



Training & Personal Development

Introduction to Clinical Research

Are you new to the industry or new to your role and need to see why you are so important? This course gives delegates an understanding of the day-to-day activities involved in the clinical research activities of drug development. It familiarises delegates with the terminology and introduces the principles of Good Clinical Practice. This course also exposes delegates to the key roles within clinical research and explains how your role and your skills are key to the drug development process.

Course dates and venues are published on www.phlexglobal.com/training

This course uses a mix of formal presentations, workshops and exercises

Book now: training@phlexglobal.com; ☎ 01494 720420

Further information: 🌐 www.phlexglobal.com/training

Course Outline:

- Introduction to the pharmaceutical industry
- Different departments in a pharmaceutical company
- Phases of a clinical trial (I-IV)
- The critical path of a clinical trial
- Clinical Trial Administrator within a clinical research team
- Good clinical (Research) Practice
- Standard Operation Procedures
- Trial Master File & essential documents
- Serious Adverse Events
- Checklists and tracking – when, where, what?
- Audit, QA and QC
- Archiving and document management
- Understand statistics and data management
- External relationships
- Skills required to develop to be successful

Course Benefits:

The course will use a blend of trainer input and group discussion to ensure that delegates will be able to:

- Understand the clinical trial process
- Identify trial documentation involved in the clinical trial process
- Describe the terminology used in clinical research & Good Clinical Practice (GCP)
- Gain an understanding of roles and responsibilities of the clinical research team

Leader Biography:

Gareth Hayes is a regular speaker at many clinical research conferences and events both in the commercial and non-commercial arena. He is at the forefront of the industry's training approach and regularly contributes articles to key publications. He completed the Monograph Communication and Presentation Skills for the Institute of Clinical Research in 2005; is co-editor of the Institute of Clinical Research's Principles of Clinical Research (2001); and is author of three chapters (CRA, CTA/SSC, Training and Education) in Careers with the Pharmaceutical Industry (2003). A Quick Guide to Clinical Trials published in May 2008 features a chapter by Gareth entitled The Clinical Trial Process: Monitoring. In April 2006 Gareth was awarded an Honorary Fellowship by the Institute of Clinical Research and in 2008 was Vice Chairman of their Board of Directors. In March 2009 he was awarded Chartered Scientist status by the Science Council.

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