

PREPARING INVESTIGATOR SITES & R&D DEPTS FOR GCP INSPECTIONS

A one day training course

Who should attend?

This course is for all clinical research professionals in the non-commercial sector working on trials subject to inspection by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Course Structure

The morning session will concentrate on issues and systems at an organisational level from within the R&D department together with a practical exercise looking at the steps and inputs needed when preparing your GCP Inspection Dossier. The afternoon will drill down further to focus on issues relevant at the trial site level including the key departments of pharmacy and clinical laboratory.

Course Venues

The one day course is currently being held on
29 February – London

Contact us if you would like to host this course at your organization.

Course Objectives

Upon successful completion of this course, participants will be able to:

1. Explain the objectives of GCP inspections and what inspectors' will review
2. Develop an action plan to prepare for Inspection
3. Identify and use at least 3 positive approaches for interviews during inspections
4. State 6 common inspection findings in relation to systems, Investigational Medicinal Product management and training
5. Formulate corrective actions and preventative actions

Fees and Registration

Fees: £285. The course fee includes a course workbook, light lunch and refreshments. Accommodation is not included.

To view the agenda and further details and to book online see:
www.rdforum.nhs.uk

Feedback from previous attendees:

One of the best I have been on, highlights the importance of Inspections - also reflects that as an R&D team we should be aware of each others roles and expectations.

Plan well ahead for MHRA inspection i.e. NOW!!

Excellent course. I would recommend to colleagues.

Very comprehensive - feel able to prepare for inspections and focus on areas for improving practice