The role of the Archivist and the operation of a GLP archive

The course will be run by Qualogy Ltd at the Qualogy Regulatory Archive facility in Rushden, Northamptonshire.

The course has been designed to provide practical training and guidance to those responsible for the management and operation of a Good Laboratory Practice (GLP) regulatory archive. The course covers what constitutes an archive and the specific regulatory requirements which apply to such facilities.

09.30 Welcome and Introductions

09.35 Regulatory Requirements

An examination of the current GLP regulations and guidance as they apply to the archiving and retention of regulatory materials. Reference to UK MHRA GLP Statutory Instrument 3106 and the published guidance for GLP archives as well as the OECD Monograph No.15 on the operation of a GLP archive. Reference is also made to other standards covering the archiving of records.

10.10 Records management

The foundations for a well run archive operation is based upon sound records management. This presentation examines the principles of records management and the establishment of a records retention schedule.

10.30 Coffee

10.45 Responsibilities

The role and responsibility of staff involved in the regulatory archiving process, specifically:

- Facility Management including definition
- Study Director
- Principal Investigator
- Contract Research Organisation (CRO)
- Data management
- Archivist
- Sponsor Study
- Quality Assurance
- Study Staff

11.20 Design of the archive

A presentation on what constitutes a “regulatory” archive, its definition, design and environmental conditions of operation.

11.45 Operation of an Archive

This session examines the practical issues associated with operating an archive. It will include the receipt of material from the depositor, indexing material, maintenance of the facility and material deposited, retrievals from the archive and eventual return or destruction of material retained. This session will also address the issue of how long regulatory material should be retained?

12.30 Lunch

13.15 Tour of the archive facility. Leigh Tate, Archivist

The opportunity to view a regulatory archive in operation. A discussion session relating to any specific issues associated with the running of the archive will follow the visit.

14.00 What to Archive

This session will not only address the specific requirements of raw data but will also identify some of the other records and materials (samples) which would be required to demonstrate/support the compliance of GLP studies.

14.20 Archiving of electronic records and Data Integrity

Today many of the records retained and archive are electronic. The specific requirements for the archiving of electronic records and the role of the archivist will be covered during this presentation. Reference to the UK MHRA Data Integrity Guidance document will be included in this presentation.

15.00 Tea

15.15 Third Party Archive Facilities

When a sponsor contracts a non-clinical study to a CRO the data is often retained by the CRO that conducted the work. This session will examine some of the factors to consider and other options that exist in order for the sponsor to manage their data. The issue of data ownership is also addressed.

15.35 Problem Areas

The retention of most records and materials is routinely straight forward but from time to time material or situations arise which challenge the routine. This session is designed to examine some of those challenges whilst also providing the delegates with the opportunity to discuss their own.

Areas to be covered will include; perishable materials, microfilming or scanning records, study samples and specimens, Multi site studies, return of sponsors data and disaster recovery plans.

16.10 Inspections

Periodically the archive will be inspected by Quality Assurance and GLP Regulatory Inspectors. What can the Archivist expect from such inspections? This session will examine both types of inspection and their approach.

16.30 Close of course

Course Presenter

Tim Stiles is a Director of Qualogy Ltd, an internationally renowned consultancy firm that provides assistance to organisations implementing GCP and GLP regulations and GCLP guidelines. Qualogy Regulatory Archive Services provide dedicated contract archiving facilities to those organisations working in compliance with GLP, GCP and GMP.

Tim has worked within the regulatory arena for over thirty five years. He was a member of the International Expert Group within The Organisation for Economic Co-operation and Development (OECD), which worked on the 1997 revision of their principles of Good Laboratory Practice.

He is currently a member of the Board of the Research Quality Assurance (RQA), formally The British Association of Research Quality Assurance (BARQA), He is a past Chairman of the Association and has served on numerous committees and working groups of the group.

Tim has worked, lectured and trained within the UK, Europe, Asia, Australia, Canada, China India, Bulgaria, Japan, Kenya, South Africa, Tanzania, Rwanda, Uganda, Singapore, South America and USA on many aspects of GLP, GCP and GCLP.