

# **GOOD CLINICAL PRACTICE AND EU DIRECTIVE TRAINING SESSIONS FOR ANYONE INVOLVED IN RESEARCH**

**Monday 26<sup>th</sup> April 2010 (am half day) Full course**  
**Venue – Seminar Room 2, Clinical School**  
**Tuesday 25<sup>th</sup> May 2010 (am half day) Full course**  
**Venue – Seminar room 3, Clinical School**  
**Tuesday 25<sup>th</sup> May 2010 (pm 2 hrs) Refresher\*\***  
**Venue – Seminar room 3, Clinical School**

## **Course Outline:**

These sessions held at Addenbrooke's Hospital and led by Tanya Symons, will provide an informal but intensive overview of the fundamentals of Good Clinical Practice (GCP). The training is based on the ICH GCP guidelines but also introduces The Medicines for Human Use (Clinical Trials) Regulations, which have transposed the EU Clinical Trials Directive into UK law (1 May 2004).

*It is recommended that GCP training is undertaken every two years and many commercial companies are now insisting that researchers involved in Clinical Trials have received GCP Training.*

Tanya Symons has worked in the field of clinical research for over ten years, monitoring and managing a variety of trials. For the past eight years, she has worked as a freelance GCP & clinical trials consultant training sponsors, ethics committees and study site staff in the processes and requirements of clinical research.

## **By the end of this course you will be able to:**

- **Understand the fundamentals of the EU Clinical Trials Directive and the implementing UK Regulations**
- **Differentiate between the statutory requirements and the Good Practice requirements in clinical research**
- **Formulate strategies for incorporating the principles of GCP at the trial site**
- **Be aware of the changes to the ethics process and the definition and responsibilities of the Sponsor and Investigator**
- **Understand the requirements for informed consent and safety reporting**
- **Define an Essential Document and understand the requirements for clinical trial documentation and data quality**
- **Be aware of the best sources of further information and practical guidance**

## **The Refresher course\*\***

This is only aimed at those who have taken the full course within the last two years and are coming up to renewal. Copy of your current GCP training certificate needs to be attached to your application for the refresher course.

**To reserve your place, please complete the registration form and return to Sylvie Robinson at [sylvie.robinson@addenbrookes.nhs.uk](mailto:sylvie.robinson@addenbrookes.nhs.uk) or by post to Research and Development Department, Box 277, Addenbrooke's Hospital, Hills Road, Cambridge, CB2 0QQ**