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