

General European OMCL Network (GEON) QUALITY MANAGEMENT DOCUMENT

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PRINCIPLES OF CONTRACTING THE TESTING SERVICE PROVIDER AND OMCL MODEL CONTRACT FOR OUTSOURCING TESTING SERVICES

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Custodian Organisation	The present document was elaborated by the OMCL Network / EDQM of the Council of Europe
Concerned Network	GEON

N.B. This OMCL Quality Management System document is applicable to members of the European OMCL Network only. Other laboratories might use the document on a voluntary basis. However, please note that the EDQM cannot treat any questions related to the application of the documents submitted by laboratories other than the OMCLs of the Network.

ANNEX II

CONTRACTING PRINCIPLES AND OMCL MODEL CONTRACT FOR OUTSOURCING TESTING SERVICES

Part 1. CONTRACT WITH THE TESTING SERVICE PROVIDER

In some cases, such as confirmatory testing, a formal contract may be 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 testing service provider, both parties when accepting the order shall at least sign an agreement on data protection and confidentiality agreements.

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

“The testing service provider mentioned below undertakes to treat all the data, documents and information from OMCL XXX as confidential. The testing service provider 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 testing service provider is used on a regular basis), the contract should be signed by both parties before the service starts and include the following responsibilities:

Contract giver (OMCL) shall:

- provide all the relevant information related to the outsourced testing, 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 relevant information (including shipment).
- control of out-sourced activities.
- review the results and the performance of the testing provider.
- define decision rules, if needed.
- define the procedure for investigating out-of-specification (OOS) results (checklist), if applicable.
- define the ownership of information and any consequent actions.

Contract acceptor shall:

- be independent, assure confidentiality and have no conflicts of interest (refer to the GEON Terms of Reference).
- assure the conditions exist to perform the test (premises, equipment, infrastructure, knowledge, experience, competence of the personnel, documentation, quality system).
- not outsource any of the provided work to a third party.
- inform the OMCL about any deviations or changes to methods/protocols.

- maintain the records related to the out-sourced activity.
- allow the “customer” 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 below.

Part 2. OMCL MODEL CONTRACT FOR OUTSOURCING TESTING SERVICES

This model contract is only intended as an aid to highlight elements considered important when OMCLs are preparing outsourcing arrangements. As an example, testing work outsourced between OMCLs in the EU/EEA OCABR Network is described. The model is based on the internal OCABR document PA/PH/OMCL (06) 102 DEF. This model may also be applied by OMCLs preparing outsourcing work in other fields of testing. However, individual OMCLs entering into outsourcing agreements should develop their own agreements, taking into account their own specific situation, and do not need to follow this model contract explicitly. The items highlighted in grey are those that should be completed according to the specific circumstances of the agreement.

Between *The full name of the OMCL requesting testing service, City - Country* (hereinafter referred to as the contractor), represented by *Name of Contact, Job title*

on the one part,

And *the Full Name of Institute - City - Country* (hereinafter referred to as the contracted laboratory) represented by *Name of Contact, Job title*

on the other part,

with respect to the testing of *Name of product(s) (or product group(s))*

THE FOLLOWING HAS BEEN AGREED

Article 1 - TESTING

1.1 The contractor shall supply the contracted laboratory with:

- necessary details from MA SOPs in a language comprehensible to the testing laboratory operators
- *(add or delete appropriate elements) e.g.*

- *data reporting sheet(s)*
- *required reference substances (as determined in the annex)*
- *special reagents (e.g. sera or other reagents provided by the MAH) (as determined in the annex)*
- *approximate date(s) of supply of the test material to allow programming of the testing activity in the contracted laboratory*

Test samples *(and special reagents)* will be *(provided by the contractor or sent directly by the MAH, as arranged by the contractor)* under appropriate shipping conditions to be stored as indicated upon receipt. An acknowledgement of receipt shall be provided.

Instructions used for testing shall be agreed by the two parties, as shall final details of the methods, and be made available to the contractor upon request. Any deviation from the agreed instructions must be reported to the contractor with justification. The results obtained in the modified conditions must be of a sufficient quality to support the decision on release of the product. If the justification and, where necessary, additional validation does not support this decision, then the contractor has the right to request a re-test and/or make arrangements with another laboratory.

In accordance with the deadlines set out in the timetable agreed by the contractor and the contracted laboratory, the contracted laboratory shall ensure that the testing of samples is carried out and a test report produced in accordance with the annexed details and the agreed SOPs.

The report is due *X* working days after receipt of the test samples has been duly communicated to the contractor (acknowledgement of receipt).

The contracted laboratory shall, without delay, inform the contractor of any actual or anticipated difficulty in meeting this deadline. Where necessary, the contractor may ask another OMCL to be appointed during the course of testing.

- 1.2** The testing report shall be of the highest possible scientific quality and be prepared in accordance with the procedures and guidelines adopted by the EU/EEA OMCL Network. The completed reporting sheet(s) should, where necessary, be accompanied by records and raw data (e.g. graphs, print-outs) generated from the instruments used. Furthermore, it should be ensured that testing is performed under a quality assurance system that is in compliance with ISO/IEC 17025.

Article 2 – CONFIDENTIALITY

- 2.1** The contracted laboratory abides by its obligations of confidentiality and agrees to handle all drafts, preparatory information, documents and all other matters connected with the above-named product under conditions of confidentiality and not to make use of or disclose any facts, results or documents acquired in the performance of their duties, and in the scope of this contract, to any third party without the approval of the contractor.

2.2 The confidentiality obligations extend beyond the term of this agreement.

Article 3 - FINANCE

3.1 The *contractor* shall pay the contracted laboratory €XXX per test package (as defined in the annex).

The testing fees payable to the contracted laboratory shall also include exceptional costs, such as the purchase of reagents or consumable material of special grade or animals not usually available at the contracted laboratory, but required for the specific testing tasks.

Evidence of these exceptional costs must be duly documented (invoices and explanatory note) and presented to the contractor. Costs are payable only when approved in advance by the contractor in writing.

3.2 Payments shall be made *e.g. a) no later than X days after receipt of the completed report; b) on a monthly/bi-monthly/half-yearly schedule based on estimations of the number of test packages to be completed within the period, with differences between the actual numbers and estimations to be accounted for in the next payment period.*

3.3 The contractor reserves the right to withhold up to 50 % of the total financial contribution in case of undue delays in the provision of the testing report by the contracted laboratory.

Where the reference quality criteria, i.e. those set out by the EU/EEA OMCL Network, are not met for the testing report, the contractor also reserves the right to withhold payment until an acceptable report has been provided.

Article 4 – PERIOD OF THE AGREEMENT AND TERMINATION CONDITIONS

4.1 The conditions of this agreement take effect from the final date of signature and are valid until *DD/MM/YYYY and may be renewed at the end of this period on the agreement of both parties.*

4.2 The agreement may be terminated before the above-specified date by either party under the following conditions

(examples)

Due notice of (define appropriate time period X month(s)) - for a systematic testing scheme.

Notice given within X days of submission of a given test report – for occasional testing that takes place at broad time intervals.

4.3 *Demonstration of continuous testing competence must be provided by the contracted laboratory to the contractor at least once (define period, e.g. yearly or a specified number of months) in the form of at least one of the following: PTS certificate, report*

from an audit carried out by external bodies to assess compliance with ISO/IEC17025, or a specific audit carried out by the contractor.¹

Failure to provide the above-mentioned documentation or to meet the required reference standards, such as those valid in the EU/EEA OMCL Network, within (state period) of the date envisaged will entitle the contractor to terminate the agreement without further recourse.

- 4.4 Termination by either party, outside of the conditions noted in Article 4, can result in compensation for costs incurred as a result of the termination up to a limit of €X, provided sufficient documentation of the costs incurred is provided.

Article 5 – ARCHIVING OF DATA AND SAMPLES

Archiving of the final reports on the testing performed under this agreement are the responsibility of the contractor and should adhere to rules established for the EU/EEA OMCL Network and national rules. Raw data generated by the contracted laboratory should be archived by the contracted laboratory for at least a period of *X time* after the submission of the report. Before destruction of the raw data by the contracted laboratory, the contractor should be given the option to recover it for longer-term storage if desired.

Article 6 - DISPUTE SETTLEMENT AND JURISDICTION

Any dispute relating to the execution or application of this contract, failing a friendly settlement between the parties, shall be submitted for decision to an Arbitration Board composed of two arbitrators, with each party selecting one, and a presiding arbitrator appointed by these two arbitrators. In the event of no presiding arbitrator being appointed under the above conditions within a period of six months, *name of appropriate authority (to be defined on a case-by-case basis by the two signatory parties)* shall make the appointment.

For the contractor
(Name of the Institution)

Name:
Name of Contact

At: *City – Country*

Date:

Signature:

For the contracted laboratory

Name:
Name of Contact

At: *City – Country*

Date:

Signature:

¹ Note: 4.3 is only applicable if the period of the contract is of reasonably long duration and, thus, may not apply if the contract is intended for one-off testing or testing of only 2 or 3 batches in series.

Bank information for the contracted facility:

Account Holder:

Bank Name:

Address:

.....

.....

Bank code, BLZ or sort code:

Branch code:.....

Swift code:

Account number (IBAN):.....

Annex to Contract

Testing Specifics

Type of samples to be tested:	<i>e.g. list product(s) – final product and/or bulk</i>
No. of vials of each sample to be supplied:	<i>to be determined for the specific case (can be based on recommendations in the product-specific guidelines)</i>
Test(s) to be performed: (based on the requirements in the relevant product-specific guidelines)	<i>list the tests to be performed on the samples</i>
Reference preparations to be used:	<i>list the reference preparations needed for each type of test, together with details of the exact material to be used (i.e. ISs, BRPs, manufacturer's in-house preparations, etc.)</i>
Reference preparations supplied by:	<i>e.g. contractor or contracted laboratory (or MAH on request by the contractor)</i>
Special reagents and source:	<i>e.g. any special sera or reagents supplied by the MAH and whether they will be provided by the contractor or the MAH directly</i>
Frequency of testing:	<i>e.g. occasional (on demand) or systematic (approx. number of batches/month) over a given period</i>
Data reporting sheet(s) supplied:	<i>yes or no</i>
SOPs:	<i>e.g. internal SOPs of contracted laboratory or supplied by contractor (or by the MAH on request by the contractor)</i>
A 'test package' includes: <i>performance of the tests indicated above on the samples provided and the provision of a completed report for a given batch of the above-mentioned product.</i>	