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

The course will be run 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 Clinical Practice (GCP) regulatory archive. The course will define what constitutes an archive and the specific regulatory requirements which apply to such facilities. The course will be very interactive with delegates being encouraged to participate in discussions and raise any questions which are of particular concern regarding the operation of the archive facility and the archive process.

The times given in this programme are intended as a rough guide only. The programme will be adjusted to meet the collective needs of the delegates attending the course. More or less time will be spent on the specific topics as required by the delegates.

09.30 **Welcome and Introductions**

09.35 **Regulatory Requirements**

An examination of the current GCP regulations and their application to the archiving and retention of regulatory materials. Reference to the EU Clinical Trial Directive and ICH GCP will be made as well as to other relevant standards such the OECD Monograph No.15 on the operation of a GLP archive and ISO.

10.05 **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 archiving process, specifically:

Sponsors	Archivist	Study Monitors
Principal Investigator	Clinical Laboratories	Study staff
Data management	Contract Research Organisations	

11.15 **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 a GCP archive.

It will include the receipt and indexing of material, maintenance of the archive facility, 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 and the ICH requirements for the retention of the Trial Master Files.

12.30 Lunch

13.15 Tour of the archive facility

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.

14.00 What to Archive

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

14.30 Archiving of electronic records

Today many of the records we 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.

15.00 Tea

15.15 Third Party Archive Facilities

When a sponsor conducts a clinical trial data is often retained at the various sites that conducted the work, including the Investigator site. This session will examine some of the factors to consider when managing data from the different locations involved in a trial. Some of the options that exist in order for the sponsor to manage their data are explored. 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, withdrawal of subject consent, scanning records, study samples and specimens retained for possible future research, return of sponsors data and disaster recovery plans.

16.10 Inspections

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

16.30 Course ends

Course Presenters

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 a past Chairman of The British Association of Research Quality Assurance, now RQA, and has served on numerous committees and working groups of the Association.

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.