IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Successful Medical Writing – from Protocol to CTD

25-26 September 2025

Success in the pharmaceutical industry depends on the speed and efficiency of new drug approvals and the quality of documentation submitted to the regulatory authorities. This intensive, practical medical writing course will benefit participants by enabling them to achieve this standard.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Success in the pharmaceutical industry depends on the speed and efficiency of new drug approvals. This process largely relies on the quality of documentation submitted to the regulatory authorities, and a high standard of medical writing plays a vital role in ensuring a positive outcome. This intensive two-day medical writing course will help you to improve your skills and achieve this standard.

Benefits of attending

- **Gain** in-depth knowledge on general writing and data presentation skills, specifically in the kind of documents most frequently encountered in clinical research
- **Understand** the international guidelines and standards
- **Explore** both the theoretical and practical aspects of writing for regulatory authorities through illustrative examples

Who should attend?

The course will be of interest to all those in the pharmaceutical industry who prepare research reports and documentation intended for regulatory authorities. Although the focus of the seminar is on clinical research, many of the principles will also apply to other types of reports, including pre-clinical, CMC and veterinary documentation. The practical training will benefit not only those new to medical writing but also those wishing to perfect their existing writing skills, including full-time medical writers and those who only occasionally write research documentation or regulatory submissions.

Programme

Day 1

Day 1 – Fundamentals of Regulatory Medical Writing

Introduction to regulatory medical writing

- Overview of medical writing in the pharmaceutical industry
- Types of documents
- Project management
- Working cross-functionally
- Document reviews
- Quality checks

Regulatory environment and guidelines

- Regulatory agencies and key regulatory guidelines
- Drug development lifecycle and regulatory milestones

Regulatory documents

- What are they and why are they needed?
- Developing the protocol and ICFs
- Developing the CSR
- Developing the Investigator's Brochure
- Developing the DSUR

Day 2

Day 2 – Scientific Advice and Marketing Applications

Briefing documents

- What are they?
- Why are they needed?
- How are they developed?

Importance of real-world evidence and patient-centred outcomes

The Common Technical Document

- Introduction to clinical submission dossiers
- Writing the clinical overview & the clinical summary

Presenter

Cheryl Roberts

Cheryl is currently the Global Head of Medical Writing at BioMarin Pharmaceutical Inc., and specialises in medical writing for serious and life-threatening rare diseases. She joined the pharmaceutical industry in 2001 in drug development, and continued in positions in medical editing and medical writing in both the pharmaceutical and consultancy industry. She holds a degree in Medical Biology and a Masters in Neuroscience. Cheryl has been an approved workshop leader for the European Medical Writers Association since 2015 and gives training on subgroup analyses and orphan medicinal products.

Course date

25-26 September 2025 **Live online**
09:00-16:00 **UK (London)** (UTC+01)
Course code 15102

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 21 Aug

How to book

Online:
ipi.academy/889

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

★★★★★

I expected to gain knowledge of clinical regulatory writing, particularly clinical documents and CTD modules. I accomplished this. Very informative.

Céline Tiffon
Medical Writer
Indegene Inc
Jan 16 2025

★★★★☆

Speaker knew contents very well. I achieved goal to gain a general understanding of regulatory documents and the best way to present results. Very Good.

Jumanne MATUMLA
Laboratoires THEA
Jan 16 2025

★★★★★

Overall very very pleased with the course and it has thoroughly extended my interest and drive to become a full medical writer

Louise Bussey
Senior Clinical Study Manager
Vaccitech (UK) Limited
Apr 27 2022

★★★★★

The content for each day was great and very informative, as a new starter to the industry it really helped me to gain an understanding of the layout, structure and what to look out for in study reports and submission documents etc. The presentations were clear and concise, and it is clear that each speaker is very passionate about their role, which is shown through their strong knowledge and experience. [...] each speaker came across very well and their understanding of medical writing, along with their expertise really helped me to understand each aspect of their presentations thoroughly.

Ruby Morrissey
Regulatory Writer
Imperial Brands
Apr 27 2022

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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