

Preparing for an Inspection and/or Audit

Practical information: Number of participants: Between 5 and 12
Duration: ½ day (13:00 – 17:30)
Price per person @ Valesta office: €450

Course Overview

Audits and inspections are key aspects of everyday clinical trials and are essential for the safe and efficient functioning of any clinical environment. They are designed to improve patient care and outcomes through the systematic review of care against certain criteria and are a very important part of Good Clinical Practice.

Being prepared for an inspection/audit is critical to the success of a trial site and your organisation. This practical half-day course will comprehensively guide clinical research professionals through each step of a clinical inspection/audit and what checks and processes need to be in place to achieve a successful outcome.

By attending this course you will gain:

A comprehensive refresh of the GCP guidelines through interactive and case-study based learning:

- ✓ Hands-on experience on how to prepare
 - a clinical trial team for an inspection and/or an audit
 - a site for an inspection and/or an audit
- ✓ An understanding of the quality management processes that needs to be followed
- ✓ The ability to ensure all documentation is accurate and up-to-date
- ✓ An understanding of the different types of inspections/audits
- ✓ An understanding of what will be inspected and what an inspector/auditor is looking for
- ✓ An understanding of general inspection and preparation instructions

Course Content

This course will cover the basics of inspection and audit readiness, the processes to follow and provide an update on the main regulations regarding global and local inspections and/or audits.

- The purpose of an inspection/audit
- The differences between inspections and audits
- The different types of inspection/audit
- What can be reviewed, when and why
- Steps to take when an inspection/audit of a project is announced
- How to act and communicate during an inspection/audit (do's and don'ts)
- General inspection instructions

Simulations of real-life situations (e.g. role play and workshop concept) will be used so that you will learn more about the “do's and don'ts” before, during and after an inspection and/or audit.

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.