The HSRAA: Health Sciences Records & Archives Association

- Global, not-for-profit professional association serving the records management and archiving community within health sciences
- Primary focus on GxP-regulated activities, including training, influencing, interpreting, networking
- Annual conference:HSRAA23 - HSRAA Conference (the-hsraa.org)
- Membership (£60): Regular newsletter, reduced training & conference fees, online discussion forum, peer networking, opportunities to contribute to the organisation, plus recognition

https://the-hsraa.org/

HEALTH SCIENCES RECORDS & ARCHIVES ASSOCIATION

Your presenters

Neil has been Head of Records Management at UCB since 2004, where he is responsible for all GxP, research, legal, corporate and commercial archiving for the R&D and commercial operations in the UK and Germany, including legacy archives from previous mergers and acquisitions. He also manages the controlled documentation system in the UK, and engages in global projects for document and records management.

He has been a member of the SAG and HSRAA committee and board since 2005.

Your presenters

Sarah has worked in a GCP environment in the pharmaceutical industry for more than 30 years specialising in TMFs and Records Management in 2005. As Director of Records Management in a medium sized CRO, Sarah set up an eTMF to handle over 80 TMFs and oversaw the archives.

Sarah has run HRM since 2018 contracting her TMF and clinical trial services into the Pharmaceutical industry. She is a member of CDISC and the Health Sciences Records and Archives Association (HSRAA).

Course Overview: The Principles of Managing a GxP Archive

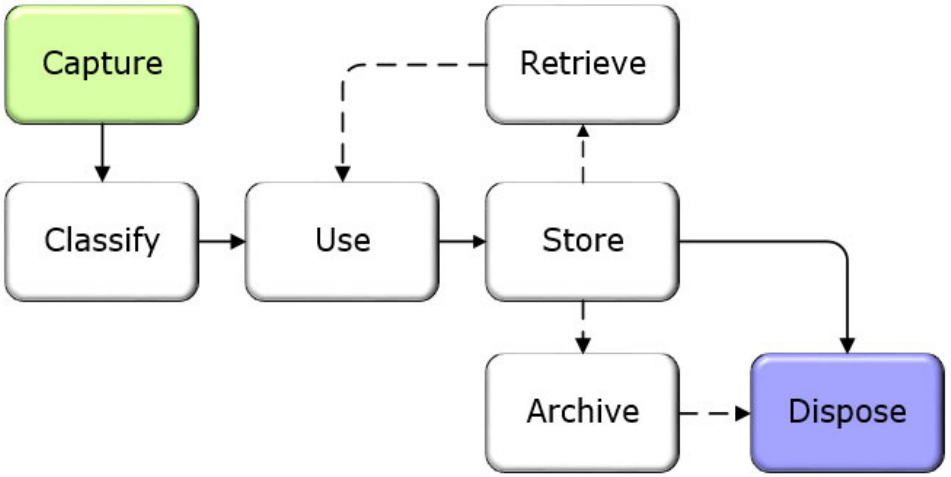
This training workshop will cover the following topics:

- Principles of Archiving
- GxP Regulations
- The GxP Archivist
- The GxP Archive
- Outsourcing

Principles of Archiving

Archiving is part of the Record Management Process

- The manner in which information is generated, processed, reported, checked, used for decision-making, stored and finally discarded
- Optimum process should reflect full records management process
- Management controls best applied at capture
- Good controls downstream facilitate processes upstream
- Archiving is one step in records management process



What is a record?

- "Information created, received or maintained as evidence or information by an organisation or person in pursuance of legal obligations or in the transaction of business." [ISO 15489-1:2001]
- "Documents that individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced" [CPMP/ICH/135/95]
- "All records, in any form, (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct and/or results of a trial, the factors affecting a trial, and the actions taken" [ICH E6 (R2) GCP 1.22]
- Raw data means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated [OECD GLP]

Why is it Important to Retain Records?

- Regulatory/Legislative
  - Incident driven (e.g. Thalidomide)
  - Increasing legislative and regulatory environment in EU and elsewhere
  - Emergence of Good Practices (GLP, GCP, GMP/GDP, GPvP)
  - International Conference on Harmonisation (ICH) and OECD
- Statutory compliance
  - Companies Acts
  - Taxation legislation
  - Data privacy e.g. General Data Protection Regulation

Why is it Important to Retain Records?

- Legal
  - Intellectual property rights preservation
  - Litigation
  - To support or refute contentions in legal actions
  - To protect rights (agreements, contracts and property)
- Commercial
  - Support research and development
  - Effective knowledge and information management
  - Ensure the ready recovery of critical operations following a disaster (disaster recovery – business continuity)
  - Preserve reputation and maintain corporate memory

Why Archive?

- Critical for compliance with GxP regulatory requirements
- Preserves and safeguards records
- Facilitates long term access
- Accepted best practice
  - Records no longer needed daily
  - Improves systems efficiency
  - Reduces clutter
  - Reduces costs

What to Archive?

- All documents and data that individually and collectively
  - enable reconstruction of the activity e.g. study or manufacturing process
  - provide evidence of compliance with regulatory requirements; and
  - permit evaluation of the performance of specified activities (e.g. conduct of a study) and the quality of the data produced

- Includes other supporting documents usually considered non-specific to a particular study or manufacturing batch
  - system development lifecycle (SDLC), computer system validation (CSV)
  - training records
  - tender documents
  - building management records

Archiving Strategy

- What to archive …and for how long?
- Systematic and consistent procedures
  - Retain as when “live” i.e. by function and activity
  - Maintained in context and in relation to subject matter
- Outcome
  - Ease of location and retrieval
  - Faster, more reliable re-use of information
  - Compliance with statutes, regulation, and business need
  - Reduced regulatory and litigation discovery costs

Retention Schedule

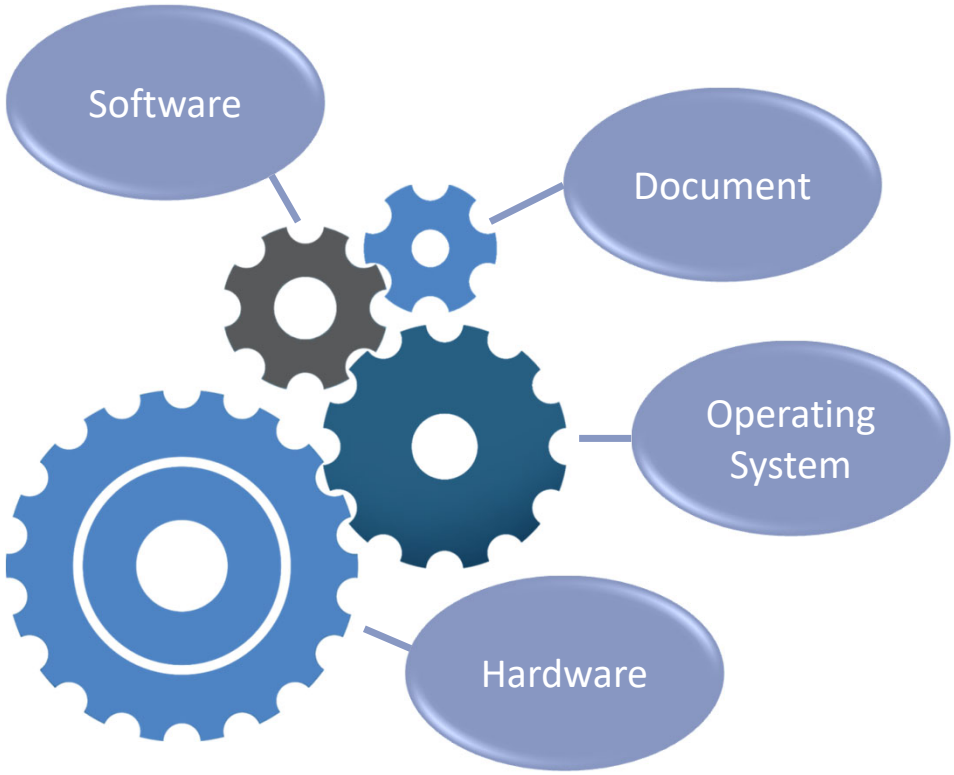
- Definition
  - A document that defines the length of time that (collections of) documents are to be retained and records the reason(s) for retention
- Purpose
  - To ensure that records are retained for as long as required and are disposed of when no longer required
- Typical Shortcomings
  - List of documents
  - No classifications
  - No context
  - No triggers
  - Subjective

Paper vs Electronic Archiving

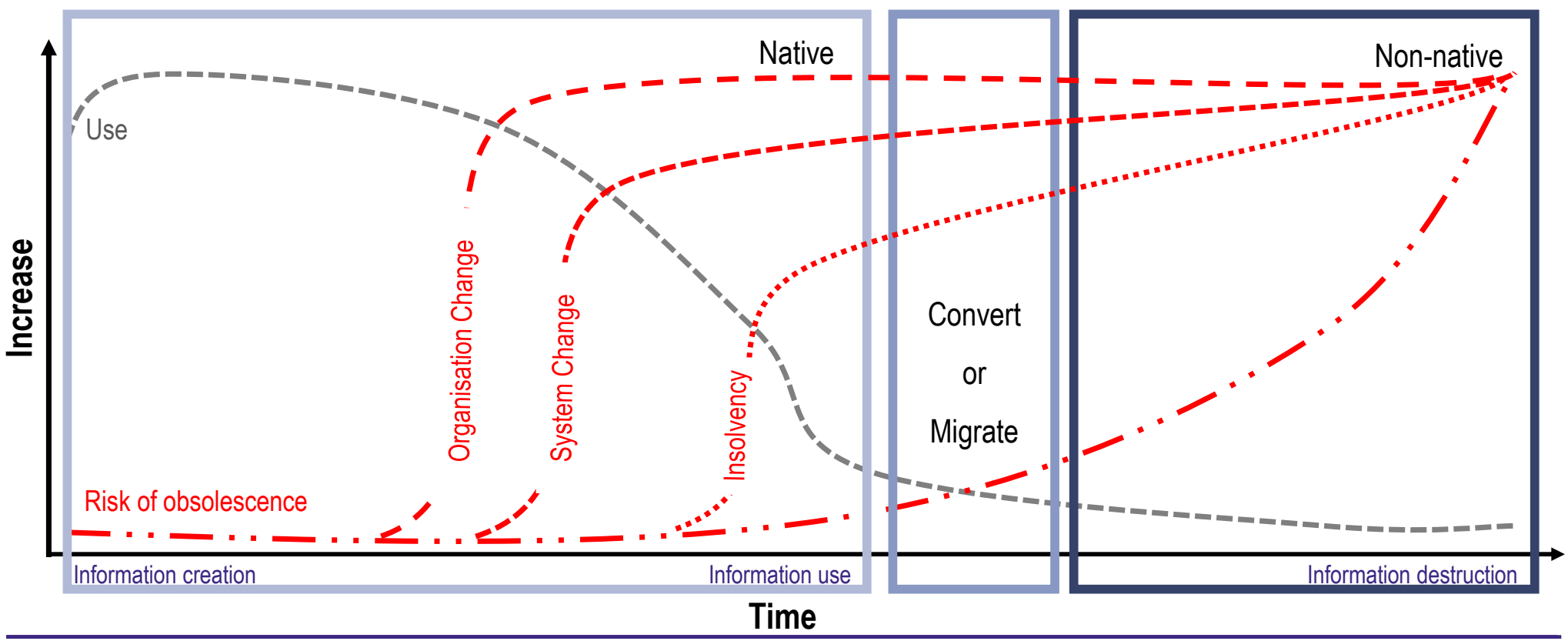
- Regulatory requirements apply equally
- Principles same for digital and paper

  …but to read a digital record you need
  - software (e.g. Microsoft Word; PDF) and
  - operating system (e.g. MS Windows) and
  - hardware (computer, device)

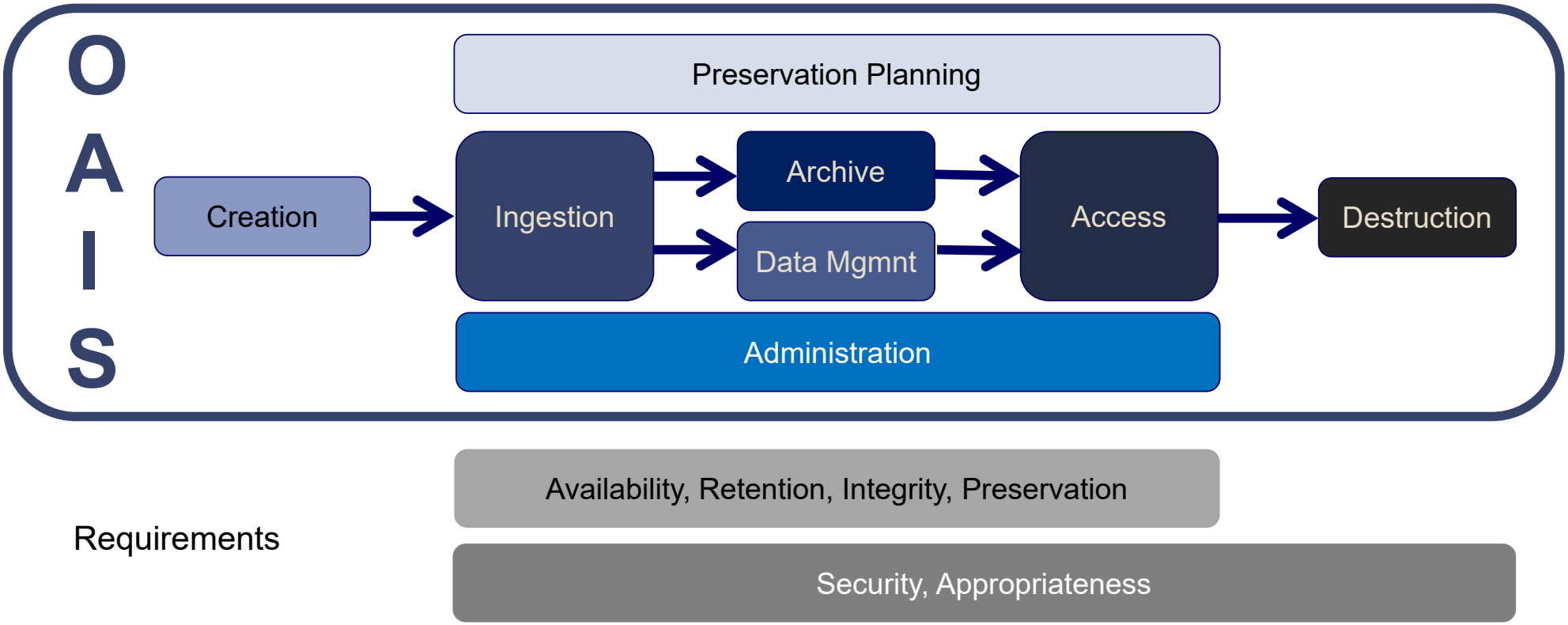
  …and have additional requirements
  - metadata, character, behaviours, accessibility etc
- Obsolescence and degradation
  - Migration? Conversion?



E-Archiving: When to Archive?



Requirements of an E-Archive (ISO 14721:2003)



What is Digital Preservation?

- The ability to use your information in the way you need, for as long as you need it
- Information is usable if you can
  - find it
  - open it
  - work with it
  - understand it
  - trust it
- Establish how to keep information
  - complete
  - available
  - useable

Principles of Archiving - Summary

- Records are required by legislation, regulation, and the organisation to provide evidence of actions, demonstrate compliance with applicable requirements, and facilitate operations
- Archiving is one process in the records timeline
- The active management of records throughout their life is essential in order to ensure their integrity, reliability and trustworthiness from creation to eventual destruction
- An effective and pragmatic approach to records management balances legal and regulatory needs with operational needs and commercial interests
- Digital information management introduces significant advantages and efficiencies but is more complex, particularly in relation to long-term retention

Any questions?

Archive Related Regulations

Archive Related Regulations

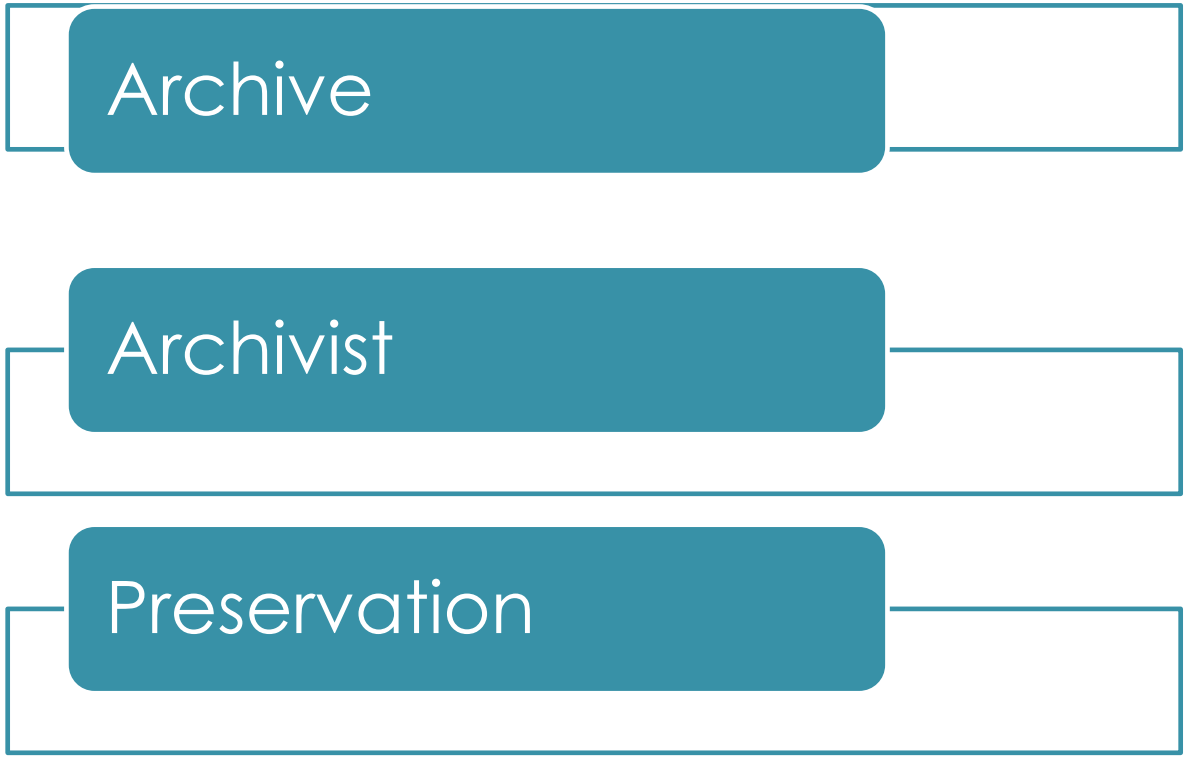
Topic / Archive feature or characteristic

- Regulations — What do the regulations say?
- Examples — Examples of things we can do to meet regulatory requirements

Poll

Do the Regulations (mostly) apply to both paper and electronic archives?

Definitions



Definitions

Archive:

The physical or electronic facility designated for the secure retention and maintenance of archived material, including the operation of that facility under the control of an archivist.

Archivist:

The individual responsible for the day to day operation and management of the archive in accordance with organisational policies, standard operating procedures and GxP**.**

Preservation:

Ensuring that records held in the archive remain accessible and readable through the application of appropriate preservation policies and processes. This includes maintenance of the authenticity and integrity of records.

The Archivist

- The sponsor shall appoint individuals (archivists) within its organisation to be responsible for archives. Access to archives shall be restricted to those individuals. [Reg (EU) No 536/2014 (58)]
- The sponsor shall appoint individuals within its organisation who are responsible for archives.
- Access to archives shall be restricted to the named individuals responsible for the archives. [EU Dir 2005/28/EC § Ch 4, Art 19]
- Withdrawal of and/or access to essential documents from archives should be under the control of the named individuals responsible for archiving. [EMA/INS/GCP/856758/2018, § 6.1 Archiving of the sponsor TMF]
- [Test facility management should] ensure that an individual is identified as responsible for the management of the archive(s) [OECD GLP Section II, 1.1.2 (I)]*

* Also includes 21CFR58 & EU Directive 2004/10/EC

Contents of the Archive

- [The Study Director should] ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting material are archived.

[OECD GLP Section II, 1.2 (i)]*

- The following should be retained in the archives for the period specified by the appropriate authorities:
  - The study plan, raw data, samples of test and reference items, specimens, and the final report of each study; Records of all inspections performed by the Quality Assurance Programme, as well as master schedules; Records of qualifications, training, experience and job descriptions of personnel; Records and reports of the maintenance and calibration of apparatus; Validation documentation for computerised systems; The historical file of all Standard Operating Procedures; Environmental monitoring records.

[OECD GLP Section II, 10.1]*

* Also includes 21CFR58 & EU Directive 2004/10/EC

Contents of the Archive

- The entire TMF should be managed securely prior to and during formal archive
- The TMF including the audit trail (for eTMF) should be archived appropriately to enable supervision after the clinical trial has ended. The dynamic character of the audit trail should be preserved, when applicable. Archiving should be undertaken after the investigator/ institution and sponsor have reviewed that their filed TMF documentation is complete.

[EMA/INS/GCP/856758/2018, December 2018]

- The sponsor and the investigator shall archive the content of the clinical trial master file …the medical files of subjects shall be archived …

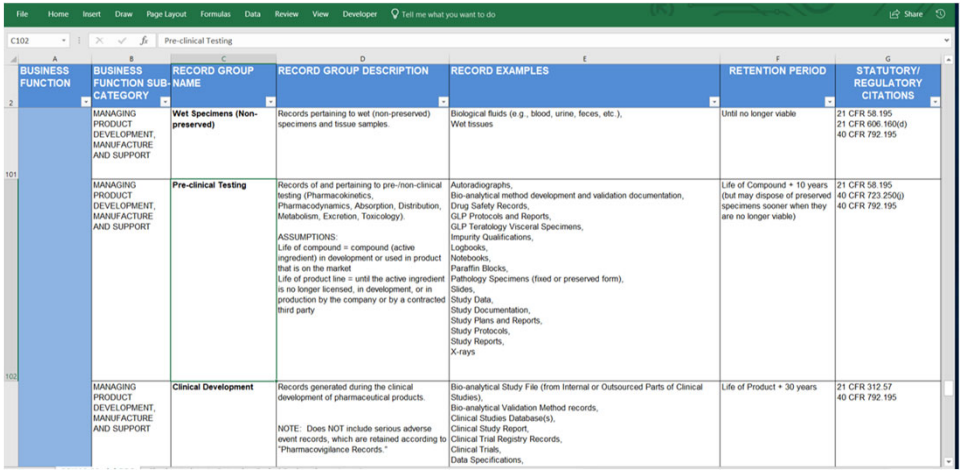
[Regulation (EU) No 536/2014 Art 58]

Exercise: Archive Contents - Examples

- Discuss in your groups examples of how you manage and track the archive contents
- Consider all formats
- Provide one example during feedback
- 5 minutes

Archive Contents - Examples

- Record types and code lists aligned to expected records
- Classification scheme / taxonomy includes all record types
- Design of system – *including retrieval processes* – can accommodate all records



BUSINESS FUNCTION	BUSINESS FUNCTION SUB-CATEGORY	RECORD GROUP NAME	RECORD GROUP DESCRIPTION	RECORD EXAMPLES	RETENTION PERIOD	STATUTORY/ REGULATORY CITATIONS
	MANAGING PRODUCT DEVELOPMENT, MANUFACTURE AND SUPPORT	**Wet Specimens (Non-preserved)**	Records pertaining to wet (non-preserved) specimens and tissue samples.	Biological fluids (e.g., blood, urine, feces, etc.), Wet tissues	Until no longer viable	21 CFR 58.195 21 CFR 606.160(d) 40 CFR 792.195
	MANAGING PRODUCT DEVELOPMENT, MANUFACTURE AND SUPPORT	**Pre-clinical Testing**	Records of and pertaining to pre-/non-clinical testing (Pharmacokinetics, Pharmacodynamics, Absorption, Distribution, Metabolism, Excretion, Toxicology). ASSUMPTIONS: Life of compound = compound (active ingredient) in development or used in product that is on the market Life of product line = until the active ingredient is no longer licensed, in development, or in production by the company or by a contracted third party	Autoradiographs, Bio-analytical method development and validation documentation, Drug Safety Records, GLP Protocols and Reports, GLP Teratology Visceral Specimens, Impurity Qualifications, Logbooks, Notebooks, Paraffin Blocks, Pathology Specimens (fixed or preserved form), Slides, Study Data, Study Documentation, Study Plans and Reports, Study Protocols, Study Reports, X-rays	Life of Compound + 10 years (but may dispose of preserved specimens sooner when they are no longer viable)	21 CFR 58.195 40 CFR 723.250(j) 40 CFR 792.195
	MANAGING PRODUCT DEVELOPMENT, MANUFACTURE AND SUPPORT	**Clinical Development**	Records generated during the clinical development of pharmaceutical products. NOTE: Does NOT include serious adverse event records, which are retained according to "Pharmacovigilance Records."	Bio-analytical Study File (from Internal or Outsourced Parts of Clinical Studies), Bio-analytical Validation Method records, Clinical Studies Database(s), Clinical Study Report, Clinical Trial Registry Records, Clinical Trials, Data Specifications,	Life of Product + 30 years	21 CFR 312.57 40 CFR 792.195

Storage & Retrieval

- Material retained in the archives should be indexed so as to facilitate orderly storage and retrieval. [OECD GLP Section II, 10.2]*
- Readily available upon request & made available for inspection [EU Directive 2005/28/EC § Chapter 4, Article 17 & Article 20]
- Can be retrieved upon the request of a regulatory authority [EudraLex Vol 10, Chapter 5 § 6. Storage conditions]
- All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period [21CFR211.180]
- The content of the clinical trial master file shall be archived in a way that ensures that it is readily available and accessible, upon request, to the competent authorities. [Regulation (EU) No 536/2014 Art 58]

* Also includes 21CFR58 & EU Directive 2004/10/EC

Exercise: Storage and Retrieval - Examples

- Discuss in your groups examples of how to manage storage and retrievals
- Consider all formats
- Provide one example during feedback
- 5 minutes

Storage and Retrieval- Examples

- Establishment and maintenance of an archive log of contents e.g. database
- Locations that are suitable for the material being stored
- Limit duration of loans

Protection from Deterioration

- Archive design and archive conditions should protect contents from untimely deterioration.
  [OECD GLP Section II, 3.4]*

- Storage conditions should ensure that essential records are maintained in a legible condition
  [EudraLex Vol 10, Chapter 5 § 6. Storage conditions]

- The media used to archive the content of the clinical trial master file shall be such that the content remains complete and legible throughout the period… [Regulation (EU) No 536/2014]

Protection from Deterioration

- It is important that access to documents and data is maintained for the entire archiving period. This could include maintaining the system (hardware and software) to access the data in its original archived format, or the use of a new system to emulate the old software or migration of the data into a new format to ensure continual access with new software. This issue should be addressed by the organisation by written procedures.

[EMA/INS/GCP/856758/2018]

- When original records are transferred to other media, for the purpose of archiving, the system of transfer should be validated to ensure that information will not be lost or altered. Such transfers should be certified for accuracy and completeness.

[EudraLex Vol 10, Chapter 5 §5]

Security and Access control

- Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. [OECD GLP Section II, 3.4]*
- Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.[OECD GLP Section II, 10.3]*
- The sponsor shall appoint individuals within its organisation to be responsible for archives. Access to archives shall be restricted to those individuals. [Regulation (EU) No 536/2014]

* Also includes 21CFR58 & EU Directive 2004/10/EC

Security and Access Control

- Secure controls must be in place to ensure the integrity of the record throughout the retention period and validated where appropriate [EudraLex Vol. 4, 4.1]
- Suitable controls should be implemented to ensure that these records cannot be altered without authorisation [EudraLex Vol 10, Chapter 5]
- A system in place locking/protecting individual documents or the entire eTMF (e.g. at time of archiving) to prevent changes to documents [EMA reflection paper § 7.2 Controls]
- Any alteration to the content of the clinical trial master file shall be traceable [Regulation (EU) No 536/2014]
- Creation of an audit trail [EudraLex Vol 10, Chapter 5 § 5. Media to be used]

Procedures

- Standard Operating Procedures should be available for, but not be limited to, the following categories of test facility activities: Record Keeping, Reporting, Storage, and Retrieval - Coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised systems

[OECD GLP Part I, 7.4.3]*

- The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs

[ICH E6 (R2)]

* Also includes 21CFR58 & EU Directive 2004/10/EC

Retention Requirements - GCP

at least 2 years after the last approval of a marketing application / formal discontinuation of clinical development in an ICH region

[ICH E6(R2)]

for at least 25 years after the end of the clinical trial.

[Regulation (EU) No 536/2014 (57)]

Retention Requirements Excerpt (GCP ICH*)

- Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirements or by an agreement with the sponsor.

[ICH E6(R2)]

*ICH: EU, USA, Japan, Switzerland, Canada

Retention Requirements Excerpt (GCP EU)

- Unless other Union law requires archiving for a longer period, the sponsor and the investigator shall archive the content of the clinical trial master file for at least 25 years after the end of the clinical trial. The content of the clinical trial master file shall be archived in a way that ensures that it is readily available and accessible, upon request, to the competent authorities

[Regulation (EU) No 536/2014 (57)]

Retention Requirements - GLP

As defined by an applicable regulatory authority / at least three inspection cycles.

[OECD GLP Monograph No. 15, Section 7.6*]

In the absence of a required retention period, the final disposition of any study materials should be documented.

[OECD GLP Section II, 10.1*]

* OECD references also includes 21CFR58 & EU Directive 2004/10/EC

Retention requirements (OECD GLP*)

- If the retention periods have not been defined by an applicable regulatory authority, it is highly recommended that records and materials should be retained for at least three inspection cycles so that inspectors can evaluate the compliance of the test facility with the Principles of GLP. For those studies that will not be submitted to regulatory authorities it may be acceptable (if justified) to dispose of the study specific records and materials after this period.

[OECD GLP Monograph No. 15, Section 7.6]

- The GLPMA currently conducts compliance monitoring inspections of most test facilities at a frequency not exceeding 24 - 27 months

[UK GLP Monitoring Authority, Jan 2015]

* Also includes 21CFR58 & EU Directive 2004/10/EC

Retention Requirements (OECD GLP)

- In the absence of a required retention period, the final disposition of any study materials should be documented. When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented.
- Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.

[OECD GLP Section II, 10.1]*

* Also includes 21CFR58 & EU Directive 2004/10/EC

Retention Requirements - GMP

Batch documentation must be kept 1 year after expiry or at least 5yrs after QP certification.

IMP documentation must be kept for at least 5yrs after completion / formal discontinuation of product

EudraLex Vol 4, 4.11

IMP kept until 2yrs after MA approved, if not approved, 2yrs after the last shipment / delivery (discontinued use) and FDA notified

21CFR211.180

Retention Requirements – GMP / GDP

- Batch documentation must be kept for one year after expiry of the batch to which it relates or at least five years after certification of the batch by the Qualified Person, whichever is the longer. [EudraLex Vol. 4, 4.11]
- For production, control and distribution records; also components, drug product containers, closures and labeling: At least 1 year after the expiration date of the batch. [21CFR211.180]
- For investigational medicinal products, the batch documentation must be kept for at least five years after the completion or formal discontinuation of the last clinical trial in which the batch was used. [EudraLex Vol. 4, 4.11]
- Critical documentation, including raw data (for example relating to validation or stability), which supported information in the MA should be retained whilst the authorization remains in force [Eudralex Vol 4]
- Until 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified. [21CFR312.57]

Retention Requirements – other types of manufacturing records

- Manufacturing Facility Records
  - Equipment/system qualification, Facilities testing, Cleaning/use logs, Computerized system equipment, Engineering and maintenance records, Staff qualification (training records)
  - [21CFR211.182] and [ICH Q7 (Step 5) section 6.2] both state requirements to retain these records but don't state specific retention periods. In practice you must retain them for as long as they are likely to be required for a pre-approval inspection.
- Special case: Advanced Therapy Medicinal Products
  - Gene therapy and Cell therapy products
  - The marketing authorisation holder shall keep the data referred to in paragraph 1 [sourcing, manufacturing, packaging, storage, transport and delivery] for a minimum of 30 years after the expiry date of the product, or longer if required by the Commission as a term of the marketing authorisation

[Regulation (EC) No 1394/2007 & EMA Guideline on GMP for ATMPs, Nov 2017]

Retention Requirements (US GMP & GDP)

- Trading partners are required to capture and maintain the applicable product tracing information for not less than 6 years after the date of the transaction.
- Dispensers are required to maintain the product tracing information for a transaction for not less 1than 6 years after the transaction

[Standardization of Data and Documentation Practices for Product Tracing, FDA Guidance for Industry]

- Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of a drug product shall be retained for at least 1 year after the expiration date of the batch

[21CFR211.180]

Retention Requirements - Examples

- Retention period MUST also accommodate other legal, regulatory and business drivers
- Typically:
  - GLP study records 10-15 years
  - GCP trial master file records minimum 25 years
  - GMP batch records until batch expiry +5 years (but see GCP for records supporting clinical trials)
  - GMP product specification file maintained current (expired records until batch expiry +5 years)
  - advanced therapy traceability records minimum 30 years
- “Life of product”….. where does this come from?

Other Regulations

- Good pharmacovigilance practice
  - All documents shall be indexed and archived so as to ensure their accurate and ready retrieval throughout the period for record-keeping.

    [Regulation (EU) No 520/2012, Art 5]
  - The pharmacovigilance system master file shall be permanently and immediately available for inspection at the site where it is kept.

    [Regulation (EU) No 520/2012, Art 57]
  - Content of pharmacovigilance system master file (PSMF) and supporting documents should be described
  - Archiving processes and systems must be documented

    [EMA Guideline on GPvP, II.B.4.7]

- With the exception of 21CFR58 (OECD GLP) and 21CFR11 (Electronic Records, Electronic Signatures), US Code of Federal Regulations do not mention archives, archiving or an archivist (other than
- FDA regulations generally require
  - retention of specific records for a stated period
    - Need for procedures that identify records to be archived and a retention schedule
  - records to be made available upon request
    - Need for suitable facilities that can ensure records are readily available and protected i.e. an archive

Summary – Archived Related Regulations

- Regulations cover many aspects of archiving
- Most principles are common across the good practice guidelines (GxPs)
- Requirements are more detailed for GLP than for GCP
  - Little detail for other GxPs other than ensuring records are available
- Regulations generally provide for a great amount of flexibility in implementation
  - Allows each company to tailor requirements to suit their own needs
  - Adopt a risk-based approach with justification

References

Good Clinical Practice

- Regulation (EU) No 536/2014 (the Clinical Trial Regulation)
- EMA/15975/2016 – EMA Guideline on GCP Compliance
- EudraLex Rules Governing Medicinal Products in the EU
  - Vol 10 (Clinical Trials), Chapter 5
- EMA/INS/GCP/636736/2012 - EMA Reflection Paper on GCP Compliance in Relation to Trial Master Files
- ICH E6 (R2) – ICH Guideline for Good Clinical Practice
- 21CFR312 – Investigational New Drug Application

Other

- Regulation (EC) No 1394/2007 Advanced Therapy Medicinal Products
- EMA/816573/2011 - EMA Guideline on Good Pharmacovigilance Practices
- Commission Implementing Regulation (EU) No 520/2012 – Performance of Pharmacovigilance Activities
- 21CFR11 – Electronic Records; Electronic Signatures

References

Good Manufacturing Practice

- EudraLex Rules Governing Medicinal Products in the EU
  - Vol 4 (Good Manufacturing Practice Medicinal Products for Human and Veterinary Use), Chapter 4
- C(2017) 7694 - EMA Guideline on Good Manufacturing Practice for Advanced Therapy Medicinal Products
- 21CFR211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- 21CFR312 – The Use of Investigational New Drugs
- ICH Q7 (R1) – ICH Guideline for Good Manufacturing Practice
- FDA Guidance for Industry - Standardization of Data and Documentation Practices for Product Tracing

Good Laboratory Practice

- ENV/MC/CHEM(98)17 – OECD Principles on Good Laboratory Practice (also 21CFR58 & Directive 2004/10/EC)
- OECD GLP Monograph No. 15 – Establishment and Control of Archives that Operate in Compliance with the Principles of GLP
- UK GLP Monitoring Authority – Retention of Study Data and Supporting Records for Inspection Purposes

Any questions?

The GxP Archivist

What we'll cover in this section

- Role and responsibilities (job description)
- Skills and training
- How the role of the archivist compares to the role and responsibilities of other key stakeholders, including the study director, sponsor, study team members, principal investigators, clinical labs, study monitors, third parties.
- Soft-skills

Need for an Archivist

- The sponsor shall appoint individuals within its organisation to be responsible for archives. Access to archives shall be restricted to those individuals [EU 536/2014]
- The archivist is responsible for the management, operations and procedures for archiving in accordance with established SOPs and the Principles of GLP. The archivist should […]
  - ensure that access to the archive is controlled;
  - ensure that the orderly storage and retrieval of records and materials is facilitated by a system of indexing; ensure that movement of records and materials in and out of the archives is properly controlled and documented [OECD GLP Mono15]
- There can be more than one Archivist
- May be specific archivist role(s) or person(s) in another role [MHRA GCP Guide 10.7.2]

Archivist / Records Manager Job Description

- Classify and organise information
- Ensure information availability
- Ensure information is held securely and is protected
- Respond to enquiries and requests for information
- Destroy information
- Establish, develop, maintain, and evaluate new and existing archiving systems
- Ensure information complies with legal, regulatory and business requirements
- Advise and train staff in archiving practices

Personal Characteristics Required

- Eye for detail …and the big picture
- Logical and organised
- Customer focussed
- Research focussed
- Interest in technology
- Understanding and patience
- Good negotiator and facilitator

Skills / Training

- Contract management
- Project management
- Information management
- Information technology (inc digital preservation)
- Governance awareness
  - Knowledge and understanding of
    - compliance
    - quality assurance
    - regulatory environment
    - relevant legislation e.g. GDPR

Distribution of responsibilities

How are activities that concern records management and archiving distributed amongst the key players?

- GxP Archivist / Records Manager
- GLP Study Director / Clinical Project Manager
- Study Team / Operational Staff
- Information & Communications Technology
- Legal / Compliance
- Commercial Records Storage Contractor

GxP Archivist / Records Manager

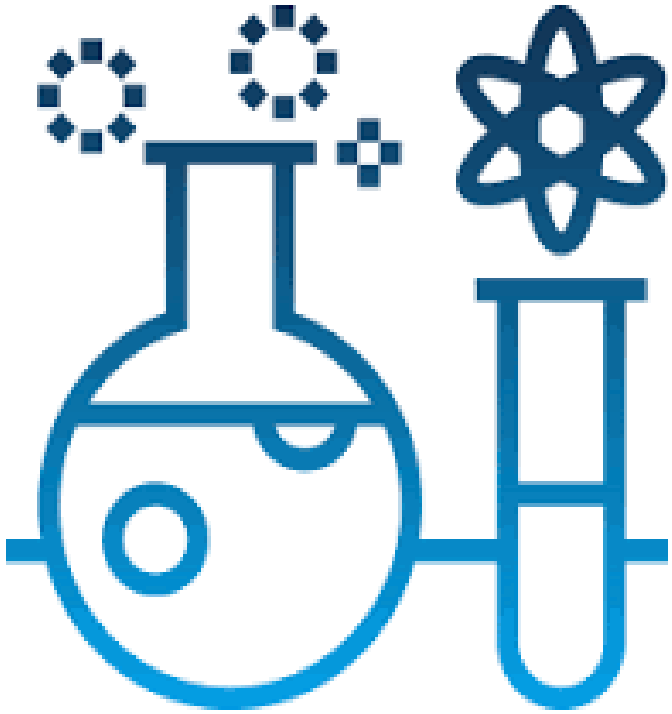
- **Archivist** responsible for
  - custody of information
  - appropriate storage of information
  - access to and availability of information
  - readability and legibility of information
  - traceability of information
  - retention of information
  - destruction of information
  - respond to requests for information
  - understanding **the value of information**

- **Records Manager** responsible for
  - advising on information classification / organisation
  - understanding the IT landscape, inc interoperability issues and dependencies
  - establishing, developing, maintaining, and evaluating new and existing [e]DR&IM systems
  - ensuring information creation and management comply with legal, regulatory and business requirements
  - training staff in good information management practices
  - overseeing transitions from paper to digital record-keeping

GLP Study Director / Clinical Study Manager

- With respect to archiving, accountable for
  - completeness of information
  - accuracy of information
  - timeliness of information
  - ownership of information
  - ensuring records are archived

Data quality and data integrity



Operations Staff

- With respect to archiving, responsible for
  - completeness of information
  - accuracy of information
  - timeliness of information
  - ownership of information
  - storage of live information
  - availability of live information
  - readability and legibility of live information
  - traceability of live information
  - transfer of information to the archive
  - destruction of live information

Data quality
Data integrity

Information and Communications Technology

- With respect to archiving, responsible for
  - provision of appropriate information management technologies
  - assisting in the management and preservation of specialist lab and manufacturing equipment data
  - provision of appropriate transfer mechanisms for digital information
  - conversion and migration of digital information
  - advising on digital preservation issues
  - *monitoring the condition of archived digital information and supporting technologies*
  - *managing access controls and permissions for digital information*
  - *safe custody of digital information*
  - *computer systems validation and systems (development) lifecycle management*

May be the Archivist

NB The same requirements apply to providers of cloud solutions

Legal and Compliance

- With respect to archiving, responsible for
  - provision of advice on legal and regulatory requirements
  - ensuring compliance with legal and regulatory requirements
  - authorisation of retention periods
  - communication of legal holds

Commercial Records Storage Contractor

- With respect to archiving, responsible for
  - safe custody of records
  - appropriate storage of records
  - access to and availability of records
  - responding to requests for records
  - provision of appropriate information management technologies
  - effective destruction of records (when requested by client)

NB Dependent upon outsourcing agreement

- Question: what can the Records Storage Contractor **NOT** do?
  - take over the Regulatory/Legislative responsibility of the client

Contract Management Skills

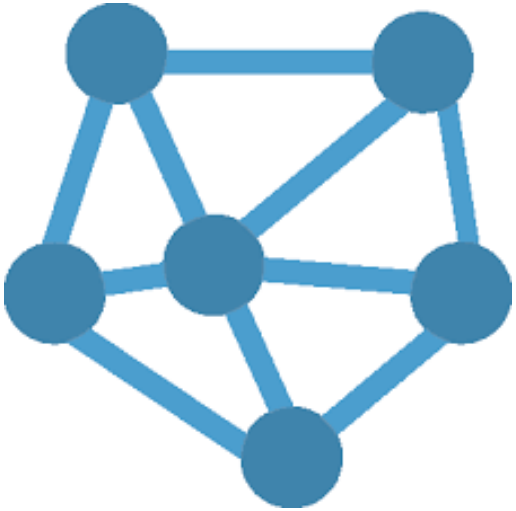
- Requirements (setting standards)
- Invitations to tender (assessment , evaluation and audit)
- Negotiations (Price, Collections, Storage, Retrievals, Supplies etc)
- Draft contract and service level agreements
- Coordinate logistics and ongoing operations
- Monitor service and performance
- Build and maintain relationship
- Manage contract close-out, extension or renewal
- Archives and “cloud” service provision differ from other contracts

Project Management Skills

- Plan and Define Scope
- Plan Activities, Sequencing & Resources
- Estimate Time and Develop Schedules
- Estimate Costs and Develop Budget
- Manage Documentation
- Analyse and Manage Risks
- Monitor and Report Progress
- Team Leadership (Partnering, Influencing)
- Strategic Influencing
- Work with Vendors
- Ensure Control Quality
- Realise Benefits
- Ensure Scalability, Interoperability and Portability (especially for digital projects)

Information Management Skills

- Understand records management lifecycle processes and terminology
- Understand records content and context, metadata concepts and requirements
- Ability to identify key characteristics of records, processes, and controls
- Ability to produce performance measurements and metrics
- Ability to apply risk assessment methods and practices
- Working knowledge of digital preservation concepts



Information Technology Skills

- Understanding of value of metadata, audit trails and logs
- Understanding of data integrity concepts and requirements
- Ability to utilise technologies to optimise processes and introduce efficiencies
- Understanding of technology dependencies and interoperability
- Working knowledge of computer systems validation methods and techniques
- Ability to produce performance measurements and metrics
- Working knowledge of technologies used to manage digital records

Governance Skills

- Knowledge and understanding of
  - compliance
  - quality assurance
  - regulatory environment e.g. CFR 21 Part 11
  - relevant legislation e.g. GDPR
- Ability to engineer compliance into processes and systems
- Drafting SOPs, procedures and work instructions
- Research skills

Summary – The GxP Archivist

- It is a regulatory requirement to have an Archivist
- Archivist should be qualified by experience, training or education
- There may be more than one Archivist
- Archiving is a shared responsibility

References

- Good Clinical Practice Guide, MHRA, 2012
- ENV/MC/CHEM(98)17 – OECD Principles on Good Laboratory Practice
- OECD GLP Monograph No. 15 – Establishment and Control of Archives that Operate in Compliance with the Principles of GLP

Any questions?

The GxP Archive

Poll

Are all GxP archives the same?

Features of a GxP Archive

1. Structure and design
2. Security and access control
3. Record preservation

Exercise: Structure and Design - Examples

- Discuss in your groups examples of what is important in the structure and design of an archive
- Consider all formats
- Provide at least one example during feedback
- 5 minutes

Structure and Design

Physical archive

- Suitable for type of materials being stored
  - e.g. refrigeration, dust free, temperature
- Load-bearing capacity of shelves and units
- Compartmentalisation
- Compliance or alignment with relevant standards
- Tracking system e.g. bay & shelf numbers

Electronic archive

- Independent of file format
- Consider back-up procedures and future migration needs
- Validated
- Metadata for tracking and management
- Some special considerations for electronic (*see next slide*)

Structure and Design: Electronic

Defined archive area in source application

- Part of system holding source data/records
- May be physically separated (e.g. specific server(s) for archived data) or virtually separated (e.g. metadata defines archived data)

Designated archive system

- Specific computerised application(s) for archiving data/records
- One system or multiple systems
- One interface or multiple interfaces
- Often integrated with system(s) holding source data/records

All archive requirements apply equally to both types of electronic archive!

Structure and Design: Electronic

- Use of portable storage media e.g. magnetic tape, CD/DVD, USB drives, removable hard drives
  - Must be managed in same way as other archived physical records
- But…
  - Longevity concerns…. some failures <5 years
  - Rapid media obsolescence
  - Migration is costly and time consuming
  - Poor search and retrieval capabilities

  …. **so avoid if possible**

Exercise: Security and Access Control - Examples

- Discuss in your groups examples of security and access control for an archive
- Consider all formats
- Provide one example during feedback
- 10 minutes

Security and Access Control

Physical archive

- Secure location, preventing unauthorised access
- Locks – physical (key) and/or digital (access cards)
- Archive log/visitor register
- Record of loans

Electronic archive

- Access control tools
- Locking of documents
- Use expiring passwords
- Audit trails
  - Alterations or corrections recorded without obliterating the original record
- Read-only

Record Preservation

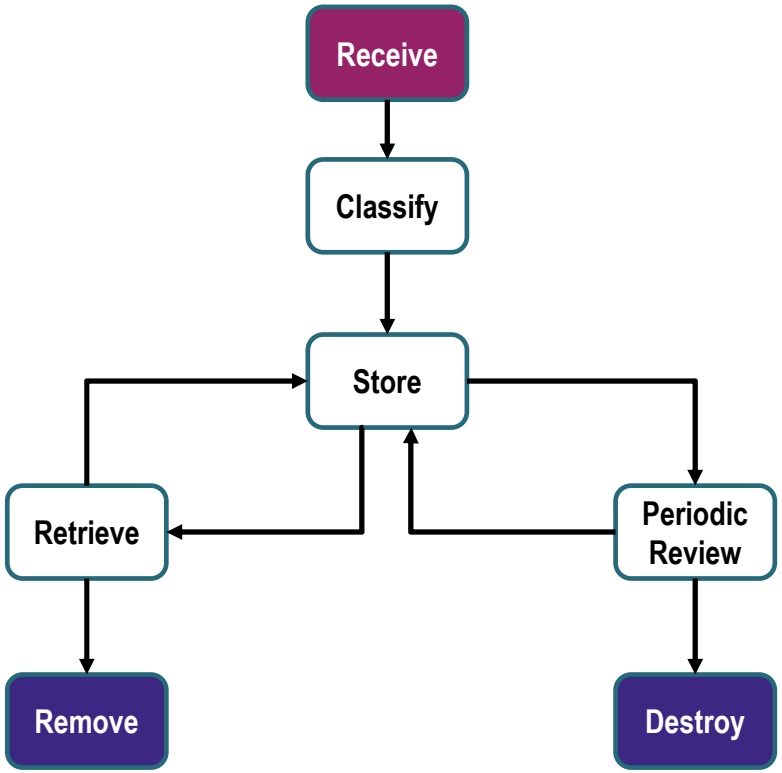
Physical archive

- Protection against weather, fire, flood, vermin (risk-based)
- Fire-rated walls and doors
- Consider overhead pipes
- Environmental controls
- Detection systems
- Minimise risks e.g. sources of heat

Electronic archive

- Mitigate obsolescence
  - hardware (e.g. floppy disks)
  - operating system (e.g. WANG o/s)
  - software (e.g. WordStar)
  - file format (e.g. PowerPoint 95)
- Storage media deterioration ('bit rot')
- Use of checksums

Operating the Archive



Archivist activities:

- Receipt
- Indexing
- Filing
- Maintenance (e.g. reviews)
- Retrieval
- Loans
- Destruction

Receipt

Physical archive

- In-person, courier, or ‘in tray’
- Checks for overall completeness / verification
- Checklist(s)
- Checks for suitability
- e.g. removal of plastic wallets, paper clips
- Consider need for ‘pre-archive’ or ‘holding area’

Electronic archive

- Receipt = Ingestion
- Confirmation of records
- Correct identification of records – including metadata
- Verification of transfer from source e.g. checksums, number of files
- Consider need for ‘pre-archive’ or ‘holding area’
- Verification that records meet acceptance criteria e.g. accessibility

Indexing

Physical archive

- Based on pre-defined indexing schema
- Metadata must provide for:
  - contents description (what is there?)
  - access management (who is allowed to access it?)
  - location management (where is it?)
  - disposition management (when should it be destroyed?)
  - search/retrieval (how can I find it?)

Electronic archive

- Same as physical archive plus:
  - source system (how can I access, read, understand and (where required) use the file content?)

Filing

Physical archive

- Various options:
  - Random (100% dependent on index)
  - Function-based
  - Record type
  - Record format

  ….. or a combination
- Consider potential future changes!

Electronic archive

- Random filing is most prevalent other than system-based solutions e.g. Archive for laboratory management system (LMS)
- File names and associated metadata should be sufficient to be able to readily identify files, file content and file context

Retrieval

Physical archive

- Need to consider:
  - Authorisation required for access & documenting this
  - Recording access (paper or electronic log)
- Consider some items may be permanently withdrawn

Electronic archive

- Authorisation may be needed but other considerations usually do not apply if archive is read-only
  - Records are not being removed and so cannot be changed
  - May not be necessary to even capture access to archived records

Loans

Physical archive

- Removal of original GxP records should be avoided, especially GLP-regulated
  - provide copies
- Need for a tracking system
- Need for time limits and escalation process
- What checks on returned materials?

Electronic archive

- In general, loans do not exist for electronic archives
  - access is given to a read-only copy of the archived records
  - tracking data is primarily for business management purposes rather than to comply with regulatory requirements

Maintenance

Physical archive

- Clean and tidy archive
- Periodic audit of archive inventory
- Periodic checks for damage
  - e.g. quarterly pull of sample of boxes archived for > x years to check for damage
- Periodically review retention schedule and classification schema
- Periodically review processes

Electronic archive

- Monitor file formats for software obsolescence
  - take action BEFORE data format becomes obsolete!
- Where applicable, monitor storage media obsolescence
- Ensure retention of relevant manuals and knowledge of the operation of the media

Destruction

Physical archive

- Authorisation for approval?
  - Implied unless informed otherwise by management; or
  - Explicit approved needed
- Avoid postponement of destruction for “just in case” reasons
- Destruction method must be commensurate with confidentiality and format of records being destroyed
- Consider “legal hold”

Electronic archive

In addition to physical

- Destruction methods should be risk-based
  - Is there a need for forensic-class destruction or is “delete” acceptable?
  - No guidance currently from GxP regulations!

Archive Contents

- In general, others determine what is archived:
  - avoid the Archivist assuming responsibility that is outside their scope
  - Archivist is the custodian of archived content, not the owner
- Design of archive and associated processes could include management of:
  - Paper records (individual pages, wallets, files, and/or boxes) of varying formats and sizes
  - Electronic storage media e.g. disks
  - Microforms e.g. microfilm, microfiche
  - Chemical samples e.g. manufacturing reserve samples, analytical reserve samples
  - Tissues e.g. fixed in wax blocks, glass slides, formalin
  - Other artifacts e.g. medicine boxes, promotional items
- How does format and content impact archive processes?

References

- 15489-1/15489-2 - International Organization for Standardization (ISO) Information and Documentation -- Records Management (Part 1 and 2) http://www.iso.org/iso/catalogue_detail.htm?csnumber=31908
- ISO 23081-1 - International Organization for Standardization (ISO) Information and Documentation – Records Management Processes - Metadata for Records – Part 1: Principles
- NISO TR01-1995 – National Institute of Standards Organization (NISO) Environmental Guidelines for the Storage of Paper Records
- BS 5454:2000 – British Standards Institute (BSI) Recommendations for the Storage and Exhibition of Archival Documents (http://shop.bsigroup.com)
- ISO 11799:2003 – International Organization for Standardization (ISO) Information and Documentation – Document Storage Requirements for Archive and Library Materials (http://www.iso.org)
- ANSI/ARMA TR-01-2002 – American National Standards Institute (ANSI) / American Records Managers and Administrators (ARMA) Technical Reference (TR) Records Center Operations (http://www.ansi.org)

References Continued

- MHRA 2006 – Medicines and Healthcare Products Regulatory Agency (MHRA) Good Laboratory Practice (GLP) Guidance on Archiving
- ENV/JM/MONO (2007) 10 – Organisation for Economic Cooperation and Development (OECD) No. 15 – Advisory Document of the Working Group on Good Laboratory Practice - Establishment and Control of Archives that Operate in Compliance with the Principles of GLP
- ICA Study 11 - International Council of Archives (ICA) Study 11, Guidelines on Disaster Prevention and Control in Archives http://www.ica.org/sites/default/files/Study11E%20Final.pdf
- ISO 18492 - International Organization for Standardization (ISO) Long-term Preservation of Electronic Document-based Information
- NFPA 232 (2007) – National Fire Protection Association (NFPA) Standard for the Protection of Records
- ISO/TC 46/SC 11/WG 7 Digital Records Preservation – Where to start guide
- ISO 14721: 2012 – Open Archival Information System (OAIS) Reference Model
- ISO-16363:2012 – Audit and Certification of Trustworthy Digital Repositories

Thank you

Any questions?

Outsourcing

Is Outsourcing permitted?

Yes, if

- outsourcing agreement is documented;
- activities being outsourced (roles and responsibilities) are clearly identified;
- vendor is suitable e.g. from assessments, audits etc;
- vendor understands what is needed to maintain compliance;
- outsourcing is managed i.e. you retain accountability and must provide oversight of the vendor

Outsourcing Models

Including…

- Full Service Provision i.e. GxP Archivist is outsourced
  - May appear as part of your organisation (aka “in-sourced”)
  - Record destruction
  - Records retention schedule
  - Inventory management
  - May have responsibilities for RM in addition to Archive responsibilities
- Storage only
  - e.g. Iron Mountain, Restore, Qualogy, Arkivum
  - Media conversion e.g. paper to digital; digital proprietary format to PDF/A

Archive Strategy & Use of Third Parties

- Practicalities:
  - Archive only once unlikely to be frequently accessed
  - How quickly can the records be retrieved – including outside office hours (e,g, product recall)
  - Interactions with the off-site contractor must be restricted to Archivists to maintain access control
  - Need to have an effective inventory management database
- For paper
  - box level or file level or document level (balance cost versus granularity)
  - active store or deep store (balance cost versus retrieval time)
- For electronic
  - transfer speed/time
  - near-line or offline
  - active preservation of data

Vendor Selection

- Archivists / records managers must work with the procurement team so the focus is on service quality and GxP compliance and not only costs efficient operations
- Need optimum balance between best value and best service provision
  - Low storage charges = high service charges
- Company details / profile, for example:
  - Established provider with national or international coverage
  - Staff training and quality management procedures
  - Experience of GxP regulations
- Consider end-of-contract scenario **at contract negotiation**
  - Avoid (or be aware of) high exit fees (especially if you have value-added services)

Vendor Selection & GxP Compliance

Does the vendor need to be GLP-certified / GCP-certified / GMP-certified?

- No, but they must comply with applicable requirements and may be subject to inspection
- Obtain evidence that they meet relevant GxP requirements for example:
  - Organisation charts
  - Training records
  - SOPs
  - IT systems: meet data integrity and ALCOA expectations?
  - Internal audit

Contractual Considerations

Contract **must*** include:

- Description of records and materials to be archived
- Transportation of records to/from the archive
- Capture of 'chain of custody'
- Access to stored records and materials
- Description of services provided
- Description of checks performed by archive e.g. degradation of wet tissues
- Safety
- Storage conditions / pest control
- Method of retrieval / access
- Method of return
- Method of disposal
- QA activities

* Mandatory for GLP compliance, recommended for other GxP's

Vendor Oversight

Key principles:

- Sponsor company retains accountability for records
- Avoid doing or repeating what the vendor has been contracted to do
- Perform QC checks periodically to monitor performance
  - Monitor against service level agreement (SLA) and pricing model
  - If performance is unsatisfactory, the vendor should take corrective action and preventative action at their own cost
- Ensure business continuity plan takes account of potential issues with third parties
  - How easy is it for you to change vendor?
  - How easy is it to permanently withdraw archived records e.g. in event of bankruptcy

Summary

- Outsourcing is permitted under all GxP regulations **but** regulatory requirements still apply
- Sponsor / client remains responsible for regulatory compliance
- Conduct a proper assessment of vendor
  - in accordance with documented SOPs
  - maintain documentation of selection process
- Ensure contractual agreement is comprehensively documented
- Monitor vendor
- Consider exit process

Thank you

Congratulations! We have reached the end of the workshop.

We hope that you enjoyed the workshop and learnt some really valuable information, to support you in your role of managing a GxP Archive.

You will receive a certificate of attendance.
Please share any feedback by contacting training@the-hsraa.org.

Thank you.