

7 April 2011

Memorandum

To: Office for Training - Steering Group

From: Cornelia Nopitsch-Mai (Chairperson of the Expert Group of Quality Assessors)

Re: Expert Group of Quality Assessors – work report

Cc: Expert Group Members

Dear Colleagues,

This memorandum has been prepared to provide you with an overview of work on the document "Competence requirements and training needs for Quality Assessors" (the document), and interactions between the Expert Group of Quality Assessors.

Background

In accordance with the point 3.4 of the Action Plan for Implementation of the 'Draft Strategy for Regulatory and Scientific Training within the European Regulatory Network' the Expert Group of Quality Assessors was created to define and document the training curricula required to meet the needs of the various, defined categories of scientific and regulatory staff working within the European Regulatory Network.

The Group is composed of quality assessors representing National Competent Authorities (NCA) and European Medicines Agency (EMA), and consists of the following members: Cornelia Nopitsch-Mai (DE) – Chairperson, Susanne Stotter (AT), Diana van Riet (NL), Gorm Jørgensen (DK), Andrea Cseh-Palos (HU), Malcolm Dash (UK), Norbert Möller (DE, vet), Piotr Kozarewicz (EMA) and Ruben Pita (EMA). In addition, the Group invited Renate McIntyre (learning and development manager at IMB) to cooperate with us.

The mandate

The Group of Quality Assessors was established to:

- (1) define and document the competence and knowledge requirements for quality assessors (basic and advanced),
 - (2) define and document the training curricula required to meet the needs of quality assessors,
 - (3) support the Training Office in preparation of a detailed inventory of training available to the network from EMA, NCAs and external suppliers of training,
 - (4) define criteria for harmonised assessment of competence to be applied by the national agencies within the network,
 - (5) assist the Office in a gap analysis to identify unmet needs in terms of training for quality assessors.
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Work report

Since establishing, the Group has held regular meetings, either via teleconference (TC) or face-to-face. Additional work has been carried out by exchange of e-mails. A proper balance between meetings (TC) and written consultations (e-mails) has been paramount in the work progress.

The work started with a kick-off TC on 25th of August 2010, during which the Group Members were introduced and familiarised with the objectives for the Group. Following this meeting the Group gathered again in September 2010 to elect its chairperson. Since then, regular cooperation was established and the work on the document started. The concept was based on a template (*Career Paths in the Pharmaceutical assessment Department*) originating from the IMB, which was provided by Renate. Several drafts of the document were prepared and discussed intensively within and outside the Group.

Meetings of the Group were aligned with the time schedule of the QWP meetings. Since majority of Group Members are also members of the QWP it was possible to follow this approach. Non QWP members either attended the meetings at EMA or participated via TC. Our face-to-face meetings were mostly dedicated to work on the milestones of the project (major drafts of the document). Two face-to-face meetings were organised, first in December 2010 and the second in February 2011. Before each meeting a dedicated TC was organised to agree the agenda for the meeting and discuss the work progress. We followed an approach of providing written comments on each draft document, always in advance, prior to the meeting (or TC). Documents summarising received comments were circulated prior to the meeting (TC) to ensure that we all were working on the same document.

Alignment with the QWP time schedule allowed involving Jean-Louis Robert (Chairman of the QWP) in our meetings. Jean-Louis Robert participated in both face-to-face meetings and provided additional comments on the document. His involvement in the project facilitated interactions with the QWP, which was consulted during the preparation of the document. Although no additional comments were provided by the QWP members, the WP was informed about the project and its objectives.

No problems were encountered during the preparation of the document. The administrative part of the project was coordinated by the EMA. The work was accomplished as all Group members actively participated in the project by providing feedback on time and within the agreed deadlines. Involvement in the project of a limited number of experts (10 members) was optimal and facilitated interactions within the Group. Having larger number of members in the Group would make interactions more complex and less efficient. As a room for improvement, we would suggest inclusion of a consultation phase with all NCAs at earlier step of the project so all countries would be able to provide their comments. Such consultation could be done at CMD level. Earliest feedback from other stakeholders would improve the document and facilitate its finalisation.

The document was extensively discussed within the Group and represents a common position agreed by all members. Our aim was to prepare a set of recommendations that NCAs may wish to use as a useful instrument to the professional development of quality assessors. These recommendations should not be seen as mandatory requirements. The document outlines the competence requirements and proposed training needs for the quality assessors. The key objectives of this document are to clearly define criteria for competence requirements for quality assessors and to establish a consistent framework against which training needs can be identified and accordingly planned for.

Following the discussion within the Group it has been agreed that 3 grades of quality assessors existed in majority of NCAs and therefore similar approach was adopted. Furthermore, it has been agreed that two sub-grades (Senior Assessor and Expert Assessor) should be clearly recognized within the Grade 3 of Quality Assessors. This was done to accommodate some Member States specific differences and also not to indicate that a quality assessor grade 3 would always have a managing role.

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The document provides that within each grade the amount of training needed will depend on the previous experience of the individual, and that the extent of training should be customised accordingly. The individual should be assessed and mapped against the requirements of the job. This should determine the type of work which can be carried out at present and a rotation programme to ensure the individual gains exposure to the key areas. Detailed criteria for determination of the training needed for a quality assessors are specified in the document.