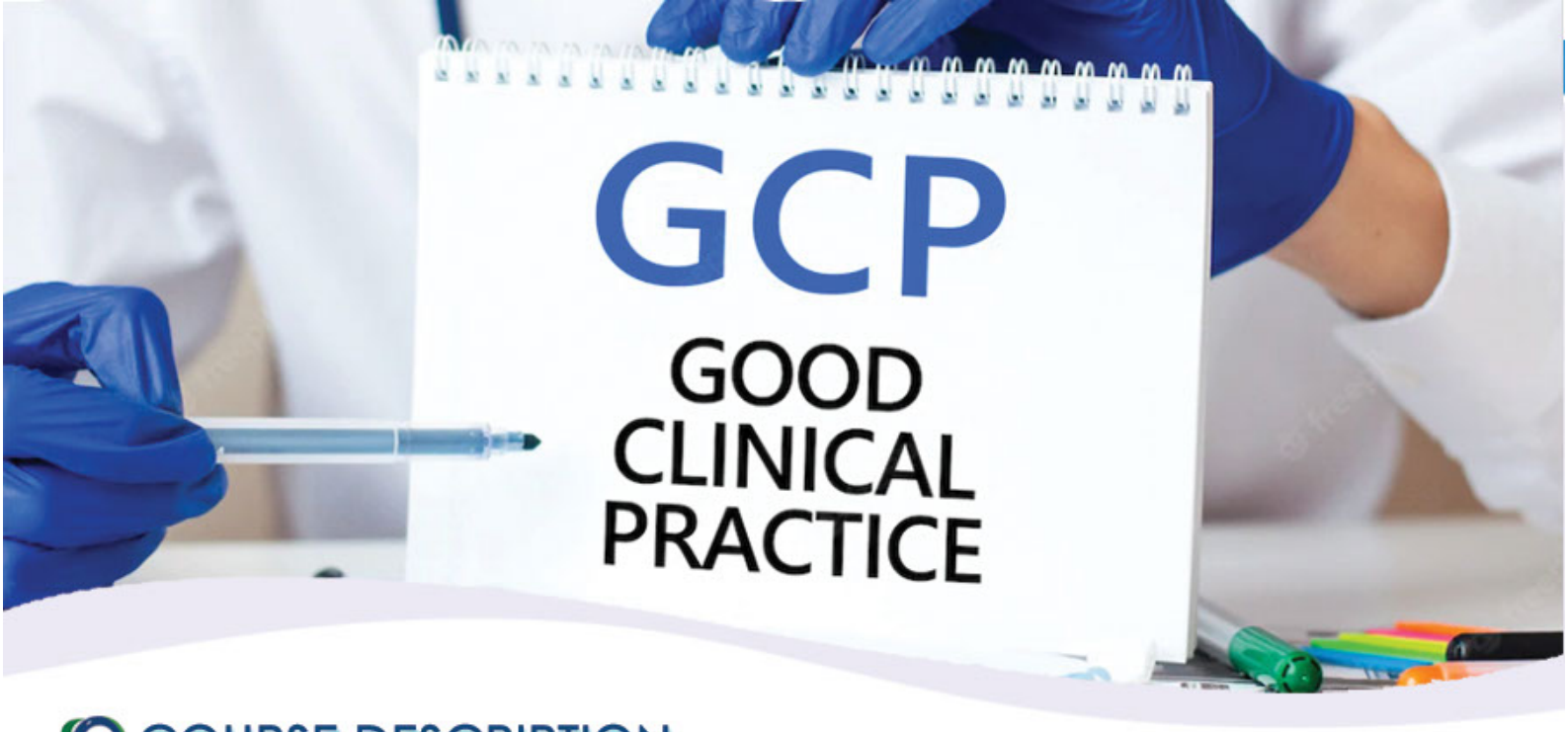
CPD MEMBER
The CPD Certification Service

Osten

Good Clinical Practice (GCP)



COURSE DESCRIPTION

This course is designed for healthcare professionals, who have limited experience and no formal training in Good Clinical Practice (GCP). It offers a comprehensive yet concentrated overview of the principles of GCP, FDA and Global Regulations, and the roles and responsibilities of the clinical investigator/site, IRB, sponsor, and study monitor.

TOPICS COVERED

Mentioned in the program schedule below.

COURSE LEARNING OBJECTIVES

At the end of the training, participants will:

- Understand the basics of GCP and the current legal regulations and guidelines
- Have the confidence to identify and describe the main responsibilities of the IRB, the investigator, the sponsor and the monito
- Be familiar with the essential documents related to GCP and understand the essence and purpose of important trial-related files, such as the informed consent forms, the investigator's brochure, and the clinical trial protocol

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

History and principles of ICH / GCP

- An overview of the history and rationale behind GCP
- Ethical principles (Declaration of Helsinki, Nuremberg, Belmont Report, etc.)

Session 2

What is GCP?

- Introduction to GCP, consequences of non-compliance
- An overview of the language and common terms for investigators, sponsors, and ethics committees

Session 3

Role of Institutional Review Boards (IRB)

- An overview of role, responsibilities, composition, function, and operations of the IRB

Session 4

Roles of investigator and Sponsor

- The process of selection of the investigators as well as the investigators' qualifications and responsibilities as specified by the regulatory requirements
- An overview of the sponsor's trial-related duties and functions

DAY 2

Session 1

Essential documents for the conduct of clinical trials

- An overview of records retention as well as the required documents in different clinical trial phases

Session 2

Clinical trial protocol compliance and amendment

- Introduction to the different parts and sections of the protocol (objective, trial design, selection and withdrawal of subjects, treatment, safety assessment, quality control, and record keeping), as well as its amendment

Session 3

Investigator's brochure

- An overview of the responsibility of the sponsor in the development of the investigator's brochure

Session 4

Informed consent

- Basic elements of informed consent, samples of informed consents

DAY 3

Session 1

Safety reporting

- Principles of Adverse Drug Reactions (ADRs), Unexpected ADRs and Serious Adverse Events (SAEs) reporting

Session 2

Records and reports management

- Accurate maintenance, completion, and submission of records and reports

Session 3

Management of premature termination or suspension of a trial

- Process and implications of premature termination or suspension of a trial

Session 4

Audits, inspection, and monitoring of clinical research studies

- Reviews auditing, inspections, and monitoring of drug studies in clinical research

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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