



Training & Personal Development

## Introduction to Good Clinical Practice

A one-day seminar covering the essential background to Clinical Development, Regulations and Research Practices.

Course dates and venues are published on [www.phlexglobal.com/training](http://www.phlexglobal.com/training)

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

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

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### Course Outline:

- Introduction to Clinical Development
- Phases of a Clinical Trial (I – IV) and Clinical Trial Design
- The Critical Path of a Clinical Trial
- The Clinical Research Team
- Good Clinical (Research) Practice: legislation, regulation, guidelines
- EU Directive and Statutory Instrument
- Ethics Committees, Patient Consent and Pharmacovigilance
- Standard Operation Procedures and Essential Documents
- Audit, QA, QC and Inspections

### 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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