GIQAR Position Paper on 'Archiving and Good Laboratory Practice'†

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Summary

Archiving of documents and specimens generated during a non-clinical laboratory study is a basic Good Laboratory Practice (GLP) requirement. The records and materials that should be archived as well as the characteristics and the organisation of archive facilities are addressed in the *OECD Series on Principles of Good Laboratory Practice* No. 1 (*OECD Principles of Good Laboratory Practice* (as revised in 1997) [1]. However, in recent years, questions concerning archiving have been raised and the need for a more detailed guidance on this matter has become evident. The aim of the Society for Applied Pharmacological Sciences/Italian Group of Quality Assurance in Research (SSFA/GIQAR) working group on 'Archiving according to GLP' was to issue a position paper, present it for discussion in an *ad hoc* round table with representatives of the Italian GLP monitoring authority to promote common standards and to provide additional recommendations on storage and retention of records. Copyright © 2005 John Wiley & Sons, Ltd.

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Preliminary Remarks

This position paper is the result of the round table discussion organised by the Society for Applied Pharmacological Sciences/Italian Group of Quality Assurance in Research

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recognised as capable of providing secure storage of information for a time period' [1].

Then the requirement to archive raw data is not limited to study/experimental raw data, but includes the facility raw data. Examples of raw data, cited in the Principles of GLP [1–6] are given below:

- Responsibility delegations (e.g. statement identifying the individuals responsible for management of test facility).
- Records of environmental conditions, characterisation, identification, health status evaluation and care of test systems.
- Records of source, date of arrival, and arrival condition of test systems.
- Records of acclimatisation of biological test systems to the test environment before the first administration/application of the test or reference item.
- Records of regular cleaning and sanitisation of housing and/or containers for test systems, change of bedding for animals and use of pest control agents.
- Certificates of analysis of material (food, bedding, water) that comes into contact with the test system.
- Records including test item and reference item date of receipt, quantities received and used in studies.
- Records/documents identifying each batch of the test or reference items for identity, batch number, expiry date, purity, characterisation, composition, concentrations, or other characteristics.
- Documentation of homogeneity, concentration and stability of the test item in a vehicle, as appropriate.
- For each study, correspondence relevant to the management of the study (e.g. communications between Study Director and sponsor, between and within sites as well as any communication plan (multi-site studies) if not included in the study plan and any memoranda and notes.

Note: E-mail communication is a standard nowadays. It is considered acceptable to keep printed e-mails, signed and dated by the Study Director/Principal Investigator, as raw data.

Quality of documents/raw data

Raw data/documents should be complete, legible, accurate, unambiguous, and authentic. Verified copies are to be produced as necessary (e.g. copies for thermolabile print-outs of data to be signed, dated and archived with the original data).

Discontinued studies

Whenever an ongoing study (with an approved study plan) has been stopped, interrupted and then discontinued, any raw data/documentation and specimens related to the study, including a statement from the Study Director declaring that the study has been interrupted and the reasons for this decision, should be documented and archived.

Archiving of Electronic Records

Media containing electronic records

The media used to store required electronic records should ensure that these electronic records are promptly available, complete, legible and printable throughout the required period of retention.

Electronic records can be stored either in physical electronic magnetic media, which are archived in a 'conventional' archive or in an electronic archive.

Physical electronic media may include optical disks, CD-ROMs, DVDs and magnetic tapes. Re-writable materials should be protected against both accidental and deliberate erasure.

Documentation providing details of the material's content (meta-data) and, as applicable, its layout, format, mode and density of recording or other technical information considered necessary to its present and future accessibility, should be retained.

considered as an exact transcription of the raw data. Conversion from hard copies to electronic or optical reproductions should be considered as a solution to optimise the management of the space of the archive facility. After conversion, the hard copy records become electronic records and all the requirements reported in Archiving of Electronic Records section must be fulfilled.

Archive Management

The management of the archive should minimise the risk of damage or loss of materials generated during studies conducted in compliance with GLP principles.

Management of archived materials

In order to ensure adequate management of archived materials a minimum of the following is required:

- Management should appoint an archivist and a substitute; the archivist's role and responsibilities should be clearly documented.
- Access to archives and to materials should be restricted to authorised personnel; access should be duly documented.
- A complete index/log of archived materials should be maintained by the archivist in order to clearly identify materials and facilitate tracking and retrieval.
- Chain of custody of archived materials should be properly documented.
- Confidentiality should be guaranteed.
- Specific SOPs should be in place in order to clearly define procedures and assigned responsibilities. As a minimum, the following aspects should be addressed:
  - Archive description, general organisation and responsibilities.
  - Transfer of materials to archive.
  - Chain of custody of archived materials.
  - Handling of materials at the end of established archiving period, including final disposal and destruction.

Facility specifications

Adequate and suitable space should be provided for safe storage of all materials. Appropriate clean and hygienic conditions should be guaranteed.

Each kind of material to be archived (paper, electronic media, specimens) has its own individual requirements for proper storage and may have different retention times.

A separate area should be provided for any material that requires specific storage conditions. Where the archive facility cannot provide the storage conditions appropriate to a particular material, the use of a specialised archive facility (e.g. commercial archives/repositories) is recommended. For magnetically-recorded electronic media, which may be damaged or erased by magnetic fields, electrical or electronic equipment that could cause such erasure should not be permitted in the archive and magnetic media should not be brought into the vicinity of such equipment.

Security

Security precautions are normally subject of national legislation, local by-laws and building codes. In order to ensure adequate security at least the following should be ensured:

- The archive area should not be close to high-risk sites (e.g. risk of fire).
- An adequate anti-intrusion system should be in place (e.g. doors fitted with locks, no windows or windows that are adequately protected).
- A pest control system, as appropriate, should be in place.
- Heating and air conditioning system, electricity, water supplies and drainage should be adequately designed in order to minimise risks of damage to the archived materials.
- Fire detection and an automatic extinguishing system should be in place, or readily accessible fire extinguishing equipment should be available. Fire extinguishers should be adequate for the different types of material stored. Water is not recommended due to the damage it can cause (e.g. paper records).

tion should be kept in all involved locations (site of origin and site of arrival).

Where archived materials are being transferred between locations (e.g. from Principal Investigator to Study Director, from a test site to a commercial archive), precautions should be taken to ensure the integrity, security and safety of materials at all times, including during transport.

Materials should be appropriately identified and when necessary placed in sealed containers (e.g. embedded tissues). The accompanying documentation should include a detailed list of delivered materials and the chain of custody should not be interrupted. Transport procedures should comply with applicable regulations.

If a Contract Research Organisation (CRO) goes out of business, without a legal successor, the archived materials should be transferred to the archives of the sponsor of the study.

Multisite studies

When data are transferred to another site (e.g. Study Director – site/sponsor/commercial archive), before the time retention period stated in the next section, the test site management should ensure that adequate records are available to demonstrate the test site involvement in a study [6,7].

A site policy should be available specifying the minimum records to be retained at the site during the study phase(s).

Documentation should include at least the following:

- Master schedule sheet (MSS).
- A copy of the study plan.
- List of data/materials generated at the site and transferred to a different site.
- Copy of the results sent to the Study Director (final report/tables/ .).
- Copy of the QA statement.
- Copy of the GLP Compliance statement.

The above listed documentation is considered facility data and the retention time period stated in the next section should be applied. QA documentation and documentation not specifically study-related (facility data) should also be retained.

Studies contracted out

When data are returned to the sponsor, before the time retention period stated in the next section, the CRO management should ensure that adequate records are available on site to demonstrate the CRO involvement in a study. A CRO policy should be available specifying the minimum records to be retained for each study/study phase(s).

The minimum documentation to be retained is listed in previous subsection.

Retention Time of Records and Specimens

Please note that the retention times indicated in this section are to be considered as a proposal and there are no GLP rules to support them.

Retention time

The proposed minimum retention times for records and specimens are specified in Table 2.

The electronic records must fulfil the same requirements of hard (paper) copy records. All other specimens not listed in Table 2 should be archived as long as the quality of preparation permits evaluation.

Prolonged retention

Prolonged retention periods could be determined in compliance with a facility storage policy based on risk management approaches (e.g. evaluation of the impact of the documentation on submission files for registration or notification).

Multi-site studies

The test facility (all sites involved in a study) can directly refer to the content of this document. The storage period for the study data and

Segregation

A conventional archive facility and/or electronic archive can be used to store records/specimens either related to studies/tests carried out under the scope of GLP and studies/test not carried out under the scope of GLP (e.g. GLP studies not to be included in a submission, like preliminary studies, quality control tests carried out under Good Manufacturing Practice regulations, etc.). In case the regulatory requirements regarding materials archived in the same archive facility are different, the most restrictive requirements should be applied to all types of records/specimens stored therein.

Conclusion

This GIQAR position paper was issued by the GIQAR working group on Archiving & GLP to provide additional information and recommendations on storage and retention of records and specimens generated during the conduct of nonclinical laboratory studies according to GLP. Recently, questions concerning archiving have been raised for different reasons:

- GLP principles provide only general information on archiving, and clarification was required for the management of a GLP-compliant archive facility, including acceptable standards for environmental conditions and the documents/specimens to be retained.
- Advances in technology and the increasing use of computerised systems make it necessary to provide guidance on how to archive electronic records/data and electronic documentation.
- Increasing quantity and diversity of materials to be archived require clear specifications regarding retention periods.
- The growing use of CAO for archiving of GLP study materials has not been addressed in regulatory GLP requirements.

This document includes the experiences of the GIQAR working group members in this field and represents their current approach. It must not be regarded as a legal document. Nevertheless, this position paper supports the need for regulatory guidance on archiving with the aim to give advice to test facilities regarding implementation of GLP-compliant archives, to harmonise regulatory authorities interpretation of GLP principles regarding archiving and to promote common standards.

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Glossary

Audit trail: (1) Data in the form of a logical path linking a sequence of events, used to trace the transactions that have affected the contents of a record. (2) A chronological record of system activities that is sufficient to enable the reconstruction, reviews, and examination of the sequence of environments and activities surrounding or leading to each event in the path of a transaction from its inception to output of final results [8].

(*Electronic*) *archive*: A lasting collection of computer system data or other records that are in long-term storage [8].

(*Electronic*) *copy*: A duplicate record/media that is generated from, and is substantially equivalent to, the original record. The copying of archived data is considered to have the least influence on their integrity.

Electronic data conversion: The transfer of archived data from one application environment to another (newer application environment with little or no change of information that would compromise the content, structure, and context of the archived data preserving its authenticity) [9].

Electronic data migration: The transfer of data from one format or system to another. The

http://www.picscheme.org (accessed 8 July 2005).

Archiving of multi-site studies

6. OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. No. 13. *The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies.* ENV/JM/Mono(2002)9. Available at http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)9 (accessed 8 July 2005).
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Further Readings

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3. FDA Guidance for Industry. *Part 11, Electronic Records; Electronic Signatures – Scope and Application.* August 2003. Available at http://www.fda.gov/ohrms/dockets/98fr/5667fnl.pdf (accessed 8 July 2005).

Retention times

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process of transferring electronic data from one computer platform to another in an environment that does not provide automatic conversion between the platforms. Migration is considered to have the greatest impact on the electronic data [9].

Electronic record: Information recorded in electronic form that requires a computerised system to access or process it.

Electronic media: Hardware intended to store binary data; e.g. integrated circuit, magnetic tape or magnetic disk [8].

Electronic media refreshment: media are copied in order to avoid deterioration of documents and to ensure future access.

Hard copy: A record that can be accessed and read without the use of a computerised system.

Meta-data: Data that describes the attributes of other data. Most commonly data that describes the structure, data elements, interrelationships and other characteristics of electronic records.

Raw data: Any work-sheets, records, memoranda, notes or exact copies thereof, that are the result of original observations and activities and which are necessary for the reconstruction and evaluation of a work project, process or study report, etc. Raw data may be hard/paper copy or electronic but must be known and defined in system procedures [10].

References

The reference section also contains documents which are not explicitly referenced in the manuscript, but which may be of use to the readers.

Archiving

1. OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. No. 1. OECD *Principles of Good Laboratory Practice* (as revised in 1997), ENV/MC/CHEM(98)17. Available at http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/env-mc-chem(98)17 (accessed 8 July 2005).
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Archiving of electronic records

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9. Working Group on Information Technology (AGIT). *Guidelines for the Archiving of Electronic Raw Data in a GLP Environment*. 9 May 2003. Available at http://www.glp.admin.ch/legis/ArchElectRawData1_0.pdf (accessed 8 July 2005).
10. PIC/S Guidance. *Good Practices for Computerised Systems in Regulated GxP Environments*. PI 011-2. 1 July 2004. Available at

specimens must be agreed upon with each test site in advance.

A test facility policy is recommended on how to manage the archived materials at the end of the agreed retention period (e.g. return to the Study Director/sponsor site) to meet the requirements of OECD Consensus Document No. 13 on 'The Application of GLP to the Organisation and Management of Multi-site Studies' [6].

For the facility data, the test facility should consider the recommendations made in this document as well. If a test facility goes out of business and has no legal successor, the archive must be directly transferred to the Sponsor. If the same situation happens to a test site, the archive must be directly transferred to the Study Director/sponsor site.

Destruction

At the end of the required retention period, study records and specimens may be destroyed after the test facility (or test site) management receives written authorisation by the sponsor. The record of such authorisation as well as destruction documentation should be retained for at least ten years after destruction. During the destruction activities, measures must be put in place to maintain the confidentiality of information. If the destruction is subcontracted, documented evidence of such activity must be kept.

In case any record/specimen is destroyed before the required retention time period for any reason, the destruction should be managed as described above and, in addition, it should be justified in writing.

For studies contracted out, any prolongation of the retention time should be documented in a written agreement (see Prolonged retention section).

Temporary Archive

Temporary archive is a facility used to store records and specimens for a short time period, during the study or at the end, while waiting for final archiving.

Requirements for a temporary archive could be less restrictive than for a long-term archive, and less restrictive than those described in this document as well. Nevertheless, temporary storage facilities should be secure and protect the integrity of stored materials. Limited and controlled access to records and specimens, identification of materials in order to ensure easy tracking and retrieval, and clear responsibility definition should at least be ensured.

Non-GLP Certified Archives

Sponsor

GLP [1] expressly requires (Section II § 10.4) that if a test facility or a contracting facility goes out of business and has no legal successor, the archive should be transferred to the archive of the sponsor(s) of the study.

However, since there is no reference in the GLP principles to the sponsor(s) having to be GLP-certified, it is not considered mandatory that a sponsor's archive be GLP-certified. Nevertheless, GLP principles and these recommendations should be applied to the sponsor's non-certified archives. It should be kept in mind that, in any case, the ultimate responsibility for the quality, integrity, confidentiality and retrieval of the materials resides with the sponsor.

Commercial Archive Organisation (CAO)

The conditions of storage and the systems and procedures, as defined by this document, should apply equally to a CAO. A documented agreement, which details the service to be provided by a CAO, should be in place. A CAO should be regarded as a supplier and as such, it is not considered mandatory for a commercial archive to be GLP certified, unless required by local GLP rules. Nevertheless, a CAO should be included in the internal supplier qualification process and QA inspection/audit should be carried out as needed.

Smoking must be forbidden and doors should be fire- and smoke-proof.

Packaging for storage

Materials should be protected by appropriate packaging. Containers should be adequately and permanently identified (labelled) in order to ensure retrieval and confidentiality.

Environmental conditions

The environmental conditions, under which materials are stored, are more critical during long-term storage. Materials are sensitive to changes in temperature and relative humidity. They should be stored in environments appropriate to their respective specifications. Nevertheless, the environmental conditions considered acceptable for archiving paper, electronic media and most of the standard specimens that are generated during a GLP study (see Table 2) are a temperature between 15°C and 20°C and a relative humidity between 40% and 65%. However, a stable environment is as important as keeping the mentioned parameters within the stated ranges.

Transfer of materials between locations

General

Any change in the ownership and any transfer of the materials should be documented in order to allow adequate tracking. Adequate documenta-

Table 2. Minimum retention times

Records and specimens		Retention time period
(a)	Study plan (including any amendment) raw data and the final report (including any amendments)	15 years from the issue of the final report
(b)	Specimens:	
	Samples of test and reference items	10 years or until 1 year after batch expiry date if this is less than 10 years
	Histopathology frozen sections	2 years from the issue of the final report
	Specimens in formol saline or alcohol	5 years from the issue of the final report
	Stained foetal material	12 years from the issue of the final report
	Paraffin blocks	12 years from the issue of the final report
	Paraffin sections	12 years from the issue of the final report
	Electron miscroscopy – blocks	12 years from the issue of the final report
	Electron miscroscopy – slides	12 years from the issue of the final report
	Histochemistry – slides	12 years from the issue of the final report
	Electropherograms, cellulose acetate films	5 years from the issue of the final report
	Bone marrow smears	12 years from the issue of the final report
	Blood smears (formula)	5 years from the issue of the final report
	Blood smears (reticulocyte count)	2 years from the issue of the final report
	GTX study specimen (e.g chromosomal aberration, DNA repair, sister chromatoid exchange, autoradiography)	12 years from the issue of the final report
(b.1)	Wet and degradable specimens	Until the issue of the final report or as long as the quality of the preparation permits evaluation, if this is less
(c)	QA documentation and master schedules	20 years from generation
(d)	Records of qualifications, training, experience and job descriptions of personnel	20 years (for personnel who left the company)
(e)	Records and reports of the maintenance and calibration of equipment	20 years from generation
(f)	Validation documentation for computerised systems	20 years from generation
(g)	Historical SOPs	20 years (from SOP retirement)
(h)	Environmental monitoring records	20 years from generation
(i)	Study plan, raw data and specimens of each discontinued study	2 years from discontinuation

Any alteration to records should be traceable; suitable controls should be implemented to ensure that the stored records cannot be altered without appropriate authorisation and the creation of an audit trail.

Where original records are copied or transferred to other media for archiving, the system for copying or transfer should be validated to ensure that information will not be lost or altered. Copies or transfers to other media should be certified for completeness and accuracy by an individual with appropriate authority (as part of a quality control procedure).

Media containing electronic records should be regularly refreshed, as necessary.

Where documents are unique, of particular importance, perishable, and security copies are needed, copies should be made immediately after deposit, and only these copies should be used for normal reference. For security and environmental reasons, copies should be kept apart from the originals.

When applicable, standard file formats should be used in formatting electronic information to ensure long-term preservation and archiving. Examples of international standard formats are reported in Table 1.

Where the use of standard formats is not possible, information about the proprietary format and, where relevant, a copy of the source code of a program capable of reading the electronic record in an internationally-standardised computer language, should be stored with electronic records. However, appropriate computerised systems to access files in proprietary formats should be maintained or it should be ensured that appropriate software is archived for long-term storage.

When changes to the hardware or software used to access stored electronic records are planned, the ability to access the data with the new computerised system should be confirmed in advance. If access is not possible, the electronic data should be converted into a format that can be accessed by the new system.

Any data conversion should be validated (carried out without modification to the original entries).

It is considered acceptable to convert electronic data into a printed paper format.

Electronic archive

Electronic records, including data, meta-data and audit trails, can be archived in an electronic archive. The management of this kind of archive needs to be defined in the same way as for a conventional archive facility.

Access to an electronic archive should be restricted and a procedure for requesting, authorising, granting and revoking access should be in place. Responsibility regarding management of the electronic archive should be clearly defined. The electronic archive should ensure safe long-term retention and facilitate retrieval in a timely manner by a specific application software.

The computerised system used to store, retrieve and transfer electronic records should be validated. Since this system retains electronic files that should be properly indexed, any retrieval of data should be performed by making a copy of the files stored in the electronic archive, to prevent any manipulation of the original data.

Conversion

Conversion of hard copies of raw data into electronic or optical records should be

Table 1. Examples of International Standard Formats

	Name	Format
Document formats	PDF	Portable document format
	XML	Extensible markup language
Image formats	TIFF	Tagged image file format
Data encoding formats	BASE-64	Base 64 encoding

(SSFA/GIQAR) working group on 'Archiving according to Good Laboratory Practice (GLP)' ('Archiving & GLP'), held on 16 November 2004, in Pomezia (Rome), Italy. The round table brought together auditors from Quality Assurance (QA) units in industry, inspectors from GLP compliance monitoring authorities as well as Study Directors, principal investigators and management representatives. A background document, prepared by the GIQAR working group on Archiving & GLP, was used as the starting point for discussion in order to reach harmonisation between all the involved parties.

Background

The principles of GLP have been in force for over 20 years and have provided general information regarding archiving. Valuable experience has been gained at test facilities where these principles have been applied. In light of this experience, this document was produced by the GIQAR GLP working group on Archiving & GLP to offer additional recommendations on storage and retention of records and specimens.

Introduction

The archiving of records and specimens is essential to evaluate compliance with GLP of non-clinical and environmental safety studies. The records and specimens that should be stored and retained and the characteristics of the archive facility are addressed in the OECD Series on Principles of Good Laboratory Practice. No 1 [1].

However, due to the fact that in recent years an increasing number of questions concerning archiving have been raised, it was felt there was a need for more detailed guidance on this matter.

The purpose of this document is to provide additional recommendations on aspects such as:

- Minimum set of documents/specimens to be retained.
- Media to be used and storage of electronic data.
- Minimum standards for storage conditions.
- Retention times.
- Archiving requirements for multi-site studies.
- Use of commercial archives.

Records/Specimens to be Archived

Records/specimens

Paragraph 10 'Storage and Retention of Records and Materials' of the OECD Series on Principles of Good Laboratory Practice No. 1 [1] defines the main records and specimens to be archived:

- 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 QA 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 equipment.
- Validation documentation relating to computerised systems.
- The historical file of all standard operating procedures (SOPs).
- Environmental monitoring records.

Note: Archiving of personnel data (e.g. Curriculum Vitae and training records) is subject to applicable national regulations.

The study plan and the final report listed above are considered as including any amendments.

Raw data

Raw data, according to the GLP definition, include '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