

## Global Cooperation Group

### Strategy on Training and Capacity-building Related to the Use of ICH Guidelines

#### Issue

The GCG's role in addressing requests from Regional Harmonisation Initiatives (RHIs) for training and capacity-building related to the use of ICH guidelines is considered important in ensuring their proper interpretation and effective utilisation by industry and regulators alike. Given the considerable resource and logistical implications associated with such activities, it is necessary to take a strategic approach to managing requests and ensuring that prioritized needs are addressed in an efficient and effective manner.

It should be noted that the scope of this discussion document is not intended to encompass all training activities contemplated by RHIs, but rather those related to ICH guidelines. Ideally, training opportunities delivered through the GCG would complement and be integrated within regional and country level training strategies. It is also important to acknowledge the essential role of the WHO in facilitating training efforts aimed at strengthening regulator capacity and harmonisation activities relating to both ICH and non-ICH topics.

#### Background

Training activities involving ICH experts have been seen by the GCG as an important means of promoting a better understanding of ICH and ICH guidelines beyond the ICH regions. With an ever-growing interest in and use of ICH guidelines globally, together with a closer engagement with RHIs under new Terms of Reference, the GCG has experienced an increase in the number of requests to deliver training on ICH topics, either as stand alone workshops or as part of larger meetings and conferences. At the same time, regulators representing the RHIs have expressed a need for capacity-building in order to adequately assess studies and data generated in accordance with ICH guidelines. This latter need has in fact been recognized in the recently adopted GCG Mission Statement:

*To promote a mutual understanding of regional harmonisation initiatives in order to facilitate the harmonisation process related to ICH guidelines regionally and globally, and to facilitate the capacity of drug regulatory authorities and industry to utilise them.*

With an increase in the number and scope, as well as the ad hoc nature of many training requests, it has become apparent that a more strategic and proactive approach is required to better manage this key GCG activity. This need is further reinforced by the fact that:

- No special funds are available to the GCG for this activity
- Topics and specific training objectives have not always been defined with sufficient lead time to allow for the identification and participation of appropriate speakers, a particular concern for regulatory authorities
- There has been no conscious coordination of training effort amongst ICH (and non-ICH) parties, nor an attempt to optimize and evaluate the effectiveness of such effort.

## **Principles and Recommendations of the GCG in responding to Training Requests**

With the above considerations in mind, a set of principles, procedures and recommendations are proposed in order to make best use of resources, opportunities and technology, thereby ensuring that training activities directed through the GCG are as effective and efficient as possible.

Whenever possible, training initiatives directed through the GCG should:

- *Optimally, be regionally-based, with flexibility to consider nationally-based training, if deemed appropriate*

In line with the GCG principle of regional engagement (as described in the revised Terms of Reference), training and capacity-building activities should be regionally-based as a preference, although nationally-based activities are not excluded as an option. The goal in either case is to derive the maximum benefit from the training event. The approach should promote interaction, support and a common understanding of the ICH guidelines amongst the countries and stakeholders within a given region.

- *Be coordinated amongst ICH parties and RHIs and leverage existing regional training activities and events*

ICH related training and capacity-building in non-ICH regions should be coordinated amongst ICH parties and the respective RHI to avoid overlap, promote synergy and ensure an equitable distribution of training requests. **Such activities should, in particular, take into consideration and complement WHO training initiatives.**

It is also important to make best use of existing training events and programmes occurring within both ICH and non-ICH regions, including:

- ICH-related workshops and conferences. In support of the need for synergies in training efforts, it is proposed that any future ICH public conferences be structured, at least in part, as interactive training opportunities rather than the traditional informational symposium.
- Routine and specialised training organised by ICH regulators for assessors and inspectors, with a view to inviting counterparts from the RHIs<sup>1,2</sup>
- Specialised training courses offered by industry experts on technical/scientific topics
- Bilateral regulatory exchanges and visiting expert programmes<sup>2</sup>
- Meetings and training sessions organised by the RHIs. ICH-related training could take place either as part of or as a satellite to such sessions. Similarly, consideration should also be given to organising satellite training sessions for industry and regulators from RHIs around the biannual ICH meetings, as deemed appropriate.
- Country-based events. When a regulatory member of a RHI identifies training and capacity-building needs, consideration should always be given to gauging the interest of other regulators and industry within the region, as well as members of other RHIs.<sup>3</sup>

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<sup>1</sup> The GCG takes note of the expression of interest by the RHIs in the possibility of observing Q7 based inspections in the respective RHI members by the ICH regulatory authorities.

<sup>2</sup> Alternate strategies may also be in place for optimizing the management of training requests, such as the CDER Forum for international Drug Regulatory Authorities. Training opportunities offered by ICH regulators may in fact combine both ICH and non-ICH related topics.

<sup>3</sup> The same would apply to regionally organized events and the possible interest of other RHIs.

Towards this end, it is recommended that a clearinghouse of important training initiatives/events be considered to promote awareness and facilitate coordination of training efforts. Subscription to electronic event announcements is also an effective way of promoting awareness of relevant training events.

- *Leverage the experience and resources of non-profit training organisations*

As an initial step in planning ICH public training and information-dissemination events, consideration should be given to co-sponsoring the event with an established training organisation or society in order to help clearly defining learning objectives and target audiences, better promote the event through membership announcements, ease the burden of logistical arrangements and minimize expenses incurred. It is important to note that rules of conduct preclude many regulatory agencies from participating in for profit events. Preparation of a listing of such organisations (including through self-identification against a set of criteria) may be useful.

- *Be planned and reviewed on a periodic basis*

Requests for training and capacity-building should, to the extent possible and practical, be forecast on periodic basis in order to:

- identify priorities
- better define requirements/objectives, plan for and promote events
- identify opportunities for synergies, including training events planned in the ICH regions and the use of recorded training modules.

The use of a training request template and calendar would assist in tracking and delivering training that meets the most pressing needs of the RHIs in a proactive manner. It is equally important that training outcomes be monitored regularly and evaluated on a periodic basis to assess whether training objectives were achieved and to identify areas for improvement. In selecting evaluation methods to assess the outcome or impact of training activities, a review of existing indicators developed by RHI is recommended.

- *Take full advantage of appropriate training modalities/technologies*

The use of distance training, including web casts, web seminars and recorded training modules, should be considered as an adjunct to organised workshops and conferences. Recorded material has the advantage of allowing exposure to a wider in-house audience and to new employees.

### **Delivery of training and capacity-building within a regional strategy**

In order to derive the greatest benefit from training and capacity-building initiatives within a given region, activities should ideally occur within the context of a regional strategy which has taken into consideration the needs and capacities of member countries. Elements of such a strategy should include:

- A step-wise approach that considers the results of a needs assessment and the capacity of interested parties, thereby ensuring that the most pressing needs are addressed first. Focusing effort and resources on a selected areas considered of greatest value to key players within a pragmatic, overall regulatory strategy is most likely to lead to successful outcomes in the near, medium and long term.
- The institutionalisation of training. A ‘train the trainer’ approach may include the involvement of academic institutions so as to provide for long-term stability and capacity.
- A training outcomes evaluation process.
- Strategies for securing funding for training activities and the support of Ministries of Health and governments<sup>4</sup>. The GCG should work with RHIs and reputable organisations to identify potential funding opportunities.
- Considerations described under the training component of the endorsed *ICH Guideline Implementation Tool*.

Finally, within this context, best advantage should be made of the participation of representatives of RHIs in ICH meetings to both promote an awareness and understanding of ICH guidelines and processes and act as a conduit for the views of constituents. Pre-GCG meetings also provide RHIs an opportunity to share information on training programmes for topics beyond the scope of ICH.

### **Conclusion**

The implementation of an ICH GCG strategy for addressing the training and capacity needs of regional harmonisation initiatives is essential in ensuring the most effective use of resources, opportunities and the realisation of desired outcomes. Such a strategy should help the GCG effectively respond to two key objectives, specifically:

- to promote a better understanding and use of ICH guidelines and standards in non-ICH regions, and
- to make a contribution to meeting the capacity needs of RHI members related to ICH guidelines.

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<sup>4</sup> As one example, the 3<sup>rd</sup> APEC Life Sciences Innovation Forum recommended that guidelines and a funding strategy be developed for harmonisation training initiatives.