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MANAGEMENT OF SAMPLES

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Management of Samples

Guideline for OMCLs

1. INTRODUCTION

The sections on quality and technical records (including invalid documents) in the previous document (OMCL GL Archiving (PA/PH/OMCL (07) 105 DEF) have been updated and transferred to the Guideline on "Management of Documents and Records" (PA/PH/OMCL (14) 19 3R). This document describes archiving aspects for samples and also provides requirements for management of samples in general. Sample management is critical to the accuracy and reliability of testing, and, therefore, to the confidence in laboratory test results.

2. OBJECTIVE

The purpose of this guideline is to describe how samples tested by OMCLs are managed, in what concerns: receipt, handling, protection, identification, traceability, storage, archiving and disposal of the samples.

3. REFERENCES

- ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories: 4.4 (Testing order review), 4.6 (Purchasing services and supplies), 5.7 (Sampling) and 5.8 (Handling of test items)

4. DEFINITIONS

Samples: Test items (ISO/IEC 17025), i.e. each item to be tested by the OMCL, as defined by the scope of the individual OMCL's activities (e.g. APIs, medicinal products, medical devices, cosmetics etc.).
Retained sample: samples that are archived for legal or other purposes

5. RESPONSIBILITIES

The OMCL should define the person(s) responsible for receipt, transport, identification, handling, testing, access (restricted), storage, retention and disposal of the samples. Written procedures should be in place describing how the aforementioned activities are managed.

6. RECEIPT

The condition of the sample should be inspected on arrival as per the agreement and following a clearly defined internal procedure, taking into account any legal or health and safety aspects which may apply. The outcome of the inspection (especially any deviation from standard conditions) should be recorded. Where there is any reason for doubt as to the suitability of the received item, the responsible person, where appropriate, consults the sender and agrees on appropriate action before proceeding. The outcome of this agreement should be recorded.

During receipt, care should be taken to ensure that the samples are stored in a designated area for unregistered samples, under the prescribed storage conditions.

The following actions may be taken when doubts arise or deviations are observed during receipt of a material:

Context of testing	Function/body with whom the testing order should be clarified
Samples submitted by the competent authority's sampling body (e.g. inspectorate)	Competent authority's sampling body
Quality defect samples (including samples sent directly to the OMCL)	Competent authority that is responsible for follow-up of quality defects (e.g. inspectorate)
MRP/DCP surveillance studies	The sampling OMCL
CAP testing	EDQM as coordinator of the study
OCABR	The manufacturer or marketing authorisation holder that requested batch release and submitted the samples
Samples that were taken by the OMCL (e.g. as part of an annual sampling plan)	The function responsible for carrying out the sampling plan or the scientific coordinator of the specific market surveillance project

Testing is only performed after all potential deficiencies have been resolved.

7. HANDLING AND PROTECTION

All the measures necessary to protect the integrity of the samples (deterioration, loss or damage) should be described clearly and all the staff should be aware of them. Care should be taken if special handling procedures (cool/frozen, protected from light, humidity, health and safety requirements, etc.) are required during storage, pre-testing or testing. If appropriate, the samples should be supplied with specific instructions for their handling and storage.

Restricted access levels should be described for the samples received and the samples undergoing testing.

8. IDENTIFICATION

The OMCL should describe how it ensures that samples are uniquely identified (e.g. code, reference) and marked. The type of identification system depends on the organisation, but it must be linked to the analytical study and should be kept throughout the life of the sample in the OMCL.

The identification system should allow the sample to be traced back to a single source and transport conditions. A common identifier should only be given to several items if they are from the same batch and were sampled, transported and received together.

The person(s) responsible for the identification of the samples should generate a reference number for the samples (by hand or allocated by the software), ensuring that each sample is labelled correctly and that all individual samples are clearly marked or within a marked container when individual samples are too numerous or too small or when integrity of packaging is needed.

9. TRACEABILITY

The sample's unique identifier should be recorded on all paper and/or electronic records generated by the OMCL, from receipt of the sample through to its testing and storage.

From the sample labels, it should be possible to establish when a specific sample arrived at the OMCL and, likewise, it should be possible to identify and locate the sample by the records available. Special care should be taken to avoid any possible confusion (physically or when samples are referred to in records or other documents).

10. STORAGE OF SAMPLES DURING TESTING

Once the samples have been received and accepted and it has been confirmed that the testing order submitted is complete, the samples are placed in the appropriate storage area, under the prescribed storage conditions.

It is advisable to have specially designated storage areas for samples that pose a safety risk and samples subject to special legal requirements (for instance, infectious substances, samples with high pharmacological activity, toxic substances and psychotropic drugs).

During testing, the samples are stored and handled in accordance with the OMCL's procedure and the manufacturer's requirements. Any other legal or known specific requirements should also be taken into consideration. If the manufacturer defines specific storage conditions for samples, these must be provided, maintained and monitored by the OMCL. All potential storage deviations are recorded.

11. STORAGE OF / ACCESS TO RETAINED SAMPLES

If any samples in their unopened primary packaging remain after the analysis, they should be retained until the report and all administrative actions have been finalised. For samples from the legal supply chain that were found to be out of specification and samples for illegal products (falsified medicines, illegal supply chain), the sample retention period should include the period of time required for appeal procedures to the competent authority.

If applicable (or if requested), the OMCL should define retention times meeting requirements from an accreditation body or equivalent (e.g. an audit cycle), national regulations or equivalent and any agreements with the competent authority. The OMCL should describe the location (depending on the prescribed storage conditions) and level of access to the retained samples. Particular attention should be paid to the storage rooms (or cabinets) to prevent damage, deterioration or loss (e.g., as a result of temperature, humidity, light). The storage temperature should be monitored.

12. DISPOSAL

The OMCL should ensure that a proper disposal procedure in accordance with national legal requirements is in place and that any agreements with the competent authority are adhered to.