OMCL Network of the Council of Europe
QUALITY MANAGEMENT DOCUMENT

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SUB-CONTRACTING OF TESTS

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OMCL Guideline on "Sub-contracting of tests"

1. Scope

This document provides guidance to an Official Medicines Control Laboratory (OMCL) wishing to sub-contract testing activities to other organisations (including other OMCLs).

It describes how the selection and qualification of a sub-contractor, informing the customer about sub-contracted work and the reporting of results should be handled.

Under the scope of this document, the term "sub-contracting" means the performance of testing activities on behalf of an OMCL. For OCABR and the MRP/DCP testing programme of the OMCL Network, special provisions are also in place (see item 3).

2. Introduction

An OMCL may need to sub-contract laboratory work, either on a temporary or continuing basis. The sub-contractor can be any laboratory that meets (or fulfils) the pre-defined requirements of the OMCL, such as another OMCL, a regulatory (government) laboratory, a laboratory at a university or a commercial provider.

The reasons for sub-contracting laboratory work include, for example:

- Special technique/equipment not available in the OMCL (e.g. animal testing for OCABR, NMR)
- Confirmatory testing by a second laboratory
- Work-sharing (e.g. in cases of pandemics)
- Excessive workload
- Lack of qualifications, competency or resources
- Very low number of tests per year.

The OMCL must assume responsibility for the results of sub-contracted tests with its customers, provided that the selection of the sub-contractor has been performed by the OMCL.

3. References

- *ISO/IEC 17025 (4.5 / 5.10.6)* "General requirements for the competence of testing and calibration laboratories"
- *PA/PH/OMCL (07) 79* "Terms of reference for the General European OMCL Network (GEON) of the Council of Europe", in its current version
- *PA/PH/OMCL (10) 25 6R* "OCABR: Terms of reference"
- *PA/PH/OMCL (06) 35* "OCABR Subcontracting activities between OMCL's"
- *PA/PH/OMCL (06) 102 DEF* ANNEX II "Model Agreement letter for subcontracting between OMCL's" (for OCABR)
- *PA/PH/OMCL (06) 116* "Co-operation in post-marketing surveillance of MRP/DCP products", in its current version

4. Situations related to sub-contracting

The laboratories sub-contracted for analytical work can be divided into:

- OMCL Network members
- Accredited laboratories outside of the OMCL Network
- Non-accredited laboratories outside of the OMCL Network.

Possible situations regarding sub-contracting include:

- OMCL-OMCL on a regular basis
- OMCL-OMCL on a temporary basis
- OMCL-OMCL work-sharing
- OMCL-others (a government laboratory, a laboratory in the same organisation that is not a member of the OMCL Network, a university laboratory or a commercial provider).

In all these situations, evidence of compliance with ISO 17025 and special regulation of national accreditation bodies should be in place.

5. Selection of a sub-contractor

The selection process for sub-contracted laboratories must include criteria based on technical and any additional requirements, and should include the defined criteria in **ANNEX I**, "Sub-contractor Qualification", *PA/PH/OMCL (14) 39*.

When sub-contracting an OMCL, the OMCL Inventory Database can be a helpful tool to collect information about the laboratory and its competences.

The responsibilities listed in item 7 should also be taken into account.

The final decision to select a sub-contractor can be based on a questionnaire, an audit, witness testing and/or collection of information relevant to test performance. Whichever approach is taken, there must be evidence that the laboratory will provide the expected level of performance, whilst also taking into consideration the available providers and the criticality of the service.

After a critical evaluation of the information collected, the Responsible Person of the OMCL should decide whether the proposed sub-contractor is suitable for the laboratory work.

6. Records of qualified sub-contractors

The OMCL must maintain a record of the qualified sub-contractors that is linked to the quality management system. It should contain at least the name and address of the sub-contractor, the date and scope of qualification, and the date(s) of re-qualification. It might also be appropriate to have a summary of requests placed with individual sub-contractors.

A review of the service provided by the sub-contractor should be conducted.

A record of the sub-contractors that have failed or lost their qualification, or have been qualified but have a record of complaints, should also be present to avoid repeat re-qualifications or the placement of requests with an unqualified sub-contractor.

The record of qualified sub-contractors must be checked before placing a request.

The OMCL should define criteria and the period of validity for the qualification of a sub-contractor. If the qualification of a sub-contractor is no longer valid, the sub-contractor has to be re-qualified before a request can be placed.

7. Contract with the sub-contractor

In some cases, such as confirmatory testing, a formal contract is not required. Nevertheless, documentary evidence should always exist (e.g. emails, letters, telephone records), to define conditions for the testing, even when no payment is involved.

In cases where no contract has been made with a sub-contractor, an agreement on data protection should at least be signed by both parties when accepting the order.

The following model text for an agreement on data protection might be applied:

"The sub-contractor mentioned below declares to treat all the data, documents and information from OMCL XXX as confidential. The sub-contractor will not use any information on the origin, the manufacturing process or the composition of products or any other product-related information for their own purposes and will not pass any such information to a third party.
These obligations remain valid after completion of the assignment."

Where a formal contract is required (for example, if the work is sub-contracted on a regular basis), the contract should be signed by both parties before the service starts and should include the following responsibilities:

Contract giver (OMCL)
– Provide all the relevant information related to the sub-contracted work, including health and safety, destination of the samples after testing (retain, return to OMCL, destroy, etc.), archiving of the results (records). – Provide the required quantity of the sample to be tested along with other information (including shipment). – Control of out-sourced activities. – Review the results and the sub-contractor. – Define the procedure for investigating out-of-specification (OOS) results (checklist), if applicable. – Define the ownership of information and any consequent actions.
Contract acceptor
– Be independent, assure confidentiality and have no conflicts of interests (refer to the GEON Terms of Reference). – Assure the conditions exist to perform the test (premises, equipment, infrastructure, knowledge, experience, personnel, documentation, quality system). – Should not sub-contract any of the sub-contracted work to a third party. – Inform the OMCL about deviations or changes. – Maintain the records related to the out-sourced activity. – Should permit the OMCL to carry out an audit, if necessary.

In addition, the contract can also define the payment conditions, property rights, termination of the contract and other provisions.

An example of a model contract is provided in **ANNEX II**, "OMCL Model Contract for Subcontracting", *PA/PH/OMCL (14) 40.*

8. Evaluation of the sub-contracted work

The assessment should be performed and reviewed by the contracting OMCL after receipt of each report and in light of the documented evidence of the sub-contracting and the service outcome.

9. Informing customers of the sub-contracting arrangement

If applicable, approval from customers must be obtained before work is sub-contracted. Provided that the Competent Authority is the customer, evidence should be available that sub-contracting was approved or that the OMCL has been mandated to sub-contract without formal approval of their Competent Authority.

On reports issued to customers, the laboratory must clearly indicate if a test was performed by a sub-contractor.

For market surveillance, the Competent Authority is generally considered the customer (e.g. inspectorate of a medicines agency). For OCABR, the MAH applying for OCABR is a direct customer, based on interpretations of the ISO norm. However, according to the provisions related to OCABR, advance approval for sub-contracting by the MAH is generally not required and it is not obligatory to include the information on the OCABR certificates, which do not include specific test results. OMCLs performing OCABR are either Competent Authorities or are mandated by a Competent Authority to carry out batch release, and this should also be taken into account when approving sub-contracting.

10. Policy of archiving test results (records) and samples by sub-contractors

Details about archiving may be established in a contract or when placing a request. Nevertheless, it is the responsibility of the contracting OMCL to ensure that the results are archived.

11. Associated documents

PA/PH/OMCL (14) 39 ANNEX I "Sub-contractor Qualification"
PA/PH/OMCL (14) 40 ANNEX II "OMCL Model Contract for Sub-contracting"