



**Training & Personal Development**

## **GCP and Statutory Instrument Update**

This course is essential to everyone that has a contribution to make in our clinical research arena and who have some previous knowledge and use of GCP. It will provide all the latest information on the new regulations, particularly regarding Statutory Instruments, additional requirements for informed consent and the importance of the audit/inspection process.

*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:**

- Principles of ICH GCP
- Refresher on the EU Clinical Trial Directive
- Refresher on the EU GCP Directive
- Safety Reporting
- Informed Consent
- Regulatory Authority Inspections
- Serious Breaches

### **Course Benefits:**

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

- Examine key aspects of the Directive's implementation on your clinical research activities
- Challenge and predict how processes will need to alter in line with forthcoming regulatory and legislative changes

### **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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