

## **Introduction to ICH-GCP**

The definition and main purposes of Good Clinical Practice

Historical background of GCP

Founder members of ICH (International Conference on Harmonisation)

Key facts about the Declaration of Helsinki

Importance of GCP and its 13 Core Principles

## **Ethics Committees**

Difference between IRBs and IECs

Definition and types

Composition, functions and authority

Records

## **Investigators**

Definition and responsibilities of the clinical research investigator

Definition and structure of the Investigator's Brochure

Information about investigational medicinal products

Investigation procedures

Randomization and unblinding

Records and reports

## **Informed consent**

The definition of Informed Consent

Who should give the information and how

Steps in informed consent process

What explanations should be given to the trial subject

Vulnerable and special populations

Things to consider before the trial

## **Sponsors**

Definition

Trial design and data handling

Selection of investigators

Compensation to subjects and investigators

Financing and regulatory submissions

Investigational products - manufacturing, labeling, supplying and handling

Reporting of adverse drug reactions (ADRs) and noncompliance

## **Monitors**

Definition

Purpose

Selection and qualification of monitors

Responsibilities

## **Clinical trial protocol**

Definition

Purpose

Protocol content

Protocol amendment and deviate

## **Recording and reporting**

Source data & source documents

What data is documented?

Requirements for electronic source records

Case report forms - definition & purpose

Safety data - AEs, ARs, UARs, SAEs, ADRs

How to manage and when to report ADRs?

## **Essential documents**

Definition and purpose

Clinical trial master file

Types of essential documents

Essential documents before the clinical phase of the trial commences

Essential documents during the clinical conduct of the trial

Essential documents after completion or termination of the trial

Additional essential documents