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QUALITY MANAGEMENT DOCUMENT

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MANAGEMENT OF DOCUMENTS AND RECORDS

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Management of Documents and Records

Guideline for OMCLs

1 INTRODUCTION

Management of documents and records (writing down what the OMCLs do and how they do it) is one of the pillars of a quality management system (QMS).

Several chapters of the ISO/IEC 17025 4.2 Management system, 4.3 Document control, 4.13 Control of records and 5.4.7 Control of data are dedicated to these topics.

This document replaces Guideline PA/PH/OMCL (97) 5 and the part of Guideline *PA/PH/OMCL (07) 105 DEF* related to the archiving of records.

2 OBJECTIVE

The purpose of this guideline is to help OMCLs in establishing and maintaining procedures:

- to control internal documents: generate, identify, approve, issue, review, revise and archive
- to control external documents: access, distribute, ensure availability and implementation of current versions and track/archive previous versions
- to identify, collect, index, access, file, store, maintain and dispose of quality and technical records

in order to guarantee the legibility, traceability and durability of documents and records.

3 SCOPE

This guideline is intended to address the management of internal and external documents, records and data related to the activities performed by the OMCLs.

4 REFERENCES

- ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories
- *PA/PH/OMCL (08) 69 3R*, OMCL Guideline on Validation of Computerised Systems - Core Document and Annexes
- *PA/PH/OMCL (14) 55 DEF*, EU Administrative Procedure for Official Control Authority Batch Release

5 DEFINITIONS

Internal documents – documents generated by the OMCL that provide information about policies, processes and procedures such as Quality Manual, SOPs, forms (as a template), etc..

External documents – documents generated by an external body/authority/company such as legislation, standards, guidelines, pharmacopoeias, EDQM's documentation, information from manufacturers, equipment supplier instructions, contracts, etc..

Quality and technical records (internal and external) – registered evidence on OMCLs activities on the QMS and/or the process of performing tests (e.g. work sheets, logbooks, control graphs, documentation of

equipment qualification, test requests, test reports, reports from audits, training records, records of corrective and preventive actions, etc.). A form or template containing data is considered a record.

Review – checking of the suitability of a document.

Revision – changing the version of a document.

6 MANAGEMENT OF DOCUMENTS

6.1 STRUCTURE OF INTERNAL DOCUMENTATION

The OMCL should define the structure of its internal documentation.

Internal documents may comprise the following:

- Quality Manual: defines the general organisation of the OMCL (including roles and responsibilities of technical management and the quality manager) and its quality management system (including QMS policies, SOPs (or make reference to them), the structure of documentation and reference to other documents (e.g. Regulations on internal organisation, Job Description, etc.)).
- Standard Operating Procedure (SOP): defines how a given activity related to the quality management system or to a technical task is performed and may contain or refer to operating details.
- Supporting documents: e.g. lists (equipment, personnel, premises, reference materials, reference standards), documents describing the premises, the organisation.
- Forms or Templates for quality and technical records: e.g. CAPA forms, templates for logbooks, work sheets for recording of raw data, test report templates, etc..

6.2 RESPONSIBILITIES

The OMCL should define the person(s) responsible for authorising, maintaining and reviewing of documents.

Each document must be authorised by the most appropriate person(s) based on their competence and role.

The Quality Manager may be involved in the approval process in order to ensure consistency with the Quality Management System.

6.3 GENERATION

The OMCL should describe its process for generating documents.

6.4 IDENTIFICATION

The OMCL should describe how it ensures that documents are uniquely identified. Such identification shall include at least:

- the date of issue and/or revision identification
- page numbering, the total number of pages (e.g. page x of page y) or a mark to signify the end of the document
- the issuing authority(ies)/ person(s) responsible for the issuing.

The type of identification system depends on the preferences of the OMCL (title, code, number, reference, etc.).

6.5 MASTER LIST

The OMCL should maintain a comprehensive list (or equivalent) of internal documents, with the current revision status identified.

6.6 REVIEW, REVISION AND APPROVAL

The OMCL should define a period for reviewing its documents in order to ensure continuing suitability. If the review process does not identify the need for changes, a new revision is not required. Nevertheless, evidence that the review was carried out needs to be recorded.

Review and approval of revised documents should be performed prior to their issue by the same function (position) that performed the original version (authorised the previous version), unless otherwise justified.

The OMCLs' procedure for document control should include the assessment of the impact of new or revised external documents on the QMS.

Amendments by hand are not recommended, but if the OMCL allows this type of amendments it should be ensured that:

- responsibilities for such amendments are defined;
- amendments are clearly marked, initialled and dated;
- a revised document is issued as soon as possible;
- amendments should be made to all controlled copies.

In revised documents, modifications should be identified, where practicable, for example: track changes, comments, italics, bold, strikethrough, underlined or line in the margin. If not, a section or a specific record which describes all changes is acceptable.

Rules should be defined about the use of uncontrolled copies or printouts of QMS documents.

6.7 DISTRIBUTION

The availability of both internal and external documents should be ensured.

The OMCL should describe how all staff concerned have access to the appropriate documents for controlled paper copies (e.g. record of issuing of all copies) or electronic documents (e.g. description of internal network or dedicated software).

It should also describe if external distribution is allowed and how confidentiality is ensured.

If documents are distributed electronically, the OMCL should ensure that the integrity of the information is maintained (e.g. preventing accidental change of SOPs).

6.8 OBSOLETE DOCUMENTS

The OMCL should promptly remove invalid/obsolete documents from all points of issue or use. Unintended use of invalid/obsolete documents should be avoided (e.g. by marking the documents).

Obsolete documents may become records for traceability purposes.

6.9 ARCHIVING

The OMCL should define retention times for obsolete documents considering the archiving requirements defined for quality and technical records (see section 7.4).

7 MANAGEMENT OF RECORDS

7.1 AVAILABILITY

The OMCL should define rules to access, identify, collect and index records in order to ensure that they are readily retrievable.

The OMCL can index records by carrying out an inventory of the records. The inventory should contain the identity of the record, the person responsible for the type of record, the location, the archiving organisation (cabinet, shelf, folder, binder, box…), the retention time, etc..

7.2 GENERATING RECORDS

The OMCL should ensure traceability, legibility and integrity of its records. This might be for example by:

- recording observations, data and calculations at the time they are made;
- making sure that data on records are original (raw data), exact, clear, accurate and complete (records on thermal paper should be copied);
- identifying the person who performed the test or the activity and when the activity took place;
- prohibiting the use of pencil, eraser, correction fluid, sticky notes or similar;
- assuring each mistake shall be crossed out, not erased, made illegible or deleted and the correct information entered alongside with the date and identification of the person making the correction and if appropriate, a reason for modification;
- crossing out empty fields to ensure they were not forgotten and to avoid filling-in afterwards (e.g. N/A), if applicable;
- signing across a paper that is attached or glued to a support paper (e.g. printout from the balance glued in the laboratory notebook), to clearly identify if a piece of information is lost.

For logbooks, pages should be marked sequentially so as to ensure that no page is removed.

Specific measures should be in place for electronic records to avoid loss and trace changes of original data (e.g. by an electronic audit trail).

Protection and back-up of records should be described according to *PA/PH/OMCL (08) 69 3R,* OMCL Guideline on Validation of Computerised Systems - Core Document and Annexes.

7.3 CONTROL OF DATA

The OMCL should implement a procedure for protection of data. This includes, but is not limited to, integrity and confidentiality of data entry, collection, storage, transcription, transmission and processing of data.

Calculations and data transfer shall be subject to appropriate checks (e.g. double checking when appropriate, avoiding the transcription of data or ensuring transcription is checked).

7.4 STORAGE AND ARCHIVING

The OMCL should describe how quality and technical records are stored in order to ensure security and confidentiality.

Records should be easily accessible and readily available. For electronic records, legibility should be checked periodically, for example after software updates.

The OMCL should define retention times to meet requirements from national regulations, accreditation body or equivalent (e.g. an audit cycle) as well as any other requirements (e.g. from customer). Records should be archived for at least 5 years after the date of issuing.

Records from Batch Release activities should be archived in accordance with the EU Administrative Procedure for Official Control Authority Batch Release.

Particular attention should be paid to the storage system to prevent damage, deterioration or loss of information.

7.5 DISPOSAL

The OMCL should describe the process for the disposal of records after their retention time (destruction or long term storage) according to national regulations or any other requirements.

Confidentiality should also be considered.