

## Introduction to Good Clinical Practice Guidelines (ICH GCP and ISO14155)

**Practical information:** Number of participants: Between 4 and 12

Duration: 1 days (09:00 – 17:00)

Price per person @ Valesta office: €750

### Course Overview

All professionals within clinical trials need to be aware of Good Clinical Practice (GCP) requirements to ensure they work in accordance with the highest standards set for clinical trials.

This one day course will introduce you to the GCP guidelines and the applicable regulatory requirements that have been put in place for the conduct and monitoring of clinical trials.

Both the pharmaceutical guidelines (ICH GCP) and the medical devices standards (ISO14155) are covered. The course content has been recently updated to include the changes of the latest revision of ICH GCP E6 (R2) such as quality management and monitoring of clinical trials.

This training course provides the essential foundation to anyone new in this area and is a great starting point to ensure a successful career in the world of clinical trials.

### By attending this course you will gain:

- ✓ A comprehensive understanding of the GCP requirements
- ✓ Knowledge on the set of essential documents required in clinical trials
- ✓ An understanding of the responsibilities of all involved parties.

### Course Content

The topics covered during this course include:

- Product development cycle
- Main players involved in clinical research and their responsibilities
- Applicable regulations for clinical research
- Informed Consent requirements – content and process
- How to deliver high quality clinical trials
- Document requirements per Good Documentation Practices

Using exercises and quizzes, this interactive course will provide attendees with a comprehensive level of knowledge on GCP. Real life examples are used to illustrate the requirements. Upon completion of the course, each participant will be provided with a GCP certification.

**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.***