OECD Good Laboratory Practice: Frequently Asked Questions (FAQ)

Updated November 2026

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Abbreviations

CMA: compliance monitoring authority
COTS: commercial off-the-shelf products
CRO: contract research organisation
eArchive or E-Archive: electronic archive
GCP: good clinical practices
GLP: good laboratory practices
GMP: good manufacturing practices
GMO: genetically modified organisms
ISO: International Standard Organisation
IT: information technology
NOEL / NOAEL: no observed effect level / no observed adverse effect level
OECD: Organisation for Economic Co-operation and Development
QA: quality assurance
SOP: standard operating procedure
TF: test facility
WSI: whole slide image

Test Facility Organisation and Personnel (Sponsor/CRO/Sub-Contractor Responsibilities - Including IT Providers)

1. **Can the organisation chart of a test facility include functions other than those described in the GLP Principles, such as head of department, coordinator of the study directors, laboratory technician, personnel responsible for veterinary services, etc.?**

   It can but there is no requirement for this in the GLP Principles. The GLP responsibilities and who fulfils these GLP roles must be described and this can be in the organisational chart or other documents.

   (Posted on 15 June 2020)

2. **What are the responsibilities of Test Facilities (TF) and sponsors with respect to overseeing the work and ensuring the qualifications of the full range of GLP service providers / subcontractors (e.g. those who supply commercial assay kits to Contract Research Organisations (CROs))?**

   See OECD document No. 21, section 6.1. (Posted on 28 February 2018, reviewed on April 2024)

3. **Some TF activities may be performed by external suppliers (e.g. IT services, eArchive, metrology, computer system validation). What are the responsibilities of TFs with regard to these types of suppliers when these suppliers are not GLP certified (i.e. the suppliers are not included in a national GLP compliance monitoring programme)?**

   Test facility management has overall responsibility to ensure that the facilities, equipment, personnel and procedures are in place to achieve and maintain the validated status of computerised systems in order to establish “GLP compliant” study results. This includes the responsibility for internally as well as externally provided services (e.g. third parties, vendors,

internal IT departments, service providers including hosting service providers). Depending on the provided services, a supplier's facility need not be part of a GLP compliance monitoring program or conform to GLP regulations, but it must have an appropriate quality system for the provided GLP services verified as acceptable by test facility management with input from its QA unit (see also OECD Document No. 23, section 11.7). (Posted on 28 February 2018)

4. **Which roles can be amalgamated by or allocated to one person (for example study director and test facility manager, test facility manager and QA, archivist and study director) and which roles cannot?**

   For QA, see OECD Document No. 23, section 4.

   The other scenarios of amalgamating functions should be considered on a case-by-case basis, taking into account the workload of each individual and that the potential conflicts of interest could determine if some roles cannot be allocated to one single person. The accumulation of multiple GLP roles is likely to be something which should be discussed with the relevant GLP Compliance Monitoring Authority, and individual situations would need to be assessed. (Posted on 15 June 2020, reviewed in November 2023)

Quality Assurance

(See also OECD Document No. 23)

Quality Assurance Statements

1. **What should appear on a QA statement?**

   See OECD Document No. 23, sections 7.9 and 8.4.

   (Posted on 15 July 2014, reviewed in November 2023)

2. **Who should sign the QA statement?**

   See OECD Document No. 23, section 7.9.

   (Posted on 15 July 2014, reviewed in November 2023)

Audit of the QA department

3. **How should the frequency of QA audits be determined?**

   See OECD Document No. 23, section 7.2.

   (Posted on 15 July 2014, reviewed in November 2023)

4. **Is an audit of QA activities required?**

   See OECD Document No. 23, section 7.6.

   (Posted on 15 July 2014, reviewed in November 2023)

Access to QA reports

5. **When is it appropriate for inspectors to look at the contents of a QA report?**

   National GLP compliance monitoring authorities may request information relating to the types of QA inspections conducted and the dates they were performed and reported to management. They

may also request the names of the QA auditors who performed specific activities so that their training records can be reviewed.

Compliance monitoring authority inspectors will also need to verify the extent of QA inspections and the effectiveness of QA activities as part of the inspection of QA. In order to do this, it is highly likely that they will need to review QA procedures and other supporting records (which can include the inspection reports). These documents will be used to verify key requirements including that critical study phases are monitored in accordance with the TF's policies and that the frequency of audits is sufficient.

Some national monitoring authorities may occasionally require access to the contents of inspection reports in order to verify the adequate functioning of QA or to verify that management has received and acted upon reports from QA concerning problems that are likely to seriously affect the quality or integrity of the TF or a study.

Under no circumstances should QA reports be used as an easy way to identify inadequacies within the TF or problems associated with a specific study.

(Posted on 15 July 2014, reviewed in November 2023)

Equipment and Computerised Systems

IT Issues

1. **According to OECD Document No. 17, section 1.3, any function involved in the validation of a computerised system (e.g. system owner, process owner), needs to be part of the TF organisation chart. Does this include personnel who are external to the TF but still within the same company?**

   Personnel who are performing a role within the validation of a GLP relevant computerised system (and one which can have an impact on compliance of a TF and studies) and who are not directly part of the GLP TF (e.g. external contractors, IT department staff) are providers of services, even if they are within the same company. Such arrangements should be included in the organisational chart and/or described in a service level agreement and/or in a test facility management delegation agreement depending on the provided services and the way the arrangement is implemented. Training records for these personnel in relevant GLP procedures should also be available.

   (Posted on 15 June 2020, reviewed in November 2023)

2. **How should hosted services ("cloud" computing) and the retention of electronic data be treated in the context of GLP?**

   See OECD Document No. 17 supplement 1.

   (Posted on 28 February 2018, reviewed in November 2023)

3. **For some national GLP compliance monitoring programmes, it is acceptable to archive electronic data in a primary database with the use of appropriate access rights (i.e. read only permission for the study director / the study staff / QA and full rights for the archivist etc.). For other national programmes, data can be physically transferred to another location or to a storage medium (also with the corresponding access right modifications) for archiving. Are both acceptable?**

   Archived electronic data should be protected physically and logically in order to meet the requirements of a GLP archive. Electronic data should be accessible and readable, and its integrity maintained, during the archiving period (OECD Document No. 17, paragraph 112).

Electronic records may be moved from the production part of a computerised system to a discrete, secure archive area on the same computer system (e.g. physically separated file record systems), or explicitly marked as archived (e.g. logically separated database record systems). Records should be locked such that they can no longer be altered or deleted without detection. Records archived in this way must be under the control of a designated archivist and be subject to equivalent controls to those applied to other record types (OECD Document No. 15, section 8.3).

(Posted on 28 February 2018)

4. **If a GLP inspector requests information retained in an archive, can a TF respond by retrieving electronic records from a company's global electronic archiving system (physically located in another country)?**

   The response would be satisfactory as long as all required records can be retrieved from the archive. All electronic records should be verifiable on screen in human readable format and retained (OECD Document No. 17, paragraph 79).

   The GLP Principles for archiving must be applied consistently to electronic and non-electronic data. It is therefore important that electronic data is stored with the same levels of access control, indexing and expedient "retrieval" as non-electronic data (OECD Document No. 17, paragraph 110).

   Electronic data should be accessible and readable, and its integrity maintained, during the archiving period (OECD Document No. 17, paragraph.112).

   (Posted on 28 February 2018)

5. **Would such global archives need to be declared by each TF to their national GLP compliance monitoring authority?**

   The use of a global archive should be included in the appropriate SOPs. TF SOPs must define and describe the archive facilities and processes, including contracted archiving services or storage at a different physical location. Routine QA inspections and audits should be conducted of the services provided.

   Some GLP compliance monitoring authorities include external archiving sites, even electronic ones, in their compliance monitoring programme, while others may inspect them during the GLP inspection of the TF.

   In the event of the closure of a TF or an archive contracting facility, any data transfer to an archive within another country should include informing both GLP compliance monitoring authorities in order to ensure the coverage by the GLP compliance monitoring programme if required by that country (OECD Document No. 15, section 11).

   (Posted on 28 February 2018)

6. **Under what conditions is the use of a relational database permissible for the acquisition, retention, or processing of raw data?**

   Note: A relational database is a database system that stores information in tables and links these tables through relationships (relations).

   If a relational database is used to capture, process or store raw data, the requirements to ensure data integrity should be met as for any other GLP regulated computerized system.

   The validation approach should be based on a clearly defined validation strategy. This strategy should include a risk assessment of the extent to which its functionalities pose a risk to data integrity.

There are several aspects that may be particularly critical for a relational database, and their relevance can vary depending on the specific context. Accordingly, they are provided as illustrative examples and do not constitute a complete or exhaustive list:

- Definition and control of keys (primary, foreign), and referential integrity rules.
- Completeness, accuracy, and protection of metadata - including table definitions, data types, constraints, triggers, and stored procedures.
- Appropriate preventative and mitigation measures should be implemented throughout the life cycle.

The handling of data using a relational database should be controlled by a data governance system which should be an integral part of the quality system.

The data governance and risk control activities should be justified and should be commensurate with the risks to data integrity.

The test facility should be able to demonstrate the data flow, identify which data a system stores, explain how this data is assessed in terms of its criticality, and describe the preventive and mitigation measures implemented to protect its integrity.

The test facility should ensure the completeness, consistency, and accuracy of all data (raw data, meta data, and derived data). The test facility should demonstrate whether derived or processed data can be reliably traced back to the raw data.

For derived or processed data, it must be possible to demonstrate that all data processing activities can be fully reconstructed.

Solutions for archiving relational database content must be implemented.

(Posted on 10 August 2026)

Validation of Software Programmes which Support OECD Test Guidelines

7. **Do software programmes which have been developed by outside vendors or academia to support calculations by test facilities using an OECD Test Guideline, and are referenced in OECD Test Guidelines, need to be validated by test facilities?**

   It is important to note that use by test facilities of the software programmes for these Test Guidelines is voluntary. That is, a TF is not required to use the programmes to complete a test. However, if a TF uses such a programme it must have the appropriately scaled validation documentation of risk assessment, user requirement specifications, acceptance testing records, and a listing in the computerised systems inventory.

   While these software programmes were not developed by OECD, they are referenced in the Test Guidelines, and can be downloaded for free on the OECD public website. These software programmes are provided as a courtesy of the developers of the test methods, but have not been validated, reviewed or approved by OECD. The developer, and not the OECD, should be described as the supplier of the software. In addition, the maintenance of the software or of the calculation sheets is not guaranteed by OECD.

   If a TF uses one of these products, and if that TF wishes its test results to be compliant with OECD GLP, it must follow the guidance as described in OECD Document No. 17.

   These software programmes are considered “Commercial Off-The-Shelf products (COTS)”, as described in OECD Document No. 17, section 1.7. Therefore, they require appropriate validation depending on the risk and the complexity of any customisation. If an application (e.g. a spreadsheet) is not complex, it might be sufficient to verify functions against user requirement specifications. In addition, user requirement specifications should be written for any application that

is based on a COTS product. Documentation supplied with a COTS product should be verified by test facility management to ensure it is able to fulfil user requirement specifications.

A TF should perform a validation of a COTS software programme to ensure that it meets their needs, depending on prior validation by the provider. There must be documentation from the supplier that they have done the validation. Documentation must be available on the validation performed by the TF.

Therefore, if a TF uses one of the software programmes to support data intended for a regulatory submission or to support a regulatory decision, and a validation has not been conducted by the vendor or documentation to support that validation is not available, there would be an expectation that the TF would perform a full validation to ensure that it meets their needs as described in OECD Document No. 17. Even if a validation has been conducted by the vendor, and documentation exists, it is still the test facilities' responsibility to determine whether that is sufficient and, thus, further validation is not necessary. As mentioned above, the extent of the validation would likely depend upon prior validation (and documentation to support such a validation) as well as adaptation by the TF (configuration) to meet their individual needs. And, if the user modifies the software programmes (customisation), there would be an expectation that the TF would perform a full validation to ensure that it meets their individual needs. Documentation must be available on the full validation performed by the TF.

(Posted on 27 March 2017, reviewed in November 2023)

Test Systems

1. **What is a physical/chemical test system?**

   The OECD GLP Principles define a physical/chemical test system as an “apparatus used for the generation of physical/chemical data”. It is the equipment or apparatus to which the test item or reference item is applied during the conduct of a study. Some examples of physical/chemical test systems which may be used to evaluate the physical/chemical properties of a test item may include basic equipment such as pH meters, spectrophotometers and other analytical equipment and/or highly sophisticated and complex equipment such as gas chromatography – mass spectrometry, or those which utilise amplification and analysis of genetic material.

   (Posted on 28 February 2018)

Test items, reference items and samples/specimens (including Biotechnology, GMOs, etc.)

1. **Do concentration, homogeneity and stability of test items in a vehicle need to be done for all test items that are prepared during a study?**

   a) General situation

   If a test item is prepared in a vehicle for a GLP study and data on homogeneity, concentration and stability are not determined, this constitutes a deviation to GLP and the study director should report it in the GLP compliance statement of the final report and assess the impact of this deviation on the validity of the study (see OECD Document No. 1, section 6.2.5 and OECD Document No. 19, section 8.2).

   The following paragraphs describe how this can be interpreted for specific cases:

   b) Formulations used in field studies

Although the study director may not have determined homogeneity, concentration, and stability of the test item in a vehicle for their study, they must still ensure that the test item is appropriate for use. This includes knowing that the processes to be used to prepare the test item for application are appropriate. The study director should also know of any restrictions relating to the application and use of the test item and these should be specified in the study plan.

The required information including data on homogeneity, concentration, and stability and/or information on how to prepare the test item before application may be provided in different ways. If these data are to be determined in a GLP study, this will be detailed in a study plan, however, these data may also be determined through separate laboratory experiments. For some studies, the sponsor may provide it via a report, certificate of analysis or other documents. For crop studies, sufficient information may be available on the label information or package insert as these products are already registered for use in other crops. Regardless, the source of the data should be clear in the final report.

Homogeneity, concentration, and stability of tank mixes in used field crop studies does not need to be determined for every residue trial. For these trials, the test item is normally added to water and/or other dispersants in the field, immediately prior to application, to mimic the normal conditions of use. Collecting, transporting, and analysing samples of tank mixes is therefore often impractical. Actual values of preparation of the test item and its application, including volumes of each component added, as well as the time of mixing and the termination of the application, should be recorded in the raw data. OECD Document No. 6 provides further information.

If the study director does not have sufficient information to know if the test item was prepared correctly or the source of this information is not known, then this constitutes a deviation from the GLP Principles. This should be reported in the compliance statement in the final report and the impact on the validity of the study be assessed.

c) Determination of concentration, homogeneity and stability of test items in a vehicle and OECD guidelines for the testing of chemicals

Some OECD test guidelines do not require the concentration, homogeneity and stability of test items in a vehicle to be determined. However, if the study is to be claimed as compliant with the GLP Principles the general situation as described in a) above applies.

(Posted on 11 October 2022)

2. If a test item is provided by a sponsor as a "ready-to-use" formulation, should a sample from each batch be retained and archived (for long term studies)?

The GLP Principles state that a sample from each batch of a test item should be retained for analytical purposes, except for short-term studies. This also applies to test items that are provided prepared and ready-to-use.

(Posted on 15 June 2020)

3. How can an internal standard used in bioanalysis without the expiry date be managed?

The GLP Principles require the reference items and the reagents used in studies to be labelled with information including expiry date. If a reagent or a reference item is used out of expiry date or without any known expiry date (or any other stability indicator), this point constitutes a deviation from the GLP Principles. The final report should explain and justify why this deviation does not have an impact on the study data (i.e. by demonstrating the suitability for use of the reagent or reference items).

(Posted on 15 June 2020)

4. **Under what scenarios should the accountability of the use of formulated test or reference items be performed?**

   The goal of the traceability of the use of test or reference items is to ensure that the correct quantities have been used for the preparation of the doses administered or applied to the test system. The GLP Principles require accountability for test and reference items. If the test item is supplied as a prepared test item, accountability of this should also be maintained. For further preparations of the test item in the TF, the traceability of consumptions of the preparations of test and reference items administrated or applied to the test systems would be a mechanism to monitor the exact amount of applied/administrated test and reference item to the test systems.

   (Posted on 15 June 2020)

5. **How should samples/specimens collected during a GLP study for exploratory research outside of the GLP study be handled and reported?**

   For exploratory samples during the conduct of the study, please refer to OECD Document No. 21, section 6.2.

   If the decision to use study specimens for exploratory research is taken after the study has been completed and, as a result, the GLP compliance of the study could be jeopardised, the study director should issue an amendment to the final report.

   (Posted on 15 June 2020, reviewed in November 2023)

6. **Can the residual samples from bioanalysis be retained for a limited period, outside the archive, after the report is finalised and then be destroyed provided this is clearly stated in the study plan and report?**

   Residual samples from bioanalysis are specimens from a GLP study and therefore should be retained as study materials as long as their quality permits evaluation (e.g. at least until the end of their validated stability period). They should be stored in the conditions that ensure their stability. The study plan should include the list of records to be retained and the final report should mention the location of the archived items.

   All study materials such as raw data, records and documents must be archived. However, the decision of what study material should be deposited in the archives to fully reconstruct the study remains the responsibility of the study director (OECD Document No. 1, section 1.2.2.i). If specimens are discarded before the end of their stability period, the justification for this should be included in the study plan and in the final study report, except if national regulations provide for the disposal of labile specimens.

   If the study is completed when the decision is taken to dispose of study specimens, the study director should issue an amendment to the final report to describe it.

   (Posted on 15 June 2020)

7. **Which TF "area of expertise" should be used for test items different to conventional chemicals?**

   GLP studies on non-conventional test items that are currently performed in accordance with the OECD Principles of GLP can be assigned to one of the existing nine areas of expertise, as defined in the OECD Document No. 2, Appendix to Annex III, section. 4.

   The areas of expertise are of a general nature and can be used for many product types (e.g. industrial chemicals, pharmaceuticals, plant protection pesticides etc.). This may also apply to test items different from classical chemicals (e.g. Biologicals, GMO, Medical Devices, etc.), in the

context of non-clinical health and safety studies. In general, a product type will not have a specified area of expertise.

(Posted on 28 February 2018, reviewed in November 2023)

8. **Are Biologicals/GMOs test items or test systems?**

   Biologicals/GMOs can serve both as a test item and as a test system, depending on the circumstances, and this distinction can only be made on a case-by-case basis. For example, there are studies in which a GMO is used as a test system for characterising properties of a chemical test item, e.g. an Ames test under area of expertise No. 3 - "Mutagenicity testing".

   There are also other studies in which biologicals/GMO, or parts thereof, are used as test items such as when environmental or health effects of a biological/GMO are being investigated. Some other examples include wild-type biological agents in virus validation studies, environmental fate studies of a GMO product and feeding studies. Another example of a biological/GMO being used as a test item would be in a study to determine the concentration of a known gene product of a transgenic sequence.

   The identification of the test item is one of the pivotal aspects of GLP studies. Due to the biological nature of such test items (e.g. stem cells or viral vectors) the unequivocal identification may require a more complex analysis than for a chemical substance.

   It should also be noted that it is not within the remit of the OECD Working Party on GLP to give guidance on the expectations of regulators with regard to biologicals/GMOs. The national/local receiving authority should be contacted regarding this. It is however acknowledged that some countries have established rules on the content of dossiers for the authorisation of novel foods or GMO (e.g. Regulation (EU) No. 503/2013 of the European Commission).

   (Posted on 28 February 2018, reviewed in November 2023)

SOPs

1. **Must the review of SOPs be performed by QA personnel or can it be performed by personnel with other functions? Is there a limitation on the number of signatures that can be included in an SOP?**

   See OECD Document No. 23, section 11.1.

   (Posted on 15 June 2020, reviewed in November 2023)

Management of the Study

Study Reporting

1. **Under what circumstances can a GLP study be reopened after the final report has been finalised?**

   See OECD Document No. 21, section 6.2.

   (Posted on 21 January 2016, reviewed in November 2023).

2. **Following the early termination of a GLP study is there a requirement to produce a final report?**

The early termination of a study may occur prior to, or after, the completion of the experimental phase of the study, but before the data has been assessed or incorporated in a final report. In both situations, a study plan amendment must be produced providing an explanation of why the study was terminated. The status of the study in the master schedule should be updated. Some compliance monitoring authorities may expect that the key findings up to the point of termination are summarised and that the summary report is subject to a QA audit.

(Posted on 21 January 2016, reviewed in November 2023).

3. What are the expectations on study report amendments?

The expectations on a study report amendment are described in OECD Document No. 1 and Guidance for Receiving Authorities on the Review of the GLP Status of Non-Clinical Safety Studies (OECD Document No. 20), "Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director" and the role of QA in amendments is mentioned in Advisory Document of the Working Party on Good Laboratory Practice on Quality Assurance and GLP (OECD Document No. 23), "Amendments to the study report should be inspected in the same way as the study report".

A study report amendment should be justified and signed by the Study Director and include the original and the amended/changed section of the original study report, a Study Director statement on GLP compliance related to changes, and a signed QA statement. As reported in Advisory Document No.23: "Any correction of or addition to a completed final study report (e.g. amendment to the final study report) must be inspected by QA. A revised or additional QA statement would then need to be provided, listing at least the inspection of the amendment". The Study Director is also expected to inform, if applicable, the sponsor. In case of the Study Director no longer belongs to the test facility, this should be stated and the amendment signed by newly appointed study director.

Receiving authorities may ask for additional information after receiving a study report, and such information may be recognized by Study Director and submitted as a formal study report amendment in case of substantial information changes that should be added to the original study report. For example, details on the methods may be requested by the assessor in order to fully understand the procedures and practices used in the conduct of the study. Such a request may be the result of lacking details in the report and, therefore, a formal study report amendment should be considered. In addition, if a study audit request from a receiving authority results in findings which require a report amendment, this should be communicated to the receiving authority so that they can actively follow up and request the report amendment from the sponsor.

All amendments to the study report should be forwarded promptly to the sponsor for submission to the receiving authorities.

(Posted on 10 August 2026)

Method Validation

4. What standard should be applied to the validation of methods which are used in GLP studies and how should it be applied?

Unless stipulated in national regulations, there is no requirement to perform method validation in compliance with GLP. Since parameters of the validated method are used in the GLP study (for example threshold, linearity, accuracy, precision, stabilities, equipment settings, etc.), data should be accurately recorded and stored in a manner that protects its integrity. Validation data may be

required for study reconstruction and, consequently, it should be retained for an appropriate period of time.

(Posted on 21 January 2016)

5. **Should method validation be completed prior to the initiation of a GLP study?**

   There is no requirement to finalise the validation of all methods that will be used to conduct a GLP study before the initiation of the study. However, there is an expectation that methods are fully validated before the results of the study are considered valid.

   (Posted on 21 January 2016)

Histopathology

Digital Histopathology

Technical improvements allow histopathology slides to be digitised as an electronic replica or whole slide images (WSI). The life cycle of WSI consists of digitisation of the histology slide by a slide scanner and transfer or migration of the image to a viewer, which could also be remote from the location of the digitisation and storage.

1. **Is there any objection from the GLP compliance monitoring authorities to implement digital pathology in GLP studies?**

   The OECD Principles of GLP do not preclude the use of digitised histopathology slides in GLP studies for the histopathological assessment of tissue samples. This would include the initial read of tissue slides by the study pathologist and histopathology peer reviews, either prospectively or retrospectively.

   Nevertheless, the following points associated with the use of whole slide images in GLP studies should be considered:

   - the digitised slides should be a faithful replica of the original histology slides, so that the reading of the whole slide image should be equivalent to that of the histology slide
   - the digitisation process should ensure traceability from the tissue sample to the digitised slides
   - integrity of the digitised slides should be ensured during the different steps of the process
   - equipment used for digitisation and viewing of the whole slide image/digitised slide should be fit for purpose and adequately maintained
   - computerised systems implemented to manage equipment and store, transfer or migrate the digitised slides should be validated
   - when the digitised slides are transmitted to a remote location from where they were generated (e.g., for review by an external pathologist), the validation of the system for transfer should include both the sender and the receiver
   - study personnel and pathologists involved in this process and QA personnel should be trained
   - SOPs describing the whole process, including quality control steps if relevant, should be implemented and
   - the use of digitised slides for histopathology assessment and the computerised systems involved should be detailed in the study plan and the final study report.

   (Posted on 15 June 2020)

2. **Should digitised slides be retained in the archives if used in GLP studies?**

Some preliminary considerations are:

- all study materials essential to reconstruct the study should be retained in the archives
- study specimens and the histology slides should be archived
- the dated and signed histopathology raw data (or the dated and signed pathology report) are/is the final contribution of the study pathologist
- when a prospective or contemporaneous histopathology peer-review is conducted, the final contribution is the result of an agreement between the study pathologist and the peer-reviewer(s) under the final responsibility of the study pathologist and
- when a retrospective peer-review is conducted, comments by the peer-reviewer(s) result in an amendment of the study pathology contribution or report.

If the study pathologist uses digitised slides for the initial read or if the peer-reviewer uses them for the retrospective peer-review, they should be retained in the archive for as long as the other study materials as they were used to generate raw data.

Digitised slides should be archived in an electronic format that ensures their integrity over time and allows their review if required for regulatory purpose.

(Posted on 15 June 2020)

Peer Review of Histopathology

3. **OECD Document No. 16, section 2.5 indicates that all correspondence regarding the histopathological evaluation of the slides used for peer review between the sponsor and the representative of the TF and the peer reviewing pathologist should be retained in the study file. Could the interpretation of this requirement be clarified?**

   Correspondence refers to any communication that is needed to reconstruct how slides were selected and reviewed. This should include communications regarding the interpretation of any observations (preliminary or final) on adverse or non-adverse effects made during the review.

   (Posted on 27 March 2017)

4. **OECD Document No. 16, section 2.8 indicates that where the peer reviewing pathologist's findings were significantly different from the original interpretation of the study pathologist, a description of how differences of interpretation were handled and changes made to the study pathologist's original interpretation should be discussed in the final report. Does this apply to both retrospective and contemporaneous peer review?**

   Section 2.8 relates specifically to a retrospective peer review. For a contemporaneous peer review, there is an expectation that all correspondence (letters, e-mail, etc.) relating to differences in the interpretation (preliminary or final) of slides between the original pathologist and the peer reviewing pathologist which may impact on the conclusions of the study (e.g. NOEL/NOAEL) are to be retained in the study file.

   (Posted on 27 March 2017)

Archives Including E-Archives

1. **Can a system administrator conduct electronic archiving of GLP data?**

   Electronic archiving is under the responsibility of the archivist. It could be delegated by test facility management to a suitable person (e.g. a system administrator), within the TF, usually because (s)he has the specific technical competence. This person works under the supervision of the

designated archivist and the respective tasks, duties and responsibilities must be specified and detailed in SOPs. Test facility management must ensure that potential conflicts of interest are avoided for any person within the TF.

Test facilities are expected to perform a thorough risk assessment – including taking into account that there are no limitations on the system administrator's privileges with respect to the use of a computer system - and to apply suitable risk control procedures.

(Posted on 15 June 2020)

2. **How is GLP applied to traceability and archiving of communications between study director, sponsor, principal investigators and pathologists in the context of new information technology tools (such as client portals, encrypted documents, electronic messaging, social networks tools)?**

   See OECD Document No. 22, section 6.14.

   (Posted on 15 June 2020, reviewed in November 2023).

3. **Is it possible to harmonise retention times for archived records?**

   Retention period harmonisation across countries is not anticipated given that the periods "defined by an applicable regulatory authority" are based on country-specific legal requirements of the registration receiving organisation, the nature of the specific GLP program (human health, animal health, agricultural chemicals, GMO etc.) and approaches aimed at minimising burdens on the regulated industry.

   (Posted on 28 February 2018, reviewed on April 2024)

4. **What are the responsibilities of TF management with respect to supporting records?**

   Refer to OECD Document No. 15, sections 4.2 and 7.2.2.

   GLP records and materials include both the study and the facility records. Facility records (supporting records, or related records and materials) would include non-study specific records such as equipment maintenance, staff training, organisational charts, SOPs, Master Schedules, QA inspections, validation for computerised systems, environmental monitoring, and archiving processes (record transfers, specimens or electronic media disposals).

   (Posted on 28 February 2018)

Monitoring of GLP Compliance of Test Facilities by GLP Compliance Monitoring Authorities (CMAs)

1. **How can the GLP compliance status of a TF or test site be checked?**

   Many CMAs have publicly available information with details of test facilities that are in their GLP programmes (contact points for national CMAs can be found on the OECD website). Some CMAs also issue GLP certificates; however, this is not a requirement of the GLP Principles.

   (Posted on 28 February 2018)

2. **Is there a standard format and content for the Study Director's statement?**

   The OECD GLP Principles only require that the statement clearly describes what aspects of the study have been conducted in accordance with the Principles (or not) and, where applicable, what

other standards/ guidelines were used. It should be noted that some CMAs may also have their own requirements due to national regulations.

(Posted on 28 February 2018)

3. **Can GLP studies be done in TF that utilise other quality standards (GMP, GCP, ISO etc.)?**

   The implementation of other standards within a facility (cGMP, GCP etc.) should not preclude the use of the OECD GLP Principles within that TF. Most quality standards contain requirements which are compatible with the OECD Principles. Test facility management must ensure, however, that for any GLP study conducted, the OECD GLP Principles are adhered to fully. Sponsors who commission the study with the TF should also be aware of their role in ensuring that the TF complies with the GLP Principles.

   (Posted on 28 February 2018)

Use of test sites and multi-site studies

1. **What should the study director, test facility and/or sponsors do to ensure study phases conducted outside the test facility premises comply with the OECD principles of GLP, including the possibility for their GLP compliance to be verified by a GLP compliance monitoring authority?**

   In multi site GLP studies, the study director should ensure, prior to making any claim of GLP compliance, that the GLP compliance status of all test sites is known, verifiable and appropriately documented, especially where test sites are located outside the country of the test facility.

   In particular, the study director should have confirmation that the test sites performing phases of her/his studies are capable of claiming GLP compliance for their respective phases, which would require that such test sites are located in countries that are full adherent to the OECD Mutual Acceptance of Data (MAD) system and are subject to GLP inspection by their national competent GLP CMA.

   Test facility management should support the study director by ensuring that accurate and the latest information on the GLP compliance and inspection status of all participating test sites is available. Sponsors, when choosing test sites, should ensure that the selection and use of test sites, particularly those outside the country of the test facility, do not compromise the study director's ability to make accurate and transparent GLP compliance statements in accordance with the OECD Principles of GLP. In addition, Test Facility Management should approve the selection of test sites.

   When a study audit or a regulatory inspection of a study involving multiple sites occurs, all phases of the studies can potentially be verified for their GLP compliance. This applies regardless of whether the study phase is conducted at the test facility or outside the test facility premises, at test sites, fields, etc. and whether the study phase is under the direct responsibility of the study director or is entrusted to a principal investigator.

   If the test facility located in one country has used a test site located in a different country, the CMA of the country in which the test site is located may receive, from the CMA of the test facility, a request to inspect the phase(s) of the study conducted at that test site.

   If national regulation prevents the local CMA to conduct the inspection, both CMAs should consult with each other to determine whether, as an exception, the requesting CMA may conduct the inspection.

   If the legal or regulatory framework of the country in which the test site is located does not permit either the local CMA or the requesting CMA to conduct such an inspection (e.g., a site not covered by the GLP CMA programme), the GLP compliance of the work performed at the test site cannot

be verified, and consequently cannot be considered as GLP compliant by the requesting CMA. The study director should assess the impact of the circumstances to the GLP compliance of the whole study.

Therefore, study director, test facility management and sponsor should ensure that every selected test site is able to be subject to a GLP inspection by their national competent CMA and determine whether any restrictions apply under the GLP regulations of the country where the test site is located. When in doubt, study director, test facility management and sponsor might contact their GLP CMA.

(Posted on 10 November 2026)