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

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General European OMCL Network (GEON) QUALITY MANAGEMENT DOCUMENT

PA/PH/OMCL (10) 15 4R

PREFACE AND NOTES FOR USE OF OMCL QUALITY MANAGEMENT DOCUMENTS

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

The Quality Management System requirements that are applicable to 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 additional and detailed technical guidelines (OMCL Guidelines) have been developed by the OMCL Network.

The OMCL Network guidelines are drafted by ad-hoc groups of experts from within the Network and are adopted by all OMCL members of the Network.

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 and blood derived 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 requirements that have to be complied with 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 be adulterated or that may be counterfeit.

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.

The OMCL Network has reinforced the collaboration with the EA by following the necessary steps to ensure that the same status is gradually obtained for other OMCL Network guidelines.

The EDQM's Department for Biological Standardisation, OMCL Network & HealthCare (DBO) 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 OMCL Network. Any laboratory from the OMCL Network can make a request to EDQM's DBO Section to participate in any of these programmes, by following the established procedures.

The QM-related documents may be downloaded from the website of the European Directorate for the Quality of Medicines & HealthCare (EDQM) (www.edqm.eu).