CPD MEMBER
The CPD Certification Service

Qsten

Academic and Regulatory Medical Writing

COURSE DESCRIPTION

This course will introduce the attendees to the two main types of medical writing: academic and regulatory. It will present the different types of scientific documents. Moreover it will cover the basics of writing a research proposal and a scientific manuscript, as well as regulatory documents.

TOPICS COVERED

Mentioned in the program schedule below.

COURSE LEARNING OBJECTIVES

At the end of the training, participants will:

- Understand what is academic and regulatory writing
- Be familiar with the ethical considerations in medical writing
- Be acquainted with the different sections of a scientific research paper
- Be introduced to the guidelines of writing each section of a scientific research paper
- Learn how to write regulatory documents, for example: consent forms , clinical trial protocol, and clinical study report

AUDIENCE

This course targets:

- Medical doctors and other healthcare personnel involved in clinical research
- Investigators and researchers willing to improve their knowledge in clinical research
- Pharmaceutical industry employees involved in clinical research
- Students of health-related disciplines (Medicine, Pharmacy, Nursing)

TEACHING / LEARNING METHODOLOGY

Training sessions are delivered through 3 most-commonly used modes of delivery, mainly:

- **Didactic Lectures:** delivering PowerPoint presentations which cover the theoretical and practical aspects of the workshop topics
- ***Hands-on exercises where applicable:*** applying the theoretical content through exercises and assignments
- **Group discussions:** practicing the theoretical and the practical topics covered through group work, discussions, and presentations

PARTICIPANTS EVALUATION

Post-course test delivered to the attendees to test their knowledge.

PROGRAM SCHEDULE - 12 CONTACT HOURS / 3 DAYS

DAY 1

Session 1

Introduction to the Clinical Research Process

- Basic concepts of clinical research
- Infrastructure required in performing clinical research

Session 2

Literature review basics and referencing techniques: (PubMed) and (Endnote)

- Strategic plans and techniques for searching the literature, primary sources of evidence, PubMed, browser methods (MeSH terms, clinical queries)
- Citing the literature, formats for citing references, Endnote citation manager program

Session 3

Types of medical writing

- Meaning of the term 'Medical Writing'
- The different types and categories of medical writing

Session 4

Basics and techniques of scientific writing and reporting

- Basic scientific writing skills, and the use and importance of style guides and templates)

DAY 2

Session 1

Research proposal writing

- The different sections of a research proposal and the function of each section
- The basics of writing a research proposal

Session 2

Scientific article writing

- The different sections of a scientific article and the function of each section
- The basics of writing a scientific article

Session 3

Introduction to clinical trials : definition, design, management, and reporting

- Introduction to the clinical trials design
- Clinical trials reporting guidelines

Session 4

Clinical trial essential documents

- The essential documents needed in the different phases of clinical trials and the function of each document

DAY 3

Session 1

Case Report Form and Investigator's Brochure (IB)

- The meaning of Case Report Form and Investigator's Brochure (IB)
- The content and write-up of Case Report Form and Investigator's Brochure (IB)

Session 2

Clinical Trial Protocol

- Clinical trial protocol function, description, structure and, regulatory requirements
- Clinical trial protocol different sections and the write-up of each section

Session 3

Clinical Study Report

- Clinical Study Report function, description, structure and, regulatory requirements
- Clinical Study Report different sections and the write-up of each section

Session 4

Clinical trial results reporting and presentation

- Guidelines and requirements for reporting and presenting clinical trial results

The Trainer

Dr. Samaa Al Tabbah

BSc. MLT, PharmD

Dr. Samaa Al Tabbah holds a B.S. in Medical Laboratory Technology from the American University of Beirut and a PharmD in Clinical Pharmacy from the Lebanese American University. She is currently the co-founder and CEO of the Medical Agency for Research and Statistics (MARS). After graduation, she held a position as a chief pharmacist at the World Health Organization (WHO), Beirut office. Through her work, she has been involved in research projects and training workshops carried out at the national and regional level. She is the author of many scientific papers published in peer-reviewed journals as well as a booklet titled “The Clinical Research Process from Initiation to Publication”. She is an editorial member of two peer-reviewed scientific journals and an Assistant Professor at the Lebanese Red University Institute for Nursing. She was lately appointed as the Global Pharmacovigilance Society Ambassador of Lebanon where she also acts as an acting board member of the society.

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About Osten Healthcare

Osten Healthcare is an ISO specialized training provider based in Ireland, created to provide holistic healthcare trainings and development courses to enhance the knowledge and skills of Healthcare Professionals, Consultants,and other stake holders in the field.

Whether, online or onsite, Osten Healthcare's course objectives are unique.

We use systematic methods in transferring technical and managerial skills to participants and meticulously design our offereings to encompass the multifaceted experience of our consultants and experts.

Our team is made up of international teaching experts, characterized by their robust practical experience, specialized knowledge, and skills in designing high-quality courses that focus on providing participants with a fruitful and tailored learning experience. This would improve participants' competencies and equip them with valuable practical skills allowing them to thrive in their profession.

Osten Healthcare is remarkable when it comes to the follow-up & personalized support offered after the course completion, ensuring participants are satisfied with their learning outcomes.

In fact, our service extends beyond the workshop as our experts are always ready to answer any question.

International Organization for Standardization ISO 9001

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

IAS INTERNATIONAL ACCREDITATION SERVICE

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For Registration

www.ostenhealthcare.com

For Any Inquiry

WhatsApp: +961 3 947827

Email: info@ostenhealthcare.com

CPD MEMBER
The CPD Certification Service

HEADQUARTER
IRELAND
Pigott's Street, Loughrea, Co.
Galway, H62 H721; Ireland
Tel: +353 91398122

MENA REGION
EGYPT
Romex
32 Mostafa, El-Nahhas St.
Nasr City, Cairo
Tel: +20 1283175522

EUROPE
CYPRUS
Themidos 8, APSIS COURT, 3rd floor,
office 301, 6057 Larnaca, Cyprus
Tel: +357 96131181

Osten