



OMCL Network of the Council of Europe QUALITY MANAGEMENT DOCUMENT

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STANDARD AIDE-MEMOIRE FOR THE MJA/MJV OF OMCLs

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Concerned Network	GEON

EUROPEAN NETWORK OF OFFICIAL MEDICINES CONTROL LABORATORIES

“Aide mémoire” for MJA/MJV of OMCL

I. General

This “aide-mémoire” was elaborated on a standard checklist for EN ISO/IEC 17025 and corresponding EA and ILAC guidelines, published by an accreditation body on the internet. Specific OMCL requirements arising from adopted OMCL guidelines were incorporated.

The questions in the first column are addressed to the testing laboratories; they are to be answered thoroughly by the laboratory itself before the evaluation takes place, with indication of corresponding reference documents (e.g. Quality Manual, SOP, working instructions etc.) to provide an efficient assessment basis to the auditors. Should any requirement of the standard be non-applicable, this must be indicated by "NA" under the "References" column and duly justified.

During the MJA/MJV, this document provides a practical tool for the auditors to make sure that all elements of the ISO/IEC 17025 standard and OMCL guidelines are covered, but it will not be used as such to prepare the MJA/MJV report.

This document may also be used by OMCLs as self-assessment of the implementation status of the Management System, independently of any external assessment.

II. Definitions and Abbreviations

Documents, records: documents and records can be stored in paper or electronic (computer) form. Rules must be defined for the availability of, access to and safeguarding of electronic records.

QM = quality manual

OMCL = Official Medicines Control Laboratory

MJA = Mutual Joint Audit

MJV = Mutual Joint Visit

OOS = Out of Specification

NB: in the text, « Authority » refers to the competent Body or person (e.g. Inspectorate, Minister of Health, Head of Medicines Agency, etc) that gives the order to test a medicinal product.

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SUMMARY

(figures in parentheses refer to standard EN ISO/IEC 17025)

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1. Organisation	Y	N	References / Comments
1.1 Organisation and management (4.1)			
1.1.1 (4.1.1) - Name and address of the OMCL			
-Legal identity of the organisation (entry in the commerce register or public institution)			
-Field of activities of the OMCL			O Market surveillance testing O Official Batch release testing O Others:
-Name and address of the laboratory			
-Field of activities of the laboratory (general)			
Has the OMCL already been accredited?			
If YES, scope for which accreditation has been granted and by which accreditation body			
If NO, scope of the applied Management System			
Scope of activities to be audited during the MJA			
1.1.2 (4.1.4) Is the laboratory part of a parent organisation? If YES what organisation?			
1.1.3 (4.1.5e) Is there one or several organisational chart(s) for the whole OMCL showing the position of the testing laboratory, and is such a chart available for the testing laboratory itself?			
1.1.4 (4.1.4) Are the responsibilities and authorities of the key personnel in the laboratory suitably defined so that conflicts of interest can be avoided?			
1.1.5 (4.1.5b) Is it possible to exclude any influence on the results exercised by persons or organisations external to the testing?			
1.1.6 Is it ensured that the OMCL is not engaged in other activities that may endanger its impartiality, its independence and its integrity?			

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1.1.7 (4.1.5b)	Is the technical and financial independence between the laboratory and external customers ensured?			
1.1.8 (OMCL)	How is it ensured that the OMCL performs the testing of products independently from any contract work by order of a pharmaceutical manufacturer or entrepreneur?			<i>(Note for auditors: see contracts with other customers, see if the OMCL controls products from the contractor)</i>
1.1.9 (4.1.5h)	Name of the technical manager who has the overall responsibility for the operation of the laboratory.			
1.1.10 (4.1.5h)	Are the qualifications (training, courses, publications, experience) of the technical manager documented?			
1.1.11 (4.1.5h/ 4.2.6)	Is the area of competence of the technical manager defined?			
1.1.12 (4.1.5j)	Has a deputy technical manager been appointed?			
1.1.13 (4.1.5i)	Name of the quality manager responsible for the follow-up of the prescribed working procedures and of the management system.			
1.1.14 (4.1.5i)	Are the qualifications (training, courses, publications, experience) of the quality manager documented?			
1.1.15 (4.1.5/ 4.2.6)	Is the area of competence of the quality manager defined?			
1.1.16 (4.1.5j)	Has a deputy quality manager been appointed?			
1.1.17 (4.1.5i)	Does the quality manager have direct access to the highest level of management for the laboratory?			
1.1.18 (4.1.5k)	Is it ensured that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system?			
1.1.19 (4.1.6)	Have appropriate communication processes been established within the laboratory?			
1.1.20 (4.1.6)	Does communication regarding the effectiveness of the management system take place?			

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2. Management System	Y	N	References / Comments
2.1 Management system (4.2)			
2.1.1 (4.2.1) Has the OMCL established and implemented a management system covering the full range of activities for which an audit is requested?			
2.1.2 (4.2.1) Is the management system documented to the required extent?			
2.1.3 (4.2.1) Has the documentation been made available to all staff members concerned?			
2.1.4 (4.2.1) Have the staff members understood the management system?			
2.1.5 (4.2.2) Are the various steps of the management system, including a quality policy statement, documented in a quality manual (QM)?			
2.1.6 (4.1.3) Does the management system cover all the activities of the OMCL that are performed inside and outside the permanent and mobile facilities for which the audit is requested?			
2.1.7 (4.2.2) Has the responsible management defined in writing the quality policies and objectives?			
2.1.8 (4.2.2) Are overall objectives established, and are they reviewed during management review?			
2.1.9 (4.2.2) Does the quality policy statement include at least the following:			
a) the laboratory management’s commitment to good professional practice and quality of the testing,			
b) a statement of the management’s intentions with respect to the standard of service the laboratory will provide,			
c) the purposes of the management system,			
d) a requirement that all personnel concerned with testing activities within the laboratory familiarise themselves with the quality documentation and implement the policies and procedures in their work,			

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	e) the laboratory management’s commitment to compliance with the international standard ISO/IEC17025 and to continually improve the effectiveness of the management system?			
2.1.10 (4.2.3)	Has the top management provided evidence of commitment to the development and implementation of the management system and to continually improve its effectiveness?			
2.1.11 (4.2.4)	Has the top management communicated to the organisation the importance of meeting authority requirements as well as statutory and regulatory requirements?			
2.1.12 (4.2.5)	Does the quality manual include or make reference to all the technical and supporting procedures, requirements and rules, and does it outline the structure of the documentation used in the management system?			
2.1.13 (4.2.7)	Is it ensured that the integrity of the management system is maintained when changes to the management system are planned and implemented?			
2.2	Document control (4.3)			
2.2.1 (4.3.1)	Is a procedure established to control all documents (of both internal and external origin) that are necessary for the correct performance of testing operations?			
2.2.2 (4.3.2.1)	Does the procedure specify who is responsible for the establishment, review, approval for use and maintenance of the management system documents?			
2.2.3 (4.3.2.1)	Is there a list, table or equivalent system for identifying all management system documents, with the current revision status and distribution?			
2.2.4 (4.3.2.2)	Does the procedure ensure that:			
	a) authorised editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed,			
	b) documents are periodically reviewed and where necessary revised to ensure continuing suitability and compliance with applicable requirements,			
	c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use,			
	d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked?			

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2.2.5 (4.3.2.3)	Are all management system documents clearly identified?			
2.2.6 (4.3.2.3)	Does such identification include:			
	a) the date of issue and/or approval for use,			
	b) the page numbers and the total number of pages,			
	c) the persons authorised for issuing the documents?			
2.2.7 (4.3.3.1)	Are the responsibilities and authorities for the revision and amendment of documents clearly and suitably defined?			
2.2.8 (4.3.3.1)	Has a procedure been established for the amendment of documents?			
2.2.9 (4.3.3.2)	Are the changes made in documents clearly identified?			
2.2.10 (4.3.3.2)	Is it possible to trace the changes made in documents?			
2.2.11 (4.3.3.3)	Is the amendment of documents by hand allowed? If yes, has a procedure been defined for such amendments?			
2.2.12 (4.3.3.4)	Is there an established procedure to describe how changes are to be made in documents maintained in computerised systems?			
2.3	Record control (4.13)			
2.3.1	Is there a procedure for:			
(4.13.1.1)	a) identification,			
	b) collection,			
	c) registration,			
	d) access,			
	e) indexing,			
	f) storage,			
	g) maintenance,			
	h) retrievability,			
	i) legibility			
	of quality and technical records?			
2.3.2 (4.13.1.2)	Is there a procedure for the archiving of such records including the definition of minimum retention times?			

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2.3.3 (4.13.1.3)	Are records handled in confidence and held safely protected from loss and damage?			
2.3.4 (4.13.1.4)	Is there a procedure for the protection and safeguarding of data held on computers?			
2.3.5 (4.1.5c)	Has the laboratory established rules to ensure the protection of its authority’s confidential information and proprietary rights, and do these rules also cover the electronic storage and transmission of data?			
3.	External Cooperation (with competent authorities and suppliers)	Y	N	References / Comments
3.1	Testing order review (4.4)			Note: for definition of « Authority », see page 1
3.1.1 (4.4.1)	Has the OMCL established procedures for the review and internal handling of testing orders arriving from the competent authorities?			
3.1.2 (4.4.1)	Do these procedures ensure that:			
	a) testing orders are only accepted where the requirements including the methods to be used are adequately defined and documented,			
	b) the laboratory has the technical capability and resources to meet the requirements,			
	c) the appropriate test methods are selected and capable of meeting the authority’s requirements?			
3.1.3 (4.4.1)	Is it ensured that any differences between the testing order and the testing possibilities of the OMCL are resolved before any work commences?			
3.1.4 (4.4.2)	Are records also maintained of any technical advice to the authority in relation to testing?			
3.1.5 (4.4.3)	Does the testing order review also cover any work to be subcontracted by the laboratory?			
3.1.6 (4.4.4)	Is any departure from the contract or agreed testing order reported to the authority, even if occurring after work has commenced?			
3.2	Subcontracting of tests (4.5)			
3.2.1 (4.5.3)	Is the OMCL aware that it is responsible to the authority for the work of any subcontractor (unless this has been selected by the authority itself)?			

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3.2.2 (4.5.2, / OMCL)	Is the authority informed in writing, if a subcontractor will be regularly involved in the performance of the testing?			<i>Note: for reasons of practicability the OMCLs as part of the competent authorities organisational framework are <u>not obliged to seek approval</u> for individual cases of subcontracting.</i>
3.2.3 (4.5.1)	It is ensured that any special arrangements with the authority (confidentiality, specified test methods, etc.) are also transmitted to the subcontractor?			
3.2.4 (4.5.1)	Has the laboratory established a procedure for the selection of subcontractors based on technical and qualitative evaluation criteria?			
3.2.5 (4.5.1)	Does the laboratory regularly verify that the authority's requirements are fulfilled by the subcontractor?			
3.2.6 (4.5.2)	Is the subcontractor an accredited or formally recognised laboratory? Otherwise, is it ensured that the subcontractor complies with the relevant requirements of the ISO 17025 norm and the OMCL guidelines?			
3.2.7 (4.5.1/ 4.5.3)	Is the competence for establishing the requirements to be applied to subcontractors defined?			
3.2.8 (4.5.4)	Is a register maintained of all subcontractors? Does this register give information on subcontractors' compliance to standard ISO 17025 and OMCL guidelines?			
3.3	Purchasing services and supplies (4.6)			
3.3.1 (4.6.1)	Has the laboratory a procedure for the selection of services and supplies it uses that can affect the quality of the tests?			
3.3.2 (4.6.1)	Are there procedures for the purchase, reception and storage of materials, reagents and consumables relevant for the quality of the tests?			
3.3.3 (4.6.2)	Has the laboratory a procedure for cases where the products or services to be purchased (including hard- and software) do not comply with the specified quality requirements?			
3.3.4 (4.6.3)	Do purchasing documents contain the relevant specifications for products and services critical for the quality of the laboratory output?			
3.3.5 (4.6.2)	Is it ensured that purchased supplies, reagents and consumables are not used until they have been inspected or otherwise verified to be suitable for use?			
3.3.6 (4.6.4)	Does the laboratory maintain records of the approved suppliers for products or services critical for the quality of the tests?			
3.3.7	Has it established criteria for supplier evaluation?			

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3.3.8 (4.6.2)	Is the quality of critical products adequately tested by either the laboratory or the suppliers or are they purchased from suppliers with certified QM system?		
3.3.9	Are corresponding records maintained?		
3.4	Service to the authority (4.7)		Note: for definition of « Authority », see page 1
3.4.1 (4.7)	Is there a procedure generally ruling the cooperation with authorities?		
3.4.2 (4.7)	Where appropriate, is there any agreement with the authority relative to confidentiality?		
3.4.3 (4.7)	Are confidentiality rules also applied to the personnel not belonging to the laboratory (e.g. cleaning or service personnel)?		
3.4.4 (4.7 note 1)	Are there agreements with the authority concerning: 1)		
	a) the access to the laboratory for the witnessing of specific tests,		
	b) the extent and limits of the access to the documentation relating to the tests?		
3.4.5 (4.7 note 2)	Is the authority timely informed of any delays or major deviations in the performance of the tests?		
3.4.6 (4.7.2)	Is any feedback procedure (e.g. authority surveys) used to evaluate the service to the authority?		
3.5	Complaints (4.8)		
3.5.1 (4.8)	Are there established and documented rules and procedures to deal with complaints?		
3.5.2 (4.8)	Are there records of all complaints and of the resulting investigations and corrective actions, and are they taken into account in the management evaluation?		
4.	Maintenance of the Management System	Y	N
4.1	Control of nonconforming testing work (4.9)		Note: Investigation of Out of Specification (OOS)-results is dealt with in chapter 8.4
4.1.1 (4.9.1)	Has the laboratory established procedures to deal with any observed departures from its own procedures or the agreed requirements of the authority?		

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4.1.2 (4.9.1)	Do the procedures ensure that:			
	a) responsibilities and authorities for the management of nonconforming work are settled (cancellation, withholding of test reports, traceability),			
	b) an evaluation of the significance of the nonconforming work is undertaken,			
	c) corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work,			
	d) where necessary, the results of nonconforming work already released to authority are recalled,			
	e) the responsibility for authorising the resumption of work is defined?			
4.1.3 (4.5.3)	Do the procedures also define the actions to be taken when the errors originate from suppliers or subcontractors?			
4.2	Improvement (4.10)			
4.2.1 (4.10)	Does the laboratory continually improve the effectiveness of its management system through use of:			
	a) quality policy			
	b) quality objectives			
	c) audit results			
	d) analysis of data			
	e) corrective and preventive actions			
	f) management review?			
4.3	Corrective action (4.11)			
4.3.1 (4.11.1)	Has the laboratory established procedures for implementing corrective actions when nonconforming work has been identified?			
4.3.2 (4.11.2)	Does this procedure include cause analysis?			
4.3.3 (4.11.2)	Have the possible causes of the problem been identified by the laboratory?			
4.3.4 (4.11.3)	Are corrective actions to a degree appropriate to the magnitude of the problem and commensurate with the risks?			
4.3.5 (4.11.3)	Who is responsible for deciding on the implementation of corrective action and whether it is appropriate to the magnitude and risk of the problem?			

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4.3.6 (4.11.3)	Are the changes resulting from corrective actions documented?			
4.3.7 (4.11.4)	Has the laboratory settled the responsibility for the follow-up of corrective actions?			
4.3.8 (4.11.4)	Are the results evaluated and the effectiveness of the corrective actions monitored so as to prevent any recurrence of the problem?			
4.3.9 (4.11.5)	Is an additional internal audit performed where there are doubts on the laboratory's compliance with its own procedures?			
4.4	Preventive action (4.12)			
4.4.1 (4.12.1)	Are the management system and the technical procedures regularly checked for possible sources of non-conformances?			
4.4.2 (4.12.1)	Is a list/record of potential problems and corresponding corrective actions available?			
4.4.3 (4.12.1)	Are preventive action plans developed, implemented and monitored to reduce the likelihood of occurrence of non-conformances and to take advantage of improvement opportunities?			
4.4.4 (4.12.1)	Who is responsible for the follow-up of preventive actions?			
4.4.5 (4.12.2)	Do preventive actions involve:			
	a) analysis of data,			
	b) trend analysis,			
	c) analysis of interlaboratory comparison results (such as PTS, collaborative trials, etc.),			
	d) risk analysis?			
4.5	Internal audits (4.14)			
4.5.1 (4.14.1)	Is there a procedure for scheduling and performing internal audits?			
4.5.2 (4.14.1)	Is it the responsibility of the quality manager to plan and organise the audit?			
4.5.3 (4.14.1)	Are audit plans subject to the approval of the competent management?			

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4.5.4 (4.14.1)	Are audits performed on the basis of activity-specific checklists or other working documents?			
4.5.5 (4.14.1)	During a given time interval, does the internal audit program address all the elements of the management system, including testing activities?			
4.5.6 (4.14.1)	Are audits carried out by qualified and, wherever possible, independent personnel?			
4.5.7 (4.14.2)	Do audit records give information on:			
	a) the compliance to the procedures included in the management system,			
	b) the compliance with the ISO 17025/OMCL Network standard,			
	c) the observance of the actions prescribed in the management system?			
4.5.8 (4.14.2)	Do the procedures specify that timely corrective action is to be taken and authorities notified if the laboratory results may have been affected?			
4.5.9 (4.14.1)	Does the executive management of the laboratory conduct critical reviews of the audit records?			
4.5.10 (4.14.3)	Are the laboratory sections concerned informed on the audit results?			
4.5.11 (4.14.3)	Are audit findings and corrective actions recorded?			
4.5.12 (4.14.2)	Are relevant corrective actions timely taken and monitored when internal audits cast doubt on the effectiveness or correctness of the operations?			
4.5.13 (4.14.1)	Is the effectiveness and completeness of the internal audits reviewed and documented?			
4.6	Management reviews (4.15)			
4.6.1 (4.15.1, note 1)	Does the management review take place at least once a year?			
4.6.2 (4.15.1)	Are the suitability and effectiveness of the management system comprehensively reviewed by the executive management of the laboratory?			

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4.6.3 (4.15.1)	Does the review at least consider the following items:			
	a) suitability of the basic rules and procedures,			
	b) reports from managerial and supervisory personnel,			
	c) outcome of recent internal audits,			
	d) corrective and preventive actions,			
	e) feedback from authorities,			
	f) results of interlaboratory comparisons or proficiency studies,			
	g) changes in the volume and type of the work undertaken,			
	h) complaints,			
	i) recommendations for improvement			
	j) other relevant factors such as quality control facilities, future plans, resources and staff training,			
	k) assessments by external bodies?			
4.6.4 (4.15.2)	Are the corrective actions arising from management reviews implemented and monitored?			
4.6.5 (4.15.1, note 2)	Do the results of management reviews include the goals, objectives and action plans for the coming year?			
5.	Personnel (5.2)	Y	N	References / Comments
5.1.1 (5.2.1/ 4.1.5)	Is it ensured that the OMCL personnel has the required qualification and is in sufficient number for the work to be done?			
5.1.2 (5.2.3)	Have all employees a binding contract to the laboratory?			
5.1.3 (5.2.1/ 5.2.2)	Is there a policy for the introduction of new personnel, including temporary employees?			
5.1.4 (5.2.1)	Is an appropriate supervision by a competent person provided during the introductory period?			
5.1.5 (5.2.1, note 1)	If there are legal requirements to perform specific tasks, are they fulfilled?			

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5.1.6 (5.2.2)	Has the OMCL formulated goals with respect to education, training and experience?			
5.1.7 (5.2.2)	Is there an agreed training program to ensure that the personnel keep up with the latest or a sufficient state of knowledge?			
	Is it documented?			
	Does this program include:			
	a) the goals defined with respect to education, qualification and training,			
	b) the identification of training needs,			
	c) the provision of training?			
5.1.8 (5.2.2)	Is the effectiveness of the training actions taken evaluated?			
5.1.9 (5.2.4)	Are there activity descriptions (job descriptions) for the various activities of the laboratory?			
5.1.10 (5.2.4)	Does such a description at least define responsibilities with respect to the following:			
	a) managerial duties,			
	b) performing tests,			
	c) planning tests and evaluating results,			
	d) giving opinions and interpretations,			
	e) method modification and development and validation of new methods,			
	f) expertise and experience,			
	g) qualifications and training programs?			
5.1.11 (5.2.5)	Does the laboratory maintain records, e.g. as lists/tables, of the specific personnel authorised to perform particular tasks?			
5.1.12 (4.1.5f)	Are the competencies of all personnel responsible for performing tests established?			
5.1.13 (4.1.5f)	Are the employees aware of the extent and limitations of their duties and responsibilities?			

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5.1.14 (4.1.5f)	Are overlapping or gaps between responsibility fields, that could lead to misunderstandings, avoided?			
5.1.15 (4.1.5f)	Are all responsibility fields identified?			
5.1.16 (4.1.5g)	Is the internal supervision of all activities related to testing carried out by competent and qualified personnel?			
5.1.17 (4.1.5g)	Is the numerical balance between supervisors and supervised reasonable?			
5.1.18 (5.2.1, Note 2)	Do the persons responsible for the assessments and interpretations in test reports:			
	a) have appropriate knowledge of the technologies involved in the manufacturing of the items, materials, products, etc. to be tested, of the way they are to be used and of the faults and defects that may occur when in use,			
	b) know the general requirements as expressed in legal texts and standards,			
	c) understand the meaning of any deviations observed in the ordinary use of the items, materials, products etc. in question?			
6.	Premises and Equipment	Y	N	References / Comments
6.1	Premises (5.3)			
6.1.1 (5.3.1)	Are the premises available to the personnel sufficient for the correct performance of tests?			
6.1.2 (5.3.1)	Are the premises suitable and functional with respect to the performance of tests?			
6.1.3 (5.3.1)	Are the facilities available in the premises (electrical power, water, lighting, temperature, pressurised air, humidity and temperature control) sufficient for the performance of tests?			
6.1.4 (5.3.1)	Are the premises suitably protected from interference factors such as:			
	a) temperature,			
	b) dust,			

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	c) humidity,			
	d) vapour,			
	e) sound,			
	f) vibrations,			
	g) electromagnetic fields,			
	h) contamination,			
	i) other,			
	in view of the tests to be carried out in these premises ?			
6.1.5 (5.3.1)	Are these requirements also fulfilled when tests are performed at sites outside permanent laboratory facilities?			
6.1.6 (5.3.1)	Are the technical requirements also fulfilled when tests are performed at sites outside permanent laboratory facilities?			
6.1.7 (5.3.2)	Are important environmental data monitored and recorded (relevant environmental conditions for the evaluation of test results)?			
6.1.8 (5.3.3)	Is it ensured that any influence of activities in neighbouring areas or environment is excluded (cross-contamination, shocks, vibrations, explosions, gases, odours)?			
6.1.9 (5.3.2)	Are tests stopped when jeopardised by environmental conditions?			
6.1.10 (5.3.4)	Is access to testing areas sufficiently and appropriately controlled so as to prevent any unauthorised access?			
6.1.11 (5.3.5)	Are the responsibility and procedures (where necessary) for good housekeeping settled?			
6.2	Equipment (5.5)			
6.2.1 (5.5.1)	Is the laboratory furnished with sampling, measurement and test equipment required for the correct performance of tests?			
6.2.2 (5.5.1)	Is it ensured that sampling, measurement and test equipment, outside the permanent control of the laboratory, also meet the standard specifications (e.g. in cases where external equipment is used)?			
6.2.3 (5.5.2)	Are the specifications for relevant equipment and its software suitably established in writing so that it is possible to assess the accuracy required for the test results?			
	a) Have calibration programs been established for key quantities or values of the instruments?			

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	b) Is the equipment subject to reception testing?		
6.2.4 (5.5.4)	Is the equipment used for testing and its software uniquely identified?		
6.2.5 (5.5.5)	Are records maintained of each relevant item of equipment and its software, which include the following information:		
	a) identity of the item of equipment and its software,		
	b) manufacturer's name, type identification and serial number or other unique identification,		
	c) checks that equipment complies with the specifications,		
	d) current location, where appropriate,		
	e) the manufacturer's instructions, if available, or reference to their location,		
	f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria and due date of next calibration,		
	g) if applicable, a maintenance plan and the maintenance operations carried out to date,		
	h) damage, malfunction, modification or repair of the equipment?		
6.2.6 (5.5.7)	Is it ensured that test and measurement instruments that either do not provide reliable results any more or have been overloaded or mishandled are immediately identified and again subjected to maintenance and if necessary calibration operations?		
6.2.7 (5.5.7)	Are the effects on previous tests of defects as described in 6.2.6 examined and is the procedure on "Control of nonconforming testing work" as described in 4.1 applied?		
6.2.8 (5.5.8)	Are all items of equipment requiring calibration identified, and is the personnel concerned aware of their calibration status?		
6.2.9 (5.5.8)	Are the dates of last and next calibration or the signs indicating need for recalibration established for all equipment requiring calibration?		
6.2.10 (5.5.11)	Where calibrations give rise to a set of correction factors, is there a procedure ensuring that any applications (e.g. also computer software) are correctly updated?		

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6.2.11 (5.5.9)	When equipment is used either outside the laboratory or by persons not belonging to the laboratory, are the function and calibration status of the equipment checked before it is returned to service?			
6.2.12 (5.5.10)	Are any intermediate checks required carried out according to a defined procedure?			
6.2.13 (5.5.3)	Are there up-to-date instructions on the use and maintenance of equipment and are they readily available to the personnel?			
6.2.14 (5.5.6)	Do the maintenance instructions specify the necessary criteria to ensure the proper functioning of instruments, especially with respect to:			
	a) safe handling, transport, storage,			
	b) use, modifications,			
	c) maintenance, repair,			
	d) impairment?			
6.2.15 (5.5.12)	Is test equipment, including hardware and software, safeguarded from adjustments which would alter the test results?			
6.2.16 (5.5.6)	Are specific procedures established for cases when equipment is used outside the laboratory?			
6.2.17 (5.5.3)	Is equipment (including instruments from outside) only operated by qualified and authorised personnel?			
6.3	Control of data (5.4)			
6.3.1 (5.4.7.1)	Are calculations subject to appropriate checks in a systematic manner with respect to the requirements, and is it also the case for calculation implementations with respect to functionality and suitability for use?			
6.3.2 (5.4.7.1)	Are data transfers subject to appropriate checks in a systematic manner with respect to data integrity, reliability, and transfer performance?			
6.3.3 (5.4.7.2b)	Are reliable data, when transferred outside the reliability sphere by technical means, protected from unauthorised access and handling?			
6.3.4	Are there procedures established for data coding and authentication?			
6.3.5 (5.4.7.2b)	Are rules defined for data access authorisations and storage in the computer system, and are such rules also transposed in an authentication system?			
6.3.6 (5.4.7.2)	Have secured data been classified according to significance, value and reliability?			
6.3.7	Is a clear rule applied here (e.g. access or storage requirements)?			

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6.4	Measurement traceability (5.6)		
6.4.1 (5.6.1)	Is all equipment used for measurements adequately qualified before being put into service? (this not applicable to equipment having only a negligible effect on the accuracy and total uncertainty of the results)		
6.4.2 (5.6.1)	Has the laboratory established programs and procedures for the calibration of its equipment?		
	Such a program should include a system for:		
	a) selecting,		
	b) using,		
	c) calibrating where applicable,		
	d) checking,		
	e) surveillance,		
	f) maintenance of measurement standards,		
	g) using reference materials.		
6.4.3 (5.6.2.1.1)	Are calibrations and measurements traceable to the SI units of measurement, when applicable?		
6.4.4 (5.6.2.1.1)	Are calibrations traceable to certified reference materials or to other mutual-consent methods, when relevant and/or when traceability to SI units of measurement is not possible?		
6.4.5 (5.6.2.1.1, note 1)	Are calibration certificates issued by calibration laboratories accredited for the relevant field of activity?		
6.4.6 (5.6.2.1)	Are calibrations by the laboratory itself performed using appropriate certified reference materials or standards?		
6.5	Reference standards (5.6/PhEur)		
6.5.1	Is there a concept for ensuring correct storage, management and handling of reference standards?		
6.5.2	Is there a concept for the use of reference standards?		
6.5.3	Is there a concept for the establishment of standards to be used in the OMCL?		
6.5.4	Have responsibilities been assigned for:		
	a) ordering,		
	b) receiving, labelling, inspection and testing (if applicable),		

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	c) identification,			
	d) handling,			
	e) storage,			
	of the reference standards used by the OMCL?			
7.	Handling of Test Items	Y	N	References / Comments
7.1	Sampling (5.7)			<i>Note: chapter 7.1 has to be answered only when sampling is part of the activities to be evaluated)</i>
7.1.1 (5.7.1)	Is sampling performed according to a sampling plan and to sampling procedures, or to a special agreement with the authority?			
7.1.2 (4.5)	If sampling, though normally under the responsibility of the laboratory, is performed by the authority, the latter then acts as a sub-contractor. Does in this case the authority fulfil the criteria described under chapter 3.2 "Sub-contracting of tests"?			
7.1.3 (5.7.1)	Are the sampling plan and procedures available at the location where sampling is undertaken?			
7.1.4 (5.7.1)	Are sampling plans based on appropriate statistical methods or on appropriate testing specifications?			
7.1.5 (5.7.3)	Are following sampling data recorded:			
	a) identification of the sampler,			
	b) sampling date, time, location,			
	c) sampling plan or sampling procedure used,			
	d) environmental conditions,			
	e) any special events,			
	f) any sampling aids?			
7.1.6 (5.7.2)	Is the sampling procedure discussed with the authority and established in writing?			
7.1.7 (5.7.2)	If yes, are all relevant documents made available to the appropriate personnel?			
7.2	Handling of test items (5.8)			
7.2.1 (5.8.1)	Are procedures described for:			
	a) packing,			

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	b) transportation,			
	c) receipt,			
	d) identification,			
	e) handling.			
	f) protection of integrity,			
	g) storage			
	h) retention,			
	i) disposal of samples or test items,			
	and are they known to the laboratory sections concerned?			
7.2.2 (5.8.1)	Are measures taken in case samples are delivered out of opening hours?			
7.2.3 (5.8.4)	Is it ensured that no deterioration, loss or damage of test items will occur during:			
	a) storage,			
	b) handling,			
	c) preparation,			
	d) testing?			
7.2.4 (5.8.2)	Is the system used for identifying test items designed so as to ensure that the identification will remain visible, legible and non confusable throughout the life of the item in the laboratory?			
7.2.5 (5.8.2)	Is the identification of test items consistent with the data in testing documents and records?			
7.2.6 (5.8.2)	Is the system used for identifying test items suitable?			
7.2.7 (5.8.2)	Is unique identification ensured so as to prevent any confusion of individual samples within a group or of test items from different groups?			
7.2.8 (5.8.3)	Are the suitability of test items for proper testing, and their conformity to the description provided, checked and recorded upon receipt of the samples?			
7.2.9 (5.8.3)	Are any peculiarities or abnormalities stated when recorded upon receipt?			
7.2.10 (5.8.3)	Does the procedure specify that in doubtful cases contact should be taken with the authority and the outcome of the discussion recorded?			

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8. Test Methods	Y	N	References / Comments
8.1 Test methods and procedures, including validation (5.4)			
8.1.1 (5.4.1) Are test procedures, study plans etc. adequately documented so as to be reproducible by trained personnel?			
8.1.2 (5.4.1) Do these documents describe at least the following points:			
a) handling of the test items			
b) use and operation of the test equipment			
c) interpretation and data processing (possibly with statistics)?			
8.1.3 (5.4.1) Is it ensured that the test methods used comply with the authority’s requirements (validated methods)?			
8.1.4 (5.4.2) Where appropriate, is the authority informed as to the method chosen (especially when alternative validated methods are used by the laboratory in replacement of standard methods or methods published by reputable organisations)?			
8.1.5 (5.4.2) Is the authority informed by the laboratory when the method it has proposed is considered to be inappropriate or out of date?			
8.1.6 (5.4.2) Does the laboratory demonstrate that it can properly operate the approved methods when using them (system suitability test, analytical acceptance criteria)?			
8.1.7 (5.4.2) Are the documents related to all test methods as well as specifications, important regulations and working papers available to the staff within a reasonable delay?			
8.1.8 (5.4.1) Are any deviations from standardised methods documented, technically justified and reported to the authority?			
8.1.9 (5.4.6.1) Has the laboratory established procedures for estimating the measurement uncertainty of the methods?			
8.1.10 (5.4.6.3) Do these procedures take into account the relevant parameters likely to contribute to the uncertainty (e.g. preparation, measurement procedures, result processing, etc.)			

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8.1.11 (5.4.1)	Is the personnel involved in the application of these methods adequately instructed and if necessary supervised? Is there a suitable exchange of experiences?			
8.2	Questions relevant for method transfer and screening (5.4/OMCL)			
8.2.1 (5.4.3)	Is the transfer/adaptation of existing methods, and corresponding validation, exclusively assigned to qualified personnel equipped with adequate resources?			
8.2.2 (5.4.3)	Does the OMCL have a procedure in place that regulates the extent of necessary validation to be considered?			
8.2.3 (OMCL)	Is this procedure in accordance with the OMCL guideline “Validation of analytical procedures”?			
8.2.4 (5.4.3)	Are the transferred/adapted methods checked accordingly for their suitability for the intended use and released as such by a competent person?			
8.2.5 (5.4.3)	Do those persons possess the required level of education, training and experience?			
8.2.6 (5.4.1)	Is the personnel involved in the application of these methods adequately instructed and if necessary supervised? Is there a suitable exchange of experiences?			
8.2.7 (OMCL)	Does the OMCL participate on a regular basis in collaborative trials and Proficiency Testing Studies?			
8.2.8 (OMCL)	Are the results of such testing evaluated and is the necessary corrective action carried out and appropriately documented?			
8.2.9 (OMCL)	In the case of screening analyses does the laboratory perform appropriate confirmatory testing?			
8.3	Questions relevant to laboratory-developed methods (5.4)			
8.3.1 (5.4.3)	Is the development of methods and corresponding validation a planned activity that is exclusively assigned to qualified personnel equipped with adequate resources?			
8.3.2 (5.4.2/ 5.4.5.2)	Are new methods checked for their suitability for the intended use according to an established procedure and thereby validated?			

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8.3.3 (5.4.5.3)	Are the characteristics of the method (e.g. detection and quantitation limits, selectivity, linearity, repeatability, robustness, cross-sensitivity, accuracy, precision, measurement uncertainty, etc.) established on the basis of the authority's needs?			
8.3.4 (5.4.3)	Do the established procedures also provide for comprehensive and appropriate instruction of the personnel before the introduction of newly developed methods?			
8.3.5 (5.4.5.2)	Are all investigations, clarifications and considerations associated with the development of the method documented in such a way that they can be easily understood by specialists?			
8.3.6 (5.4.4)	Are testing instructions produced prior to the application of new methods and do they include at least the following information:			
	a) appropriate identification,			
	b) scope,			
	c) description of the type of item to be tested,			
	d) parameters or quantities to be determined, and range,			
	e) apparatus and equipment, including technical requirements,			
	f) reference standards and materials required,			
	g) environmental conditions required, and any stabilisation period needed,			
	h) description of the procedure, including: affixing identification marks, handling, transporting, storing and preparing of items, checks to be made before the work is started, checking that the equipment is working properly, calibrating and adjusting the equipment, methods of recording the observations and results, any safety measures to be observed,			
	i) criteria and/or requirements for approval/rejection,			
	j) data to be recorded and method of analysis and presentation,			
	k) uncertainty or procedure for estimating uncertainty?			
8.3.7 (5.4.2)	Is it reported to the authority, when relevant, that new or laboratory-developed methods were used?			

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8.4	Assuring the quality of test results (5.9/OMCL)		
8.4.1 (5.9)	Are working schemes (responsibilities) defined so as to provide appropriate assurance regarding the quality of test results (e.g. trends detectable through statistical techniques, investigation of out of specification (OOS) results)?		
8.4.2 (5.9a)	Does the laboratory, where relevant, make regular use of certified reference materials or secondary reference materials?		
8.4.3 (5.9b)	Does the laboratory, where possible, participate in interlaboratory comparison or proficiency testing programmes?		
8.4.4 (5.9c)	Are replicate tests performed where appropriate using the same or different methods?		
8.4.5 (5.9d)	Is a re-testing of retained items performed where appropriate (e.g. for trend analysis)? Are quality control charts used?		
8.4.6 (5.9/ OMCL)	Does the OMCL follow a procedure regulating OOS situations?		
8.4.7 (OMCL)	Does this procedure regulate regular failure investigation and when and how to conduct re-testing?		
8.5	Technical records (4.13.2)		
8.5.1 (4.13.2)	Is it ensured that all records required for traceability (results, calculations, observations, etc.) are documented and retained?		
8.5.2 (4.13.2.1)	Where relevant, are the factors affecting uncertainty estimations registered in the records?		
8.5.3 (4.13.2.1)	Do the records include the identity of the personnel who has performed sampling and testing?		
8.5.4 (4.13.2.1)	Are there forms or work sheets for proper establishment of records?		
8.5.5 (4.13.2.2)	Are the records established in the course of testing?		
8.5.6 (4.13.2.3)	Is it ensured that, when mistakes occur, they are crossed out, not erased nor made illegible, and the correct value is signed or initialled by the person making the correction?		

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8.5.7 (4.13.2.3)	In the case of computer-collected data, are similar measures taken to avoid loss or untraceable change of original data?			
9.	Test Reports	Y	N	References / Comments
9.1	Reporting the results (5.10)			
9.1.1 (5.10.1)	Is there a procedure (responsibility and working schemes) for establishing test reports and ensuring the proper format, presentation, comprehensiveness and content?			
9.1.2 (5.10.8)	Does the procedure guarantee that:			
	a) due attention is paid to the establishment of test reports,			
	b) test reports are clear and comprehensible for the authority,			
	c) headings are standardised whenever possible,			
(5.10.9)	d) amendments or additions to test reports are made in the proper way,			
	e) test results are presented completely and clearly (graphical information, tables, photographs etc. can be used),			
	f) for test results obtained from the sampling of a lot, the conclusion to this lot is independent of the results?			
9.1.3 (5.10.2)	Does each test report include at least the following information:			
	a) a title (e.g. "Test Report"),			
	b) name and address of the laboratory, and location where the tests were carried out if different from the address of the laboratory,			
	c) on each page, unique identification of the test report (e.g. serial number) and page number as well as total number of pages in the report,			
	d) name and address of the authority,			
	e) description of the test method used for each individual result,			
	f) description, condition and unambiguous identification of the test item,			

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	g) date of receipt of the test item and date of performance of the test,		
	h) where relevant to the results, reference to the sampling procedures used: date, location (diagrams, sketches, photographs), sampling plan applied, environmental conditions, other specifications or deviations from specifications,		
	i) as appropriate, test results with units of measurement,		
	j) name, function and/or equivalent identification of the person(s) approving the test report as well as date of issue,		
	k) where relevant, a statement to the effect that the results relate only to the items tested,		
	l) recommended: a statement specifying that the test report shall not be reproduced except in full, without written authorisation of the laboratory?		
	m) Is any omission to this list justifiable?		
9.1.4 (5.10.3.1/ 5.10.3.2)	Do test reports, where necessary for the interpretation of the test results, also include the following information:		
	a) deviations from the test procedure, and specific test conditions,		
	b) where relevant, a statement of compliance/non compliance with requirements and specifications,		
	c) a statement on the estimated uncertainty when so required by the authority or when uncertainty affects compliance with specified limits,		
	d) date of sampling,		
	e) unique identification of the substance, material or product sample, name of manufacturer, etc.,		
	g) any standard or other specification referred to for sampling, and deviations thereof.		
9.1.5 (5.10.1)	Is the report complete with respect to order and content (e.g. in mentioning the authority's requirements or indicating partial fulfilment of the authority's requirements).		
9.1.6 (5.10.1)	Is it ensured that test reports include all the information requested by the authority?		

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9.1.7 (5.10.5)	Are there rules for the inclusion of opinions and interpretations (e.g. opinion on conformity with requirements, fulfilment of contractual requirements, recommendations on how to use the results, guidance for improvements)?			
9.1.8 (5.10.5)	Do opinions and interpretations rely, where relevant, on a documented basis?			
9.1.9 (5.10.5)	Are opinions and interpretations unambiguously identified as such, and is it clearly apparent that they are not to be confused with conformity statements in the sense of inspection or product certification?			
9.1.10 (5.10.5)	Is, in particular, the authority and responsibility for the expression of comments and interpretations well established?			
9.1.11 (5.10.9)	Do amendments made in a test report after issue occur in the form of a further document, with the statement "Supplement to test report, serial number..." or an equivalent statement?			
9.1.12 (5.10.9)	Is it ensured that, when it is necessary to issue a new test report, this report is uniquely identified and contains a reference to the original that it replaces?			
9.1.13 (5.10.7)	Is it ensured that, in the case of transmission of test reports by electronic means such as telephone, facsimile, diskettes, etc., the integrity of the report is maintained?			
9.1.14	Is it ensured that test reports are only transmitted after approval by the competent person(s)?			
9.1.15 (4.13.2.1)	Is it ensured that the laboratory retains a copy of every test report issued?			
9.1.16 (4.13.2.1/ OMCL)	Is the time limit for retaining reports defined and in agreement with the OMCL guideline for archiving?			
9.2	Tests performed by subcontractors (5.10.6)			
9.2.1 (5.10.6)	Are results obtained from subcontractors, if any, clearly identified in the test report?			
10.	Validation of Computerised Systems (5.4.7/OMCL)	Y	N	References / Comments
10.1	General requirements			
10.1.1	Is a general policy or a validation master plan dealing with validation of Computerised Systems available?			
10.1.2	Is an inventory of all computerised systems available, including software and spreadsheets with calculation functions?			

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10.1.3	Is a backup strategy in place (e.g. responsibilities, storage media, retention times, storage place separated from the location of the original data)?			
10.1.4	Is the access to the computers restricted and are the electronic data protected from unauthorized changes (e.g. password, authorisation concept, antivirus software, audit trail)?			
10.1.5	Are the responsibilities and the retention times of superseded software versions described?			
10.1.6	Is a change control process implemented?			
10.1.7	Are risk management activities and/or audits performed on a regular basis for computerised systems?			
10.2	Computer controlled equipment/Databases/LIMS/ELN			
10.2.1	Is a configuration management and plan available for each computer system?			
10.2.2	Is a disaster recovery plan implemented, e.g. workaround (temporary fix, used until an appropriate solution to the problem is found), recovery of software programs and data, rollback procedure (operation which returns the database to some previous state), release?			
10.2.3	Is an incident management described and is a periodic review of the incidents performed, to ensure a proactive maintenance of the system or the process?			
10.3	Calculation software / Calculation spreadsheets			
10.3.1	Are the versions of software and spreadsheets controlled and documented in a traceable way and are the different versions for the intended purpose released?			
10.3.2	Are the calculation formulas documented and the relevant fields protected?			
10.3.3	Are the functions and the correct calculations validated, e.g. compared to an independent system?			
10.3.4	Does a procedure for periodic verification of calculation software/spreadsheets exist?			