

OMCL Network of the Council of Europe QUALITY MANAGEMENT DOCUMENT

PA/PH/OMCL (14) 40

OMCL MODEL CONTRACT FOR SUB-CONTRACTING

Full document title and reference	“OMCL Model Contract for Sub-contracting” <i>PA/PH/OMCL (14) 40</i> Annex II to the Guideline “Sub-Contracting of Tests”
Document type	Guideline for the General European OMCL Network (GEON) of the Council of Europe
Legislative basis	Council Directive 2001/83/EC and 2001/82/EC, as amended
Date of first adoption	
Date of original entry into force	June 2014
Date of entry into force of revised document	n/a
Previous titles/other references / last valid version	n/a
Custodian Organisation	The present document was elaborated by the OMCL Network / EDQM of the Council of Europe
Concerned Network	GEON

ANNEX II

OMCL MODEL CONTRACT FOR SUB-CONTRACTING

This model contract is only intended as an aid to highlight elements considered important when preparing sub-contracting arrangements by OMCLs. As an example, sub-contracted testing work 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 when preparing sub-contracting work by OMCLs in other fields of testing. However, individual OMCLs entering into subcontracting 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 sub-contract testing, 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
sub-contracted lab) 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 sub-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 sub-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.

SOPs 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 SOP 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 to by the contractor and the sub-contracted laboratory, the sub-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 sub-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 graphs and print-outs from the instruments used. Furthermore, it should be ensured that testing is performed under a quality assurance system that is in compliance with ISO 17025.

Article 2 – CONFIDENTIALITY

- 2.1 The sub-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 sub-contracted laboratory €*XXX* per test package (as defined in the annex).

The testing fees granted to the testing OMCL shall particularly take into account exceptional costs, such as the purchase of reagents or consumable material of special grade or animals not usually available at the sub-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 withdraw up to 50 % of the total financial contribution in case of undue delays in the provision of the testing report by the sub-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 sub-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 ISO17025, or a specific audit carried out by the contractor etc.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 are provided.

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.

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 sub-contracted laboratory should be archived by the sub-contracted laboratory for at least a period of *X time* after the submission of the report. Before destruction of the raw data by the sub-contracted lab, the contractor should be given the option to recover it for longer 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 Sub-contracted Laboratory

Name:
Name of Contact

At: *City – Country*

Date:

Signature:

Bank information for the sub-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 etc.</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 sub-contracted lab (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 sub-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>	