



Training & Personal Development

## Inspection Readiness

This course allows delegates to develop a strategy for undertaking a successful audit or inspection. Audits and inspections need not be intimidating if the work has been done to prepare for them. This course helps delegates to be effective in planning and putting in place activities for forthcoming audits and inspections.

**Duration:** One Day  
**Course leader:** Gareth Hayes  
**Cost:** £  
**Venue:** TBC

Book now: [training@phlexglobal.com](mailto:training@phlexglobal.com); ☎ 01494 720420

Further information: 📄 [www.phlexglobal.com/training](http://www.phlexglobal.com/training)

### Topics:

- Demystifying the inspection
- What is being inspected?
- Preparedness and organisation
- TMF Technical Review
- History, sheets and File Notes
- The Introductory meeting
- Interviews and questions
- Taking notes
- The exit meeting
- Responding to inspection findings
- What can go wrong and what will go well!
- Checking, QC, Monitoring, Auditing, Inspecting

### Benefits:

- This course uses a blend of trainer input and group discussion to ensure that delegates will be able to:**
- Understand the process and procedures of an audit/inspection
  - Recognise and prioritise methodologies to prepare for an audit/inspection
  - Identify key stakeholders in the audit/inspection process
  - Plan and prepare efficiently for an audit/inspection
  - Learn how to reduce anxieties and minimise surprises

### Leader Biography:

**Gareth Hayes** is European Head of Training and Personal Development at Phlexglobal Ltd. With twenty-eight years industry experience, Gareth continues to be at the forefront of our industry's training needs specific to research. He completed the Monograph Communication and Presentation Skills for the Institute of Clinical Research in 2005 and is Co-editor of the Institute of Clinical Research's Principles of Clinical Research (2001), is author of three chapters (CRA, CTA/SSC, Training and Education) in Careers with the Pharmaceutical Industry (John Wiley 2003). A Quick Guide to Clinical Trials (edited by Davies and Kermani) published in May 2008 features a chapter by Gareth entitled The Clinical Trial Process: Monitoring.

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