

Clarification of the role of the Office of Training Steering Group in new training initiatives within the network

The Office of Training Steering Group (OTSG) was set up by HMA to oversee the implementation of the Joint HMA/EMA Strategy for Regulatory and Scientific Training within the European Regulatory Network. The OTSG is a strategic and not an operational group. In line with the decision of the HMA, the Office of Training (the Office) is currently virtual and plays a coordinatory and advisory role.

The HMA MG and the Office have received several requests to assist with, or to take over, training on behalf of the network. This note seeks to clarify the assistance that the office is able to provide and the factors that need to be taken into account in determining the ability of the office to provide assistance in response to a particular request and the prioritisation that should apply.

In order for the OTSG to assist with a request for training,

- The request should be in an area of training identified as a priority in the Joint HMA/EMA Training Strategy and Action Plan (currently priority is being given basic regulatory and scientific training)
- The proposer of the training should have already either set up a core group of volunteers to work on preparing a competence framework in the relevant area or at least be confident that they are capable of establishing such a group
- The proposer should be willing either to put themselves forward to act as the coordinator of the group or to have identified another individual to act as coordinator
- The OTSG should agree that its involvement will bring added value to the training initiative proposed

The OTSG will consider any requests that meet these criteria and prepare a prioritised list for endorsement by HMA as part of the routine reports prepared by the group. OTSG will then successively work on proposals in line with these priorities and according to the resources available, as detailed in annual workplans approved by HMA.

The assistance provided by HMA will be in the form of

- Assistance with preparation of
 - Competence frameworks
 - Curricula required to meet competence frameworks
 - Establishing methodologies for competence assessment (future objective)
- Quality control of training providers (future objective)
- Communication of training events
- Input from training professionals into the training provided in terms of content and training vehicles (e.g. eLearning, web tools, presentation and training materials etc.)