CPD MEMBER
The CPD Certification Service

Osten

Clinical Research Associate (CRA) – Foundations

COURSE DESCRIPTION

This course provides practical training as it relates to the CRA job function, and covers core sponsor and research site activities that promote the successful monitoring of studies for investigational medicinal products. Good Clinical Practice (GCP) skills are reinforced as well.

TOPICS COVERED

Mentioned in the program schedule below.

COURSE LEARNING OBJECTIVES

At the end of the training, participants will:

- Understand the CRA's critical role in the conduct of clinical trials
- Learn how to choose and set up sites (clinics, hospitals) for clinical trials
- Develop and document clinical research protocols
- Create tools such as forms and surveys for data collection
- Train doctors, nurses and other staff to follow the protocol
- Monitor ongoing clinical trials to ensure compliance

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
- **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 HOURS / 3 DAYS

DAY 1

Session 1

Drug development process

- Background of medicines development
- Research and discovery stage & product development
- Regulatory submission, Health Technology Assessment, lifecycle management

Session 2

Good Clinical Practice (GCP) guidelines

- ICH GCP and other applicable regulations

Session 3

Regulatory environment in the EU and USA

- ICH GCP E6 (R2)
- FDA Regulation
- EU Regulation

Session 4

Clinical trial design, protocol, & clinical research roles and responsibilities

- The Study Protocol (Elements of a Study Protocol according to ICH GCP, Trial Design, Methodologies)
- Roles and Responsibilities (Ethics Committees, Sponsor / Monitor, Investigator, Competent Authority)

DAY 2

Session 1

Clinical Research Associate (CRA) job function

- The CRA's critical role in the conduct of clinical trials

Session 2

Selecting and initiating clinical trial sites

- Selecting an investigational site (assessing investigational sites, training and upgrading investigational sites)
- Initiating investigational sites (organizing the initiation visit, setting up the required documentation – Essential Documents)

Session 3

Monitoring clinical trial sites

- Effective monitoring (planning, conducting, documenting, and reporting monitoring visits, managing issues)

Session 4

Closing clinical trial sites

- Closing investigational sites (organizing the close-out visit, documentation, reporting)

DAY 3

Session 1

Patient protection & adverse events

- Patient protection (patient information, collecting patient consent, patient populations)
- Adverse Event Reporting (types of adverse events, identifying and reporting Serious Adverse Events)

Session 2

Investigational medicinal product management

- Managing the Investigational Medicinal Product (definition of investigational medicinal product (IMP) / study drug, provision of the imp, drug accountability, managing expiry dates, collecting IMP after site close-out)

Session 3

Data management for clinical research associates

- Data collection (Clinical Research Form, process of data collection, data collection systems)
- Data validation (data validation process, query process, data quality assurance)

Session 4

Quality Assurance: audits and inspections

- The role of Clinical Research Associates in regulatory compliance and quality assurance: audits and inspections

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

BQSR

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