Training Course

GxP-Regulated Archives and the GxP Archivist

Dates: see website

The course is available as either a 1-day classroom-based course (scheduled twice each year) or as a series of monthly web-based seminars (webinars). The course content for both is identical.

The course has been designed to provide practical training and guidance to those responsible for the management and operation of a GxP-regulated archive, including GLP and GCP archives. The course defines what constitutes an archive and the specific regulatory requirements which apply to such facilities, highlighting any differences where they exist between different regulations. Delegates will understand how the principles described apply both to the management of traditional physical records (e.g. paper, tissues, samples) and to digital records. The classroom course will be interactive, with delegates being encouraged to participate in discussions. There will be some opportunity for interaction on the web-based course, but this will be limited.

Course Outline

Welcome and Introductions

Module 1 Records Management Principles

An overview of essential records management principles, including the records lifecycle. This will demonstrate the importance of good practices during the creation and use of records prior to their archiving and how this can impact archive process. We will describe the function of a records retention schedule and how this relates to archive management. We will show that the archive is one component of a broader discipline.

Module 2 Regulatory Framework for GxP Archives

This session will review the current regulations pertaining to archiving and long-term preservation of records, identifying the commonalities between GxP regulations and highlighting regulations that are specific to GCP, GLP, etc. The primary focus will be on regulations pertinent to the main ICH regions (ICH, EU and Japan) and OECD principles. We will include regulations that are specific to electronic records.

Module 3 The GxP Archivist

This session will describe the roles and responsibilities of the nominated Archivist and review the roles and responsibilities of other key stakeholders, including:

- Study Director / Study Manager
- Facility Manager / Sponsor
- Study Team Members, including monitors
- Third parties, including laboratories, principal investigator

We will review the differences between an Archivist and Records Manager.

Module 4 The GxP Archive

This session will review the features of an archive that meets regulatory expectations, including both physical archives and electronic archives. We will discuss archive design and structure, security, and environmental controls.

We will review the day-to-day operation and management of a regulated archive, including processes such as receipt and indexing, maintenance (e.g. reviews), access control, retrievals, loans, destruction.

This session will also cover what should be archived and what should be rejected from the archive.

Module 5 Use of Third Parties

Third parties (vendors) may be used during the conduct of a study and/or to assist with the archiving of study records. This session will identify different scenarios for involving third parties and will review issues that need to be managed.

We will discuss how to select a suitable vendor, what contractual issues need to be assessed and how to provide vendor oversight.

For the classroom-based course, lunch and refreshment breaks will be taken at appropriate times during the day. For web-based courses, each module is of approximately one-hour duration.

For course attendees who would like to see an operational archive facility, we have an arrangement for the provision of tours with a number of commercial archives who are HSRAA-member companies and provide storage for GxP-regulated material. Please contact us after completing the course and we will provide details.

Course Presenters

Between them, the two course presenters have over 50 years of GxP industry experience. This includes:

- Responsibility for the management and day-to-day operation of a GxP archive for two Top-10 multi-national pharmaceutical companies;
- First-hand experience of numerous regulatory inspections, including PMDA/MHLW, FDA, EMA and MHRA (GLP, GCP and GMP);
- Audit and assessment of commercial archive vendors on behalf of pharmaceutical industry clients;
- Development of SOPs for GLP, GCP and GMP archives, including SOPs for electronic archives;
- First-hand experience working with over 60 individual pharmaceutical and biotechnology companies.

Eldin Rammell began his records management career in 1986 at Glaxo. He held a variety of information and records management positions of increasing seniority, which continued following his move to Pfizer in 1993. His experience spans most areas of information and records management. In 2004, Eldin established Rammell Consulting, a management consultancy specialising in the provision of records management support, primarily to the pharmaceutical and biotech industries. He is a recognized expert globally in the area of trial master file management, completing over 30 TMF-related consulting projects and being a Steering Committee member of the TMF Reference Model Project. Since 2019, he has worked as a TMF Consultant for Phlexglobal Ltd. He co-authored 'Good Clinical Practice: A Guide to Archiving' and 'A Guide to Archiving of Electronic Records'. He is a regular speaker for IQPC and ExL-Events.

Russell Joyce is an independent, freelance records management and information governance consultant with over 20 years' experience in the pharmaceutical, health, legal, banking, professional services and public sectors. He is co-chair of the Drug Information Association (DIA) Document and Records Management Community and Steering Committee Member for the DIA TMF Reference Model Project, leading a team developing a model for non-interventional studies. He is a member of the HSRAA Operations Committee and author/co-author of numerous HSRAA publications including: 'eTMF Evaluation and Selection', 'TMF Relevant Communications Guidance', 'Scanning and Destruction of TMF Documents', 'Impact of EU 536/2014 on Clinical Records Management' and 'Evaluation and Selection of Commercial Archive Contractors'. He is a frequent speaker on records management topics for SMi, ICR, DIA, GAMP and HSRAA.

Registration Fees

	HSRAA-Member Rate	Standard Rate
Classroom-based Course (includes lunch and refreshments)	£390	£440
Webinar Modules (each)	$100	$110

Note: Our webinar IT platform is provided by a US company and is only enabled for charging in US dollars. The approximate equivalent cost (depending on the exchange rate) is £76 & £83 respectively.

All attendees (classroom and webinar courses) will receive a certificate of attendance and full training slides (PDF), including an invaluable list of references.

For more details, including how to book:

https://the-hsraa.org/training/gxp-archivists-training-course