



Presented by
Management Forum

Successful Medical Writing – from Protocol to CTD

27-29 November 2024

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:
18 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 three-day medical writing course will help you to improve your skills and achieve this standard.

Aims and objectives

This event combines presentations from our expert faculty with practical exercises to provide a thorough introduction to the basics of medical writing that goes beyond the usual 'overview' courses. It will provide in-depth training in general writing and data presentation skills, and specifically in the kind of documents most frequently encountered in clinical research.

You will learn both the theoretical and practical aspects of writing for regulatory authorities as well as the sensible use of international guidelines, standards and useful writing tips. Many illustrative examples will be used, drawn from the course leaders' wide experience of the pharmaceutical industry.

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

Overview of writing: substantive and technical aspects

- Helping your reader

The Protocol

- Developing the protocol
- The most important clinical document?

The CSR

- General aspects
- CSR templates
- Content – results-independent text

The CSR continued

- Content – patient information & efficacy

Day 2

Completing the CSR

- Content – safety & discussion

Improving readability, for example:

- Brief overview of punctuation specifics affecting readability
- Verb force

Designing tables for clinical documents

- Table types
- Elements of table design

More on improving readability, for example:

- Prepositions
- Abbreviations

Summary Documents

- Overview including abstracts and synopses

Day 3

The Common Technical Document

- Introduction to clinical submission dossiers
- Purpose & types of clinical summary documents
- Writing the clinical overview & the clinical summary
- Recent regulatory developments: really a common technical document?

Project Management

- Improving the process, for example considering:
 - Timelines
 - Document review

Quality aspects

- Just how perfect does your document need to be?

Final checks

- Proofreading: just a spell check?

Additional writing tips and tools

Course date

27-29 November 2024

Live online

09:15-17:30 **UK (London)** (UTC+00)

Course code 14071

GBP **1,349** ~~1,649~~

EUR **1,939** ~~2,359~~

USD **2,201** ~~2,669~~

Until 23 Oct

How to book



Online:

ipi.academy/889

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



Email:

info@ipi.academy



Phone:

[+44 \(0\)20 7749 4749](tel:+442077494749)

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

Reviews



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



The content was targeted, appropriate and informative. Presentations were good, incorporating both text and visual elements to keep us engaged, and the speakers were friendly and involved. I am new to medical writing. I hoped to gain knowledge regarding the different documents I may be working on, how to coordinate different contributors, and how to involve statistics and data presentation in my writing. This course substantially helped to clarify these things.



Holly Smith
Medical Writer (Graduate Program)
WriteSource Medical
Jul 11 2022



Overall, I found the webinar interesting and worthwhile. The speakers were all highly knowledgeable and gave good advice. I believe this webinar is suitable for beginner medical writers.



Dulama Richani
Medical Writer
WriteSource Medical Pty Ltd
Jul 11 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:



ALEKSANDRA BEER

Tel: +44 (0)20 7749 4749

Email: inhouse@ipi.academy



YESIM NURKO

Tel: +44 (0)20 7749 4749

Email: inhouse@ipi.academy



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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy

Tel: +44 (0)20 7749 4749

Email: info@ipi.academy