

GCP Refresher

Practical information: Number of participants: Between 5 and 12

Duration: ½ day

Price per person @ Valesta office: €450

Course Overview

All personnel involved in clinical studies must be aware of the Good Clinical Practice guidelines and it is highly recommended to have a refresher course every 3 years to keep their knowledge up to date.

This course provides a comprehensive refresh of the clinical studies process and covers the key GCP requirements and responsibilities for the different involved parties. The updates made to ICH GCP in 2016 are included in this training.

This interactive refresher course on ICH-GCP meets all minimum criteria for TransCelerate BioPharma ICH E6 (R2) GCP Investigator Site Personnel Training.

By attending this course you will gain:

A comprehensive refresh of the Good Clinical Practice guidelines through interactive and case-study based learning outlining:

- Principles of ICH-GCP and requirements
- Overview of the different phases in clinical studies
- Responsibilities of the main players
- Essential GCP related documents
- Audit & Inspection criteria
- Responsibilities and tasks of different involved parties in a clinical trial

Course Content

This interactive half day training will provide all basic Good Clinical Practice information to persons looking to update their knowledge of clinical trials. Real life examples are used to illustrate the different requirements.

Topics that are being covered during this training are:

- Drug/Device Development cycle
- What is Good Clinical Practice?
- Responsibilities of main Players in a Clinical Study
- 13 Principles of ICH-GCP
- Good Documentation Practices
- Requirements for Essential Documents

The course will provide certification for the completion of GCP refresher training.

For more information or to reserve a seat on this training course please contact us today!

We are flexible! Should you require training to be carried out in-house, we would be happy to discuss your needs and come up with a suitable solution for you.

Call our office on +32 15 28 15 05!