

Effective Medical Writing and Transcription





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Introduction

In medical writing, it is important to deliver accurate documents in timely manner that adhere to the highest ethical and scientific standards. This course provides an overview of how to present product information clearly and concisely for targeted audiences. It teaches participants how to control sentence structures for precise delivery of data and how to increase clarity and effectiveness.

Course Objectives of Medical Writing and Transcription

- Exploring the meaning of medical writing
- Learning how to write documents that meet the company's goals and objectives
- Understanding the importance of publishing as an essential part of therapeutic product position
- Writing an abstract or manuscript
- Creating effective data displays
- Understanding the role of the writer in producing and issuing documents
- Discussing the best ways to manage the review process
- Providing and receiving feedback in useful way
- Reaching concurrence in the review process

Course Outlines Medical Writing and Transcription

Day 1

Getting to Know Medical Writing

- The scope of medical writing
- Effective medical writing
- The writer's role
- Assessing the audience
- · Identifying and placing key messages

Medical writing Regulation

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- INDs/IDEs
- Clinical protocols and amendments, and study reports
- IBs and product labels
- NDAs/BLAs/PMAs
- Annual reports
- Product labeling
- · Abstracts and posters for scientific meetings
- Manuscripts for publication in scientific journals

Day 2

The Clinical Study Report

- Using templates
- Purpose of each section
- · Clarity and consistency in writing

Writing for Publication

- Publishers' requirements for manuscripts
- Standard manuscript elements: abstract, introduction, materials and methods, results, and discussion
- Abstracts and posters for professional meetings
- Preparation, review, submission, acceptance, revision, publication
- Identifying key information and paring the language

Day 3

Controlling the Sentence

- Objectivity and tone
- Fundamentals of sentence construction
- Controlling voice for readability
- Select punctuation

Day 4

Achieving Flow and Cohesiveness

- Writing effective paragraphs
- Using transitions
- Effective data displays
- Using style guides for consistent medical writing
- · Overcoming writer's block and finding time to write

Day 5



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Managing the Review Process

- Charting the process flow
- Establishing metrics for managing regulatory submissions
- Putting a disclosure process in place
- Effective review practices
- Managing disparate comments from reviewers



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