European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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PREFACE AND NOTES FOR USE OF OMCL QMS DOCUMENTS

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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.

PREFACE AND NOTES FOR USE

The Quality Management System requirements that are applicable to Official Medicines Control Laboratories (OMCLs) within the OMCL Network are based on the ISO/IEC 17025 standard. To further clarify and facilitate the application of such requirements within OMCLs, a series of supporting technical guidelines (OMCL Guidelines) have been developed by the Network.

As a rule, the OMCL Network guidelines are drafted by ad-hoc groups of experts from within the Network and are adopted by representatives of all OMCL Network members.

These guidelines are technically detailed; they are science-based and take into consideration the specific nature of OMCL work, which is characterised by the following:

- With the exception of official batch release testing of vaccines, blood derived medicinal products and certain immunological veterinary medicinal products [known as Official Control Authority Batch Release (OCABR) testing], OMCLs do not normally have a pre-defined routine testing programme that is based on the use of fixed analytical methods. Instead, OMCLs are expected to apply, on a daily basis, various analytical methods to the analysis of different medicinal products (and active substances).

  In this regard, there are method validation/verification requirements that have to be fulfilled and which have specifically been developed by the OMCL Network.

- Testing often has to be performed on a limited amount of sample, and therefore, a risk-based approach for the selection of the tests to be performed has to be applied. (This is often decided in conjunction with the National Competent Authority.)

- OMCLs may also be expected to determine the identity and composition of unknown samples, for example during the analysis of samples that may have been falsified.

Many of these OMCL Network Quality Management (QM) guidelines obtained the status of *Advisory Documents* in 2005 and in 2007 by the European co-operation for Accreditation, Laboratory Committee (EA/LC). Documents developed subsequently have also been recognised by EA/LC as important to the quality management systems of OMCLs. Their use is strongly encouraged during any type of external audit at the facilities of an OMCL, performed either by an accreditation body member of EA, or by the experts of the OMCL Network/EDQM within the framework of the OMCL Network Mutual Joint Audit (MJA) or Mutual Joint Visit (MJV) programmes.

Since the OMCL Network has reinforced the collaboration with the EA in the context of joint audits, the OMCL Network QM guidelines are referred to as supplementary documents that may be applied during accreditation audits. The reference can be found in the document EA/INF15 “Joint EA - EDQM Communication regarding cooperation when carrying out (joint) audits/assessments in Official Medicines Control Laboratories”.

The Department for Biological Standardisation, OMCL Network & HealthCare (DBO) at the EDQM (European Directorate for the Quality of Medicines & HealthCare) acts as administrator for a series of activities put in place within the OMCL Network. These activities aim to ensure that a harmonised Quality Management approach is in place amongst all OMCLs throughout the Network. Any laboratory from the OMCL Network can make a request to the responsible DBO Section to participate in any of these programmes, by following the established procedures.

The QM-related documents are freely available and can be downloaded from the EDQM website (www.edqm.eu).