



Training & Personal Development

GCP Compliance in Document Management

Document management, archiving and electronic records management are at the heart of everything we do in clinical research. The quality and integrity of clinical research depends entirely on how we handle the data and how we strive to comply with legislation against corporate business needs in this highly regulated arena. This course examines the problems and provides the solutions for this rapidly changing and demanding topic.

Run in association with The Institute of Clinical Research



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

Book now: training@icr-global.org; ☎ 01628 536967

Further information: 📍 www.phlexglobal.com/training

Course Outline:

- Impact of regulatory changes (EU CT Directive, Declaration of Helsinki, Data Protection Act)
- Current GCP issues – consent, ethics and essential documents
- The what, where, when, why and how of archiving
- Electronic records management and electronic archiving
- Investigator and site archiving
- Preparing for audits/inspections and what the inspectors expect
- Archiving and retention requirements of GCP/EUCTD and regulatory authorities
- Preparation of documents for archiving and tracking of archived documents
- Requirements of archives for long-term storage and alternative long-term storage media
- How to select a suitable off-site storage company

Course Benefits:

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

- Gain familiarisation with and latest updates on European & UK Regulations for handling clinical documents
- Identify issues in electronic document management
- Understand how to handle those 'problem' documents such as correspondence and e-mails
- Learn how to prepare for an audit/inspection
- Understand the procedures for preparation and transfer to archive for clinical research documents

Leader Biography:

Liz Hooper trained as a librarian working in a film library and then for BBC TV news as a photographic librarian. Liz joined Roussel Laboratories in 1990 and became assistant records manager. Whilst at Roussel and through three company mergers, Liz gained vast experience of site closures and preservation of company records. Liz joined Phlex in 2000 to establish their Records Management and Archiving department. Liz is an experienced trainer for GCP Documentation and Archiving and has published several articles. Liz is also a member of ICR, BARQA and GCP-RMA and the organising committee of the scientific Archivist Group.

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